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## 1 UNITED STATES OF AMERICA

## 2 NUCLEAR REGULATORY COMMISSION

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## 4 ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

5 + + + + +

## 6 OPEN MEETING

7 + + + + +

8 FRIDAY, SEPTEMBER 23, 2011

9 The meeting was convened in Room T2-B3 of Two  
10 White Flint North, 11545 Rockville Pike, Rockville,  
11 Maryland, at 8:00 a.m., Leon S. Malmud, M.D., ACMUI  
12 Chairman, presiding.

13  
14 MEMBERS PRESENT:

15 LEON MALMUD, M.D., Chairman

16 BRUCE THOMADSEN, Ph.D, Vice Chair

17 MILTON GUIBERTEAU, M.D., Diagnostic Radiologist

18 SUSAN LANGHORST, Ph.D., Radiation Safety Officer

19 STEVEN MATTMULLER, Nuclear Pharmacist

20 CHRISTOPHER PALESTRO, M.D., Nuclear Medicine  
21 Physician

22 JOHN SUH, M.D., Radiation Oncologist

23 ORHAN SULEIMAN, M.D., FDA Representative

24 WILLIAM VAN DECKER, M.D., Nuclear Cardiologist

25 LAURA WEIL, Patients' Rights Advocate

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1 MEMBERS PRESENT (CONT'D):

2 JAMES WELSH, M.D., Radiation Oncologist

3 PAT ZANZONICO, Ph.D., Nuclear Medicine Physicist

4  
5 NRC STAFF PRESENT:

6 JAMES LUEHMAN, Acting Director, Division of  
7 Materials Safety and State Agreements

8 CHRIS EINBERG, Designated Federal Officer

9 MICHAEL FULLER, Alternate Designated Federal  
10 Officer

11 ASHLEY COCKERHAM, Alternate Designated Federal  
12 Officer & ACMUI Coordinator

13 NEELAM BHALLA, FSME/DILR/RB-B

14 SUSAN CHIDAKEL, OGC/GCLR/RMR

15 SAID DAIBES, Ph.D., FSME/DMSSA/LISD/RMSB

16 KERSTUN DAY, OE/EB

17 JOSEPH E. DeCICCO, FSME/DMSSA/NMPD/SMP

18 JONATHAN EVANS, FSME/DILR/RB-B

19 SOPHIE HOLIDAY, FSME/DMSSA/LISD/RMSB

20 DONNA-BETH HOWE, Ph.D., FSME/DMSSA/LISD/RMSB

21 DEBORAH JACKSON, FSME/DILR

22 VARUGHESE KURIAN, FSME/DWMEP/DURLD

23 ED LOHR, FSME/DILR/RB-B

24 ANGELA McINTOSH, FSME/DMSSA/LISD/RMSB

25 KEVIN O'SULLIVAN, FSME/DILR/RB-B

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1 NRC STAFF PRESENT CONT'D:

2 PATRICIA PELKE, R-III/DNMS/MLB

3 GRETCHEN RIVERA-CAPELLA, FSME/DMSSA/LISD/RMSB

4 DUANE WHITE, FSME/DMSSA/RMSB

5 SHIRLEY XU, FSME/DMSSA/LISD/LB

6  
7 ALSO PRESENT:

8 ARMIN ANSARI, Ph.D., CDC

9 KAREN BISHOP, JOHNS HOPKINS HOSPITAL

10 ART CHANG, CDC

11 PETER CRANE

12 ANDREA CUZMANES, JOHNS HOPKINS HOSPITAL

13 WILLIAM DAVIDSON, UNIVERSITY OF PENNSYLVANIA

14 LYNN EVANS, Ph.D., CDC

15 LYNNE FAIROBENT, AAPM

16 MARC GARLAND, Ph.D, DOE

17 MICHAEL HAGAN, M.D. DEPARTMENT OF VETERANS'  
18 AFFAIRS

19 TRACI HOON, JOHNS HOPKINS HOSPITAL

20 FAIZ HUSSAIN, JOHNS HOPKINS HOSPITAL

21 ALBERT HYACINTH, CDC

22 FRANCES JENSEN, M.D. CMS/HHS

23 ROBERT JONES, Ph.D., CDC

24 IRA KREFTING, Ph.D., FDA

25 ALEX LIMA, JOHNS HOPKINS HOSPITAL

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1 ALSO PRESENT CONT'D:

2 KATHY LISING, JOHNS HOPKINS HOSPITAL

3 MARY McCORMICK, Ph.D., JOHNS HOPKINS HOSPITAL

4 JANETTE MERILL, SNM

5 GEORGE MILLS, M.D., PAREXEL

6 THALIA MILLS, Ph.D., FDA

7 ADRIAN NUNN, Ph.D., BRACCO RESEARCH

8 MICHAEL PETERS, ACR

9 DENNIS PHILLIPS, DOE

10 SATISH PILLAI, Ph.D. CDC

11 MICHELLE PODGONIK, CDC

12 COURTNEY RADCLIFFE, JOHNS HOPKINS HOSPITAL

13 DWAIN RIEVES, Ph.D., FDA

14 GLORIA ROMANELLI, ACR

15 WOLFGANG RUNDE, Ph.D., DOE

16 DAVID SAUNDERS, CDC

17 JOSEPH SHONKA, Ph.D., CDC

18 LAURA SIERRA, ALSTON & BIRD

19 CINDY TOMLINSON, ASTRO

20 ANN WARBICK CERONE, MDS NORDION

21 ROBERT WHITCOMB, Ph.D., CDC

22 JENNA WILKES, ASNC

23 GARY E. WILLIAMS, VA NHPP

24 LUCIE YANG, Ph.D., FDA

25

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## TABLE OF CONTENTS

|    |  |     |
|----|--|-----|
| 1  |  |     |
| 2  | Strontium/Rubidium Discussion - FDA Perspective, |     |
| 3  | O. Suleiman, ACMUI                               | 5   |
| 4  | Strontium/Rubidium Discussion - NRC Perspective, |     |
| 5  | DB. Howe, NRC                                    | 14  |
| 6  | ACMUI's 2008 Recommended Revision to the Medical |     |
| 7  | Event Abnormal Occurrence Language, A.           |     |
| 8  | McIntosh, NRC                                    | 64  |
| 9  | Medical Related Events, D.B. Howe, NRC           | 87  |
| 10 | NRC Rulemaking Workshop, M. Fuller, NRC          | 122 |
| 11 | Permanent Implant Brachytherapy Subcommittee     |     |
| 12 | Discussion, J. Welsh, ACMUI                      | 137 |
| 13 | Part 35 Rulemaking Update, N. Bhalla & E. Lohr,  |     |
| 14 | NRC  | 218 |
| 15 | Administrative Closing, S. Holiday, NRC          | 224 |
| 16 | Adjourn  |     |
| 17 |  |     |
| 18 |  |     |
| 19 |  |     |
| 20 |  |     |
| 21 |  |     |
| 22 |  |     |
| 23 |  |     |
| 24 |  |     |
| 25 |  |     |

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

8:14 a.m.

CHAIR MALMUD: Good morning, everyone. And welcome to the second day of this session of the Advisory Committee on the Medical Uses of Isotopes. I'm Leon Malmud, the Chair of the Committee.

A few housekeeping issues first. Dr. Howe has kindly distributed to the members of the Committee this handout which will go under Tab 13. It's in the manual so that you have it right in front of you. It's been distributed. For those members of the audience who are with us, the public who are visiting with us, there are several more copies available if you care to obtain one.

We'll begin the session with the discussions regarding strontium/rubidium from both the FDA and NRC perspectives. The FDA perspective will be presented by Dr. Orhan Suleiman, a member of this Committee as well. The section on the NRC perspective will be presented by Dr. Donna-Beth Howe, also a member of the NRC staff who has been extraordinarily helpful to this Committee.

So if we may, we'll begin. I apologize for the delay. It was not due to any of the deficiencies of the members of the Committee. There was an audio-

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1 visual issue which has been resolved. And with that,  
2 we'll ask Dr. Suleiman to start.

3 MEMBER SULEIMAN: That's okay. I can see  
4 it.

5 Good morning. I'll be presenting a brief  
6 overview regarding the recent recall of the Bracco  
7 CardioGen-82 rubidium generator. Since this is an on-  
8 going investigation, I will only present information  
9 that is either already in the public domain or Bracco  
10 has allowed us to share with you. If I happen to  
11 express some of my professional opinions during this  
12 talk, they are not necessarily official FDA or HHS  
13 policy.

14 I've also asked our medical officers at  
15 FDA who have been actively involved with this issue to  
16 accompany me today. Two of them aren't here yet. I  
17 think they must be hurtling through the security  
18 process. But Dr. Dwaine Rieves is the Director of the  
19 Division of Medical Imaging Products. This division is  
20 located within the Office of New Drugs in the Center  
21 for Drug Evaluation and Research. Dr. Lucie Yang, who  
22 is to my left, is the Team Leader who is responsible  
23 for the CardioGen-82 product. And Dr. Ira Krefting,  
24 who also hasn't arrived yet, is the Division's Deputy  
25 Director for Safety.

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1  
2 A brief technical review, I don't want to  
3 go into too much detail, but I think you need to at  
4 least get a grasp that this is a different type of  
5 generator. Rubidium-82 is a myocardial infusion agent  
6 with an effective dose in the 3 to 4 millisievert  
7 range. I'll discuss doses a little bit more later. It  
8 emits a positron which interacts with an electron and  
9 emits two annihilation photons of 511 keV, along with  
10 a 776 keV gamma, which helps distinguish it from other  
11 positron emitters used in PET imaging.

12 Although rubidium-82 is a positron-  
13 emitting nuclide, this is not your conventional PET  
14 nuclide which is often produced in the local  
15 cyclotron. Rubidium-82 is produced in a generator.  
16 Generators are not medical devices. They are  
17 considered part of the drug manufacturing process  
18 subject to GMP, or good manufacturing practices, and  
19 regulated by FDA and by the Center for Drug Evaluation  
20 and Research.

21 The parent nuclide for this generator is  
22 strontium-82 which decays with a 25-day half-life to  
23 its daughter product, rubidium-82, which actually has  
24 a 75-second half-life. They exist together in what's  
25 known as secular equilibrium. Strontium-82 is not

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1 detected directly. It's detected by the rubidium's  
2 emissions. Also present with the strontium-82 is  
3 strontium-85, a product of the production process.

4 For medical use, the rubidium is separated  
5 from both strontiums by elution through a chemical  
6 column with a solution of saline. So essentially the  
7 strontium is above the column, and when you're ready  
8 to undergo the medical procedure the rubidium  
9 hopefully is extracted, eluded, and the strontium  
10 stays behind and eventually is injected into the  
11 patient.

12 Early in the year, two patients, which we  
13 refer to as the index patients, underwent CardioGen-82  
14 cardiac imaging studies. One of these patients was  
15 scanned in Florida. The other patient was scanned in  
16 Nevada. They both left the country and when they re-  
17 entered the U.S. at different border entry points,  
18 they triggered radiation detectors and had spectral  
19 surveys performed. It was discovered that they had  
20 unexpected levels of strontium-82 and strontium-85.  
21 The spectral was analyzed by Los Alamos and FDA was  
22 eventually notified. The fact that they had undergone  
23 their scans several months earlier clearly raised  
24 everyone's concern. I think Homeland Security and  
25 Customs Border Protection really need to be

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1 complimented. They were pretty vigilant, but I guess  
2 that's what they're supposed to do.

3 (Laughter.)

4 Los Alamos National Laboratory, in a  
5 publicly-available report, positively identified the  
6 unique photo peaks associated with those nuclides.  
7 Clearly, breakthrough limits have been exceeded.  
8 Breakthrough was independently verified by subsequent  
9 whole-body scanning initiated by Bracco at Oak Ridge  
10 National Laboratories for both of these two index  
11 patients. Bracco has committed to continue such  
12 counting during this entire investigation. And they've  
13 been very helpful.

14 This is the spectra reported in the Los  
15 Alamos report. The blue spectrum is associated with  
16 the strontium-82's daughter rubidium-82 and shows a  
17 unique 776 photo peak here, if you can see it to the  
18 right. That really distinguishes it from the  
19 annihilation photons. And the 511 keV annihilation  
20 photons which are over here for those who can't see  
21 clearly.

22 The longer the patient has been  
23 contaminated, the more the strontium-85:-82 ratio  
24 changes because remember the strontium-85 has a 67-day  
25 half-life. So it's lingering around much longer. The

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1 strontium-82 only has a 25-day half-life. So depending  
2 on the ratio, you can get an idea of how long it was -  
3 - since the patient was actually injected. But that's  
4 been available from patient records anyway.

5 At this point, we basically wondered are  
6 there other patients out there and if so, how  
7 seriously were they contaminated? The next four slides  
8 review our July 15th FDA drug safety communication.  
9 And I have to admit I think it was written pretty  
10 well, where we expressed concern for the contamination  
11 of the potential for increased radiation exposure to  
12 patients.

13 When this presentation was prepared, we  
14 were not sure what numbers we could share with you,  
15 but we now have been given permission by different  
16 parties to share some of the information. So I will  
17 mention some numbers during this talk. The amount of  
18 breakthrough for the two index patients exceeded  
19 limits by 125 and 40 times for the strontium-82 and 7  
20 times both for the strontium-85 component. Although  
21 this clearly suggested a problem with the generator  
22 regarding excessive breakthrough, why was it breaking  
23 through, a questionable safety testing for  
24 breakthrough at the sites was also in question.

25 We considered the risk at this time of

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1 radiation harm to these two patients minimal, which  
2 was similar to the amount of radiation patients may  
3 receive from other radiation exams. But again, two  
4 patients detected at the border, was this more  
5 prevalent? Was this more widespread, if at all? And  
6 were some of the patients exposed to much higher  
7 amounts of contamination? So there was a public health  
8 concern that started to creep in. We had to look  
9 beyond our immediate regulatory authority of the  
10 medical product, the generator, why is not performing  
11 the way it was specified?

12 For initial radiation absorbed doses,  
13 based on the Customs' data, were estimated to be as  
14 high as 90 millisieverts or 9 rem. After whole body  
15 scanning at Oak Ridge, the estimated effective dose  
16 was 4.9 rem for one patient and 2.1 rem for the other.  
17 And according to the Bracco consultant, this was 10  
18 times or 4 times greater than the expected 4.8  
19 millisieverts.

20 Let me state here very carefully effective  
21 dose by itself is really inappropriate. It's a great  
22 metric for comparing doses from other procedures, but  
23 for medical risk assessment, for medical purposes, we  
24 really need to know the underlying organ doses. So I  
25 may be using effective dose here, but the real

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1 critical issue is what are the doses that the  
2 different organs are receiving.

3 And just to emphasize the need for  
4 standardization, I just want to make a point here. If  
5 one were to use the actual Bracco product insert organ  
6 dose table which actually states that these patients  
7 should have received 1.2 millisieverts, rather than  
8 the 4.8 calculated by the Bracco representative, they  
9 would have received 38 times or 18 times greater than  
10 the product label.

11 There are several sets of organ tables out  
12 there: ICRP tables, the Bracco patient insert table,  
13 the current calculation which was using OLINDA  
14 software derived from Merck dose software, originally  
15 developed by the Society of Nuclear Medicine, Medical  
16 Internal Radiation Dose Committee. Using some of these  
17 other tables can yield higher or lower dose estimates.  
18 For consistency and standardization, we prefer to  
19 limit such dose estimates to one method, fully aware  
20 of these differences.

21 We considered the OLINDA methodology  
22 satisfactory. Did not want to become sidetracked over  
23 which organ dose table or method was more accurate. We  
24 felt that if there were serious levels of  
25 contamination, the dose differences would be much

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1 greater than the differences or discrepancies among  
2 the different methodologies or organ dose tables.  
3 Having said that, as a member of this Committee, I  
4 believe, however, discussion on organ dose tables  
5 including the inherent level of uncertainty and how  
6 such dose estimates fit into the NRC's medical event  
7 criteria warrant a separate discussion, not  
8 necessarily for this session.

9 One major concern was identifying the root  
10 cause of the generator's failure, how widespread this  
11 was in terms of number of patients and what sort of  
12 radiation doses that some of these individuals  
13 actually received. Again, two patients are not an  
14 adequate sample. And there was an overriding tension  
15 in that the longer we waited to look at some other  
16 patients, the more the radioactivity would decay away.

17 There was much we didn't know then and we  
18 still don't know if this is a safety issue or a  
19 product problem involving generator failure, user  
20 error, or a combination of these. And there's some  
21 other factors that we haven't even brought to the  
22 table because the drug is administered with an  
23 injection system which is actually considered a  
24 medical device as well. And so there are questions in  
25 terms of the accuracy produced associated with that

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1 product. Obviously, we've been discussing this with  
2 Bracco, the Nuclear Regulatory Commission, as well as  
3 several other state and federal agencies.

4 As we stated in our July 15th publication,  
5 we didn't know and as I said at this point we have a  
6 better idea, but until -- FDA is a science-based  
7 agency and we respect opinions, but we really prefer  
8 facts better. So we need more data.

9 After meeting with Bracco and discussing  
10 our concerns, including the results of on-going  
11 investigations, Bracco voluntarily recalled the  
12 CardioGen-82 generator until a lot of the safety  
13 issues were resolved. As I said, at this time we  
14 haven't really determined the root cause of the  
15 problem.

16 In summary, right now there are  
17 investigations going on with Bracco, the State of  
18 Florida, and the State of Nevada. Patients are being  
19 tested and whole body counting will be performed on a  
20 number of these patients. And in closing, I actually  
21 want to thank everyone involved. It's been a bit  
22 stressful for some of the stakeholders, but the State  
23 of Nevada actually moved very quickly and has been  
24 testing patients for the last several weeks and at  
25 this point has tested about 200 patients from Nevada.

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1 And all I can say right now is there are a number of  
2 them that are contaminated, but until some better dose  
3 estimates are derived, I think it's probably -- wait  
4 just to see how all this plays out.

5 Also, I learned yesterday evening, that  
6 the State of Florida had actually begun testing some  
7 patients as of last Tuesday or Wednesday. And we can  
8 answer questions later.

9 CHAIR MALMUD: Thank you, Dr. Suleiman.

10 Dr. Howe.

11 DR. HOWE: Orhan has given you a lot of the  
12 technical details. And what I'm going to talk about is  
13 the regulatory aspect of this. And I have passed out  
14 a handout of our regulations and how they fit into  
15 this and what we're looking at.

16 The first one is 35.204, the permissible  
17 moly-99, strontium-82, and strontium-85  
18 concentrations. Our requirements and the requirements  
19 are the same as in the recommended state regulations  
20 that a licensee may not administer to humans a  
21 radiopharmaceutical that contains more than .02  
22 kilobecquerels of strontium-82 per megabecquerel of  
23 rubidium-82 chloride injection or more than 2  
24 kilobecquerels of strontium-85 per megabecquerel of  
25 rubidium-82 chloride injection. So that's our

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1 requirement. You cannot -- you are not to give any  
2 more than that.

3 How are licensees supposed to know that  
4 they've reached this maximum permissible  
5 concentration? If they use a strontium rubidium  
6 generator for preparing the rubidium, they shall  
7 before first patient use of the day, measure the  
8 concentration of the radionuclide strontium-82 and  
9 strontium-85 to demonstrate compliance with the  
10 paragraph above. And licensees are also required when  
11 they do make this measurement to keep a record.

12 So our requirements, as well as the  
13 requirements in the states, are to measure the eluant  
14 for maximum permissible concentration before first  
15 patient use.

16 The records that they have to keep are in  
17 35.2204, records of molybdenum-99, strontium-82, and  
18 strontium-85 concentrations. That says a licensee  
19 shall maintain a record of -- I'll skip the molybdenum  
20 part -- strontium-82, strontium-85 concentration tests  
21 required in the earlier requirement for three years  
22 and it has to include for each elution the ratio of  
23 the measures expressed in kilobecquerels of strontium-  
24 82 per megabecquerel of rubidium-82 and kilobecquerels  
25 of strontium-85 per megabecquerel of rubidium-82 and

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1 the time and date of measurement and the name of the  
2 individual who made the measurement. So we should have  
3 a clear record at licensee sites of these measurements  
4 and the ratios.

5 While we've been looking at these things  
6 we've discovered that some licensees may not have  
7 understood how to make the test. It's a very  
8 particular test. It's a lot more involved than the  
9 technetium generator breakthrough elution test. And  
10 one has to be very precise with it, so there may be  
11 problems in following the manufacturer's instructions.  
12 There may be other issues with equipment associated  
13 with making the measurements also.

14 So the first level of regulatory interest  
15 is whether an individual has been given in excess of  
16 the permissible limits of strontium-82 and -85. The  
17 second level of interest is when that activity reaches  
18 a high enough point that a medical event needs to be  
19 reported. And the medical event reporting requirements  
20 are in Subpart M, 35.3045, report and notification of  
21 a medical event. And in that regulation, a licensee is  
22 to report any event except an event that results from  
23 patient intervention which we don't have here, in  
24 which the administration of byproduct material,  
25 radiation from byproduct results in a dose that

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1 differs from the prescribed dose. In this case, if you  
2 were to get a normal rubidium procedure and you get  
3 two injections, one for resting and one for stress,  
4 and the maximum activity that the manufacturer  
5 recommends is 60 millicuries, and in our patients that  
6 have had whole body scanning, it's been more like a  
7 total 75 millicuries, then the maximum activity that  
8 you would expect would be .48 rem. So the dose, if it  
9 differs from the prescribed dose, it would have  
10 resulted from prescribed dosage by more than 5 rem.  
11 And we're getting close to that with one of the index  
12 patients. They're at 4.9 rem for the calculation.  
13 There's not precision in that calculation, but it is a  
14 good marker of the effective dose equivalent.

15           And then the other criteria, which is  
16 separate, would be 50 rem to an organ or tissue, or a  
17 shallow dose equivalent to the skin. And the total  
18 dose delivered differs from the prescribed dose by 20  
19 percent or more. So right now, we're looking at  
20 differing from the prescribed dose by more than 20  
21 percent. And then as soon as we hit the threshold of  
22 5 rem effective dose equivalent or 50 rem to an organ  
23 or tissue, then we'll have a reportable medical event.  
24 At this point, we don't have a reportable medical  
25 event, but we could in the future.

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1           And then if you do trigger a medical  
2 event, then the licensee has to notify the NRC no  
3 later than the next calendar day. What makes it  
4 interesting in this case is the licensees really don't  
5 have the ability to tell whether they will have a  
6 medical event or not until patients have been scanned.  
7 So they will probably be notified by the folks that  
8 are doing the scanning that there's an excess of 5 rem  
9 or 50 rem. And then the facility will have to make a  
10 medical event report.

11           And NRC has been actively involved in  
12 coordinating between FDA and the Agreement States.  
13 We've used our Memorandum of Understanding to be  
14 involved and follow what's happening. We have sent out  
15 an all-Agreement State letter after FDA did its drug  
16 safety notification, so that all the Agreement States  
17 were aware of what FDA's action was in the Bracco  
18 voluntary recall. And so we're actively monitoring and  
19 seeing at what point we need to get involved.

20           At this point, we don't have any  
21 identified patients at NRC licensees' facilities.  
22 That doesn't mean they're not there. They just haven't  
23 been identified.

24           CHAIR MALMUD: Thank you. So the  
25 investigation is on-going?

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1 DR. HOWE: Yes, it is.

2 CHAIR MALMUD: And the purpose of  
3 presenting it to the ACMUI today is?

4 DR. HOWE: To make you aware of the public  
5 information that we can share with you and to let you  
6 know a feeling of the scope of what we know right now.

7 CHAIR MALMUD: Thank you. Are there any  
8 questions from members of the Committee?

9 Yes, Dr. Zanzonico.

10 MEMBER ZANZONICO: I have several  
11 questions. One is what's the -- you say the  
12 investigation is on-going. What are the components of  
13 the investigation? In other words, what information  
14 are you trying to solicit and where does that stand at  
15 the moment in terms of anticipating when and what if  
16 the product will again be available for clinical use?

17 MEMBER SULEIMAN: Let me answer it briefly,  
18 and then I'll defer it to the other people here.  
19 There's clearly the FDA medical product which is a  
20 generator. One very obvious question why did it fail  
21 in the first place? Without failure, the users  
22 wouldn't even need to do breakthrough testing. The  
23 second aspect is why was the breakthrough testing not  
24 done properly? That addresses, that's a user issue, a  
25 licensee issue.

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1           You've got supposedly qualified personnel  
2 conducting this test. Are there deficiencies in how  
3 the test is done? So this is an area that's very, very  
4 nebulous, but it comes under very different regulatory  
5 authority. It doesn't -- FDA is really focused on  
6 product.

7           I think there's a bigger, broader public  
8 health issue. You've got patients out there that have  
9 used this medical drug and they may be contaminated.  
10 And you can argue whether the contamination is  
11 hazardous or not, but without knowing, how can you  
12 come to that conclusion? So I think there's that  
13 broader issue that's at play.

14           As I have introduced earlier, this is Dr.  
15 Ira Krefting. He's the Deputy Director for Safety. I  
16 introduced both of you in absentia.

17           DR. KREFTING: I was impressed with your  
18 Customs and Border Patrol. Yes, I'm Ira Krefting as  
19 Leon mentioned. And let me address that issue in  
20 further detail and add some granularity to the outline  
21 given by Orhan.

22           The investigation is multi-prong, multi-  
23 factorial in that obviously and most importantly the  
24 public health issue, identification of contaminated  
25 patients and quantification, as necessary, of the

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1 underlying radiation that they received. So that is  
2 being carried on, as you heard, by some of the state  
3 agencies in concert with CDC and the NRC. Nevada has  
4 moved ahead very expeditiously screening or surveying  
5 a great number of patients. Florida is doing the same.  
6 CDC, in concert with -- there are plans for further  
7 screening.

8           The other aspect of that is we are  
9 concentrated on the product. We have what is called  
10 post-marketing requirements. This is part of our  
11 legislative mandate that was made in about 2007. The  
12 FDAAA Act, FDA Amendments Act, which requires us or  
13 allows us, if you wish, if we identify a new safety  
14 issue, to mandate that the sponsor do certain studies  
15 to help define and help us solve that particular  
16 safety issue to help -- so the sponsor is obligated to  
17 look into a safety problem. This constitutes a federal  
18 contract in that the sponsor is required to a study,  
19 present us with a protocol. There are milestone dates  
20 that the study gets done and then there's a final  
21 report, usually leading to some action on either the  
22 sponsor's part or our part, revision of a product, new  
23 labeling, etcetera.

24           In that regard, there are two post-  
25 marketing requirements which we initiated over the

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1 summer. These are listed on clinicaltrials.gov. So the  
2 protocol, etcetera, is very public. One is to study  
3 patients in the two sites, two index sites that were  
4 mentioned in Orhan's presentation, Nevada and  
5 Sarasota, where patients who had received rubidium,  
6 undergoing clinical scans, at about the time as the  
7 index patients, the two identified patients had  
8 received theirs. So that's one post-marketing  
9 requirement.

10 Again, keeping with the theme, the concept  
11 that FDA primarily looks at the product, FDA has  
12 purview over Bracco, the manufacturer. The other PMR  
13 looks more broadly at the use of the product. The  
14 initial thoughts was that there may be breakthrough  
15 towards the end of expiry of the CardioGen generator.  
16 Basic chemistry sort of makes sense in that regard.  
17 The more elution that is put through the generator,  
18 the more saline to wash out the rubidium. There might  
19 be breakthrough towards the end of the life of that  
20 generator or when breakthrough was actually reported.  
21 So what's termed Study 105 is to look at patients who  
22 were receiving their rubidium scan, their rubidium  
23 CardioGen scan at the last date of use of the  
24 generator before it was sent back, before it reached  
25 expiry. So the hope there is that sites around the

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1 country will participate in that study, will be able  
2 to survey patients looking back at the records that  
3 received rubidium on the date I just mentioned, the  
4 date of expiry.

5 I must emphasize to everybody that post-  
6 marketing requirement studies are voluntary studies.  
7 They constitute clinical trials. Patients come under  
8 all of the clinical trial protections that we're all  
9 so familiar with in the clinical environment. So  
10 everything I just mentioned is of a voluntary nature  
11 and the way the legislation and the regulations are  
12 set up, it is Bracco's responsibility to expeditiously  
13 execute these studies, move forward with them, help  
14 the sites in recruiting patients. And the first  
15 indications we have are that things are moving along  
16 in the regards that I just mentioned.

17 DR. YANG: To summarize what Dr. Suleiman  
18 and Dr. Krefting had said and to also directly answer  
19 your question, we're actually interested in what is a  
20 root cause; meaning is it a product failure or is it  
21 end user misuse or failure? That's one aspect of it.  
22 And the other aspect of it is what is the magnitude  
23 and extent of this increased radiation exposure,  
24 meaning how many patients out there in the United  
25 States have had increased radiation exposure as a

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1 result of Cardio-Gen scans. And what is the highest  
2 radiation that any one of these patients may have  
3 resulted.

4 MEMBER ZANZONICO: This is Pat Zanzonico  
5 again. I guess my question is these patients were  
6 discovered fortuitously, at the borders. So can you  
7 summarize what data are available that are the basis  
8 for the regulatory limits? I guess my question is  
9 perhaps this isn't an abnormal occurrence. It's just  
10 something that was not detected previously because of  
11 less vigilance, just luck. And is it a possibility  
12 that this is the norm in terms of strontium  
13 breakthrough on this generator and that the regulatory  
14 limits may need to be adjusted to accommodate what now  
15 may be the actual behavior of this?

16 And I guess an ancillary question is has  
17 Bracco reported any change in manufacturing from its  
18 original formulation of the product to now that could  
19 be identified as a possible cause of increased  
20 breakthrough? Those are two separate, but related  
21 questions.

22 MEMBER SULEIMAN: I'll answer the first  
23 one. Let me tell you there's a lot of patients that  
24 are being -- that are scanned who don't have any  
25 breakthrough. A lot of the generators have been

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1 tested. There are lots of examples of good practice.  
2 So this is not the norm.

3 A subpart of that though is we don't know  
4 if this has been going on longer. And again, when I  
5 say the problem, I'm talking about have people been  
6 using the product inappropriately? Have they not been  
7 performing the breakthrough testing properly? Or has  
8 there been an inherent problem, major, minor, with the  
9 column itself?

10 DR. YANG: I think that was a very good  
11 answer, number one. I'm not sure we can actually talk  
12 about number two. I think we will defer to our  
13 Division Director.

14 DR. RIEVES: My name is Dwaine Rieves, I'm  
15 Director of the Division. This product has been on the  
16 market for about 20 years. During that time, it's  
17 typical to have some changes in the product just  
18 because vendors go out of business, they get a new  
19 supplier, that sort of thing.

20 And so those iterations have occurred over  
21 the years. But in terms of the root cause  
22 investigation of the company, that is still ongoing.  
23 So far, the company has not identified a root cause in  
24 terms of the actual construct of the product itself.

25 There have, obviously, been iterative

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1 changes over the years, necessary changes. But so far,  
2 I wish we had an answer, but it's going to be a few  
3 more weeks. The company is actively stressing these  
4 generators. These stress studies are ongoing. So  
5 hopefully within another six weeks or so, we'll have  
6 an answer.

7 MEMBER ZANZONICO: Can I ask a question?

8 CHAIR MALMUD: Dr. Zanzonico.

9 MEMBER ZANZONICO: Presumably, if the  
10 breakthrough were done at the point of service in the  
11 clinic where it was being used, these would have been  
12 identified. So your investigation now has disclosed  
13 that it's not being done or perhaps it was done, but  
14 not done properly? Or what's the status? That seems  
15 like a really key --

16 DR. KREFTING: All those points are very  
17 important. Those are all possibilities and those are  
18 all under active investigation.

19 MEMBER ZANZONICO: Okay, and one final  
20 point and I'll shut up. You know, some manufacturers  
21 certify users. Is that done in this case in terms of  
22 the QC? I mean it's not an overly onerous procedure,  
23 but it's not trivial either. Is that part of the  
24 marketing, so to speak, of the generator, kind of user  
25 certification by the manufacturers that they can, in

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1 fact, use the QC properly?

2 DR. YANG: There is no certification  
3 process.

4 MEMBER SULEIMAN: By us.

5 DR. YANG: By us or by Bracco, the sponsor.  
6 But they do train the users when they actually first  
7 become customers.

8 MEMBER ZANZONICO: But there's no document  
9 provided that says User X has been trained and has  
10 demonstrated that he or she can perform --

11 MEMBER SULEIMAN: I'm not aware. We have  
12 representatives from Bracco here. If you want to  
13 comment on that, it would be nice. If you don't know  
14 any more than I do, then pass, you know. I mean for  
15 some products there is. I'm not familiar that this is  
16 actually required.

17 DR. NUNN: This is Adrian Nunn from Bracco.  
18 I'm not sure that we have complete records of who  
19 exactly has been trained and names, but we do train  
20 them and we know which sites have been trained. And  
21 we don't let them use the generator without that  
22 training first time around.

23 MEMBER ZANZONICO: Right, but does the  
24 company know of formal documentation?

25 DR. NUNN: Probably not of the sort that

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1 you are looking for.

2 CHAIR MALMUD: Malmud. One of the items  
3 that you alluded to was that the problem may be  
4 attributable to the age of the generator and the  
5 amount of saline washed through in terms of the eluant  
6 so that toward the latter end of the use of a  
7 generator, there may be this problem which does not  
8 exist earlier in the use of the generator. Therefore,  
9 a question I have is was that tested for when the  
10 product was initially placed on the market?

11 MEMBER SULEIMAN: We've raised that  
12 question ourselves. The product was approved 22 years  
13 ago. I think Bracco didn't -- Bracco bought it from a  
14 previous company as well. We don't really know the  
15 answer.

16 CHAIR MALMUD: So we don't know the answer  
17 to that question.

18 MEMBER SULEIMAN: That testing actually is  
19 -- Bracco is repeating a lot of that as we speak.

20 CHAIR MALMUD: So that testing is ongoing  
21 currently.

22 MEMBER SULEIMAN: So we'll get some answers  
23 for that.

24 CHAIR MALMUD: Thank you.

25 MEMBER LANGHORST: I had a question, but if

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1 you're not done --

2 CHAIR MALMUD: Dr. Langhorst, absolutely.

3 MEMBER LANGHORST: Thank you. Dr. Howe, in  
4 regard to our Agreement States that these two patients  
5 were treated, are there reports yet on their  
6 inspection with regard to 35.204 and 35.2204 as far as  
7 the site users performing the test and documenting the  
8 test?

9 DR. HOWE: Nevada has done an inspection of  
10 the facility with the patient that came across the  
11 border and tested positive. But that report has not  
12 been finalized yet.

13 MEMBER LANGHORST: Okay.

14 DR. HOWE: And the State of Florida has  
15 done an inspection of the site in Florida and has  
16 inspected a few other sites as well. And the results  
17 of that inspection are not available yet.

18 MEMBER LANGHORST: Okay, okay, thank you.

19 DR. HOWE: And I think it might be  
20 important to note the scope of the rubidium use when  
21 the generators were still in the market. And places  
22 seem to average somewhere between 4 to 20 patients a  
23 day. And they were running five to seven days a week,  
24 so there are a lot of patients that were out there,  
25 nowhere near the number you have for molybdenum, but a

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1 really large number of patients.

2 CHAIR MALMUD: Thank you. Other questions?  
3 Yes. Laura, I think you were next, Laura.

4 MEMBER WEIL: This is Laura Weil. What kind  
5 of notification has gone out to patients who were  
6 imaged in these generators, using these generators,  
7 other than the clinical trial that's listed publicly  
8 which is recruiting?

9 DR. KREFTING: We, as was mentioned  
10 previously, don't have direct control over those type  
11 of communications and that type of communication is in  
12 the hands of the sites of the end users that actually  
13 do the studies. We understand around the country that  
14 some sites have notified patients about the situation.  
15 And we also understand that some sites have not.

16 DR. YANG: Adding on to what Dr. Krefting  
17 is saying, the sponsor's website, CardioGen, actually  
18 has like a link for patients and so --

19 MEMBER SULEIMAN: Also, our July 15th  
20 public communication pretty much was announcing it to  
21 the public, but it needed a little bit of stimulus.

22 CHAIR MALMUD: Excuse me, ladies and  
23 gentlemen, may I remind you that this is being  
24 recorded. And therefore would you please reintroduce  
25 yourselves each time you speak so that the court

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1 reporter can record it accurately. Please go on.

2 DR. KREFTING: So in summary, it is the  
3 responsibility of the local sites to notify their  
4 patients if they felt so inclined. If they were to  
5 participate in the PMR studies I mentioned to you,  
6 that would be the responsibility of the local sites to  
7 invite patients to participate and during the state  
8 investigations, we understand that the sites  
9 themselves were notifying the patients and inviting  
10 them to come in for these state screenings.

11 The other two mechanisms were just as  
12 mentioned, there is the CardioGen website that has  
13 some patient general information on it, as well as our  
14 drug safety communication. Unfortunately, I can't  
15 give you a more detailed answer than that.

16 MEMBER WEIL: Thank you.

17 DR. KREFTING: I did want to speak to your  
18 question that you addressed to Orhan a few moments  
19 ago. Again, this is Ira Krefting. You asked about  
20 the elution information and how there was testing of  
21 the generators, perhaps at their time of approval back  
22 about 1989-ish. As Orhan told you, we don't have  
23 immediate information for you, the extent of testing  
24 at that time. But the more tantalizing information is  
25 that when you look at the use of the CardioGen

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1 generator over the last few years, there has been an  
2 astronomical increase in the number of patients who  
3 are receiving the study.

4 It's perhaps appropriate because in the  
5 practice community, molybdenum is less of a radiation  
6 dose, as you heard. Some people feel the images are a  
7 little easier to interpret and a little better  
8 defined. So there's been this vast increase in the  
9 number of patients, probably well beyond the thoughts  
10 back in 1989 to the extent it was going to be used  
11 when it was first introduced in the market.

12 The other important point that was brought  
13 out by Dr. Howe and Orhan mentioned to you there is a  
14 vast difference in the number of patients who around  
15 the country at sites getting this. Some sites will do  
16 a couple patients a day. Other sites, like the most  
17 active ones can do 18, 20 patients a day and run the  
18 generator 7, almost 7 days a week. So obviously, the  
19 elution volume over that vast spectrum of patient  
20 input is going to vary tremendously.

21 CHAIR MALMUD: Thank you. Do we know the  
22 volume of patients handled in the two institutions  
23 sited in Florida and in Nevada?

24 DR. KREFTING: Yes, sir.

25 CHAIR MALMUD: Is it at the higher end?

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1 DR. KREFTING: Yes. Nevada is probably  
2 the highest site in the country and the Sarasota site  
3 is in the top tier, probably top ten. I think it's  
4 probably top five-ish.

5 CHAIR MALMUD: Thank you. If I may, Dr.  
6 Howe, you mentioned that from the data thus far  
7 collected it did not appear that the limits set by the  
8 NRC have been exceeded in these patients. What is the  
9 target organ of the two elements involved, the  
10 strontium and the rubidium and how close to the limit  
11 have we gone from the data thus far collected?

12 DR. HOWE: The strontium is the bone  
13 surface. So you have the bone surface and the red  
14 marrow.

15 MEMBER SULEIMAN: One of the patients had  
16 doses -- what's the limit, 50?

17 DR. HOWE: Fifty.

18 MEMBER SULEIMAN: It's getting close to  
19 that, but didn't. And so none of the NRC's radiation  
20 dose medical event criteria have been exceeded.

21 CHAIR MALMUD: The purpose of my asking  
22 that question was that someone else asked if the  
23 patients had been notified and in fact, the limits  
24 have not been exceeded. Is that correct?

25 DR. HOWE: The limits haven't been

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1 exceeded, but the patients that are being tested for  
2 radiation have been notified that there were issues  
3 with the generator and asked if they could come in and  
4 voluntarily participate and have a radiation  
5 measurement made. And so those patients are aware  
6 that there are issues with the generator and have  
7 voluntarily come in to have radiation measurements  
8 made.

9 We have not had the activation of the  
10 medical event reporting requirements yet.

11 CHAIR MALMUD: Again, the reason that I  
12 asked the question was that we've always walked a very  
13 narrow line between alerting patients to possible  
14 risks and panicking patients for risks that actually  
15 did not occur. So at the moment, recognizing the data  
16 is still being collected, we have not exceeded the  
17 limits that have been established by the NRC. Is that  
18 a fair statement?

19 MEMBER SULEIMAN: Officially, no. They  
20 haven't been exceeded. However, based on some of the  
21 preliminary data that we've seen, there may very well  
22 be some.

23 CHAIR MALMUD: At that point, we would  
24 expect that the patients would be notified of that  
25 area of concern rather than the current notification

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1 of patients which is that we need to retest you with  
2 regard to a concern. A concern is not the same as an  
3 actual hazard. And I think that's what Laura Weil was  
4 addressing in her role of concern for the patient. So  
5 I wanted to make sure that we all understood that we  
6 were still in a gray area where we recognize that  
7 there is a problem. But it has not reached the level  
8 at which the patient should be notified that he or she  
9 may be at any kind of risk for having received  
10 radiation exposure in excess of that which is  
11 tolerable by NRC requirements.

12 DR. HOWE: And Dr. Malmud, you hit an  
13 important part. We have -- there are on-going  
14 radiation measurements made of specific patients in  
15 Nevada and in Florida because we have high reason to  
16 believe that there are excessive contamination in  
17 those patient populations based on the Homeland  
18 Security triggering.

19 CHAIR MALMUD: And also verified at Oak  
20 Ridge. Those measurements, there has been significant  
21 product breakthrough and these patients are  
22 contaminated without little doubt about that.

23 DR. HOWE: Yes. But what I'm saying is that  
24 we have not gone out to all the other facilities  
25 because you don't want to call patients back in and

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1 unduly make them worry if, in fact, there weren't  
2 issues at that particular site. And we have seen, as  
3 Orhan has indicated, the data indicates that there are  
4 people that had procedures with no contamination. But  
5 there are others that have had contamination. So  
6 that's the issue we're balancing right now is when do  
7 you go to a site that hasn't been identified with a  
8 Homeland Security patient and start to call people in.  
9 And that's what FDA is talking about with the Bracco  
10 study and other studies.

11 CHAIR MALMUD: Another question if I may,  
12 and that is, currently are these generators being  
13 produced by any manufacturer, and (b) currently used  
14 in the United States for the record?

15 DR. HOWE: No, they are in voluntary  
16 recall.

17 CHAIR MALMUD: Total recall?

18 DR. HOWE: Yes.

19 CHAIR MALMUD: Thank you. The other issue  
20 is, of course, that --

21 DR. HOWE: And I believe they've also been  
22 recalled internationally.

23 CHAIR MALMUD: Thank you. I just want that  
24 in the record. Other questions? Oh, excuse me.

25 MEMBER GUIBERTEAU: Mickey Guiberteau.

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1 Also for the record, since 1989 is this the first  
2 incident that has been discovered of nearly or  
3 significant breakthrough in terms of these strontium  
4 and rubidium columns?

5 DR. HOWE: NRC can't answer because we did  
6 not regulate them until the NARM rule came into effect  
7 which would be 2005-2007 time frame.

8 MEMBER GUIBERTEAU: But it is since that  
9 time, is that correct?

10 DR. HOWE: Yes, that NRC is aware of.

11 DR. KREFTING: Ira Krefting here. To  
12 further answer your question, breakthrough has  
13 occurred in the past. And that has, for example,  
14 looking back at the record, there has been a  
15 breakthrough in previous -- I believe it was 2010-ish  
16 or so, but those were reported to Bracco and  
17 appropriate actions were taken such as recall of that  
18 specific generator.

19 MEMBER GUIBERTEAU: And what did they find  
20 at that time?

21 DR. KREFTING: I don't know about the  
22 investigation at that time. I can't tell you.

23 MEMBER GUIBERTEAU: Could Bracco tell us, a  
24 representative?

25 DR. NUNN: Adrian Nunn. I'm not aware of

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1 the details, but that concern was investigated and I  
2 think it has been concluded.

3 MEMBER GUIBERTEAU: And what was the  
4 outcome?

5 DR. NUNN: I don't know.

6 MEMBER GUIBERTEAU: Thank you.

7 CHAIR MALMUD: There was another question.

8 MEMBER PALESTRO: Chris Palestro. Many  
9 years ago, many, many years ago, strontium-85 was used  
10 for studying the skeletal system. I don't think it was  
11 imaging, it was scanning or counting of one sort of  
12 another.

13 So my question is do you have a sense of  
14 comparison between the doses that the index patients  
15 or however many patients you have a chance to evaluate  
16 who have been exposed to strontium-85, the doses that  
17 they've received in comparison to the doses of  
18 strontium-85 that were administered for diagnostic  
19 purposes many years ago?

20 MEMBER SULEIMAN: I am not aware.

21 CHAIR MALMUD: If I may, the studies that  
22 were done with strontium-85 were approximately 1965.  
23 The authors were Sklaroff, Charkes, and Young, a  
24 nuclear physician, a radiation oncologist, and a  
25 pathologist. The dosimetry was calculated. It's in

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1 the literature. The articles, the seminal articles  
2 were published in the Journal of the American Medical  
3 Association which made the technique clinically  
4 available.

5 Initially, their work was done on a Picker  
6 scanner with paper, rather than film. They converted  
7 to film so there were images. The patient population  
8 at that time was composed solely of women who had  
9 metastatic breast cancer, proven by x-ray and  
10 therefore had a limited life expectancy by definition  
11 of the disease and the extent of metastases.

12 Therefore, the radiation burden was  
13 accepted in 1965 considering the limitations of the  
14 population.

15 When the technique became attractive, as a  
16 means of identifying bone metastases in excess of  
17 those that could be identified by whole body x-ray  
18 studies, the next substitution for -85 was strontium-  
19 87m which was a generator. The strontium-87m was a  
20 methodology used and there's dosimetry for it as well.  
21 It's documented in the literature. I'm not certain  
22 that I can give you the reference, but it was one of  
23 the IAEA or NRC publications.

24 Subsequently, because of the radiation  
25 burden of strontium-85 which was excessive by current

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1 standards and then as well, and the impracticality of  
2 the -87m, a substitute was sought and that substitute  
3 evolved into a phosphate compound, an analog of  
4 calcium, but a phosphate compound, initially marketed  
5 as polyphosphate by a number of radiopharmaceutical  
6 companies. And that product evolved to the current  
7 products which are also phosphates, labeled with  
8 technetium-99m and therefore those technetium-99m  
9 products have been the products and remain the  
10 products which are used broadly for not only the  
11 detection of metastatic disease, but for inflammatory  
12 disease of the bone, trauma, shin splints, many things  
13 that are not well defined by radiography.

14 And that's how we got to where we are now.  
15 So the radiation burdens today are trivial compared to  
16 those of -85. And the data is in IAEA and in NRC  
17 publications from many years ago, as well as medical  
18 literature dating back to the middle 1960s.

19 DR. HOWE: Thank you, Dr. Malmud.

20 MEMBER SULEIMAN: Thank you, yes. And from  
21 '63 to '72, if my memory is right, the Atomic Energy  
22 Commission regulated the radio-labeled drugs. It  
23 wasn't until '72 that that authority was given back to  
24 FDA.

25 CHAIR MALMUD: That may be, but it was the

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1 AEC at that time, not the NRC. You're correct.

2 MEMBER SULEIMAN: But it was also  
3 regulated. FDA did not, I think at that time the AEC  
4 regulated all radioactive products including drugs.

5 DR. HOWE: And I believe at that time the  
6 major group that was looking at the drugs for approval  
7 was the ACMUI. And it's Subcommittee on Human Use.

8 CHAIR MALMUD: Thank you. A little bit of  
9 history.

10 Dr. Zanzonico?

11 MEMBER ZANZONICO: Can I just make a  
12 comment, not a question? When my clinical colleagues  
13 learned that I was attending an NRC meeting where this  
14 would be on the agenda, I got some -- let me put it  
15 strident feedback to the effect that this is -- and  
16 this is not my opinion, this is what my clinical  
17 colleagues have told me, that this is a regulatory  
18 overreaction, that the negative impact on patients for  
19 the lack of availability of the generator does not  
20 justify the total recall.

21 And so at the very least, I would ask on  
22 their behalf that whatever regulatory and corrective  
23 action is required, that really be expedited because  
24 it's felt that it's gone on much, much too long to the  
25 -- in terms of negative impact, clinical impact on

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1 patients. So that's just a little bit of  
2 editorializing that I promised I would bring before  
3 the meeting.

4 DR. KREFTING: Ira Krefting here. I  
5 appreciate that statement. I think it's important that  
6 that be answered and discussed here, if nothing else,  
7 for the public record and in understanding of the  
8 function of the FDA and to further review and  
9 reiterate the statements that have been made by my  
10 colleagues over the last few moments.

11 I also do some clinical practice on the  
12 side, so to speak, and you hear similar comments  
13 around, but I think it's important that we emphasize a  
14 couple of points. One is as we all alluded to a little  
15 bit earlier, rubidium, if the tests really work as  
16 stated and the radiation dose would be less to  
17 patients and that might be a good reason for  
18 consideration of this as an alternative of cardiac  
19 scanning procedure, but if it's not working as it  
20 should, if there's contamination of patients, without  
21 going into details, the dosing that these individuals  
22 are receiving is tantamount to approximately what  
23 they'd be getting with some of the more well known or  
24 tests that were available previously. But the more  
25 important point, as brought out by our drug safety

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1 communications, is that we are concerned that even if  
2 the drug is used as directed, even if you follow all  
3 of the labeled recommendations, the handbook from  
4 Bracco, everything else, if you follow all that, there  
5 still may be the potential for breakthrough. And  
6 that's how we stated it in our drug safety  
7 communication, particularly the one, the latter one in  
8 July.

9           So I've been approached around the country  
10 by very good, well meaning physicians saying I do  
11 everything right, what's the problem? Well, the  
12 problem may be beyond you. It may be in that either as  
13 we're learning now as brought out by the other  
14 questions that maybe the labeling instructions are not  
15 adequate, even though they appeared adequate back in  
16 the '80s and '90s. Or maybe as you heard from my  
17 director, there may be some subtle changes in the  
18 manufacturing.

19           There may be something that when these  
20 devices are used with the high-patient throughput that  
21 was never anticipated back in that generation, with  
22 the high-patient input, maybe they are breaking down.  
23 Maybe there are structural defects that we need to  
24 elucidate because so many patients are receiving it.  
25 So I think it was important to respond to your

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1 statement, sir.

2 CHAIR MALMUD: Thank you. Dr. Zanzonico's  
3 concern is a concern that the entire Committee has,  
4 namely, again we walk a narrow line between protecting  
5 the public, the patient from excessive radiation and  
6 denying the opportunity to a procedure that actually  
7 for a large number of people reduced the radiation.  
8 However, we are obligated under regulations to go  
9 through the process that we are and we hope that it  
10 will be as expeditious as possible which is what I  
11 think Dr. Zanzonico is request of us on behalf of  
12 those who spoke to him and those who speak to me about  
13 the same kind of issue.

14 MR. LUEHMAN: Dr. Malmud?

15 CHAIR MALMUD: Yes, Mr. Luehman?

16 MR. LUEHMAN: Yes, I guess one comment I  
17 would make in response to those people who have  
18 provided input to Dr. Zanzonico which is that if  
19 contacted by -- I think to bring -- to help bring this  
20 investigation to closure, then if in the studies that  
21 are going to be ongoing for patients who are yet  
22 unaffected or identified clinics, for those  
23 practitioners to encourage their patients to  
24 participate so that the FDA can get the broadest and  
25 clearest picture of the extent of this problem.

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1 Because obviously, the more data we have, and if it  
2 all shows to be that the patients are receiving less  
3 than the amounts that you would expect with  
4 breakthrough, that's going to lead us to one direction  
5 and obviously focus in more on local practices at  
6 those institutions, or as was stated earlier, the idea  
7 that maybe the problem lies in the throughput.

8 So I guess I would go back to your  
9 colleagues and say well, if contacted by the FDA for a  
10 Bracco study that one of the best ways to get this  
11 behind us so to speak is to encourage participation on  
12 the part of patients, because I think that that's  
13 going to give us, give the FDA and the NRC the most  
14 data and allow us to draw the best conclusions in the  
15 quickest amount of time.

16 CHAIR MALMUD: Thank you. Other items?  
17 Yes, Steve Mattmuller?

18 MEMBER MATTMULLER: Hi, Steve Mattmuller.  
19 A couple of comments and a question. One in regards to  
20 the training by Bracco and maybe I need to disclose  
21 that we are a clinical site that has used the rubidium  
22 generator. And we're missing ours now and do miss it.

23 But the training by Bracco from my  
24 perspective, and I wasn't heavily involved in it, but  
25 was very extensive and the technical service people at

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1 Bracco were well trained and very helpful. And it just  
2 wasn't they were in and they were out. It's been  
3 ongoing. In fact, not necessarily on generator issues,  
4 but they were also very helpful on scanning issues  
5 which we've been participating in some other issues or  
6 scanning protocols with them.

7 So I know we've had constant contact with  
8 the technical service people of Bracco on a number of  
9 issues, not directly related to problems, but our  
10 interactions have already been very positive and very  
11 good. But also to answer that question, do we have a  
12 piece of paper signed and documented? I doubt it. But  
13 I do know the training did take place and was very  
14 thorough.

15 The other statement and I'm sorry, I can't  
16 remember which FDA official mentioned it, there has  
17 been a dramatic increase in use of the product and  
18 part of that I would venture to say is one that's a  
19 very, and it may not be -- I would say the gold  
20 standard, the myocardial perfusion imaging right now  
21 in the United States, for a number of reasons.  
22 Because it is a PET agent because of the higher energy  
23 and which also has definite advantages in larger  
24 patients.

25 And the other drug factor behind that is

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1 the past headaches and lack of availability of moly-99  
2 for technetium generators that I know some sites have  
3 moved to rubidium because they couldn't get technetium  
4 on a regular basis. But then once they found out how  
5 good the rubidium is, they've stayed with it.

6 And then just my final question would be  
7 for Orhan. You mentioned that preliminary data has  
8 shown that there are patients who were scanned at  
9 these index sites -- that's my question. Preliminary  
10 data has shown that some of these patients have  
11 exceeded limits, or you think they're going to exceed  
12 limits? Are they from index sites or are those from  
13 other sites?

14 MEMBER SULEIMAN: The first round of data  
15 is from index sites because we had a lot of difficulty  
16 getting a lot of things moving. So I think if we could  
17 have had all our questions answered one or two months  
18 ago, this thing could be much closer to closure. So  
19 the lack of data, the lack of information, couldn't  
20 move quickly. And we're going to be data driven. But  
21 the first tier was basically to focus on the index  
22 sites because that was a high probability. You can't  
23 go to non-index sites when you haven't even done the  
24 index sites.

25 The first focus, if we're going to bother

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1 these patients, let's get them close to the index  
2 patients because it sounds like intuitively maybe at  
3 the end of the lifetime, the generator is breaking  
4 through more. We do plan on looking at patients  
5 earlier in that site. It's kind of terrible to have  
6 to use patients to determine the performance of a  
7 generator, but that's what we've been forced to do.  
8 And there are plans to look at some sites where  
9 nothing seems to be wrong.

10 I think at some point we'll have enough of  
11 a picture where we'll say enough, it's okay. I'd be  
12 more than happy -- I'd be more happy than anybody else  
13 if nobody was contaminated and all the doses were  
14 very, very low. And if you guys feel that that's  
15 comfortable, that's fine. But based on what we've  
16 seen, based on the fact that Customs had to pick up  
17 these first two patients and based on we have no  
18 history of how widespread and what sort of doses some  
19 of these individuals could receive, it's sort of a  
20 tiered stratified approach.

21 Ideally, you'd like to snap your finger  
22 and you deploy and you test these patients and  
23 everything is -- and then you've got the issue, hey,  
24 we've measured activity with different survey meters.  
25 And you get some sort of idea what the relative amount

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1 of activity is, but how does that translate into  
2 actual dose?

3 So I was very pleased that Bracco offered  
4 and is committed to counting the patients with whole  
5 body scanning and much more definitive dose estimates.  
6 We agree, but opinions don't carry as much weight as  
7 data does.

8 CHAIR MALMUD: Other comments or questions,  
9 members of the Committee?

10 Dr. Van Decker?

11 MEMBER VAN DECKER: Thank you, Dr. Malmud.  
12 I guess a variety of comments and then I do have a  
13 question at the end.

14 You know, first of all, I want to  
15 personally thank both the FDA and the NRC for the  
16 preliminary briefing. I mean the provider community  
17 obviously gets bits and pieces and I was trying to  
18 figure out where we are and where we go and how we  
19 provide care to patients. And so preliminary data is  
20 always helpful to us to start discussion and we  
21 appreciate that.

22 I think I can speak a little bit on behalf  
23 of all my colleagues in the nuclear cardiology  
24 community and especially on behalf of ASNC. Our goal  
25 here is twofold. Number one, to create access for

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1 patients for studies that have become a seamless part  
2 of cardiovascular care for people who have coronary  
3 artery disease which is still the number one killer,  
4 right, among every one in the United States. One  
5 person a minute dies of heart disease. So we're trying  
6 to make inroads on that.

7 As expressed to this Committee before,  
8 we've actually made some major inroads over the last  
9 30 years and some of it has been due to the technology  
10 and that's been a good thing that you guys have helped  
11 facilitate our ability to deliver that care.

12 The second part of this equation which I  
13 think you guys are bringing up is we want to do it in  
14 the safest manner possible. I mean we want to make  
15 sure that we're within realms and that the I's are  
16 dotted and the T's are crossed and we can get this  
17 across a broad provider community and see how things  
18 play out. So the safety piece to us is important.

19 I point out to my colleagues on the  
20 Committee that I think over the last ten years we've  
21 learned a lot about the challenges in mechanical  
22 systems involved with delivering radiation that's  
23 useful, Gamma Knives, microspheres, vascular  
24 brachytherapy and some of the questions that come up  
25 along the way that we need to think through and make

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1 sure that we're trying to do the best we can with that  
2 interaction which is never perfect.

3 I think to some degree this becomes a  
4 little bit of a test discussion for the understanding  
5 of generators themselves, parent-daughter  
6 relationships and other isotopes that may come to  
7 market, the whole general medical, nuclear medicine  
8 community may want to be utilizing.

9 So some concept of -- in the pill portion  
10 it's called therapeutic window, but in this portion,  
11 there's some window of safety for any device. What's  
12 the stressor to get you over that window? Are you so  
13 close to the stressor that it doesn't take much to get  
14 you over it? I mean what do we need to know about flow  
15 rates and total eluates over the month and end of week  
16 generators and that type of stuff.

17 And so the knowledge base, we think is  
18 very, very important and I think everyone wants to  
19 cooperate in getting that accomplished and whatever we  
20 can do to help in that regard.

21 I would say, I would offer at the table  
22 that ASNC certainly is very, very interested in being  
23 an educational piece of this to our membership and  
24 getting out whatever information needs to get out and  
25 is already working very hard on educational programs

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1 on QC, once again in both SPECT and PET worlds for  
2 molytech generators to make sure that the community,  
3 irrespective of any tech papers that come out of this,  
4 gets distributed to people in the trenches that are  
5 trying to deliver care to patients. And I think you  
6 have or will have contact with -- I think you'll  
7 there's been quite a bit of activity done in that  
8 regard already.

9 We want to make sure that we've fulfilled  
10 documentation requirements and that's across the  
11 board, making sure that they make scientific sense  
12 here and where we're going. And so I would offer that  
13 the provider community clearly wants to be a piece of  
14 this and wants to move this along so that we can get  
15 things going on the right track again.

16 I guess my last question to all of this  
17 because I found this interesting, was I think that  
18 ASNC made an attempt to touch bases with FDA to see  
19 what it could do on a provider bases across the  
20 Society and was actually asked to write a letter with  
21 questions that would facilitate the discussion to get  
22 in the door which was done. But, you know, whatever  
23 can facilitate that process I think you'll find  
24 professional societies as a whole, across all the  
25 constituents that represent some of the greater

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1 medical societies here are interested in being  
2 proactive in helping their membership and doing the  
3 right thing. And whatever we can do to be part of that  
4 process as opposed to being on the other side of a  
5 line, we're all taking care of the same patient, we  
6 all want to do the same thing, would be helpful.

7 That ends my little discussion. Thank you.

8 DR. KREFTING: Ira Krefting. Again, it's  
9 important to respond to those statements you've made.  
10 They're very positive statements in terms of what you  
11 can do as a provider, somebody taking care of patients  
12 and dealing with these sites as was brought up by one  
13 of the other gentleman. Encourage the site and the  
14 patients to participate in the PMRs, as I indicated in  
15 my initial presentation. Those are voluntary,  
16 voluntary on the site level. It's voluntary on the  
17 patient level, obviously.

18 In terms of FDA's outreaching working  
19 together we, this past week, had Dr. Andrew Einstein  
20 speak in what we call Visiting Professor Lecture  
21 Series exactly on some of items you just mentioned.  
22 Additionally, we've heard -- we got your letter.

23 We're in the process of setting up a  
24 meeting. We do this with -- this is not unique for  
25 your organization. We do this with a lot of

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1 organizations as the need is necessary. It's  
2 educational. It creates an interaction and it provides  
3 us with feedback. I think we've also got to say as you  
4 hear in this discussion that this is a pending  
5 investigation. There are a lot of confidential issues  
6 here. There are a lot of regulatory possible  
7 infractions. So we can't talk about specifics. But  
8 we're set to meet with you guys.

9 MEMBER VAN DECKER: My point wasn't the  
10 specifics per se which is an issue that needs to be  
11 sorted out, but the question is we need to move  
12 forward and so we can be moving forward simultaneously  
13 with everything else, just based on some global  
14 concepts here. And everyone, I think, is happy to do  
15 that.

16 CHAIR MALMUD: This is Malmud. And so in  
17 summary, Dr. Van Decker, you're speaking on behalf of  
18 nuclear cardiologists and your eagerness to assist the  
19 FDA and the NRC with their investigation. And the FDA  
20 and the NRC are responding with enthusiasm to your  
21 offer.

22 (Laughter.)

23 CHAIR MALMUD: Is that a fair summary?

24 MEMBER VAN DECKER: Yes.

25 CHAIR MALMUD: Thank you. Are there other

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1 questions? Yes, Dr. Welsh.

2 MEMBER WELSH: Jim Welsh. I know that  
3 this has been discussed already and the thought has  
4 not escaped anybody in this room, but I thought I'd  
5 just state it clearly for the record. I understand  
6 that there's an ongoing root cause analysis and we  
7 still don't know for certain whether there was any  
8 defect in the generator or if the problem is with the  
9 licensees, but using the Gamma Knife as an example, we  
10 know that this particular device, this generator might  
11 not be as complex as a Gamma Knife, but it's not  
12 trivial either.

13 And therefore, our role as an advisory  
14 committee is to provide some concrete advice. And  
15 again, using that Gamma Knife analogy, nobody is  
16 allowed to operate the Gamma Knife without having the  
17 vendor-specific training and a certification that says  
18 specifically this named individual has been trained by  
19 the vendor and anybody else who gets training and is  
20 authorized to use a Gamma Knife has to have some piece  
21 of paper that says he or she has received some  
22 training either from a vendor or from a qualified  
23 authorized individual.

24 So going forward, it would seem very  
25 appropriate that the manufacturers and/or users, who

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1 are currently qualified to operate these generators,  
2 keep detailed records and name names for those who  
3 receive the training and who are qualified at the  
4 sites. It would be relatively simple, I would think,  
5 for the vendors to just say on this particular day we  
6 went to this site and provided the training and the  
7 following people were in attendance.

8 Similarly, I think it would be relatively  
9 simple for an institution to say that the following  
10 named individuals received the vendor training and  
11 have subsequently trained the following named  
12 individuals so that for patient safety, Joe Blow, who  
13 has never received the vendor training or received  
14 formal training from the qualified technician, can't  
15 on a day when the qualified technician isn't there,  
16 step in and think that he or she can perform the  
17 measurements adequately and find out that he or she is  
18 not qualified and capable and wind up in the situation  
19 we're in now.

20 So that would just be a suggestion that I  
21 think would be relatively easy to achieve. However,  
22 depending on the outcome of the investigation, NRC  
23 might suggest that it become a requirement, depending  
24 on the specifics. Just my two cents.

25 CHAIR MALMUD: Dr. Guiberteau.

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1                   MEMBER GUIBERTEAU: Mickey Guiberteau. I  
2 understand and sympathize with what Dr. Welsh is  
3 saying. On the other hand, a bit of that presumes  
4 that this is what's caused by user error and we don't  
5 know that. And I think before we get into writing new  
6 regulations for our licensees that we also take into  
7 consideration that this device has been used safely  
8 without significant breakthroughs or other findings  
9 over the past 20 years. We use technetium generators  
10 and we have the same types of regulations that we have  
11 now.

12                   And I think before we decide that we need  
13 another layer of record keeping, and again, if it's  
14 voluntary, I'm all for that. I think some of those  
15 suppliers should keep these for their own benefit. On  
16 the other hand, I think we need to be careful before  
17 we put new regulations on the table until we find out  
18 what the results of this investigation are. Thank  
19 you.

20                   CHAIR MALMUD: Thank you. Other comments?  
21 Yes, Dr. Zanzonico.

22                   MEMBER ZANZONICO: It seems that -- it  
23 still seems that if the QC were done, this  
24 breakthrough would have been found at the time. So  
25 even if it were a product defect would precipitate and

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1 not use error or any such thing as that, it would have  
2 been found prior to administration of the rubidium to  
3 the patient.

4 So either there was -- it was not done at  
5 the point of service, it was done improperly, or it  
6 was done and the results ignored, the out of tolerance  
7 results ignored. The result may have been because of  
8 a product defect, but regardless of the root cause, it  
9 seems less likely if there is a named individual at  
10 the site who was certified and in effect, personally  
11 responsible for the disposition of the results of  
12 those tests in terms of whether they're out of  
13 tolerance or not or some such thing as that.

14 And I'm with you 100 percent. The fewer  
15 regulations and the less paperwork, the better. But  
16 it seems like there's a breakdown at the point of  
17 service. And perhaps with the product as well, but a  
18 breakdown at the point of service that could have and  
19 should have been revealed if the proper QC were  
20 followed and the QC results handled properly as well.

21 MEMBER GUIBERTEAU: Mickey Guiberteau. Is  
22 it the case or is it the current belief or are you  
23 able to comment on this, that these incidents would or  
24 should have been reported based on the QC of the  
25 eluant from the generators before administration?

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1           MEMBER SULEIMAN: Let me mention one fact  
2 that I know. The State of Florida, if there's a  
3 breakthrough, it's a reportable incident to the state  
4 regulator. I was told that early. So they said if  
5 they had breakthrough and they didn't report it to us,  
6 it's a problem. That's all I know.

7           MEMBER GUIBERTEAU: But my question was  
8 specific to these incidents. Is it the belief if the  
9 QC had been done and done properly and I have no  
10 reason to believe it wasn't, that this would have been  
11 a -- these would have been preventable incidents given  
12 that the exposures were not to the level that the NRC  
13 needed to be or the state needed to be informed?

14           MEMBER SULEIMAN: If I interpret your  
15 question correctly, yes. I think if the breakthrough  
16 testing was done properly no patients would have been  
17 receiving contaminated product. And if breakthrough  
18 occurs, they're also supposed to report this to  
19 Bracco. So if the system -- the system is not broken.  
20 The system is just not being executed properly.

21           And so -- now why the breakthrough wasn't  
22 done or whether the breakthrough was done improperly,  
23 whether there was confusion, whether there were other  
24 compounding factors which I believe exist, I don't  
25 think it's going to be A or B. I think you're going

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1 to find there was problems with A and B and there may  
2 be some other extenuating factors that are going to  
3 play into this when all is said and done.

4 So how to you execute? So you qualify  
5 people. You regulate the product. You regulate the  
6 manufacturer. Ultimately at what point periodic  
7 mistakes are acceptable? Is this an epidemic or is  
8 this just a few isolated cases that are going to turn  
9 out to be just isolated?

10 DR. KREFTING: Ira Krefting. I think  
11 there's insufficient data to fully answer your  
12 question. And I'll back it up by saying that -- by  
13 making reference to the survey studies that perhaps  
14 are ongoing or in the process of being initiated. For  
15 example, if sites around the country where there was  
16 no breakthrough reported, if we surveyed patients  
17 there and suddenly we find that there's contamination  
18 in these patients, we look back at the records and it  
19 looks like QC was done properly, then perhaps we can  
20 conclude at that juncture that the QC procedures, as  
21 outlined, are not adequate.

22 Hopefully, we'll find that there are no  
23 other contaminated patients around the country, if you  
24 wish, the sites we referred to today, one or two rogue  
25 sites where things were scribbled down perhaps, these

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1 are all hypotheses. Then, we can make another  
2 conclusion. But right now I think there's insufficient  
3 data.

4 MEMBER GUIBERTEAU: Mickey Guiberteau.  
5 Just to comment on that and again to reiterate, since  
6 there is insufficient evidence and since we are in a  
7 discovery period, I think that the assumption that we  
8 need to impose new regulations on the quality control  
9 of generators, in general, not just rubidium, that is  
10 premature.

11 CHAIR MALMUD: Thank you. Dr. Howe, you  
12 wanted to make a comment? And then Dr. Langhorst.

13 DR. HOWE: I was just going to comment  
14 that I'm not sure at this point we have a comfortable  
15 feeling that if we go in and see that the quality  
16 control was done and they indicate they know how to do  
17 it and they did it according to the package  
18 instructions, that we really have a number we can  
19 trust.

20 CHAIR MALMUD: Thank you. Dr. Langhorst.

21 MEMBER LANGHORST: Thank you. Sue  
22 Langhorst. I have a logistical question. When a  
23 product manufacturer voluntarily removes their product  
24 or recalls their product, what are the criteria --  
25 once that manufacturer proves to themselves that their

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1 product is as it is approved -- I mean what's the  
2 logistics? How does it come back to market?

3 DR. KREFTING: Okay, well, we have to,  
4 meaning the FDA, have to be assured and be convinced  
5 by the manufacturer that the product is now safe and  
6 effective and that the safety issue that led to the  
7 recall has been rectified and that any corrective  
8 action such as a change in the label, a change in the  
9 manufacturer have been instituted. So there are a  
10 variety of steps.

11 This also has now been more codified  
12 through the legislation I mentioned to you a little  
13 earlier in the discussion, the FDAAA Act, in that we  
14 can make certain contractual requirements, post-  
15 marketing requirements that would constitute actual  
16 studies or things that have to be done in terms of a  
17 contract to assure all the statements I just made to  
18 allow the product to come back to the market.

19 So the manufacturer has several steps.  
20 Sometimes if it's just a lot, one grouping of  
21 products, one manufacturing run that's a problem,  
22 that's kind of an easier situation. This is much more  
23 complicated and we have to be assured of certain --  
24 with a certain degree that all the various questions  
25 we've mentioned today are fully answered. Is the

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1 product manufactured correctly? Are the labeling  
2 instructions adequate? And has breakthrough going on  
3 and we've just not been measuring it over the last 20  
4 years.

5 In answer to some of the other questions  
6 that were brought up by the other panelists a few  
7 moments ago, certainly more regulations, more  
8 requirements of people are onerous and probably lead  
9 to more confusion. If we feel though that there's  
10 some specific problem with the product that can be  
11 rectified by various options that we have available  
12 under FDAAA, there's a term called elements to assure  
13 safe use which means that we at the FDA can restrict  
14 who actually uses the product.

15 We have REMS, Risk Evaluation Mitigation  
16 Strategy. We can institute REMS. When and if it  
17 comes back that this agent is back on the market, we  
18 can put it back on the market with a variety of  
19 regulatory options for safety. If it has nothing to  
20 do with the certification or training of individuals,  
21 well, then we don't have to worry about that. But we  
22 have these options available to us.

23 MEMBER LANGHORST: Thank you.

24 CHAIR MALMUD: Any other comments? Well,  
25 we appreciate both the leadership of the FDA and the

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1 NRC in bringing the matter to our attention so that  
2 we're informed about it and we look forward to the  
3 first step which will be the identification of the  
4 source of the problem and then a resolution to it.

5 Are there any comments from members of the  
6 public that we -- I see none. Therefore this session  
7 is ended and we will regroup after the break promptly  
8 at 10:30. Thank you.

9 (Off the record.)

10 CHAIR MALMUD: Thank you, all. We will  
11 get started with the second session of this morning's  
12 meeting. And the speaker will be Angela McIntosh, who  
13 will be discussing ACMUI's 2008 recommendation  
14 revision to the Medical Event Abnormal Occurrence  
15 Language. It's Tab 14 in your folders.

16 Angela?

17 MS. McINTOSH: Thank you, Dr. Malmud.  
18 Good morning everyone.

19 We presented some draft abnormal  
20 occurrence criteria back in 2008. And the Committee  
21 at that time voted on it. But we couldn't go forward  
22 with it and do anything with it immediately because we  
23 had direction from the Commission that the existing  
24 criteria that had just been approved in 2006, we  
25 needed to gain a certain amount of experience with it

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1 before we could open it back up for possible revision.

2 And so now that we've gained that amount  
3 of experience with it, we are ready to open those  
4 criteria back up again and revise them. And hopefully  
5 make them better, so -- but since there's several  
6 years that have expired since these particular  
7 preliminary criteria were approved by the Committee,  
8 we thought it would be best for us to bring it back to  
9 the Committee and make sure that you were still okay  
10 with it. So that's really the purpose of this  
11 presentation today.

12 And -- okay -- there we go. Let's quickly  
13 define AO, abnormal occurrence. It is an unscheduled  
14 incident or event that the NRC determines to be  
15 significant from the standpoint of public health or  
16 safety. That's the definition in Section 208 of the  
17 Energy Reorganization Act of 1974.

18 So back in 2008, we discussed a couple of  
19 things concerning the criteria. First of all, that  
20 medical AOs dominate the list of AOs that we submit to  
21 Congress every year. And we weren't sure that that  
22 was appropriate. It didn't seem appropriate that so  
23 many medical AOs were dominating the list because of  
24 the second bullet point that most were not really  
25 medically significant.

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1           So what I included on these next couple of  
2 slides is just for your information. We don't really  
3 need to go into any detailed discussion of this. But  
4 just for your information what the current criteria --  
5 how they read. There are several, you know, several  
6 parts to it.

7           Now the proposed criteria are much shorter  
8 and much more significant. The proposed criteria that  
9 the Committee approved in '08, we kept the criterion  
10 it must be a medical event first but it has to result  
11 in death or a significant impact on patient health  
12 that would result in permanent functional damage or  
13 significant adverse health effect that would not have  
14 been expected from the normal treatment regimen as  
15 determined by a physician, either an NRC consultant  
16 physician or an agreement state consultant physician.

17           And so with that in mind, that's the end  
18 of my presentation.

19           MR. LUEHMAN: Mr. Chairman? If I could  
20 just make one comment?

21           CHAIR MALMUD: Mr. Luehman, yes?

22           MR. LUEHMAN: Jim Luehman. Yes, just for  
23 the -- Angela touched on it just really briefly but  
24 hopefully everybody caught it that this in no way  
25 changes the medical event criteria. We still have the

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1 medical event criteria that are in Part 35. And AOs  
2 have traditionally, you know, been a subset of -- a  
3 subset in the medical area of the medical event.

4 So we still have the criteria. For  
5 instance, the one that we talked about today in our  
6 discussion of the strontium breakthrough, the real  
7 question is how big is the subset? How big of a  
8 subset of those medical event criteria are going to  
9 fall into this upper criteria called an abnormal  
10 occurrence, which is something that the NRC is  
11 required to report to Congress?

12 So I guess I just wanted to make it clear  
13 to the Committee that by changing these AO criteria,  
14 we're in no way changing the medical event criteria  
15 where the licensee has to report to the NRC and the  
16 agreement state on those and that the physician and/or  
17 the patient have to be notified when there is a  
18 medical event. Those still stay the same.

19 The real question becomes by changing  
20 these criteria is of those medical events, which are  
21 significant enough to meet the threshold of requiring  
22 reporting to Congress?

23 CHAIR MALMUD: Thank you.

24 Can you give us an example of a medical  
25 event -- a generic medical event versus an AO?

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1 MS. McINTOSH: A generic medical event?

2 CHAIR MALMUD: Well, say someone receives  
3 excessive radiation, would that be a medical event?  
4 If someone receives excessive radiation that results  
5 in a physical change, such as a burn, a fistula --

6 MS. McINTOSH: Okay.

7 CHAIR MALMUD: -- that would be an AO?

8 MS. McINTOSH: No, no. currently -- the  
9 current criteria is it gives dose thresholds. And the  
10 vast majority of the time, we never -- there's never  
11 any reported or recognized observable effect as a  
12 result of these thresholds having been met.

13 So, you know, we start out with a medical  
14 event, you know, for instance the written directive  
15 was not followed. And 20 percent -- greater than 20  
16 percent of the dose was given. So if that happens and  
17 then there was 10 gray or 1000 rad to -- let's say  
18 that the wrong treatments -- the wrong area of the  
19 body was treated -- well, if that area of the body  
20 received at least 10 gray and a dose greater than 50  
21 percent that was prescribed by a physician, we could  
22 stop there.

23 If those two things happened, we have a  
24 medical event. I mean an abnormal occurrence. That's  
25 all it takes.

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1 CHAIR MALMUD: And how many AOs did we  
2 have last year? Or the last year for which there is  
3 data available?

4 MS. McINTOSH: Going from memory, it was  
5 about ten -- ten medical.

6 CHAIR MALMUD: So it's a small number.

7 MS. McINTOSH: Relative to -- I'm sorry,  
8 go ahead.

9 MR. LUEHMAN: Sorry, Jim Luehman again.  
10 It's a small number relative to the number of medical  
11 events. But relative to the number of other events  
12 that we report to Congress, it's very large. So the  
13 implication, if you're just a Congressman that doesn't  
14 know much about the NRC, you would -- I think that one  
15 of the things that we're looking at is well, ma'am,  
16 the NRC is always reporting all these problems in the  
17 medical area to us. But there's none of these -- no  
18 reactor events, no industrial events, no research  
19 events meet these criteria. But over and over it's  
20 the medical event.

21 And so there's two questions, you know,  
22 are we in the right place? And, in fact, the medical  
23 area is having problems. Or are the criteria not set  
24 right such that we're over reporting what may be, like  
25 I said, medical events but are they really significant

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1 enough to rise to the level where they should be  
2 reported to Congress?

3 And I think that we've concluded -- I mean  
4 I think the Commission and the staff have concluded  
5 that as Angela said, basing it purely on dose is  
6 probably the wrong level to report to Congress because  
7 the immediate question we get back is okay, well, did  
8 anything happen to the person that got that amount?  
9 And the answer typically, historically has been no.  
10 They will be monitored but then the results are  
11 usually, you know, negative at least for the -- I mean  
12 obviously you can't look out 40 years what that  
13 exposure might do but at least for the foreseeable  
14 time, it wasn't.

15 So the real question is, are we giving  
16 Congress information that's useful to them? And that  
17 they need to know? Obviously death or serious injury  
18 was directly resulting is probably something that they  
19 do want to know about.

20 CHAIR MALMUD: Thank you.

21 Dr. Langhorst?

22 MEMBER LANGHORST: The ten that you said  
23 that you had for last year, would any of them have met  
24 the proposed criteria?

25 MS. McINTOSH: No, absolutely not.

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1 MEMBER LANGHORST: Okay.

2 CHAIR MALMUD: Steve Mattmuller?

3 MEMBER MATTMULLER: Yes, just for the  
4 record, I did actually dig up some of the reports.  
5 And in 2009, there were nine AOs and they were all  
6 medical. And in 2010, there were 15 actually. But  
7 they, too, were all medical. So as you said, Congress  
8 has this disproportionate view of the problems that  
9 the NRC has -- that there appears to be problems in  
10 medical and nothing with reactors, which clearly isn't  
11 an accurate picture. So, yes.

12 And then I suppose at some point do we  
13 need to make a recommendation to re-recommend our 2008  
14 advice to the NRC as far as how to revise the AO  
15 criteria?

16 CHAIR MALMUD: This is the proposal that  
17 Angela is presenting to us. And I think we'll take  
18 your statement as a motion to approve.

19 MEMBER LANGHORST: I'll second.

20 CHAIR MALMUD: And Sue seconds -- Dr.  
21 Langhorst.

22 Further discussion of this?

23 MEMBER ZANZONICO: I just have a question  
24 and I know this is not within the purview of the NRC  
25 because it's not byproduct-related. But, you know,

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1 there was a well advertised occurrence at Cedars-Sinai  
2 in California where subjects undergoing head CTs for  
3 profusion studies received overdoses to the scalp  
4 where they actually got -- lost hair and so forth and  
5 so on.

6 You know it's not clear whether or not  
7 that has long-term health implications beyond, you  
8 know, cosmesis and so forth. But would -- if that  
9 were byproduct -- if such an occurrence as that were  
10 byproducts-related, in your estimation would that fall  
11 within the criteria of the proposed AO?

12 MS. McINTOSH: It would seem to fall  
13 within the language that says significant adverse  
14 health effect that would not have been expected from a  
15 normal treatment regimen.

16 MEMBER ZANZONICO: Because my only concern  
17 is that, you know, I agree in principle with this. I  
18 just want to make sure it's not such a high bar that  
19 significant occurrences, you know, are not missed all  
20 together.

21 MS. McINTOSH: Well, we do -- continuing  
22 on with that language, it does have the caveat that  
23 this determination must be made by a physician.

24 MEMBER ZANZONICO: Okay.

25 CHAIR MALMUD: I think we are all

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1 supportive of this. But I have another question. And  
2 that is there was a case that was publicized last year  
3 of a man who developed a fistula between his bladder  
4 and rectum as a result of brachytherapy seeds going  
5 astray.

6           Would that be considered an AO? It's a  
7 permanent -- in a sense he had a permanent anatomic  
8 change as a result of that.

9           MS. McINTOSH: Well, if such an event came  
10 in to us, I think that our immediate reaction would be  
11 yes. But would a physician -- is a physician willing  
12 to make that determination?

13           I mean I guess the one thing that could go  
14 wrong, if you will, is if we get these types of events  
15 and then no physician will make the determination for  
16 whatever reason. Then a technicality would keep us  
17 from reporting it to Congress.

18           And so -- I mean as long as doctors are  
19 willing to make that call, then I think we're okay  
20 with reporting what is, you know, medically  
21 significant.

22           MR. LUEHMAN: Dr. Malmud, the other thing  
23 I would add though is again these criteria are, you  
24 know, the ones where we have to make specific reports  
25 to the MEU, to Congress, but keep in mind that we also

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1 -- I mean we also do an end-of-the-year evaluation of  
2 the NMED data that is available not only to Congress  
3 but to the Committee and anybody that wants to read it  
4 to the public.

5 And, in fact, members of our oversight  
6 Committees in Congress have asked us many questions on  
7 those medical events. My point being that by raising  
8 the AO criteria for what has to be reported in an  
9 immediate, you know, and call that as an individual  
10 event doesn't mean that the information on those  
11 events that may not quite make that cut aren't  
12 available. And, in fact, aren't looked at by the  
13 members of Congress who have oversight responsibility  
14 on the NRC. And, in fact, we've gotten lots of  
15 questions related to those events.

16 So I guess I would add that, too, that not  
17 that this doesn't mean -- because these criteria are,  
18 at the end of the day, you know, going to be subject  
19 to judgment, it doesn't mean the ones that clearly  
20 meet the medical event criteria are not going to  
21 available or known to Congress should Congress or a  
22 member of Congress want to review what's going on in  
23 the medical area at the NRC.

24 CHAIR MALMUD: I don't mean to belabor the  
25 point, but I guess I will. In one of the incidents

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1 from last year, the physician didn't report the  
2 untoward event. And if I had been a member of  
3 Congress, I would have wondered why I was reading  
4 about it in the newspaper. But I was not informed  
5 about it through the NRC or the VA system.

6 MR. LUEHMAN: And I think one of the things  
7 -- and this is a little bit -- I think one of the  
8 things that we've struggled with between our office  
9 and the Office of Research, which is responsible for  
10 making this report is, I think one of the issues that  
11 was involved with that event was how to handle events  
12 from prior years that were not properly reported.

13 Because the AO criteria is supposed to  
14 reflect the events that occurred in the last year,  
15 the presumption is everything was reported when it  
16 should be. One of the problems that you run into is  
17 and one of the debates that we have is should we  
18 discover an event that occurred in 2005 or 2004, even  
19 if it met these criteria, at the time we may have made  
20 the report but now the question becomes is now that  
21 the report is discovered or the issue is discovered  
22 and that patient how has had six or seven years of  
23 maybe good health, they've recovered, one of the  
24 questions you would come into is, is there a need to  
25 report it, you know, six or seven years after the fact

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1 or five years after the fact.

2 So one of the artificialities of any  
3 reporting system is the presumption that everything  
4 this done perfectly when it should be done. When we  
5 go back and discover events like we have in the  
6 brachytherapy area, there is a lot of discussion about  
7 the utility and exactly what the proper procedure  
8 should be to report those old events and make sure  
9 that Congress and the readers of the report understand  
10 that these are historical events and not events that  
11 occurred within the last year.

12 And sometimes that is a difficult issue to  
13 convey because people just say oh, there was, you  
14 know, 25 medical events. Well, yes, but read, you  
15 know if you read the report, you know, in fact many of  
16 them could have occurred a number of years before.

17 So that -- I know that doesn't directly  
18 answer our question but that is one of the issue that  
19 we struggle with. And one of the reasons that may be  
20 there are some events that in the past would have met  
21 criteria but don't then subsequently get reported when  
22 -- in the current year report.

23 CHAIR MALMUD: Dr. Suleiman?

24 MEMBER SULEIMAN: Have you considered  
25 deterministic effects? I mean Dr. Zanzonico kind of

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1 leaned that way when he was talking about the  
2 COMMITTEE hair loss where the hair loss was a  
3 deterministic effect. It's an acute -- it's a shorter  
4 term, more serious. I would think that would fall  
5 under number two.

6 MS. McINTOSH: I would think so, too. I  
7 mean but we could -- to make it absolutely clear, I  
8 mean if the Committee thinks it's, you know, prudent,  
9 we could add that actual phrase in there --  
10 deterministic effect.

11 MEMBER SULEIMAN: Now obviously in cancer  
12 treatment, some skin erythema is expected as part of,  
13 you know -- so I would that's where your definition  
14 would address that.

15 MS. McINTOSH: Okay.

16 MEMBER SULEIMAN: It would address that.

17 MS. McINTOSH: It would not have been  
18 expected from the normal treatment regimen. So if  
19 erythema would be expected from that particular  
20 treatment regimen, then it wouldn't be.

21 MEMBER SULEIMAN: Yes.

22 CHAIR MALMUD: Laura Weil?

23 MEMBER WEIL: Because these criteria are  
24 relatively subjective and the determination is made by  
25 a physician, can you explain to me who is this NRC or

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1 agreement state designated consult? Is this someone  
2 from the same institution as where the event occurred?

3 MS. McINTOSH: No, it wouldn't typically  
4 be someone from the same institute.

5 MR. LUEHMAN: We have a program, a medical  
6 consultant program. In fact, some members of the  
7 Committee have served or serve as medical consultant.

8 And when there is an event in one of the  
9 regions and there is a medical event, we have a list  
10 of -- a roster of medical consultants that we can go  
11 to, to provide us medical advice on a particular -- on  
12 that particular event. And that's how we do it.

13 MS. McINTOSH: Thank you.

14 CHAIR MALMUD: Thank you.

15 Dr. Guiberteau?

16 MEMBER GUIBERTEAU: Yes, I just have a  
17 question because I know the NRC is very careful about  
18 its language. And I wasn't a member of the Committee  
19 at this time. In Criterion 2, if we separate those --  
20 and I understand a significant adverse health effect  
21 that would have not been expected in a normal  
22 treatment regimen, that's pretty clear to me -- I'm  
23 uncertain as to what the intent of the first one is.  
24 And is that temporal in the sense that a significant  
25 impact on patient health that would result in

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1 permanent functional damage, that if there is a  
2 significant impact and it is not permanent, that that  
3 is not an event? An occurrence?

4 MS. McINTOSH: Right. That's -- I think  
5 that's correct.

6 MEMBER GUIBERTEAU: Well, for instance in  
7 the incident that was mentioned by Dr. Malmud that,  
8 you know, because radiation can cause fistulas, it  
9 wouldn't be necessarily unexpected. I mean it could  
10 happen and be a known complication. However, if it  
11 caused the fistula and subsequently the fistula was  
12 repaired, it is not a permanent issue. So would that  
13 -- then that would not be --

14 MS. McINTOSH: I don't think that would  
15 meet the criteria. And so what we need to think about  
16 is should it meet the criteria. I mean -- and so you  
17 are correct. I mean maybe there should be some  
18 language added to capture that kind of event.

19 But, again, we're trying to capture what  
20 we are terming abnormal occurrences. If that's sort  
21 of effect is -- it doesn't happen all the time but,  
22 you know, it can happen, when it does happen, is it  
23 abnormal? I mean -- is that something that Congress  
24 needs to know about? That this patient developed  
25 this, you know, side effect but it was correctable.

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1 I mean that's a bit subjective. I can  
2 argue probably not. But somebody can argue probably.  
3 Because we know that during medical treatments,  
4 sometimes there are side effects. And that's just,  
5 you know, that's to be expected. Do we need to tell  
6 Congress about that?

7 MEMBER GUIBERTEAU: But the wording is a  
8 little, as a consumer, would be a little bit alarming  
9 to me in that if there is a significant impact on my  
10 health, why isn't that reportable whether or not it is  
11 permanent? I'm just talking about the language here.

12 And I didn't know the intent of, you know,  
13 I think the intent might be better worded here. I  
14 mean I understand a permanent functional damage that  
15 leads to a significant impact on your health, which  
16 makes sense to me. But the other is extremely  
17 subjective.

18 And I'm not saying we need to make this so  
19 open that we have a lot of occurrences that really  
20 don't need to be reported. But if this -- you know,  
21 if the Committee felt this adequately expresses their  
22 intent, then I think, you know, I'm still not sure it  
23 is explained to me what the intent of this is.

24 MS. McINTOSH: Well, the intent is to  
25 capture truly significant events that --

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1           MEMBER GUIBERTEAU: Well, you've already  
2 said it is significant by using the word significant.  
3 So it is hard to define this phrase with a word that  
4 you have in the phrase.

5           MS. McINTOSH: Right. But the intent is  
6 to -- we think we are not capturing significant events  
7 right now. So the intent is to capture significant  
8 events. Now that we're in significant event space,  
9 you know, what is significant enough to raise to the  
10 level of reporting to Congress.

11           Even if we added language that would  
12 capture that kind of event that Dr. Malmud mentioned,  
13 we probably would rarely get an AO reportable to  
14 Congress. So that's an argument for coming up with  
15 something that would capture that kind of event.

16           MEMBER GUIBERTEAU: So the intent here is  
17 to make this flexible enough to meet the intent of  
18 really the whole definition.

19           MS. McINTOSH: Well, the intent is to, you  
20 know, to capture what is -- the spirit of a normal  
21 occurrence reporting is to report something that is  
22 truly abnormal. What we're reporting right now is  
23 sort of just routine errors kind of.

24           MEMBER GUIBERTEAU: Sure. Well, I  
25 appreciate that.

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1 CHAIR MALMUD: I think -- Dr. Malmud, I  
2 think what Angela is transmitting to us is what the  
3 Committee had looked at before. And it was an attempt  
4 to separate, if you will, the wheat from the chaff.  
5 That there was too much -- too many reports going,  
6 which were really no clinical significance to  
7 congress. And that was burdensome and also would have  
8 hidden some significant events that were in that large  
9 number. And this is an attempt to separate out what  
10 is significant.

11 Now the wording that was resolved is the  
12 wording before us. And it is the best that we could  
13 come to at that time.

14 But if I may, just for the record, let me  
15 give a few examples of what might occur and ask you,  
16 or whoever on the NRC, whether this would be  
17 considered an AO. Giving a patient treatment for  
18 thyroid cancer without a pregnancy test and  
19 discovering that she was pregnant. And the child will  
20 be born with hypothyroidism.

21 MS. McINTOSH: Well, that's actually not a  
22 medical event because the patient got what she should  
23 have received. It's just that no one knew of the  
24 pregnancy. That is reportable to us under I think it  
25 is 35.3047. But it's not -- that wouldn't be -- if

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1 you can come up with a different one, that wouldn't  
2 actually be a medical event.

3 CHAIR MALMUD: Irradiating a wrong organ.

4 MS. McINTOSH: So if we -- irradiating the  
5 wrong organ as a result of that, I mean is it  
6 essentially not really a big deal? I mean we know  
7 that to a patient, it is always going to be a big  
8 deal. But from a clinical significance stance, is  
9 that something significant enough to report to  
10 Congress?

11 Maybe I can -- if I can read something  
12 here, it might help the Committee out a little bit --

13 CHAIR MALMUD: Thank you.

14 MS. McINTOSH: -- that actually our  
15 attorneys forwarded to us not too long ago just  
16 clarifying the AO criteria, what it is meant to do,  
17 saying that if -- the AO criteria are trying to  
18 capture things in which the level of protection of  
19 public health and safety has been impacted.

20 I mean so is the level of protection --  
21 when we look at a medical event and something went  
22 awry, is that -- did something to awry to the degree  
23 that it can be stated that the level of protection of  
24 the public health and safety has been negatively  
25 impacted? Or did it just -- was there just a little

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1 error which you wouldn't be able to make that  
2 statement?

3 And do these draft criteria capture the  
4 idea that the level of protection of the public health  
5 and safety have been negatively impacted? I think  
6 they do.

7 CHAIR MALMUD: Well, thank you. There  
8 were other comments. I'm sorry, Dr. Thomadsen?

9 VICE CHAIR THOMADSEN: I have actually the  
10 same comment I had in 2008 I think, that it strikes me  
11 that Criterion 1 is contained in Criterion 2. And  
12 that death is certainly a significant impact on the  
13 patient's health.

14 It also seems to me that the first clause,  
15 the significant impact on the patient's health, would  
16 be contained in the second cause as significant  
17 adverse health effect. And the whole criteria could  
18 be started with the -- right after the or in the  
19 second criterion.

20 CHAIR MALMUD: Dr. Welsh?

21 MEMBER WELSH: So I appreciate all the  
22 comments that I've heard so far. And I would like to  
23 maybe follow up on some possible wording changes that  
24 are based on what Dr. Malmud has said regarding the  
25 pregnant patient with iodine-131, which in my personal

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1 opinion, properly does qualify as something serious  
2 enough to warrant the abnormal occurrence appellation.

3 But it doesn't -- it won't because it is  
4 not a medical event. Therefore, perhaps the term  
5 medical event or reportable event that results in one  
6 and two might be advisable to capture that good  
7 example that I think you provided.

8 MS. McINTOSH: Can I clarify something?  
9 That type of event would be a normal occurrence but  
10 not with the medical criteria. I'm sorry, I didn't  
11 make that clear. It would be under a different  
12 criterion in the AO criteria. It would be under human  
13 exposure.

14 So it would actually be captured but under  
15 human exposure, not under medical.

16 CHAIR MALMUD: Would it be reportable to  
17 Congress?

18 MS. McINTOSH: Yes.

19 CHAIR MALMUD: Thank you. The purpose of  
20 my question was I understand what our goal was with  
21 this. And I'm not in disagreement with it. I just  
22 don't want to put members of Congress in a situation  
23 which would be embarrassing to them in having to learn  
24 about these incidences in the newspaper rather than  
25 through the NRC or other appropriate channels.

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1 Mr. Steve Mattmuller?

2 MEMBER MATTMULLER: Yes, actually in 2009  
3 there were two AOs where they involved patients, who  
4 had pregnancy tests that were negative, were  
5 administered the I-131 then shortly thereafter were  
6 found out to be pregnant. So those have made it to  
7 the current system.

8 But fortunately because of the age, the  
9 risk to the embryo because of its underdeveloped  
10 thyroid gland, there was minimal risk to the embryo at  
11 that time.

12 MR. LUEHMAN: Mr. Chairman, can I make a  
13 suggestion?

14 CHAIR MALMUD: Yes, please.

15 MR. LUEHMAN: What I'm going to do is I'm  
16 going to ask the staff to go back and get the  
17 discussion, the Committee's discussion on these words  
18 to see if, you know, in fact the Committee itself from  
19 back then can give us some insights on exactly why  
20 they liked or didn't like some of these words.

21 And maybe I think that can inform the  
22 discussion a little bit better. So I guess I would --  
23 if we've got time in the afternoon or a little bit  
24 later, we could probably revisit this and do -- I  
25 think probably do this a little bit more efficiently

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1 than trying to figure it out just by looking at the  
2 words that we have in front of us.

3 CHAIR MALMUD: Thank you for that  
4 suggestion. Is that acceptable to the Committee?

5 (Chorus of yeses.)

6 CHAIR MALMUD: The Committee finds it  
7 acceptable. And thank you for the recommendation.

8 Thank you, Angela.

9 MS. McINTOSH: Thank you.

10 CHAIR MALMUD: Good to see you again.

11 MS. McINTOSH: You, too.

12 CHAIR MALMUD: The next item on the agenda  
13 is Dr. Donna-Beth Howe, who will be discussing the  
14 status of medical events for the Fiscal Year 2011. We  
15 appreciate your ability to be here a little early for  
16 this session.

17 DR. HOWE: The first that I'd like to say  
18 is that this is a work in progress. We have not  
19 completed FY2011 yet.

20 And so I will have to do an update to the  
21 NMED search that you receive as part of the basis for  
22 doing the ACMUI review, important things that come out  
23 of the medical events. So that will be revised once  
24 the fiscal year is over and we've got all the medical  
25 events reported.

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1           Where am I pointing? That's as good as  
2 any. One of the things I like to do each year is to  
3 show you where we've been. So I included both the  
4 medical event information for the current year with  
5 that of the past year.

6           And the first thing that probably pops out  
7 to you is that in FY2010, we had 49 medical events and  
8 now we've got 58. And you're going where are all  
9 these extra medical events coming from.

10          If you're in one group, you may think it  
11 is coming in a certain place, like 35.400. But that's  
12 not the case. The case is that we're getting more --  
13 we got more medical events in 35.200 and in 35.1000  
14 this year than we did in previous years.

15          Okay, 35.200 are the imaging and  
16 localization. So those are your diagnostic nuclear  
17 medicine procedures;

18          35.300 are your -- we call it procedures  
19 that require a written directive with unsealed  
20 material. Those are basically your therapeutic but  
21 there is one diagnostic procedure in there;

22          35.400 are your sealed source manual  
23 brachytherapy administrations;

24          600 could be a gamma knife procedure. It  
25 could be a high dose remote after loader procedure.

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1 It could be a teletherapy unit procedure. Those are  
2 your sealed sources with very high activity giving  
3 very high doses in a very short period of time;

4 And 35.1000 are those devices or sources  
5 or it could be your pharmaceuticals that don't really  
6 fit into another category. And so we've put them in  
7 what we originally call emerging technology but  
8 they've stayed there a while so it's other category.  
9 And most of those are therapeutic things. And we'll  
10 get into more detail on exactly what we're looking at.

11 So in the next slide, we're looking at the  
12 diagnostic medical events. It is very difficult to  
13 have a diagnostic medical event. And you're going to  
14 see three of them. And some of them are pretty  
15 interesting.

16 The first one is they prescribed I-123 and  
17 we've seen cases before where they've prescribed I-123  
18 and by mistake, they gave I-131. This one is even  
19 more interesting than that because they prescribed I-  
20 123, they got I-123, and when they gave the capsule,  
21 the capsule happened to be contaminated with I-131.

22 And they believe contamination came from  
23 the vial cap. And so they ended up giving 380  
24 centigray or rad to the thyroid of the child in this  
25 case. So this is a very unusual medical event for us.

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1           The second medical event, they intended to  
2 give 123. They gave I-131. They intended to give 5  
3 millicuries of 123. Instead they gave 5 millicuries of  
4 I-131. So they gave the same activity but they gave  
5 the wrong isotope.

6           And then the third one, this is another  
7 very interesting one. If there were errors that could  
8 happen, it happened in this case.

9           They had an indium-111, which is a  
10 diagnostic procedure. They had the material.  
11 Unfortunately, they also had a syringe of strontium-89  
12 from a procedure that was supposed to be given about a  
13 month before. The strontium-89 dose had expired but it  
14 was still in the department. And they picked up the  
15 wrong syringe and gave strontium-89 to the patient.  
16 And they got 63 rem dose to the bone marrow on a  
17 procedure that should not have given you anything to  
18 the bone marrow.

19           The only thing that they lucked out was  
20 that the dose had decayed or it would have been much  
21 worse otherwise. To those are our three medical events  
22 for 35.200 imaging localization.

23           Now looking at the therapeutic doses,  
24 generally we have therapeutic medical events with I-  
25 141. Every once in a while, we'll end up with one of

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1 the other therapeutic isotopes. And in this particular  
2 year, we ended up with several.

3 We've got a total of six medical events.  
4 Each one of these medical events up to this date has  
5 involved a single patient. So we don't have any  
6 multiple patients. In this particular one, we've got  
7 two patients. They were treated for cystic  
8 craniopharyngioma.

9 And the medical facility believes that the  
10 pharmaceutical that came in was mislabeled and that it  
11 actually had a lot more activity in it than was on the  
12 label. And what made them think that? Well, when  
13 they looked at the drainage around the cyst, they  
14 found inflammation from radiation type of injury.

15 And they realized that they had a problem  
16 there. They went back and calculated what they had  
17 expected to give, 30,000 and 20,000 rads and these  
18 patients got 56,000 and 50,000 rads. So well in excess  
19 of the medical event reporting requirement. And they  
20 believed it was due to the manufacturer not providing  
21 adequate measurement information on the label.

22 We also had a samarium-153. In this case,  
23 it was a delivery problem. The syringe was connected  
24 to a three-way stopcock. They removed the syringe at  
25 the wrong time. When they removed it, they lost some

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1 of the material.

2 They put the syringe back on and they  
3 continued with the delivery. But instead of giving  
4 the 25 millicuries, they gave 14, almost 15  
5 millicuries. So that was a medical event.

6 And now we get into our oral sodium  
7 iodides. We've got some typical events here. And we  
8 also have a not-so-typical one.

9 The first one I think is kind of  
10 important. Every once in a while, we end up with  
11 things that should be medical events that aren't  
12 medical events. And we also end up with things that  
13 shouldn't be medical events but are because of  
14 technicalities.

15 In this case, they received 25 millicurie  
16 I-131 dosage from the pharmacy. The physician looked  
17 at it and decided based on the patient that that was  
18 an acceptable amount to give, even though the  
19 prescribed amount was less. No, it was supposed to be  
20 25, they measured it, it was closer to 20. That's 20  
21 percent low.

22 And the physician looked at it and said  
23 well, okay, I think we can give this. But he didn't  
24 change the written directive and they went ahead and  
25 gave it. So it became a medical event because it

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1 departed from prescribed dose.

2 The next one we have the wrong patient.  
3 In this case, they were supposed to get 20  
4 millicuries. Instead they got 100 millicuries because  
5 that dose was supposed to go to another patient.

6 We've got the third one. It's one of our  
7 typical cases with I-131. The dose comes in two  
8 capsules. The capsule is in a vial. The patient gets  
9 one capsule. They don't realize they've got the  
10 second capsule still stuck on the bottom of the vial.

11 The third one is one where they prescribed  
12 two millicuries. Actually what they gave was slightly  
13 less than that. And enough less to be a medical  
14 event. And they didn't realize they had the medical  
15 event until they did an audit later.

16 So that concludes our unsealed material,  
17 our radiopharmaceuticals.

18 And now we move into the 35.400, which is  
19 your manual brachytherapy. And you'll see we've got  
20 26 medical events. We've got two that are  
21 undetermined. One of them was a biliary duct. In this  
22 case, 25 of them were prostate and then two  
23 undetermined were prostate.

24 So if we look at the biliary duct medical  
25 event, it's the iridium-192 ribbons or seeds in a

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1 strand. And they were supposed to give 20,000 rad.  
2 They gave 124 because the positioning, the guide wire  
3 that was putting this into position moved five  
4 centimeters. So they gave the treatment to the wrong  
5 site.

6 And now we get to the prostate medical  
7 events. In this case, we've got 81 patients because  
8 we had eight licensees with multiple medical events.  
9 The first two are from the state of Kentucky. And the  
10 medical events are attributable to the same physician.

11 So we have 35 medical events at one  
12 facility and three at another. The remaining medical  
13 events, most of those are going to be coming from just  
14 a few states. Wisconsin is one. And if we look at the  
15 reasons, well in the first group with 35, they had  
16 poor records. Even though there were written  
17 directives, they didn't keep the written directive  
18 records beyond the three years. And so there's  
19 questions there.

20 They had no post-implant COMMITTEE images.  
21 They had not post-implant doses recorded. And they had  
22 just a lot of record issues.

23 You also had, especially for Wisconsin and  
24 some of the other states, the states are now looking  
25 to see if licensees are comparing their

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1 administrations to the medical event criteria. In  
2 many cases, folks were not. But even though they  
3 weren't comparing them, most folks didn't meet the  
4 medical event criteria but a few patients had a few  
5 patients that did.

6 We had poor image quality post-COMMITTEE  
7 as a reason. We had -- and I'm not sure how to  
8 interpret this and I think you'll have fun with this  
9 one, getting additional information on it -- clinical  
10 limitations of the techniques and they are working on  
11 improving the processes. That's pretty obscure to me.  
12 So you'll probably want to look into that one.

13 And then we had a number where no reason  
14 was given. They just had medical events.

15 Now let's look at the other 17 licensees.  
16 In this case, we're looking at single-patient events.  
17 Our most common reason for medical events are sub-  
18 optimal dose distribution, poor placement, poor  
19 visualization, incorrect identification of the  
20 prostate.

21 We had three where the tumor volume  
22 increased due to edema. We had two where there was an  
23 underdose to the prostate but no definitive reason  
24 given. We had one of our Air kermas again where  
25 people are ordering in one unit and receiving

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1 materials in another unit and not doing a close check  
2 to make sure what they have received.

3 We had one case where when they're  
4 treating the prostate patient, they may give a  
5 combined external radiation and prostate. And if they  
6 do that, then they give a partial dose with seeds  
7 because they've already given an external radiation  
8 dose. In this case, they wrote the written directive  
9 in such a way that they got confused and instead of  
10 giving the partial treatment dose, they gave the full  
11 treatment dose as if the patient had received no  
12 external radiation.

13 Then we had a really interesting one. The  
14 patient came in -- no, the patient cancelled an  
15 appointment and made another appointment about a month  
16 later. The facility had the seeds from the first  
17 appointment and they ordered new seeds for the second  
18 appointment.

19 And when the patient came in for the  
20 second appointment, they gave the seed from the first  
21 appointment, which had decayed significantly. So  
22 there were actually two sets of seeds for one patient.  
23 And they gave the wrong set.

24 And then our last medical event was an  
25 anatomical issue where it was difficult to deliver the

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1 seeds and the physician stopped the procedure before  
2 very many of the seeds were delivered.

3 The undetermined cases, we've kind of put  
4 a hold on looking at our medical event issues that are  
5 coming in through our technical assistants for the  
6 regions. And so those are undetermined at this point.  
7 But we're expecting to get back and make our  
8 determination on whether these two licensees with  
9 over-exposures in either patients were medical events  
10 or not.

11 Moving on to our other therapy --

12 MR. LUEHMAN: Donna-Beth, before we leave  
13 that --

14 DR. HOWE: Yes?

15 MR. LUEHMAN: -- I think the one thing  
16 that needs to be clarified with that reporting, again  
17 I think Donna-Beth touched on it a little bit but in  
18 some of the cases that were reported this year that we  
19 considered, those were due to retrospective looks that  
20 some of the agreement states -- I think she mentioned  
21 Wisconsin did -- and looked back over a number of  
22 years.

23 So while the events are being reported  
24 this year, the actual occurrences occurred over a  
25 number of the previous years. So it's not like -- I

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1 think we'd want to give the impression that Wisconsin  
2 or any of those states that are doing the  
3 retrospective all of a sudden had a big group of  
4 events in this most recent year.

5 The second thing is I would say about  
6 those events, in those retrospectives pretty much what  
7 we've seen is that, you know, they are spread over, as  
8 the list indicated, a number of hospitals had one or  
9 two events over a couple year period. The one  
10 exception to that is in the state of Kentucky. They  
11 did report a large group of events at one hospital.  
12 And as Donna-Beth indicated, involving one physician.  
13 So that is a group that the state of Kentucky is  
14 taking a look at. And still evaluating as we speak.

15 But I just wanted to kind of give a little  
16 bit more context to those -- the numbers that were  
17 displayed because although they are coming to our  
18 attention, and again this sort of goes back to a  
19 little bit of the discussion that we had under AO  
20 criteria, reporting previously unreported events that  
21 may go back a number of years can kind of appear to  
22 skew the data.

23 And but, you know, they are being reported  
24 now and we are discussing them now because some of the  
25 underlying causes, as Donna-Beth said, can be

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1 important. But I just wanted to give that context to  
2 those slides on the reporting.

3 DR. HOWE: And one of the things that I do  
4 when I'm doing my medical event report to the ACMUI is  
5 I look at the events that are reported in a fiscal  
6 year because if an event was not reported back when it  
7 happened for whatever reason, then it would be lost to  
8 us as looking at data if we didn't bring it forward to  
9 where it was reported.

10 In some of these cases, you've got current  
11 medical events in FY2011. And because of that, there  
12 is a retrospective. So there's a combination of  
13 things. But I try to catch the ones that are reported  
14 in the fiscal year, not necessarily that happened in  
15 the fiscal year, so that we have a complete record.

16 MEMBER LANGHORST: Can I ask --

17 CHAIR MALMUD: Please, Dr. Langhorst.

18 MEMBER LANGHORST: Sue Langhorst. One the  
19 last one that you were talking about with the anatomy  
20 issues --

21 DR. HOWE: Yes?

22 MEMBER LANGHORST: -- was it reported  
23 because the written directive wasn't updated? Or why  
24 was that a medical event if the physician, who I  
25 assume is the authorized user, decided not to implant

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1 due to anatomical reasons?

2 DR. HOWE: He didn't give what was on the  
3 written directive. And so it met the definition of a  
4 medical event.

5 MEMBER LANGHORST: Okay.

6 DR. HOWE: And he did actually -- you know,  
7 many times we have medical events and physicians do  
8 absolutely the right thing. So a medical event is not  
9 a violation. In many cases it is reportable but it is  
10 exactly the right thing to do.

11 MEMBER LANGHORST: Okay.

12 DR. HOWE: So we aren't making a judgment  
13 that that was any kind of an error. And I think that  
14 is important to note.

15 CHAIR MALMUD: Thank you for clarifying  
16 that.

17 DR. HOWE: Now for 35.600, we've got  
18 actually three major kinds of devices here. We have  
19 the high dose rate remote after loaders where we  
20 actually have remote after loaders. Most of our  
21 medical events with remote after loaders are with the  
22 high dose rate remote after loaders. We have gamma  
23 knives. And we also have teletherapy units.

24 There are very few teletherapy units out  
25 in my licensing space. And so we rarely have one of

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1 those. So that's why you're not going to see a  
2 teletherapy this time.

3 And when I look at the -- we had 12  
4 medical events in this category. And I broke them down  
5 into the two major devices that are used. And with  
6 the high dose remote afterloaders, I've also further  
7 broken them down because I think we have seen new  
8 products come on to the market. The breast balloons,  
9 some are mammoSites, some are not. And then we've seen  
10 a new device coming on, the Savi 8. And we seem to  
11 have a number of issues with those devices. And I  
12 didn't believe that they really need to be in the mash  
13 of everything else. That they kind of show their own  
14 issues and problems.

15 And we also had some bronchials which we  
16 don't have a lot of those but we do have a few. And  
17 the gamma knife, we had two medical events.

18 So for the Savi 8, we had a total -- we  
19 had four medical events with a total of 15 patients.  
20 Our biggest problems were default settings that were  
21 not changed. In one case, they didn't reset the  
22 default dwell positions. So they gave the steps in the  
23 wrong location.

24 In another case, they didn't reset the  
25 start position default. And so instead of giving the

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1 dose as it was supposed to be given, they gave the  
2 area that was supposed to get dose got very little  
3 dose. The area that was supposed to get very little  
4 dose got a lot of dose. So you ended up with the wrong  
5 positioning there.

6 We also had issues with catheter length.  
7 That seems to be a recurring problem, in this  
8 particular case, the wire markers stopped at a point  
9 of maximum curvature. And so the licensee thought that  
10 was the length of the source -- was at the end of the  
11 catheter. But it wasn't.

12 So they had two patients. And it wasn't  
13 until they were treating the second patient that they  
14 realized what the problem was. So they weren't giving  
15 the dose to the right treatment site. They were giving  
16 it to the wrong site because the wire length was  
17 reported as being shorter than it should have been.

18 Okay. Then we also had one in which the  
19 source on the guide wire actually punched through the  
20 catheter and ended up lying on the skin of the  
21 patient. That's something we haven't seen before.

22 And then we went to the breast balloon,  
23 this was more typical of what we've seen before. The  
24 breast balloon is normally inflated with a liquid.  
25 And sometimes there's drainage of the site and people

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1 go in with needles or other things and drain the site.  
2 And in the process, they nick the balloon and the  
3 balloon drains.

4 So in this case, they did not have their  
5 COMMITTEE scanner, which they normally use to verify  
6 that the balloon is inflated and where it is supposed  
7 to be. They used ultrasound instead. And they thought  
8 the balloon was inflated but it wasn't.

9 There was drainage that was observed from  
10 the surgical incision. And later they concluded that  
11 that may have been drainage from the balloon and not  
12 from the site itself. And they discovered the balloon  
13 was drained on the next visit so they believe that it  
14 gave twice the dose that they were supposed to give on  
15 the dose -- on the visit when the balloon was  
16 deflated.

17 In the bronchial one, there's -- many  
18 times we have problems with the moving. In this case,  
19 it wasn't a question that the source moved. It was  
20 that it was put in the wrong position.

21 And in another case, the dwell positions  
22 were misrepresented on the written directive. And  
23 when they transcribed it over, they got it wrong. And  
24 they delivered more dose in both cases to the larynx  
25 region.

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1           Okay. Then we've got six patients that  
2 are in other categories. And at three institutions,  
3 sixty percent of them where the physicist didn't  
4 calculate the effect of the tube on delivering the  
5 dose. And so they didn't give the right dose. They  
6 gave an underdose.

7           The other two cases, they had -- with four  
8 patients the first time -- they picked up the wrong  
9 transfer tube. It was longer than the tubes that they  
10 normally use so they ended up with skin reddening.

11           And then they also picked up the wrong  
12 transfer tubes in three out of four of the catheters  
13 for the last treatment. And they ended up with an  
14 overdose to the skin and an underdose to the treatment  
15 site.

16           Gamma knife, we have both an equipment  
17 issue and a human factors issue. In the equipment  
18 issue, the computer screen froze so the user could not  
19 see the time and immediately aborted the procedure.

20           The manufacturer came back later and said  
21 well, even though the screen froze, the second clock  
22 was still working and would have terminated the  
23 procedure at the right time so you terminated the  
24 procedure too soon. We just, on looking at it, think  
25 the physician did the right thing.

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1 He had no way of knowing that the second  
2 clock was still working and that the procedure would  
3 have been terminated. So based on his observation that  
4 the screen was frozen, had no idea what was going on,  
5 they pulled the patient out.

6 The second one, they were supposed to  
7 deliver 1,600 rad and they delivered 85. The physicist  
8 forgot to adjust the weight factor. And so when they  
9 wrote the prescription, it gave the wrong dose.

10 Now we get to 35.1000. We have a number of  
11 devices in the 35.1000 group. We've got the Perfexion.  
12 We've got the GliaSite and a number of other devices.  
13 But the ones we see the most medical events with are  
14 the yttrium-90 microspheres.

15 We've got two manufacturers. The  
16 microspheres function slightly differently for each  
17 one. So we tend to separate these medical events out  
18 by manufacturer. And they flip back and forth as to  
19 which manufacturer has the most medical events. In  
20 this case, it is the TheraSpheres. So let's see what  
21 they did.

22 Well, we don't normally see shunting but  
23 there was a shunting event in which it appeared as if  
24 there wasn't shunting when they did the nuclear  
25 medicine procedure. But then once they finished the

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1 procedure, they found a lot of dose down in the  
2 duodenum. So they believe they gave 9,000 rads to the  
3 intestine tract.

4 Then we have typical medical events where  
5 they give the wrong site. They intend to give the  
6 right, they give the left.

7 We have transcription errors. They didn't  
8 compare the activity in the written directive with the  
9 amount of activity that they received. So they gave  
10 all that they received and not what they should have  
11 given.

12 They wrote the wrong segment volume. So  
13 he was calculating let's say for the left side and he  
14 used the volume of the center in the right side. So  
15 that gave the wrong prescription.

16 The plunger accidentally rotated. And when  
17 the plunger accidentally rotated, there was a stop in  
18 the procedure. The microspheres settled. They weren't  
19 able to get the microspheres going again. And so they  
20 received less than they were intending to give.

21 There was a clumping visualization. And we  
22 found another medical event that is not in your book -  
23 - well, it may be in your book but it didn't make my  
24 slides -- where clumping was also an issue. So we have  
25 two clumping events and then we have got a third one

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1 that maybe also related to that where you couldn't get  
2 the microspheres into the treatment site.

3 We have saline leakage so only part of the  
4 dose was delivered. We had failure of a septum vial  
5 and so you didn't receive the full dose.

6 And then in SirSpheres, we've got three  
7 medical events. One was the treatment was terminated  
8 early on because of patient pain and only 50 percent  
9 of the prescribed dose was given. And another -- and  
10 this is a SirSpheres occlusion, they believe the  
11 concentration was too high. And they couldn't get the  
12 microspheres to go through the catheter and be  
13 delivered.

14 And they tried to increase the volume and  
15 that wasn't -- would not move the microspheres. So  
16 their corrective action is to dilute their solution  
17 down more so that they don't have a high  
18 concentration. And then we have one in which the  
19 medical physicist read the written directive  
20 incorrectly and gave the wrong dosage.

21 CHAIR MALMUD: Thank you. Are there  
22 questions for Dr. Howe about any of these issues?

23 Dr. Zanzonico?

24 MEMBER ZANZONICO: Yes, thank you very  
25 much for that. That was really very instructive.

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1 I just have a couple of clarifications. I  
2 think it was on your tenth slide. Yes, slide number  
3 ten, this was a 35.400 prostate.

4 DR. HOWE: Yes?

5 MEMBER ZANZONICO: I'm just trying to  
6 clarify what the numbers mean because it says prostate  
7 81 patients. And then towards the right, it says 25.  
8 And I thought that number referred to the number of  
9 events.

10 DR. HOWE: The number in parentheses is the  
11 number of patients that were involved in the 25  
12 medical events.

13 MEMBER ZANZONICO: So there were 25 medical  
14 events but it says 81 patients.

15 DR. HOWE: Yes.

16 MEMBER ZANZONICO: So when you say 25  
17 events, you mean sort of by category?

18 DR. HOWE: By location.

19 MEMBER ZANZONICO: Okay. I thought it meant  
20 the actual individual number. And I'm trying to  
21 reconcile those two.

22 DR. HOWE: No, that's by facility.

23 MEMBER ZANZONICO: Okay.

24 DR. HOWE: And as you look down through the  
25 list, you'll see that --

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1 MEMBER ZANZONICO: Okay, that --

2 DR. HOWE: -- there are 3, 2, 6 9, 2, 3 --

3 MEMBER ZANZONICO: That clarifies it.

4 DR. HOWE: -- patients involved at a given  
5 facility.

6 MEMBER ZANZONICO: Okay. The other question  
7 I had is like it seems that in some of these  
8 instances, the medical event or the misadministration  
9 is immediately correctable. And I'm thinking, for  
10 example, in that case of samarium where the patient  
11 was underdosed.

12 It would seem that within the day -- I mean  
13 it is an intravenous injection within the day, an  
14 addition objection could have been to bring up the  
15 total administered activity to what was prescribed.  
16 If that were done, would that still be a medical  
17 event?

18 DR. HOWE: Yes. The medical event is when  
19 you have something that does not -- is something that  
20 meets the criteria of a medical event. The physician  
21 can take absolutely the correct action afterwards, can  
22 bring the dose up to what the patient needed. But that  
23 doesn't negate the fact it was a medical event.

24 CHAIR MALMUD: Thank you. Other questions?  
25 Dr. Thomadsen?

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1 VICE CHAIR THOMADSEN: On your Slide 5, I  
2 was just wondering if the facility does any check on  
3 the activity before they inject it? Is this not  
4 expected?

5 DR. HOWE: I'd have to go back and look  
6 carefully. In our license -- in our regulations, the  
7 licensee can verify -- the licensee does not have to  
8 verify what comes from the manufacturer. They can use  
9 the manufacturer if it comes in as the unit dosage.

10 And if they have to do any manipulation,  
11 they could use a volume and activity correction. I  
12 believe in this case, they made measurements  
13 afterwards because they accepted the manufacturer's  
14 information. And that's acceptable in our regulations.

15 And especially for some of these  
16 therapeutic radiopharmaceuticals where it is difficult  
17 to measure in dose calibrators, we prefer they use the  
18 manufacturer's number then think they have the  
19 accuracy that they have with technetium because we've  
20 seen many, many cases, samarium and P32 especially  
21 where they believe they can measure it more accurately  
22 on their dose calibrator and then they routinely are  
23 20, 30 percent low. And we end up a whole stack of  
24 medical events after that.

25 VICE CHAIR THOMADSEN: On your Slide 18 --

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1 DR. HOWE: Eighteen okay.

2 VICE CHAIR THOMADSEN: -- in the first  
3 one, the 60 percent under dose, physicist did not  
4 calculate the effective tube used to deliver it. What  
5 tube is that that has a 60 percent defect? Any idea?

6 DR. HOWE: Sometimes we have very skeptical  
7 information at this point. But we could go back and  
8 ask for additional information. This was the reason  
9 given that he hadn't calculated that he would lose  
10 dose based on the tube he was using to deliver the  
11 dose. I cannot tell you any more at this point. This  
12 may be one that you want to delve into more.

13 VICE CHAIR THOMADSEN: All right. I can't  
14 think of any tube they'd be using that would drop 60  
15 percent of the radiation. Interesting.

16 CHAIR MALMUD: Yes? Dr. Suh?

17 MEMBER SUH: Dr. Howe, thank you for the  
18 presentation.

19 Do you have a sense for these various  
20 medical events if these centers are using some type of  
21 safety checklist because some of these events that  
22 have occurred may have been averted if someone did a  
23 time-out to say are we treating the right location,  
24 have we calibrated the machine properly, is the  
25 catheter in the right position before we, you know,

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1 inject --

2 DR. HOWE: I think you'll see as you go  
3 through the reports in NMED and the reports back from  
4 the licensees that in many cases, that's what they're  
5 implementing now. They're now saying okay, we're  
6 going to have a time-out and we're going to check to  
7 make sure of things, which the implication is they  
8 didn't have time-outs before.

9 MEMBER SUH: Sure.

10 CHAIR MALMUD: Dr. Langhorst?

11 MEMBER LANGHORST: Thank you, also, for  
12 this report. It's always very helpful every year.  
13 And each year I understand it more. So thank you.

14 I didn't go through the reports that you  
15 gave us in here, which are very helpful, but can you  
16 give me a sense of how many of these are in agreement  
17 states versus NRC-regulated states, non-agreement  
18 states?

19 DR. HOWE: I cannot give that to you off  
20 the top of my head. I would guess most of them are in  
21 agreement states because there are a lot more  
22 agreement states.

23 MEMBER LANGHORST: Right.

24 DR. HOWE: I know if you look at the  
25 prostates, most of those are in agreement states.

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1                   MEMBER LANGHORST: I know that our  
2 agreement states are challenged with some of their  
3 resources that they are able to devote to inspections  
4 and so on. I just wonder are -- how does that impact  
5 medical events? Are things not being identified soon  
6 enough that maybe they would see precursors to a  
7 medical event? I'm just kind of asking a general  
8 sense of how you feel if there's more issues in  
9 agreements states because of challenging resources  
10 that agreement state programs have right now.

11                   DR. HOWE: I think with the very low  
12 number of medical events that we have per procedures,  
13 it would be difficult to make any sweeping statement.  
14 I think it may be easier to look and see how many times  
15 the inspectors identified medical events and therefore  
16 it is an indication that the licensees are not self-  
17 identifying medical events and may have issues with  
18 understanding the definition and reportability  
19 criteria. I think we could get to that a little bit  
20 easier than the other question.

21                   MEMBER LANGHORST: Thank you.

22                   CHAIR MALMUD: Dr. Welsh?

23                   MEMBER WELSH: Jim Welsh here. I, too,  
24 would like to reiterate the thanks and appreciation  
25 for this very comprehensive review. And since it is

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1 thorough and comprehensive, I have a number of  
2 comments or questions. And I'll go through them  
3 sequentially by section.

4           The first in Section 35.200 regarding the  
5 events involving the samarium-153 and the two iodine  
6 cases where there were underdoses. My first comment,  
7 again, is a philosophical one that I've mentioned  
8 before, that in my personal perspective, these  
9 underdoses I don't think should be categorized as  
10 medical events.

11           And I understand and appreciate NRC's  
12 perspective that it is important to identify trends,  
13 and therefore keep track of underdoses. But since  
14 underdoses fall into a different category of potential  
15 harm to a patient because they might not cure the  
16 patient, I think it should be separate from the other  
17 category of harm to a patient, which is caused by  
18 direct consequences of overdoses.

19           Having said that, I think that since no  
20 harm was done, maybe it would be nice if there was a  
21 separate category such as medical occurrence due to or  
22 violation due to under-dosing of radioactive material.

23           The other point is that these could  
24 perhaps have been taken out of the medical event  
25 category if there was permission for written directive

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1 adjustments before the patient leaves the treatment  
2 area. And I'll get back to that point again when we  
3 talk about the Y-90 cases.

4 Moving on to the 400 series, 81 patients,  
5 25 events is a lot. And I would not say that a lot of  
6 these patients were armed by these medical events or  
7 the title medical event. But the biggest reason for  
8 this many is because of the retrospective reviews that  
9 have been conducted.

10 I think I and other members of this  
11 committee have stated on many occasions that if we all  
12 went back and looked carefully at prostate  
13 brachytherapy procedures, that we would notice that  
14 disappoint, perhaps surprisingly high number of  
15 perfectly good, clinically good prostate brachytherapy  
16 procedures would have to meet the -- would have to be  
17 called medical events because of the limitations of  
18 the definition.

19 Specifically, things such as the poor  
20 image quality on postoperative CTs, we've stated in  
21 this room on many occasions that post-implant  
22 dosimetry is challenging. Imaging is difficult and  
23 the borders are fuzzy. And for that reason, using  
24 dose, especially the D90, is not a very good parameter  
25 for defining medical events from a regulatory

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1 perspective.

2           There were a few underdoses due to --  
3 three underdoses due to edema. And I would argue that  
4 they should not be medical events because these might  
5 be patient-related changes. The patient didn't  
6 intentionally change his anatomy.

7           But a perfectly good implant may be  
8 categorized as a medical event simply because of  
9 anatomical changes within the patient due to edema and  
10 the timing of the post-implant dosimetry, which  
11 artificially gives you a dose calculation that is less  
12 than the written directive for the D90.

13           There were two other that are underdoses  
14 for no definite reason. I suspect it is because of the  
15 edema. No proof of that, of course, but that would be  
16 my guess.

17           The other one that says anatomy issue, the  
18 procedure was stopped because of an anatomical change.  
19 And this meets our current definition of medical  
20 event. And, again, we know that medical event is not  
21 supposed to be a derogatory term. But I think that  
22 the average patient has a difficulty with that -- with  
23 discerning the difference.

24           And I do wish that there was something  
25 that was a separate category other than the medical

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1 event, which most patients, I believe, think is  
2 synonymous with the old term misadministration, which  
3 in the average person's mind is a very negative -- has  
4 a very negative connotation.

5 DR. HOWE: Well on the anatomical, there  
6 was not anatomical change.

7 MEMBER WELSH: But did you -- I'm sorry.  
8 What?

9 DR. HOWE: It was -- on the anatomical  
10 issue, there was no anatomical change. In other  
11 words, this patient wasn't necessarily a typical  
12 patient. So there were issues in having to deliver  
13 it.

14 MEMBER WELSH: I understand that.

15 DR. HOWE: Okay.

16 MEMBER WELSH: Which leads to the next  
17 point which is that if the written directive could be  
18 adjusted in some form or fashion before the patient  
19 leaves the control of the authorized user, this  
20 situation, which the physician probably used good  
21 judgment for, which perhaps prevented harm from  
22 occurring, would not have been labeled as a medical  
23 event.

24 MR. LUEHMAN: Dr. Welsh, I think that a  
25 lot of the comments that you are making were relative

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1 to those -- you can take those up with Mr. Fuller and  
2 his report on the, you know, the -- on Houston, on the  
3 workshops. And he'll be glad to take any additional  
4 comments we have on that.

5 I mean because I think that, you know,  
6 your points are well taken on some of these. I will  
7 say that on at least the events in Kentucky, the ones  
8 that we've looked at, seen the data on, they're  
9 clearly -- they run the whole spectrum from ones where  
10 there may be the issues you describe as well as some  
11 events which would clearly not be -- which would not  
12 be considered standard practice implants by anybody's  
13 definition.

14 So you're right. Our definitions and our  
15 consideration of, you know, this procedure, we're  
16 working on it, you know. And we had the workshops and  
17 we're continuing to move forward on that. So --

18 MEMBER WELSH: If I might just --

19 MR. LUEHMAN: Sure.

20 MEMBER WELSH: -- conclude quickly by  
21 saying that the series of events that have been  
22 presented, I think by and large prove that the ACMUI's  
23 predictions are correct. And, therefore, that the  
24 ACMUI's recommendations should be paid attention to.  
25 Thank you.

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1 CHAIR MALMUD: Thank you, Dr. Welsh. And  
2 thank you, Dr. Howe.

3 Dr. Howe, I have a question, which came up  
4 on Slide 11. And that said some of the licenses had  
5 multiple events, including no written directive.

6 That seems kind of elementary in terms of  
7 a deficiency. How could a process be ongoing without  
8 an order, a written directive, a prescription,  
9 whatever term they want to use?

10 DR. HOWE: I went back to look to see what  
11 that meant. And it meant that they believe there was  
12 originally a written directive. It wasn't the fact  
13 that there was never a written directive. It was they  
14 tossed the written directives and didn't keep them.

15 CHAIR MALMUD: They tossed them?

16 DR. HOWE: Yes. The requirements are keep  
17 things for three years. So they threw things away.

18 CHAIR MALMUD: I see.

19 DR. HOWE: And sometimes they threw things  
20 away that were less than three years.

21 CHAIR MALMUD: Do they understand now what  
22 the rules are?

23 DR. HOWE: I think they're being  
24 instructed.

25 CHAIR MALMUD: Thank you. Are there any

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1 other questions? Any other questions or comments?

2 (No response.)

3 CHAIR MALMUD: If not, thank you. Seeing  
4 the list with as many of the details as you have was  
5 very useful to us.

6 Thank you.

7 The time is now seven minutes before 12.  
8 So we will break and come back after lunch at 1:30  
9 promptly for the NRC rulemaking workshop with Mr.  
10 Fuller.

11 Oh, excuse me.

12 MEMBER MATTMULLER: Dr. Malmud?

13 CHAIR MALMUD: Yes.

14 MEMBER MATTMULLER: Just a procedural  
15 issue. During our discussion of AOs, we had a tape.  
16 We had a motion on the table. Do we need to address  
17 that? To table the motion, hold on to it until  
18 further discussion or --

19 CHAIR MALMUD: You are correct. We  
20 probably should table it because we are going to have  
21 a small meeting about the issue. So if you would make  
22 a motion to table it, if you care to, or whatever you  
23 want to do.

24 MEMBER MATTMULLER: So moved.

25 MEMBER LANGHORST: And I'll second that.

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1 CHAIR MALMUD: It's been seconded. All in  
2 favor of tabling it.

3 (Show of hands.)

4 CHAIR MALMUD: Thank you. Thank you for  
5 bringing that item to conclusion.

6 And we'll break for lunch. Thank you.

7 MR. EINBERG: We actually have something.

8 CHAIR MALMUD: Oh, it's another issue?  
9 Sorry.

10 MS. COCKERHAM: If you've completed your  
11 financial disclosure forms, could you please drop them  
12 off with me? Thank you.

13 (Whereupon, the foregoing matter went off the record  
14 at 11:51 a.m. to be reconvened  
15 in the afternoon.)

16  
17 A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

18 (1:28 p.m.)

19 CHAIR MALMUD: Good afternoon ladies and  
20 gentlemen. It is 1:30 and we'll try and keep on  
21 schedule this afternoon so that those of you who have  
22 transportation obligations later in the day can meet  
23 them.

24 And we will begin with the 1:30 session  
25 and that is Mike Fuller. And welcome again, Mike. You

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1 were away from the table for a while but I saw you  
2 sitting over here.

3 And Mike is going to discuss the NRC  
4 Rulemaking Workshops that were held in New York City  
5 and in Houston.

6 MR. FULLER: Okay, Thank you Dr. Malmud.  
7 Again, I am Mike Fuller. I am the team leader for the  
8 Medical Radiation Safety Team here at the Nuclear  
9 Regulatory Commission.

10 The purpose of my presentation today is to  
11 provide an overview of the key messages that we  
12 received during our Medical Rulemaking Workshops. And  
13 as Dr. Malmud mentioned, they were held in New York  
14 and in Houston, the first one in June and the second  
15 on in Houston in August.

16 We hosted two very successful public  
17 facilitated two workshops this summer and I am going  
18 to share with you the key messages that we received  
19 during those workshops of the things we learned as a  
20 result.

21 Just as a way of outline what I will go  
22 over again, we will talk about the key messages. The  
23 day one key messages had to do with the medical event  
24 definitions, other things related to the expanded Part  
25 35 Rulemaking we are currently in the early stages of.

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1 We are on day two of each of those workshops so we  
2 will go over those key messages that we heard.

3 In addition, we will -- Well to be  
4 specific, the first day was the medical event  
5 definitions associated with permanent implant  
6 brachytherapy. The second day had to do primarily  
7 with amending the attestation requirements and  
8 extending grandfathering to certain certified  
9 individuals, naming assistant or associate RSOs on the  
10 licenses, and additional requirements for molly-  
11 99/technetium-99 generators.

12 I will also go over some of the next steps  
13 in the rulemaking process.

14 A little background. In July of 2010 the  
15 Staff presented to the Commission a rule change for  
16 amending the medical event definition for permanent  
17 implant brachytherapy. The Commission disapproved the  
18 Staff's recommendations and directed the Staff to  
19 develop a new definition. Specifically, the Commission  
20 directed the Staff to work closely with the ACMUI and  
21 the medical community to develop event definitions  
22 that would do the following three things: protect the  
23 interests of patients; allow physicians the  
24 flexibility to take actions that they deem medically  
25 necessary; and preserve the NRC's ability to detect

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1 misapplications of radioactive material and failures  
2 in process, procedure, and training.

3           If you will recall, we devoted the April  
4 ACMUI meeting primarily for the purpose of the  
5 discussion of these same topics. We then held our  
6 first workshop in New York as I mentioned in June and  
7 our second workshop in Houston.

8           I want to take just a minute to thank the  
9 ACMUI for recommending that we shift our second  
10 meeting from June to August. If you will recall, Lynne  
11 Fairobent voiced some concern, from the American  
12 Association of Physicists in Medicine, voiced some  
13 concern that there was not enough advance notice  
14 provided for our workshops. This prompted some  
15 discussion amongst the AMCUI at that time and  
16 ultimately a recommendation.

17           This recommendation enabled us to make a  
18 change in our schedule. And the bottom line, I  
19 believe, this improved the level of participation that  
20 we were able to enjoy.

21           For each of the workshops we convened two  
22 separate panels of experts. For the Medical Event  
23 Definition Panel, it included representation from this  
24 body, the ACMUI, our Agreement State partners, ASTRO,  
25 the American Society of Radiation Oncology, the

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1 American Association of Physicists in Medicine, NRC  
2 staff, the Department of Veterans Affairs,  
3 representing our licensees, and a patient's rights  
4 advocate.

5 For the second panel, what we referred to  
6 as the Attestation Panel, I guess, we included  
7 representation again from this body, the ACMUI, the  
8 Agreement States, the American College of Radiology,  
9 and the NRC Staff.

10 I want to thank Dr. Welsh, Dr. Zanzonico,  
11 and Dr. Langhorst for their participation as panelists  
12 on these workshops. Also I wish to thank Dr. Malmud  
13 for participating in the New York workshop. Your  
14 participation and comments prompted very helpful  
15 discussion.

16 Also, Steve Mattmuller participated by  
17 webinar for both of the workshops and Dr. Langhorst  
18 participated by webinar for the first workshops and  
19 each also provided comments that added significantly  
20 to the discussions. And I want to thank everyone for  
21 that.

22 Okay. So what did we hear? What did we  
23 learn? Now there is no particular order here but I  
24 want to go through some of the key messages that we  
25 received from the workshops.

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1           The first thing was among the states we  
2 had fairly consistent regulations. And when I say  
3 states I mean the Agreement States. But there is wide  
4 variance in the interpretation and implementation of  
5 the regulations.

6           Now this message pointed out that there is  
7 a real need for inspection guidance and training. And  
8 we are currently participating in a working group with  
9 our Agreement State partners to address this need and  
10 we are working on specific guidance for inspectors for  
11 the current rule because we will have to live with it  
12 until we get the new rule, hopefully in 2014. We are  
13 expecting to a new rule in 2014.

14           Another key message that we heard is that  
15 the medical definition for permanent implant  
16 brachytherapy needs to be revised and should be based  
17 upon total source strength or activity and not  
18 absorbed dose. Now I want to say that there was  
19 extremely strong consensus for this position from all  
20 of our stakeholders in the medical community. We heard  
21 numerous reasons for this position from many people  
22 and why they all believe that this is necessary.

23           We also heard that if the medical event  
24 definition is based upon total source strength, that a  
25 tolerance of plus or minus 20 percent is a reasonable

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1 tolerance.

2 We also heard that the term "medical  
3 event" should be reserved for those instances where  
4 there is real harm to the patient or a potential for  
5 same. In other words, the medical event has been  
6 reserved for those things that are clinically  
7 significant.

8 We also heard that the term "medical  
9 event" is problematic for many stakeholders,  
10 especially in those instances where there is no  
11 medical consequence. We listened to lot of discussion  
12 at both workshops. Some suggested that we go back to a  
13 two-tiered system.

14 Well we also heard another key message and  
15 that is that what we call it is much less important  
16 than what we do with it.

17 We also heard that licensees should be  
18 trained in the policies and procedures for identifying  
19 medical events and that the patient's rights should be  
20 protected. The patient's rights advocates that  
21 participated in our panel discussions stated very  
22 clearly that whatever is ultimately decided, the  
23 patients must be kept informed.

24 We also heard that the authorized users  
25 should be required to attest in writing that the

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1 distribution of seeds within the target was implanted  
2 as intended. Now this point was made in recognition  
3 that with an activity or total source strength basis  
4 system or rule there is a possibility that all the  
5 seeds could be implanted within the target but bunched  
6 up or not as evenly distributed as intended.

7 We also heard that post-implant imaging  
8 should be required.

9 Okay now moving on to the second day of  
10 panel and the second day discussions, we also heard  
11 some very key messages there. The first had to do with  
12 attestation. We heard that the requirement for  
13 attestation for board-certified authorized users,  
14 authorized medical physicists, radiation safety  
15 officers, and authorized nuclear pharmacists should be  
16 removed. We heard that board certification coupled  
17 with recent of training requirements should be  
18 sufficient for the regulator's needs.

19 We also heard that there should be no  
20 requirement for attesting to someone's competency, but  
21 rather preceptors should be attesting to someone's  
22 training and experience necessary to carry out one's  
23 responsibilities independently.

24 Moving on to assistant or associate RSOs  
25 and whether or not they should be allowed to be named

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1 on NRC licenses, we heard that the NRC should allow  
2 for the naming of associate or assistant RSOs on an  
3 NRC medical-use license. And we also heard that there  
4 should be no arbitrary limit placed on the number that  
5 can be so named. The point was made that if we tried  
6 to somehow limit or restrict or provide some sort of  
7 specific requirements in this area, that it would be  
8 hard to apply evenly. There are needs at very large  
9 organizations and large medical centers that are not  
10 shared by some smaller medical institutions.

11 We also heard that whether they are called  
12 associate RSOs or assistant RSOs is something that we  
13 need to exercise some care when we decide what to name  
14 these individuals because the actual name associate  
15 versus assistant has some connotations within the  
16 medical community. So we will be looking into that as  
17 well.

18 Moving on to the molly-99/technetium-99m  
19 generators, we heard that there should be a new  
20 requirement for testing each elution, not just the  
21 first elution. But we also heard that there should  
22 not be a requirement for NRC licensees to report  
23 failures to the NRC.

24 So what's next? A few things that are  
25 currently ongoing and coming up soon. We are currently

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1 working to develop a regulatory basis for including  
2 the medical event definition issue in the expanded  
3 Part 35 rulemaking that is currently underway in its  
4 early stages.

5 We are also currently reviewing the  
6 regulatory bases that we developed previously for the  
7 expanded Part 35 rule to see if there are any needed  
8 changes or amendments to those. And we owe the  
9 Commission a proposed rule in December 2012 and a  
10 final rule in October 2014. And that is based upon our  
11 current schedule.

12 The next slide is the... ask if there are  
13 any questions or comments. But before I get to that,  
14 there is something I wanted to share that kind of, I  
15 guess, speaks to this whole issue of medical event  
16 definition and kind of goes back to all of the  
17 discussions that had at both the workshops and so  
18 forth. And I think it kind of brings it home. I think  
19 most of the people that participated in the workshops  
20 recognized that there is a need for a strong  
21 regulatory framework. It is just a matter of what  
22 should that look like and what should it entail and  
23 how detailed should it be and how far should it go.

24 But we had an event reported to us early  
25 this week. So it is not even public yet. We have to

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1 hold them for a few days to see how things shake out.  
2 So this is very preliminary information and so I won't  
3 divulge where it is from or anything. But let me just  
4 read to you a short summary and this is recent.

5 The licensee reported that of the 71  
6 seeds, only three were placed in the prostate. The  
7 others were located in the bowel, the bladder, the  
8 bladder wall, the lumen of the bladder. The intended  
9 dose to the target was 145 gray but the D90 to the  
10 prostate was 2.2 gray. The highest preliminary dose  
11 estimated to an unintended organ is 49.2 gray to the  
12 large bowel.

13 The patient has excreted eight seeds since  
14 the event. The licensee attributes the medical event  
15 to the non-use of fluoroscopy and absence of a medical  
16 physicist during the treatment. And those were both  
17 standard procedures that we used in the past.

18 So of course this raises all sorts of  
19 questions for us as regulators and I don't want to get  
20 into the details of that trigger event because that is  
21 really all we know. But I wanted to share that with  
22 you just to sort of highlight some of the challenges  
23 that we, as regulators, face when we are encouraged to  
24 do something that is entirely and drastically  
25 different than maybe what we have done in the past.

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1 I think again the messages that we heard  
2 at the workshops were very, very helpful to us as we  
3 start developing our regulatory bases and moving  
4 forward in rulemaking. But these types of medical  
5 events still become very, I think there always will be  
6 instances where these happen and they are reported to  
7 us and need to be reported to us so that we can  
8 follow-up and help to improve the process as things go  
9 forward.

10 So with that, I will end my presentation  
11 and take any questions that anybody might have.

12 CHAIR MALMUD: Thank you, Mr. Fuller. Are  
13 there questions? Comments? Dr. Zanzonico.

14 MEMBER ZANZONICO: Yes, in the same vein on  
15 the question of the medical event or the proposed  
16 medical event definition for implant brachy, the  
17 proposed definition is based on a 20 percent source  
18 strength, plus or minus 20 percent source strength  
19 within that prescribed. But then in the next slide it  
20 indicated that there would be a requirement for  
21 attestation by the licensee, by the authorized user  
22 that the seeds were implanted as intended and that  
23 there is also a requirement for post-implant imaging.

24 So in a regulatory sense, what would that  
25 be called if the source strength criteria was met so

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1 it wasn't a medical event on that basis, yet either of  
2 those other two requirements were not filled? Either  
3 they didn't do post-implant imaging or this  
4 attestation was not done.

5 MR. FULLER: Yes, those are good questions.  
6 Now keep in mind that these are suggestions, comments,  
7 recommendations that we heard at the workshops. We are  
8 going to have to take these and use this to develop a  
9 regulatory basis and tell our rule makers, the folks  
10 that take us through the process of developing a  
11 proposed rule. And these are things will consider as  
12 we develop that regulatory basis. So we will have to  
13 make some assumptions.

14 But assuming that we end up with a  
15 proposed rule but something along those lines, then in  
16 my way of thinking, when you are talking about medical  
17 events and if in fact we end up with a medical event  
18 definition based upon activity, then the plus or minus  
19 20 percent would be one of the criteria that had to be  
20 evaluated against the definition.

21 The other thing which again if we follow  
22 specifically the recommendations that we heard, is  
23 that these seeds need to be distributed throughout the  
24 target organ. Again, we are talking just about the  
25 prostates for this particular discussion and they

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1 would -- that there is an expectation that there would  
2 be an attestation again, that they were distributed  
3 more or less evenly or as intended.

4 Now whether or not that would end up being  
5 a medical event I think is something we are going to  
6 have to discuss further and get some clearer  
7 understanding of because it is not clear to me that  
8 that would automatically -- In other words, I guess  
9 what I hesitate to say that that would definitely be a  
10 medical event because that is a failure to create some  
11 sort of a document.

12 What if they had, based upon further  
13 observation, that they had reasonable distribution?  
14 Well we wouldn't want to call that a medical event.  
15 So maybe it might be a requirement and that if the  
16 requirement wasn't satisfied, then we would look at  
17 that and whether or not it should be cited as a  
18 violation.

19 The same way with -- I'm sorry. Let me  
20 get back to it. I'm sorry. Help me out Dr. Zanzonico.  
21 What was the other point?

22 MEMBER ZANZONICO: Well I think it was all  
23 the same question as the post-implant imaging.

24 MR. FULLER: Right, post-implant imaging.  
25 I'm sorry.

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1                   MEMBER ZANZONICO: That was the second  
2 requirement.

3                   MR. FULLER: I lost my place there.

4                   MEMBER ZANZONICO: Yes.

5                   MR. FULLER: Yes, again I think and this is  
6 just at this point in time, this is really, really  
7 early. So these would be the types of discussions  
8 that would be going on as we start looking at this.

9                   I think whether or not it would be a  
10 medical event would have to be determined based upon  
11 the other criterion. But the failure to do post-  
12 implant imaging, if in fact that is something that  
13 becomes a rule, I think would be something that would  
14 need to be dealt with more in the enforcement space,  
15 rather than in the medical event space.

16                   MEMBER ZANZONICO: Right.

17                   MR. FULLER: Because again, it would have  
18 to depend, in my opinion, and this is just my opinion.  
19 I think medical event would have to be tied more to  
20 ultimately what did you find out about whether or not  
21 things were done in accordance with the intentions of  
22 the authorized user.

23                   MEMBER ZANZONICO: I mean, as we have heard  
24 this, whether intended or not, there is a pejorative  
25 connotation to "medical event." And I think there was

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1 some discussion, though no consensus, at the New York  
2 workshop that maybe there is another category, another  
3 term that should be introduced where there is sub-  
4 optimal management but yet with no significant  
5 clinical effect on the patient.

6 What is the status of that in terms of the  
7 NRC's current thinking?

8 MR. FULLER: Again, all of these are things  
9 that we have heard this summer. We are going to take  
10 them back. We are going to examine them, develop some  
11 regulatory bases-type document. In other words, when I  
12 say regulatory basis, that is the way we start the  
13 process of getting what we feel like we want in terms  
14 of what our needs are to the folks that are working in  
15 the rulemaking. And it goes into the rulemaking  
16 working group, which tends to sort of polish and work  
17 on these sorts of things and develops a proposed rule.

18 But back to this issue of not having post-  
19 implantation imaging and so forth. It kind of reminds  
20 of the issue there was something that was very  
21 controversial in the proposed rule that was  
22 disapproved by the Commission where failure to develop  
23 a written directive was going to be called a medical  
24 event. That was extremely controversial.

25 Now again, that proposed rule was not

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1 approved by the Commission and for lots of reasons.  
2 But so that is something that is kind of recognized as  
3 being very, very controversial.

4 CHAIR MALMUD: Thank you. Dr. Welsh.

5 MEMBER WELSH: I was just going to  
6 reinforce what Dr. Zanzonico has said, that should  
7 things evolve such that the attestation writing by the  
8 authorized user that the seed distribution was  
9 according to his or her intentions and plan become a  
10 requirement, this would be a classic example of why I  
11 personally have felt that the term "medical event"  
12 would be best left for those events that are truly of  
13 medical consequences to the patient; whereas a  
14 different term might be appropriate for some violation  
15 such as this.

16 And I'm sorry that I can't come up with an  
17 appropriate neutral term. I thought of maybe policy  
18 violation as something that would be acceptable. But I  
19 do wish that there could be some distinction between  
20 something that happens to the patient that could  
21 possibly be of medical consequences, versus something  
22 such as the authorized user forgot to write the  
23 attestation after the procedure and is a violation of  
24 the policy.

25 And I think this would be a good example

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1 of why I personally have felt this way and there are  
2 many other examples that I have used in the past but  
3 this one is pretty concrete and obvious to most of us.

4 MR. FULLER: Yes, let me say a couple of  
5 things. First of all, with regards to whether or not  
6 we have a two-tiered system again, that is something  
7 we need to consider as we develop this. We heard it  
8 loud and clear in the workshops. We have heard it loud  
9 and clear actually in the April meeting as well. And  
10 so we will definitely seriously consider that as we  
11 draft the regulatory basis.

12 But as far as what we call it, let us come  
13 up with something. Sometimes it is easier for somebody  
14 to throw one out there and then we will bring it back  
15 to you guys and you all can tear it up for us. You  
16 know, tell us what you like and don't like. In other  
17 words, we will try and come up with something and see  
18 what you all think about it, again, if we get to that  
19 point.

20 CHAIR MALMUD: Thank you. Are there other  
21 -- Yes, Dr. Langhorst.

22 MEMBER LANGHORST: I just wanted to mention  
23 it was extremely helpful after the June meeting  
24 workshop that, and I know you guys struggled whether  
25 you should or should not do this, but you came up with

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1 a summary of the key items that you heard from that  
2 workshop for those of us who then attended the second  
3 workshop. And I commend you on doing that and I  
4 thought that was very helpful in my understanding and  
5 kind of summary of the comments that were made for the  
6 first workshop. I was not able to hear all of it but I  
7 did participate in some.

8 I think that there is maybe one key  
9 message that should be in your slides for our  
10 presentation and that is the discussion of the  
11 authorized user being able to change the written  
12 directive as he or she is doing this procedure and  
13 before the patient leaves. I think that is a very  
14 important item that is a key message that impacts like  
15 the question I asked earlier of Dr. Howe of that one  
16 medical event she presented that there was a  
17 difference because the anatomical situation did not  
18 allow all the implanted seeds.

19 So I would suggest that you might add that  
20 one to your list of key messages.

21 MR. FULLER: Thank you.

22 MEMBER LANGHORST: On the RSO, listing more  
23 than one RSO, that may not be as needed if we drop the  
24 requirement of preceptor statement for those who are  
25 Board certified. It may not be quite as needed but

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1 there may be certain licensees that it would be very  
2 helpful to have that ability to list more than one  
3 RSO, to list the associate assisted deputy, whatever  
4 fits their organization.

5 So while it may not have the same  
6 necessity, if that other problem is addressed, I think  
7 it should be allowed.

8 Then as far as the moly/tech generators  
9 and the question about whether or not there should be  
10 a requirement to report breakthrough failures to NRC,  
11 I ask that as you are considering that question, that  
12 you think of what other requirements there are in that  
13 case. It may not be NRC requirements. It may be FDA or  
14 good manufacturing requirements or whatever. And  
15 whether NRC's requirements really do apply to those  
16 who can fix the problem.

17 And I know in Houston a lot of us were  
18 talking about if the licensee has to report this, we  
19 don't have the ability to correct it. It is the  
20 manufacturer. And so I just ask you to consider that  
21 as you are doing your proposed rule drafting.

22 MR. FULLER: And if I might. A little bit  
23 related but not entirely related, we heard this  
24 morning about the issues with the rubidium/strontium  
25 generators. So one thing we are already thinking

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1 about, just so you know, is the regulatory basis that  
2 we developed for this particular change as part of the  
3 expanded Part 35 rule was in response to some very  
4 specific things that came up a few years ago. And we  
5 are already, at least amongst the Staff, recognizing  
6 that perhaps we need to step back from that just a  
7 little bit, look a little bit more globally.

8 We heard a few comments about this in  
9 Houston and see if there is not a better way to  
10 address these concerns but in a more, like you said, a  
11 more generic way. Instead of having some rule changes  
12 specifically to a moly-99 generator, we need to step  
13 back and look and say okay how can we maybe better  
14 address this issue. Because we don't know what the  
15 next one might be or other types of generators.  
16 Because we don't want to necessarily put ourselves  
17 within such a tight box that the next time something  
18 happens we have got to go to rulemaking to deal with  
19 it. So we are already considering that as well.

20 CHAIR MALMUD: Other comments or questions?  
21 Dr. Van Decker.

22 MEMBER VAN DECKER: Two, I guess. Number  
23 one, just to pick up on the last point you just made  
24 because I think this morning's discussion is ripe for  
25 growth of the field of new generators down the line,

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1 and I would just point out that a piece of the  
2 solution to the Board's question on the last rewrite  
3 was to use an appendix to kind of do more with  
4 guidance in some things for individual things and to  
5 have the rulemaking space be much more specific to  
6 construct and then refer to an appendix where you  
7 might be able to change things over time as the field  
8 evolves and not be so rigid as to where we need to be.  
9 Just a thought.

10 The second comment, I guess I missed  
11 Debbie Gilley several times these two days. My usual  
12 -- Since I am the one who usually will make the state  
13 comment while having the most people affected by this  
14 all the time.

15 You know recognize that, if you get a  
16 final rule in 2014 that the States get three years to  
17 comply. So everything we are talking about here is  
18 really 2017 before we get uniformity around the  
19 country. You know part of our goal is many of us  
20 training people and sending them to different states  
21 would like to have some consistency in what everyone  
22 is reporting and how we are training them for what  
23 environment they are really going to be in. So I guess  
24 my concept was around your slide on the medical event  
25 definition that said: "Among the states -- fairly

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1 consistent regulations, but wide variance in the  
2 interpretation . . ." I guess, you know, medical event  
3 definition needs to be a Category B, right? Everybody  
4 should be working off the same definition and it  
5 should be clean and tight enough that the  
6 interpretation of something that has this much import  
7 and this much impact on people's practices and on  
8 patients, that the guidance needs to be -- I never  
9 heard of compatibility guidance but I mean we should  
10 all be looking at the same thing and speaking the same  
11 dialect when it comes to something along that lines.  
12 And whatever kind of wordsmithing or educational or  
13 technical papers it takes and whatever else, we don't  
14 want this to look like, I won't say about other  
15 continents, but are one nation.

16 MR. FULLER: Thank you for that comment.

17 It is something we are always challenged by and we do  
18 the best we can to deal with it but it is a huge  
19 challenge for us as regulators as well.

20 CHAIR MALMUD: I have a question for you.

21 MR. FULLER: Yes?

22 MEMBER VAN DECKER: Are there plans afoot  
23 for the next workshop?

24 MR. FULLER: Not at this particular. For  
25 this particular rulemaking activity, thanks to the

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1 ACMUI, and the workshops and what we anticipate to be  
2 a continued relationship here, and keep coming back to  
3 you along each step of the way, we haven't anticipated  
4 further public outreach prior to the proposed rule.

5 Now that being said, I think it is fairly  
6 normal that once we have a proposed rule, and I can't  
7 speak for our rulemaking folks, but I know it is  
8 fairly common practice that once we have a proposed  
9 rule and we have it published for comment at that  
10 point in time, we may hold some further workshops on  
11 the proposed rule.

12 CHAIR MALMUD: Thank you. The reason I  
13 asked is I know we need a certain number of months'  
14 lead time to do an announcement. And therefore, if we  
15 are considering another one, we ought to begin the  
16 consideration process early so that if it needs to be  
17 implemented, it can be implemented with ample time  
18 notice.

19 MR. FULLER: Thank you for that reminder.

20 CHAIR MALMUD: Any other items on the --  
21 Dr. Van Decker.

22 MEMBER VAN DECKER: Sorry. You just jogged  
23 a question in my mind.

24 So if the proposed rule is going to be the  
25 end of 2012 for the next set of public workshops and

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1 going towards a final, what do you see as the timeline  
2 for what ACMUI will hear next spring? I mean, is there  
3 going to be a full year of you guys in comment  
4 digestion? What is going on in that period of time?

5 MR. FULLER: Well, I'll have to pull my  
6 calendar. You are going to get -- What's that?

7 MR. LUEHMAN: They are going to get a  
8 briefing on it. Right?

9 MR. FULLER: That's right. This afternoon  
10 there will be a briefing on all of that.

11 But just so you know, because this is  
12 medical major -- major medical policy and its  
13 rulemaking, you will get 90 days before it actually  
14 gets sent to the Commission as a proposed rule.

15 So early in the process, the ACMUI will  
16 have their opportunity to weigh in. And again, when  
17 you deliberate on that and discuss it, that will have  
18 to be in a public forum. So there are more  
19 opportunity, at least for public -- I won't speak for  
20 the chairman of the committee as far as participation,  
21 but there will be an opportunity for public awareness  
22 at the very least.

23 CHAIR MALMUD: Thank you. Dr. Suleiman.

24 MEMBER SULEIMAN: I'm not sure if -- We are  
25 just listening to the results of the workshops.

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1 MR. FULLER: Right.

2 MEMBER SULEIMAN: My comment this morning  
3 during my presentation that the uncertainty in  
4 radiation organ dose estimation is something that  
5 ought to be considered in future medical event  
6 criteria, has that registered with the NRC so I don't  
7 need to bring that up here again? Did I make myself  
8 clear?

9 MR. FULLER: Yes, it was very clear in the  
10 context of the discussion this morning. But I  
11 appreciate the comment now because we definitely need  
12 to consider uncertainty from a lot of different  
13 places, not the least of which is some of the tables  
14 that are used and the various tables that are used for  
15 the organ dose calculations.

16 So there is a lot of uncertainty. And you  
17 are right, sometimes we kind of focus in on a number  
18 as if that is somehow, because we use a single in a  
19 lot of these, because the clinicians, the authorized  
20 users use a singular number, that somehow we attach to  
21 that some sort of certainty. But what we ought to  
22 recognize as we develop these rules that there is a  
23 lot of uncertainty around those numbers.

24 MEMBER SULEIMAN: Right. And then I think  
25 I stated in previous meetings of the ACMUI that the

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1 precipitin in accuracy of dose estimation using  
2 external beam therapy is probably the state of the  
3 science. Then you get into seed implants; it gets  
4 softer. Then you get into unsealed sources; it is  
5 much, much more greater variability.

6 And so one size doesn't fit all. So that  
7 somehow needs to be addressed, taken. Unless it is  
8 exam-specific or modality-specific, it could get  
9 misinterpreted and run into some of the problems, I  
10 think, that we have run into.

11 That's all.

12 CHAIR MALMUD: Dr. Welsh?

13 MEMBER WELSH: Jim Welsh. If I might  
14 follow-up on Dr. Suleiman's point. I think it is quite  
15 apropos because we tend to think of prostate  
16 brachytherapy as being in the same category as  
17 external beam in terms of its precision in dosimetry,  
18 when in reality for a number of reasons that we have  
19 discussed on several occasions, it truly is not.  
20 Therefore, using dose for regulatory purposes is going  
21 to be challenging.

22 I don't think that anybody would really  
23 want to use dose for radioimmunotherapy. That is self-  
24 evident for anybody who is familiar with the modality.  
25 But we have misled ourselves into believing that dose

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1 is acceptable for prostate permanent implant  
2 brachytherapy and it is truly is not. And I am glad to  
3 hear that it was brought up and I hope that the point  
4 has not been lost on NRC. I doubt that it has.

5 But I would like to specifically address  
6 your slide number 10 in reference to this particular  
7 point. Under key messages, the last bullet point on  
8 slide 10 alludes to post-implant imaging should be  
9 required. And I like this, despite the fact that I  
10 think that there is a typo here. Because my  
11 interpretation was that post-implant dosimetry should  
12 be required but that wouldn't be consistent with what  
13 I have just said.

14 I think that it is good practice to  
15 attempt to do post-implant dosimetry to get some  
16 feedback on whether or not if I did an implant, did I  
17 hit my targets, my aims as far as giving this  
18 approximate dose to this approximate volume. But it  
19 would be inappropriate to use this for regulation.

20 Therefore, the wording might be better  
21 post-implant imaging should be required but using that  
22 post-implant dosimetry maybe shouldn't be required.

23 So I am curious about where the imaging  
24 versus post-implant dosimetry came from and whether it  
25 was intentional --

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1 MR. FULLER: It was.

2 MEMBER WELSH: -- for this purpose.

3 MR. FULLER: It was and I will tell you  
4 why. This is in the context as if we have a rule that  
5 is based upon total source strength or activity, then  
6 imaging is more appropriate. Again, there is an  
7 assumption here. And as it was explained during the  
8 workshops by a number of folks, if we end up with an  
9 activity-based rule, it becomes a simple matter of  
10 being able to go in and do post-implant imaging and  
11 then it is as simple as counting the sources and doing  
12 a simple arithmetic calculation to see if you are  
13 within the allowable tolerances. So that is why we did  
14 the imaging.

15 Because the dosimetry -- And again if we  
16 go to an activity-based rule, a total source strength-  
17 based rule, then the imaging becomes something that is  
18 outside. In that particular scenario, the dosimetry  
19 does become something that is outside the purview of  
20 the rules for the target of what we would call the  
21 treatment site. I think we are going to probably stick  
22 with that term, by the way. It is very generic and we  
23 will let folks deal with the others.

24 But if we are talking about to the  
25 treatment site, now I think for unintended tissues and

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1 organs, we are going to have a need to be able to  
2 understand what the dose consequences are for things  
3 that are not carried out in accordance with the  
4 authorized users' intentions. Now I know that we heard  
5 it both ways. In one workshop we heard that it was  
6 appropriate for us as regulators to maintain a rule.  
7 That is why again, I only included the key messages  
8 that were loud and clear. So let me be clear on that.

9 For things that maybe there was a little  
10 less consensus or disagreement on, I didn't include  
11 those because I wouldn't, at this point in time,  
12 consider those key messages. There are things that we  
13 heard and things that we will consider.

14 But we heard in New York that, as  
15 regulators, we should maintain the requirements or the  
16 criteria for determining a medical event based upon  
17 absorbed dose to unintended tissues and organs. Then  
18 when we got to Houston we heard just the opposite;  
19 that we should not. So we are going to have to look at  
20 that again to see what our needs are. But I know when  
21 we think in terms of radiation safety, in my way of  
22 thinking, the latter. And also in the need to not  
23 interfere with the practice of medicine, which is  
24 something we take very seriously or study very  
25 seriously.

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1           We, I believe, are on stronger footing  
2 when we focus on unintended tissues and organs than  
3 maybe for the dose or the activity implant or what  
4 have you for the treatment site.

5           CHAIR MALMUD: Thank you.

6           MEMBER LANGHORST: Sue Langhorst. Going  
7 along that line, Mike, we had that discussion in  
8 Houston about dose and activity. And I think the  
9 important point there is that it all really does come  
10 back to dose but you need a metric that people can  
11 measure and especially in a somewhat accurate sense,  
12 as far as compliance goes.

13           And so the activity base, even if it is so  
14 many percentages of the seeds that are outside the  
15 treatment site or whatever term you use, that could be  
16 a metric that relates reasonably well with dose, much  
17 like NRC uses other types of activity-based  
18 regulations that are intended to help meet dose  
19 requirements, such as air concentration releases. And  
20 that is intended to meet a public dose but it is a  
21 concentration because that is an easily measured  
22 metric that substitutes for that.

23           So while you may think you have heard two  
24 different things, I think in Houston we were really  
25 trying to say what is the metric that you can use that

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1 makes it inspectable and good for showing compliance.

2 Thank you.

3 MR. FULLER: Thank you.

4 CHAIR MALMUD: Other comments? I believe -

5 -

6 MR. CRANE: I have a question from a member  
7 of the public.

8 CHAIR MALMUD: Yes, I believe we have a  
9 member of the public who wishes to comment on the  
10 subject we are discussing now.

11 Would you please introduce yourself?

12 MR. CRANE: Yes, my name is Peter Crane. I  
13 am the retired Counsel for Special Projects in the  
14 Office of General Counsel.

15 And my question is for Dr. Welsh. I  
16 understand your point about differentiating; the need  
17 to differentiate between events that are potentially  
18 harmful for patients and that simply involves  
19 violation of procedures. Would it solve the problem if  
20 each medical event were designated, medical event,  
21 paren, potential health consequences, or medical  
22 event, paren, no potential health consequences. Would  
23 that solve the problem very simply?

24 MEMBER WELSH: Jim Welsh here. I can  
25 respond that conceptually the answer is yes. That if

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1 there were categories that could be of potential  
2 medical consequence to a patient, it would be nice to  
3 have them so labeled, whether they are in parentheses  
4 or given a different term altogether versus those that  
5 are simply violations because requirements have not  
6 been met. And your categorization might be  
7 appropriate.

8 I am sure there are various permutations  
9 on this thing that might solve the problem but the  
10 short answer is yes. Conceptually that might solve  
11 some of the problems and be better than some of the  
12 proposals that we have heard, including my own, of  
13 policy violation or regulation requests not met,  
14 something of that sort. But the concept is similar and  
15 the answer is yes, it might work.

16 MR. CRANE: Thanks. That's all I have to  
17 say.

18 CHAIR MALMUD: Thank you. And thank you,  
19 Dr. Welsh. Other questions? If not, we will move on to  
20 the next item on the agenda, thanking Mr. Fuller for  
21 his presentation.

22 And the next item on the agenda is Dr.  
23 Welsh, who will present the discussion on the  
24 Permanent Implant Brachytherapy Subcommittee  
25 discussion.

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1 Dr. Welsh will discuss possible changes to  
2 the Subcommittee report. It is agenda item number 17  
3 in your book.

4 MEMBER WELSH: Thank you, Dr. Malmud.

5 The first thing I would like to say before  
6 going into the conversation in-depth is that I might  
7 disappoint folks if they were expecting major changes  
8 or possible changes to our prior recommendations.

9 So if that was what you were expecting  
10 because of what was in the handout, I apologize. And I  
11 will say that for the most part we are going to stick  
12 with our prior recommendation. And the reasons are  
13 evident on this first slide.

14 We are down membership in our  
15 Subcommittee. Some of our Subcommittee Members  
16 unfortunately have left the ACMUI and therefore their  
17 input is not available. And so yes it is a fact that  
18 our current recommendations might be potentially  
19 different from our prior recommendations. I will  
20 refrain from introducing any significant changes for  
21 fear of NRC misinterpreting this as ACMUI wavering.  
22 ACMUI is not wavering. ACMUI just has different  
23 constituency in its Subcommittee. And therefore, the  
24 opinions that will be discussed in our conversation  
25 and discussion today could be slightly different from

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1 what you have heard in the past. But it is perhaps  
2 more due to the change in the makeup than in changing  
3 attitudes and general recommendations.

4 I am going to start by reviewing some of  
5 the prior medical events in 2010 that involve 75  
6 patients, 26 medical events, and the majority of these  
7 were permanent prostate implant brachytherapy  
8 involving 69 of the 75 patients. Some of these were  
9 overdoses and they are described here as excess dose  
10 to normal tissue, incorrect seed activity, and one  
11 overdose that was importantly retracted, based on  
12 repeat post-implant dosimetry, which underscores the  
13 fact that post-implant dosimetry is not an exact  
14 science.

15 However, the rest of these were  
16 underdoses. And this seems to be a general theme that  
17 we have seen over and over again and is a function of  
18 the current medical event definition. Importantly, two  
19 of these underdoses were subsequently retracted and  
20 not felt to be genuine medical events because the  
21 prostate swelled and, therefore, the volume was  
22 different and the dose calculation was altered. And  
23 the final reevaluated dose calculation turned out to  
24 be within 20 percent and, therefore, this was not  
25 considered a medical event. Again, underscoring the

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1 fact that our post-implant dosimetry is not an exact  
2 science.

3           Unfortunately for some of us who have gone  
4 on record saying that this could never happen, there  
5 was a very unusual event in this time period that has  
6 subsequently been retracted because of the definition.  
7 In this particular case, the D90 was less than one  
8 percent. And I am sure that anybody who has ever  
9 performed prostate brachytherapy, who does this  
10 regularly, would agree that in this highly unusual  
11 circumstance, something has gone awry.

12           Nonetheless, this particular event was not  
13 regarded a medical event because 39 of the 41 seeds  
14 implanted were within the target but they were all  
15 implanted within a few millimeters of each other on  
16 the so-called isoline. And according to the licensee  
17 report, the seeds "could have been placed in better  
18 location." And I am sure that everybody would agree  
19 that that is true. It was attributed to poor image  
20 quality but there is probably more to it than that.

21           Having said that, this unusual event again  
22 underscores the inadequacy of the current medical  
23 event definition because I think most of us would  
24 concur that this probably should be classified as a  
25 medical event. According to definitions it might

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1 escape the definition.

2 The majority of these medical events were  
3 based on dose, D90 for the most part. And the  
4 question, of course, is would these be categorized as  
5 medical events if a different definition were used.

6 And an important prediction was made a  
7 year or so ago that since many of these events that  
8 were reported in this reporting period actually  
9 occurred in prior years, the prediction was that many  
10 more would be expected in future years. And we learned  
11 today from Dr. Howe's presentation that that is indeed  
12 a prediction that has come true. And it is due to  
13 states retrospectively reviewing their permanent  
14 implant brachytherapy series and picking up cases that  
15 might have been acceptable but meet the definition of  
16 medical event.

17 So the Subcommittee reaffirms its belief  
18 that activity-based metrics for the definition of  
19 medical event remains preferable. And our prior  
20 recommendation that the NRC seek specific help from  
21 stakeholders, we are happy to see that that advice has  
22 heeded and these workshops have been carried out.

23 Most Members of the Subcommittee felt that  
24 the term "medical event" should be of potential  
25 medical significance. And the definition should be

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1 sensitive enough to detect potential harm to a  
2 patient. And harm, in most people's opinion, would be  
3 direct harm from radiation itself. However, we  
4 understand, and for the most part agree, that the NRC  
5 is also attempting to identify trends and patterns  
6 that could lead to patient harm but not necessarily  
7 are overdoses that cause harm to a patient directly  
8 and underdoses might fit into this particular  
9 category.

10 And we have heard from Mike Fuller today  
11 that whatever it is called, should we come up with  
12 different categorizations. We have heard from a member  
13 of the public, Mr. Crane, that maybe "medical event"  
14 parenthesis this or parenthesis that would be  
15 appropriate terminologies. But whatever it is called  
16 is less important than what is done with it.

17 And for the most part, I agree with that.  
18 However, I think we also have to be sensitive to what  
19 patients -- how patients might interpret that and  
20 legal repercussions of the terminology selected might  
21 have.

22 Another key point of the ACMUI  
23 Subcommittee report is that post-implant dosimetry is  
24 important and should be performed. We learned, much to  
25 everybody's pleasure, that NRC has been listening to

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1 us carefully during the workshops and this bullet  
2 point probably should be amended to say post-implant  
3 imaging is important and should be performed. And I'm  
4 glad to see that the workshops are not falling on deaf  
5 ears. NRC is listening and is actually a step ahead of  
6 ACMUI in this particular bullet point.

7           However, is post-implant imaging or  
8 dosimetry is required, a timeline because a  
9 controversial point. Certainly patient-related  
10 factors, such as a patient who can't make it or  
11 decides not to come in, that should not qualify as a  
12 medical event.

13           How about a slight delay beyond the 60-day  
14 proposed limit? Should that be a medical event? Well  
15 what if it is 61 days? Is that a medical event? I  
16 would say that this is another example of where the  
17 term "medical event" might not be the correct word,  
18 terminology for such an occurrence and maybe policy  
19 violation or something else would be acceptable here.

20           I understand that if we say that a  
21 timeline -- post-implant imaging is important and  
22 should be done, you can't divorce that from some type  
23 of timeline.

24           For example, if we are going to say that  
25 it is mandatory, what if it is not done within two

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1 years and the inspectors come and the licensee just  
2 says well we do ours for two years and one day? We  
3 were going to do it tomorrow. Well, that is an obvious  
4 and maybe ridiculous example but it is an example of  
5 why a timeline is important.

6 If a timeline is to be imposed, perhaps 60  
7 days should be extended to 90 days. Again, for medical  
8 purposes, post-implant dosimetry probably should be  
9 done earlier. But for regulatory purposes, if there is  
10 going to be a timeline at all, it probably should be  
11 more lenient than stringent.

12 The Subcommittee has suggested in the past  
13 that two categories of permanent implant brachytherapy  
14 be created. Number one, those which can result in  
15 significant rearrangement of the implant location  
16 during completion of the surgical implant procedure,  
17 such as mesh brachytherapy for lung implants and  
18 category two, those procedures that do not have such  
19 rearrangements normally. And prostate implants would  
20 fall to this category.

21 Not all stakeholders agree with this  
22 recommendation and not everybody on the Subcommittee  
23 concurred that this division of categories is  
24 appropriate or necessary. I think at this point we do  
25 acknowledge that if an acceptable medical event

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1 definition is created, the need for such distinctions  
2 goes away.

3 Here is -- This slide refers to some of  
4 the language that still exists and is a holdover  
5 perhaps from bygone eras that might no longer be  
6 appropriate for this particular modality. In  
7 particular, the 0.5 sievert is a very small amount  
8 compared to the doses that are being prescribed, much  
9 less than one percent.

10 Number two, a 50 percent overdose might be  
11 very medically inconsequential if the original  
12 expected dose to that tissue was very low.

13 And another point that was brought up by a  
14 former Subcommittee Member was that the units are  
15 inconsistent and confusing and it is suggested that  
16 the final rule use appropriate units in a consistent  
17 manner or maybe drop this section altogether would be  
18 the best solution.

19 ACMUI has brought this up in the past and,  
20 therefore, we felt that it is appropriate to again  
21 present these slides. But for the most part, if NRC is  
22 in agreement with the activity or source-based  
23 definitions, that these alternatives are not  
24 necessary.

25 And I think that this is an important to

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1 time, this is an appropriate time for us to request  
2 some feedback from NRC about whether or not our voice  
3 is truly being heard. It would seem ample evidence  
4 that it is, for example, the post-implant dosimetry  
5 being changed to post-implant imaging is a reflection  
6 of the fact that NRC is listening. But if NRC is truly  
7 listening and moving in the direction of an activity-  
8 based definition, our proposed alternative is  
9 superfluous.

10 In the absence of direct feedback to date,  
11 the alternative that someone at the Subcommittee has  
12 bandied about as suggested is that for the target, D90  
13 less than 70 percent of the CTV and importantly, this  
14 is a Boolean and, a dose of less than five percent of  
15 the sources occupying any octant of the PTV, except by  
16 intent, and specified in the written directive. So  
17 those would be the alternative definitions for the  
18 target and for the normal tissue, bladder and rectum  
19 D5 on post-implant dosimetry exceeding 150 percent of  
20 the prescribed dose. Or for the urethra, D5 exceeding  
21 150 percent of its value on the planned, approved dose  
22 distribution.

23 The definition has some attractive  
24 features, including the fact that it would catch an  
25 event such as the one that occurred last year where

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1 all of the seeds were bunched together. And it would  
2 not signify as a medical event an implant where  
3 sources are intentionally missing an octant, provided  
4 that the overall dose coverage is above 70 percent.

5 I will conclude by pointing out some  
6 statistics on the overall safety of this procedure and  
7 the prevalence of this procedure.

8 First of all, in the years that I have  
9 been alluding to in the past, in 2010, 20,000  
10 procedures and only 69 medical events, which amounts  
11 to 0.33 percent medical event rate. It looks like it  
12 is quite low. It is quite low. It should be much  
13 lower, though, because I think that this low figure  
14 exaggerates the hazards of this safe and effective  
15 procedure. It is safe but I believe that in part due  
16 to the inadequate definition, there have been some  
17 consequences to this safe and effective procedure's  
18 use.

19 In 2004, 192,000 prostate cancer  
20 treatments were administered in the United States.  
21 And of those approximately 42,000 were prostate seed  
22 implants, accounting for 22 percent of the total.

23 If you fast forward to 2009 with all the  
24 negative listing and the medical event series that  
25 have prompted this discussion, we see that there were

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1 220,000 prostate cancer treatments but only about  
2 17,000 permanent implant brachytherapy procedures.  
3 The dramatic drop in absolute numbers and more of  
4 dramatic drop in overall percentage.

5 So, I have said this before but I think it  
6 is a reasonable analogy to keep bringing up that in  
7 prostate cancer brachytherapy, in prostate cancer  
8 treatments we have gone from two-dimensional conformal  
9 radiotherapy to 3D conformal radiation therapy to  
10 improve the targeting and the conformality of our dose  
11 cloud. Then we developed intensity modulated radiation  
12 therapy for external gain. Now people are talking  
13 about proton beam radiation therapy, which is even  
14 more conformal. Ultimately, these techniques are going  
15 to be almost good as prostate brachytherapy.

16 And it may sound facetious but it is  
17 important to remember that this is a safe and  
18 effective treatment and it does provide the best in  
19 overall conformality of our radiation dose  
20 distribution. But perhaps in part because of the  
21 inadequate definition of medical event, sadly for  
22 patients in the United States, this treatment is  
23 almost disappearing. And I think that is an  
24 unfortunate reality.

25 I will conclude discussion today by

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1 pointing out a few things that were brought up by Dr.  
2 Howe in her 2011 medical events presentation. Twenty-  
3 five events involving 81 patients. That's a large  
4 number. And I don't think it is because of prostate  
5 brachytherapy being more hazardous than the other  
6 procedures we do involving radiation, involving  
7 byproduct material. This is an artificially elevated  
8 number due to the fact that some states have been  
9 retrospectively reviewing their records and,  
10 importantly, not all of these occurred in 2011, which  
11 tells us that the ACMUI prediction that if you went  
12 back and reviewed very strictly prostate brachytherapy  
13 procedures and applied the definition, you might find  
14 disappointing results. And these disappointing results  
15 are being found.

16 We have seen that some of these medical  
17 events were due to edema, volume changes, or that  
18 there was no definite reason for the underdosage, or  
19 that there was poor image quality. Underdoses in these  
20 situations probably would not be medical events if a  
21 proper definition were used.

22 Another medical event reported that we  
23 have heard about today is due to anatomical issues.  
24 And if the written directive could be amended prior to  
25 completion of the procedure however we define that,

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1 whether it is when the patient leaves the recovery  
2 room, leaves the care of the authorized user,  
3 whatever, if that written directive could be amended,  
4 something like this where the authorized user was a  
5 hero and prevented unnecessary harm to the patient,  
6 this would certainly not be categorized as a medical  
7 event. But with the current definition and  
8 regulations, it is called a medical event and I think  
9 that is unfortunate.

10 So it underscores the fact that we do need  
11 to change the definition. And coming up with the  
12 appropriate definition is critically important because  
13 you don't want to see the treatment that provides the  
14 best conformality in radiation dose distribution  
15 become unavailable to our patients.

16 VICE CHAIR THOMADSEN: Thank you very much,  
17 Dr. Welsh. Comments from the committee?

18 MEMBER ZANZONICO: I just have a question.  
19 You mentioned the timing of the post-treatment imaging  
20 and that being as long as 60 days or perhaps somewhat  
21 longer if the treatment might be or could be  
22 legitimate.

23 And my question is -- I would have thought  
24 that the purpose of the post-treatment imaging would  
25 be to verify the placement of the seeds, and perhaps

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1     unsaid, the possibility of implanting additional seeds  
2     at some point to correct underdosing and so forth.  If  
3     that is the case, would it be more logical for the  
4     imaging to be done early rather than later or is there  
5     some other rationale for the post-treatment imaging?

6             MEMBER WELSH:  Jim Welsh.  You are correct  
7     that those are some of the purposes for which we would  
8     like to do post-implant dosimetry and imaging.  And you  
9     are correct that if we want to make some changes, the  
10    sooner we know that information the better.

11            But there are some realities.  One is that  
12    prostate cancer treatment rarely is something that  
13    demands urgency.  So while there might be an ideal  
14    time and an optimal time to do post-implant dosimetry  
15    for the purposes of clinical trial reporting or maybe  
16    for determining whether or not an additional treatment  
17    is necessary, that timeline should be separate from  
18    the timeline for which regulatory consequences are to  
19    be imposed.  And that is why I recommend that for  
20    regulatory purposes, if NRC is going to impose such a  
21    timeline, that the timeline be lenient rather than  
22    stricter.

23            But you are correct.  From a clinical  
24    perspective and what are we going to do, maybe sooner  
25    is more logical.

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1 VICE CHAIR THOMADSEN: Yes, Ms. Weil?

2 MEMBER WEIL: I am having a little trouble  
3 parsing out this timeline for post-implant imaging.  
4 If the clinical purpose for post-implant imaging is  
5 driven by better treatment, better outcomes for the  
6 patients, then wouldn't the regulatory requirement be  
7 driven by exactly the same imperative? Why would the  
8 regulatory timeline need to be different if we are  
9 trying to regulate good care?

10 MEMBER WELSH: Jim Welsh again. I think  
11 that is a very good question. But I can answer by  
12 saying that post-implant dosimetry in an ideal world  
13 would give us truly accurate feedback on that  
14 particular procedure.

15 But in the real world, unfortunately, we  
16 don't have that degree of accuracy and confidence that  
17 the post-implant dosimetry is truly going to give us  
18 something that reflects reality. Because as we  
19 discussed on many occasions, there are caveats to the  
20 post-implant dosimetry, such as the edema and atrophy  
21 that routinely occur following prostate brachytherapy  
22 and the impact that has on volume. And since dose is  
23 energy per unit volume, your dose is going to be  
24 slightly inaccurate for that reason alone. And there  
25 are numerous other variables such as inter-observer

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1 depth variations. There are modality differences;  
2 ultrasound versus CT that further introduce  
3 inaccuracies in the dose estimation.

4 So while we would like feedback and we get  
5 that feedback from things like the D90 to learn more  
6 about prostate and brachytherapy in general and report  
7 this in the medical literature and conduct clinical  
8 trials, or we learn on our own as clinicians who  
9 perform this procedure and get feedback on am I  
10 getting better with time, am I getting worse with time  
11 using this particular parameter, we have to  
12 acknowledge that the parameter is not perfect and is  
13 probably not valid for regulatory purposes.

14 Getting back to your particular point  
15 about the timeline, if the post-implant dosimetry  
16 procedure itself has inaccuracies imposing a specific  
17 timeline would perhaps not be the best thing for a  
18 regulatory purpose.

19 MEMBER WEIL: This is Laura Weil. But I was  
20 specifically talking about imaging. Does that give you  
21 a different -- It gives you different information,  
22 clearly, than dosimetry.

23 MEMBER WELSH: You are correct. This is  
24 Jim Welsh.

25 The imaging could be fluoroscopic imaging.

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1 It could be CT imaging. It could be any host of  
2 appropriate modalities to image. And I would  
3 personally recommend that any practitioner of prostate  
4 brachytherapy do post-implant dosimetry but I would  
5 not recommend that NRC impose rules and restrictions  
6 and punishments if post-implant dosimetry is not  
7 performed.

8 Imaging on the other hand, can be done  
9 early using fluoroscopy and a simple seed count and an  
10 estimate of how many seeds are in the target but it is  
11 probably better done with a more anatomical imaging  
12 modality such as CT. And I think that the more lenient  
13 time frame is probably better for this purpose.

14 VICE CHAIR THOMADSEN: If I may, sort of in  
15 answer to your question -- This is Bruce Thomadsen.  
16 There is sort of a dichotomy right now in that an  
17 early image would allow you to make corrections and  
18 additions to, well not subtractions, obviously, but  
19 additions to, parts of the prostate that may appear to  
20 be undertreated. Whereas, the dosimetry done  
21 immediately is not very indicative of what the  
22 dosimetry should be for the prostate. That comes  
23 later. Although later is harder to go back and fix  
24 something that you didn't do. Particularly doing two  
25 studies is not practical right now because of

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1 reimbursement, which will reimburse one of those  
2 studies.

3 And so the question is, what is somebody  
4 going to do? And if they right now have to show that  
5 the dosimetry was within the 80 percent, then they are  
6 better off doing the image later, when the dosimetry  
7 is going to be more like it was at the time of the  
8 procedure.

9 VICE CHAIR THOMADSEN: Other comments from  
10 the committee? Yes.

11 MEMBER WEIL: One more general comment.  
12 This is Laura Weil. The title Dr. Welsh for your  
13 presentation is permanent implant brachytherapy. But  
14 this is specific to prostate.

15 MEMBER WELSH: Jim Welsh. It is not  
16 intended to be specific to prostate. It is intended to  
17 be a general request for a medical event definition  
18 that is appropriate for all categories of permanent  
19 implant brachytherapy.

20 Because of the challenges and the  
21 significant differences between prostate brachytherapy  
22 and the others, we have suggested that maybe there be  
23 two separate categories. Basically, prostate and non-  
24 prostate or procedures in which there is a  
25 rearrangement and not rearrangement. But if we could

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1 come up with an appropriate medical definition, it  
2 should and would encompass everything in permanent  
3 implant manual brachytherapy. And that is our ultimate  
4 goal, to seek a definition that would be appropriate  
5 for all of them. If we cannot, then maybe having  
6 subcategories is a better idea.

7 But our initial charge was to address the  
8 entire category of permanent implant brachytherapy but  
9 the reality was that during the time frame that  
10 prompted all of this in the first place, the majority  
11 of medical events were prostate brachytherapy, the  
12 overwhelming majority, and the negative publicity in  
13 the press was focusing on the prostate seed  
14 brachytherapy problems.

15 And so it looks that the majority of our  
16 discussion is focusing on prostate brachytherapy for  
17 those reasons.

18 VICE CHAIR THOMADSEN: Yes, Mr. Einberg?

19 MR. EINBERG: Chris Einberg here. Dr.  
20 Welsh, is it safe to assume then that your  
21 Subcommittee report does not have any changes to it?  
22 And the reason I ask that is that we are -- the NRC  
23 Staff needs to provide ACMUI its views on prostate  
24 brachytherapy implants or definition of medical events  
25 to the Commission.

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1           And so has the report changed? Or if not,  
2 can the Committee re-endorse the Subcommittee report?

3           MEMBER WELSH: Jim Welsh. I am going to ask  
4 for input from the remaining Subcommittee Members as  
5 to whether or not there is consensus on whether or not  
6 there needs to be any changes.

7           My general feeling is that we don't have  
8 to make very many changes but I am just one of three  
9 people.

10          VICE CHAIR THOMADSEN: I think you are  
11 asking two very different questions. And one is  
12 whether the Subcommittee's report has changed, to  
13 which Dr. Welsh has pointed out his reasons why maybe  
14 not, only because the Subcommittee is not what it was.

15          And the other is, what is the ACMUI's  
16 position on this. I think that the ACMUI is going to  
17 have to make a statement on that.

18          Yes, Mr. Fuller.

19          MR. FULLER: This is Mike Fuller. Just to  
20 kind of remind folks of one, I think important, point.  
21 Last April when we were talking about delaying one of  
22 the workshops, it all comes down to schedule. Well not  
23 all, but sometimes. When we were talking about moving  
24 one of the workshops from June to August, it was with  
25 the caveat and the assurance that by this meeting we

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1 would have the ACMUI's view or endorsement or whatever  
2 you want to call it of the brachytherapy  
3 subcommittee's report. Because as we explained then,  
4 we need that to help us meet our schedule. We owe the  
5 Commission something in November on this.

6 So I think that is what has popped in  
7 Chris' question. In other words, does it need to be  
8 changed further before the ACMUI can take it up or is  
9 it good enough for the ACMUI to endorse? So that is  
10 really what we are getting at.

11 VICE CHAIR THOMADSEN: I understand your  
12 question and I think that by the end of the meeting we  
13 should have the answer. I don't see that that is a  
14 conflict at the moment.

15 Dr. Langhorst, did you, as the other  
16 Member of the Subcommittee, have you a comment?

17 MEMBER LANGHORST: This is Sue Langhorst.  
18 I know, given that we have lost two members of our  
19 Subcommittee, Dr. Welsh rightly so was concerned about  
20 the remainder of us having a little different opinion  
21 in changing the Subcommittee report without those  
22 other inputs.

23 And so I think that was one of the  
24 questions we were bringing to the Committee today. We  
25 felt it was unfair to ask someone to jump in and give

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1 a quick opinion if they were, for instance like Laura  
2 Weil, brand new to the Committee.

3 So I think that is one of the questions we  
4 kind of had of the Committee as to whether you think  
5 the three of us should go ahead and propose a final  
6 Subcommittee report and have the full Committee take  
7 that up or would you feel that we need to have a  
8 couple of our people's input on where we are with the  
9 Subcommittee report and bring it to the full Committee  
10 say in the next few weeks or so through a  
11 teleconference?

12 So I think that was kind of the question  
13 we had of the full Committee, how you wanted us to  
14 proceed, given the change in our membership.

15 CHAIR MALMUD: This is Malmud. I would  
16 assume that the Committee, even absent the two former  
17 members, did come up with a recommendation. And the --  
18 let me see if I can explain to you how I see this in  
19 my mind and maybe that will help, though it may cloud  
20 it as well. I can't predict that.

21 By way of background, particularly for  
22 those who have just joined the Committee, the prostate  
23 is like a lemon that sits in the perineum through  
24 which a straw runs the urethra. Okay. That's the way  
25 it sits. The implantation of seeds in the prostate is

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1 done with the man in the dorsal lobotomy position most  
2 often, a grid placed over the perineum, and the seeds  
3 put through holes that are perforated in this metal  
4 grid.

5 The implantation is a skill, it is  
6 imperfect, and it appears that those institutions that  
7 do it frequently do it well, and those institutions  
8 that monitor and teach those who do it do it extremely  
9 well. However, as soon as a rod containing the seed  
10 penetrates the lemon, the lemon begins to swell, and  
11 it swells in an irregular fashion, assuming no  
12 infection, just the mere penetration of the tissue it  
13 swells.

14 Hence, the geometry changes. Hence, what  
15 was imaged before the process is now distorted. It's  
16 distorted by the very process itself. And as each seed  
17 is implanted, the distortion increases due to the  
18 physiologic swelling in response to the prostate being  
19 penetrated.

20 The seeds can sometimes go into the  
21 urethra and sometimes go into the adjacent organs, the  
22 bladder or the rectum, where the lemon is sitting  
23 ensconced.

24 The experts in this area -- and I am not  
25 one of them, so I'm describing -- this is as someone

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1 who doesn't do this procedure but has only been  
2 educated by the members of this Committee. The process  
3 results in, when done well and when it reaches the  
4 clinician's goal, is a very effective therapy in  
5 treating prostate cancer.

6 The complications are obviously those of  
7 the implantation of the seeds, and that can be  
8 irradiation to excess of the bladder, the rectum, and  
9 also grouping the seeds too much in one part of the  
10 lemon, leaving the other portion of the lemon, which  
11 may contain some tumor, untreated. And these are all  
12 possibilities in the hands of even the best  
13 therapists.

14 When things go awry, when too many of  
15 these seeds -- and there is no firm definition for the  
16 number, what that number is as a percentage of the  
17 total -- go into the wrong area or are concentrated in  
18 one area, the physician, from the medical perspective,  
19 is disappointed in the result, and the patient may be  
20 disappointed in the result as well.

21 So what we are dealing with is a technique  
22 which is a skill and for which there is no guarantee.  
23 Now, add to that the following, the imaging has been  
24 done in the past by ultrasound, and more currently by  
25 CT. But it isn't done by CT in every institution

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1 currently. And please stop me when I make an error,  
2 Dr. Welsh. It doesn't done by every institution  
3 currently. Some still use ultrasound.

4           Some have not even done post-therapy  
5 imaging for a variety of reasons -- perhaps downtime  
6 in their equipment, patient non-compliance. There may  
7 be a number of issues, and, therefore, there is no  
8 attempt to estimate the results of the therapy by  
9 imaging and by calculations of doses, except for the  
10 theoretical that was done pre-therapy.

11           So what we are looking at, from the NRC's  
12 perspective, is not the practice of medicine, which is  
13 not technically our responsibility -- it's not the  
14 mission of the NRC -- but the radiation hazards  
15 associated with this and to look at incidents in which  
16 radiation outcomes result in untoward effects to the  
17 patients.

18           We have been careful not to intrude into  
19 the practice of medicine. Now, as an observer, as a  
20 non-radiation oncologist, it seems to me that at this  
21 point in history that the specialty group that governs  
22 radiation oncology should require of its practitioners  
23 that they do post-implantation imaging. And I'm using  
24 the term "imaging," not "dosimetry."

25           From the imaging, a skilled radiation

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1 oncologist will estimate the radiation burdens to the  
2 various parts of the organ that were intended to be  
3 treated, as well as to adjacent organs that were not  
4 the goal, the target.

5 It is like pornography, defined by the  
6 Supreme Court, "when you see it, you know it." But  
7 it's very difficult to define. And this is a skill;  
8 this is an art form, for lack of a better term.

9 And to judge severely a treatment that has  
10 gone awry may be unjust, in that the treatment may  
11 have gone awry for purposes which are -- have nothing  
12 to do with the skill or the goal or the patients with  
13 which the procedure was performed.

14 We, in the NRC ACMUI, are concerned about  
15 the severe untoward effects that could have been  
16 prevented. And what can we do in the future about  
17 preventing them? And this has been an ongoing struggle  
18 for all of us, and it seems to me that if the  
19 governing board for the radiation oncologists don't  
20 demand that there be at least post-therapy imaging,  
21 assuming patient compliance, that it may be our  
22 responsibility to recommend that it must be done, so  
23 that at least there is a record, if necessary, some  
24 documentation of whether or not something really was  
25 done improperly.

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1 My understanding, though, as an outsider  
2 again, is that not all the institutions that perform  
3 this procedure have CT available to them all the time.  
4 And I don't know whether it is the state of the art  
5 currently, but that could be demanded or that would  
6 cause some institutions which provide this therapy to  
7 stop providing the therapy, which itself would be  
8 perhaps an unhappy event for the members of the public  
9 who need treatment.

10 But it is very difficult to measure the  
11 unknown with the unknown. It is very difficult to  
12 judge the unknown with the unknown. And at least if we  
13 had post-therapy imaging, we would know where to begin  
14 in the event that an investigation were necessary.  
15 But I wouldn't -- I would be hesitant to charge  
16 someone with having done less than optimal therapy if  
17 it turns out that the seeds were not exactly where  
18 they were wanted in a percentage or some percentage  
19 above what the goal was.

20 Let's say the goal was to get 80 percent  
21 to the target, if that particular patient had an  
22 unusual amount of swelling -- and I'm not even  
23 discussing the fact that infection, if present, would  
24 even distort the lemon further. I don't think we have  
25 the data. Despite the volume of cases, I don't think

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1 we have the data that we need to make a recommendation  
2 other than the recommendation that we have made, which  
3 I concur with, which I personally concur with.

4 But I would like to see the specialty  
5 board, if not us, demand that the protocol include  
6 post-therapy imaging. Not necessarily the calculation  
7 of the dose, if the dose calculation is going to get  
8 them into trouble, but at least demand the post-  
9 therapy imaging.

10 Dr. Welsh, your response, please.

11 MEMBER WELSH: A quick response to this  
12 important point is that the professional societies  
13 have uniformly endorsed post-implant dosimetry or  
14 post-implant imaging. And the reality is that our  
15 professional societies are not regulators, and,  
16 therefore, although it is strongly recommended the  
17 recommendations of ASTRO, American Brachytherapy  
18 Society, other professional societies, are  
19 recommendations and not absolute requirements. And  
20 somebody who fails to comply with these  
21 recommendations is not in violation of any particular  
22 law.

23 Now, having said that, it would at this  
24 point fall outside the standard of care in 2011, 2012,  
25 for any practitioner or institution that routinely

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1 does prostate brachytherapy to not routinely comply  
2 with the professional society recommendations. So if  
3 they are not complying with those recommendations,  
4 they should not be doing the prostate brachytherapy.

5 CHAIR MALMUD: It's my understanding, in  
6 response to your statement, that if that's the  
7 recommendation of the professional societies, and  
8 those recommendations are not being met, that there is  
9 no penalty that can be imposed by the professional  
10 societies except that the credentialing committees of  
11 the individual hospitals could reject it. But if it's  
12 done in a freestanding regular therapy unit, there is  
13 no similar body.

14 So does it then become our responsibility  
15 in protecting the public to dare to enter the realm of  
16 requirements? We do that in some areas. We do that in  
17 requiring dose calibrators for regular  
18 pharmaceuticals. We do that in radiation oncology's  
19 groups. We are thinking of the best interests of the  
20 patient, and also in not preventing the patient from  
21 getting a modality at the same time.

22 MEMBER WELSH: This is Jim Welsh. It's a  
23 difficult question to answer, because there is a very  
24 fine line between intruding into the practice of  
25 medicine here. Nonetheless, there is nothing that our

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1 professional societies can do that is legally  
2 enforceable, and, therefore, if we were trying to come  
3 up with some way of saying, "How can we make sure that  
4 post-implant imaging is truly being performed?" it's  
5 not going to come from a professional society's  
6 recommendation.

7 It could only come from a regulator's  
8 insistence, which, again, is a very fine line. And it  
9 could intrude into the practice of medicine, and it  
10 could further exaggerate these already alarming  
11 figures that show a decrease in the prevalence of this  
12 treatment.

13 But it is important to follow up with  
14 another point regarding your lemon analogy. And, yes,  
15 this is a procedure that is fraught with some  
16 technical challenges. There is an art to it. There is  
17 definitely a skill to this. There are a number of  
18 areas that things can go awry.

19 But having said that, it is important to  
20 remember that the published literature supports the  
21 fact that of the available modalities for early stage  
22 prostate cancer, this may be the best in terms of its  
23 effectiveness and side effect profile when viewed  
24 together. And it compares very nicely with the gold  
25 standard of surgery, including the modern robotic

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1 surgical procedures, and with external beam radiation  
2 therapy, which has improved immensely over the past  
3 decade. This prostate brachytherapy remains a very --

4 CHAIR MALMUD: I didn't choose the lemon  
5 as a piece of fruit to judge the --

6 (Laughter.)

7 Perhaps I should substitute kiwi for lemon  
8 to make it more acceptable. I was trying to reach the  
9 size of the organ that is being treated approximately.  
10 I thought an orange or a grapefruit would be  
11 excessive.

12 MEMBER WELSH: Nonetheless, the lemon might  
13 be better than the kiwi, because trying to penetrate  
14 that capsule can cause the needle to bend in a  
15 direction that you don't expect or don't want it to  
16 bend, introducing further need for skill and  
17 experience on the part of the user.

18 And in the hands of an experienced  
19 prostate brachytherapist, this treatment is very  
20 effective and very safe.

21 CHAIR MALMUD: Dr. Thomadsen.

22 VICE CHAIR THOMADSEN: I would guess that  
23 requiring post-procedure imaging would not be one of  
24 the factors that would be reducing the number of cases  
25 being done, and that that sort of has been the

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1 standard practice for a long time now. And I'm not  
2 sure that that would really reduce the number of  
3 opportunities for patients to receive this care.

4 In the past, people have done it because  
5 they have had to show that the dosimetry is within the  
6 80 percent as in the guidelines by the regulations.  
7 If they now just have to show that the number of seeds  
8 are correct, I don't think that that would affect or  
9 reduce the number of cases that would get done.

10 CHAIR MALMUD: If I may, the reason that I  
11 brought up that suggestion was because of the  
12 notoriety surrounding the last major instance at the  
13 Philadelphia VA in which there was no imaging done.  
14 Had imaging been done -- and I'm not privy to all the  
15 details with the case, but had imaging been done  
16 earlier they would have recognized that they were  
17 going astray long before they did, even without  
18 calculating the precise dosimetry.

19 Am I correct in that assumption, Dr.  
20 Welsh?

21 MEMBER WELSH: I believe that you are, and  
22 I believe that if there were a series of patients who  
23 did not have post-implant dosimetry for a variety of  
24 reasons, including I believe problems with the  
25 operation of the equipment technically and making it

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1 unavailable for a while, if the institution was  
2 routinely insisting on performing as recommended by  
3 professional society standards, and doing the post-  
4 implant dosimetry regularly, that it probably would  
5 have curtailed the number of reported events.

6 CHAIR MALMUD: Dr. Suleiman.

7 MEMBER SULEIMAN: Conceptually, stepping  
8 back, the way I see things is that it works into the  
9 culture. You know, the societies advocate, adopt,  
10 recommend certain things like imaging or whatever.  
11 And at that point, hopefully, the vast majority of  
12 practitioners are doing -- are behaving that way.

13 And if that becomes accepted practice in  
14 standard of care and problems occur because people are  
15 deviating from that now accepted standard of care, I  
16 think it's at that point that maybe it becomes a  
17 regulation to ensure that people are doing things  
18 properly.

19 I think for a regulator to step in before  
20 it has been established as a standard of care is  
21 presumptuous and can cause problems. So I think the  
22 natural progression of voluntary standards, and then,  
23 at some point -- if there is a safety issue. So I  
24 don't see anything wrong in this progress.

25 MEMBER WELSH: Jim Welsh. I would reply

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1 that I concur that the society recommendations, the  
2 policies that have been set forth, the guidelines that  
3 have been published and recommended, do demonstrate  
4 that this is standard of care. And it has been  
5 standard of care since this was published over a  
6 decade ago. And, therefore, it is perhaps not  
7 unreasonable for a regulator to step in now to make  
8 sure that the standard of care is being adhered to.

9 In general, I don't like the idea of the  
10 regulators coming in and imposing this because of the  
11 possibility that it is encroaching on the practice of  
12 medicine. But your point is well taken that there is a  
13 sequence, and the sequence is that this is the  
14 established standard of care, and those who have not  
15 been adhering to it have caused a lot of ruckus and  
16 problems for all parties involved, including the  
17 regulators, to the point that it is probably  
18 appropriate that the regulators could step in and  
19 insist on this.

20 CHAIR MALMUD: Dr. Thomadsen?

21 VICE CHAIR THOMADSEN: In addition, no  
22 matter what definition ends up being selected for the  
23 event criteria, in order to evaluate it will require  
24 imaging. Otherwise, there will be no way to know if  
25 the criteria are met.

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1 CHAIR MALMUD: That's a valid statement.  
2 Dr. Langhorst?

3 MEMBER LANGHORST: Getting back to the  
4 Subcommittee's report, I do think that there are a few  
5 what I'll call tweaks that we probably would like to  
6 make to the report. An example would be about using  
7 the current nomenclature of -- oh, gosh, help me with  
8 that.

9 MEMBER WELSH: GTB, CTB.

10 MEMBER LANGHORST: Right. That maybe we  
11 don't agree with that recommendation anymore, that we  
12 like the term of treatment site, given its generic  
13 use, that that doesn't require regulations to be that  
14 prescriptive. And I guess the question is, is whether  
15 the Committee would be comfortable with the three  
16 remaining Subcommittee members making those few tweaks  
17 and providing that updated report to the Committee for  
18 approval.

19 CHAIR MALMUD: For the record, would you  
20 indicate the specialties of the two members who have  
21 left the Subcommittee?

22 VICE CHAIR THOMADSEN: One is a radiation  
23 oncologist, and who is the other one? Oh, yes, the  
24 other is the state representative.

25 MEMBER WELSH: I think there was a third,

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1 then. The patient advocate.

2 MEMBER LANGHORST: Patient's advocate. We  
3 had five members of this most current report, and that  
4 was Debbie Dilley, Dr. Fisher, myself, Dr. Thomadsen,  
5 and Dr. Welsh. So it was our patient advocate and our  
6 state -- Agreement State representative.

7 CHAIR MALMUD: We currently have no  
8 Agreement State representative, but could we add back  
9 to the Committee, if it could -- if the Subcommittee  
10 would accept it, the new patient advocate and then let  
11 that Subcommittee make its final report? Dr. Welsh.

12 MEMBER WELSH: If I might request or  
13 suggest that Dr. Thomadsen's point about the radiation  
14 oncologist leaving is not in error. It is that when we  
15 were first starting this, we had Dr. Nag as a member  
16 of our ACMUI. But before the Subcommittee could get  
17 fully operational, Dr. Nag's term expired, and there  
18 was a long interval in which there was no other  
19 radiation oncologists that were -- it sure seemed long  
20 to me.

21 Now that we do have another radiation  
22 oncologist, in that we had -- and this is a radiation  
23 oncology issue, I'm wondering if our other radiation  
24 oncology member on the ACMUI would be better -- would  
25 be an ideal additional member.

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1 CHAIR MALMUD: Dr. Suh?

2 MEMBER SUH: Let me just share my thoughts.  
3 So prostate cancer is obviously a very common  
4 malignancy among men. It's a very important cancer  
5 that we have a number of treatment options for.  
6 Prostate brachytherapy has been clearly shown that, in  
7 the right hands, it is a very effective treatment  
8 option for patients.

9 It is unfortunate with the events that  
10 occurred in Philadelphia VA that a lot of attention  
11 and scrutiny have been pointed towards the prostate  
12 brachytherapy procedure, which has been shown for many  
13 years to be an effective treatment.

14 The current definition is a source of  
15 concern from not only myself, but also several  
16 societies as well, because the current definition is  
17 -- makes some implants be perceived as a medical event  
18 when probably in all actuality it is probably not a  
19 medical event.

20 I support the idea in terms of the  
21 Subcommittee. I have been here for about a year now.  
22 In terms of using an activity-based metric, that makes  
23 more sense than a dose-based metric for all the things  
24 that you mentioned earlier, and others here have  
25 mentioned as well.

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1 I think it is important that we have post-  
2 implant dosimetry, because if you don't know what you  
3 have implanted, you will never have an idea of whether  
4 or not you have done a good or perhaps a suboptimal  
5 implant.

6 So in terms of Dr. Welsh's volunteering me  
7 to be part of the Committee, I would be happy to do  
8 that if that would be valuable to the rest of the  
9 members.

10 CHAIR MALMUD: The Committee would be very  
11 pleased if you would do that.

12 MEMBER GUIBERTEAU: Could I ask -- John,  
13 could I ask a question? When you say that post-  
14 implant dosimetry should be part of the procedure, do  
15 you mean it should be required?

16 MEMBER SUH: Well, it's something that,  
17 again, I would like to discuss with the other  
18 Committee members.

19 MEMBER GUIBERTEAU: All right. That's  
20 fair. But -- so you haven't reached that decision  
21 at --

22 MEMBER SUH: I think imaging -- imaging is  
23 important, and I think that it's something I would  
24 like to get a better handle on from the Subcommittee  
25 as well.

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1           MEMBER GUIBERTEAU: But if I could just  
2 add, it's confusing to some of us who don't do this  
3 that I think the Committee needs to come back with a  
4 recommendation, when you say "it should" or "it's  
5 recommended." I mean, either, you know, this Committee  
6 in terms of being -- in terms of the safety and  
7 regulation of what is being done, I mean, we either  
8 are requiring it or we're not.

9           And, you know, we are not really in a  
10 position to recommend it, because that is really the  
11 practice of medicine, and people should be doing that.  
12 So I would ask personally, just for my benefit, to  
13 come back with some clear wording as to what we are  
14 doing with post-implant imaging.

15           CHAIR MALMUD: Dr. Welsh?

16           MEMBER WELSH: I would respond to Dr.  
17 Guiberteau by saying that -- absolutely right. And our  
18 Subcommittee report has alluded to this, but I like  
19 what I heard today from Mr. Fuller in his slide number  
20 10 saying that post-implant imaging should be  
21 required.

22           I think that states it very succinctly,  
23 and I think that the Subcommittee in general, and the  
24 ACMUI as a whole, probably endorses that statement and  
25 likes it better than post-implant dosimetry should be

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1 required, because it then doesn't impose on the  
2 practice of medicine nearly as much, and --

3 MEMBER GUIBERTEAU: Thank you.

4 CHAIR MALMUD: I presented it as a step. I  
5 didn't want to intrude on the practice of radiation  
6 oncology, and ACOG already has recommended it. So  
7 we're not really -- we're not really endorsing  
8 anything that has been opposed by the professional  
9 society.

10 Dr. Suleiman?

11 MEMBER SULEIMAN: I think, really, it's an  
12 issue of verifying somehow. And I think dosimetry is  
13 used pretty loosely, and I think you can't do the --  
14 you can't do good dosimetry in this situation without  
15 some imaging. So I think imaging, to me, seems more  
16 logical. And the proof of the pudding, to me, would  
17 be, without the imaging, is there a safety issue?

18 You know, are there populations out there  
19 that hadn't done the imaging and clearly there is a  
20 greater risk to those patients? And I think if that  
21 answer could be yes, then it is a step to adopting  
22 what -- good practices in a more mandatory way.

23 CHAIR MALMUD: Dr. Welsh?

24 MEMBER WELSH: I will respond by saying Dr.  
25 Thomadsen's point is important, that you can't apply

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1 this proposed definition without imaging. And so  
2 imaging is an inherent component of the definition.  
3 It is perhaps reasonable to explicitly state that  
4 imaging is necessary and should be required. But post-  
5 implant dosimetry is a subset.

6 And although the professional societies  
7 and I personally think that we should all be doing  
8 post-implant dosimetry, it, in my opinion, might be  
9 best kept out of the regulatory realm, because post-  
10 implant dosimetry leads to a dose calculation which  
11 takes it down the wrong path.

12 CHAIR MALMUD: Dr. Langhorst?

13 MEMBER LANGHORST: Thank you. I just want  
14 to remind the Subcommittee, and also the Committee, to  
15 be mindful of NRC's request of timeliness of this  
16 revision and then review by the Committee. And so I  
17 think we need to be mindful that we need to do this on  
18 a fast track to hopefully help support that effort.  
19 So --

20 CHAIR MALMUD: Thank you for reminding us  
21 of that. Are the members of the Subcommittee prepared  
22 to do that in a reasonable --

23 MEMBER LANGHORST: I am.

24 CHAIR MALMUD: You are. Dr. Welsh?

25 MEMBER WELSH: Yes.

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1 CHAIR MALMUD: Dr. Suh?

2 MEMBER SUH: Yes.

3 CHAIR MALMUD: This may be late for you to  
4 join in on this, given the fund of knowledge here has  
5 taken several years to accrue. All right. So then,  
6 Dr. Thomadsen, you are going to join the group as  
7 well?

8 VICE CHAIR THOMADSEN: Absolutely. Would  
9 you like to propose a deadline for the Subcommittee's  
10 report?

11 CHAIR MALMUD: I would like to hear the  
12 chair of the Subcommittee propose a deadline  
13 aggressively, so that we can endorse it.

14 MEMBER WELSH: This is Jim Welsh. In order  
15 -- before I can propose a definite deadline, could  
16 somebody repeat the deadlines that are necessary for  
17 the Commission, so we have a good idea again?

18 CHAIR MALMUD: Mr. Fuller? The deadline  
19 that you would like to see met?

20 MR. FULLER: According to our current  
21 schedule, we owe the Commission what we call a CA note  
22 with this Subcommittee's report attached by  
23 November 4th. So it's very -- and, of course, Neelam  
24 can keep me honest, but that's the right date,  
25 correct?

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1 MS. BHALLA: That's correct.

2 MR. FULLER: Okay. So --

3 VICE CHAIR THOMADSEN: Can I ask, Mr.  
4 Fuller, in order for you to do that, how soon do you  
5 need to have the Committee's decision?

6 MR. FULLER: Ashley has her hand up. I  
7 think -- did I misspeak, Ashley?

8 MS. COCKERHAM: No, you didn't misspeak.  
9 But I think we also have a SECY paper that needs to be  
10 drafted that also includes this that's due -- is that  
11 -- that's due in -- I can't remember the date.

12 CHAIR MALMUD: October?

13 MS. COCKERHAM: We need this in mid to  
14 early October, if possible. Does that answer the  
15 question?

16 MR. FULLER: Yes, I -- we were just talking  
17 about that normally, you know, for us to get something  
18 -- after we have received it, to get it through  
19 concurrence, and so forth, we look at 10 days or two  
20 weeks, but we could try to -- we could try to really  
21 fast track it ourselves. In other words, you know, run  
22 it around and brief various people.

23 So it -- Ashley has her hand up again.  
24 She is going to keep us straight again.

25 CHAIR MALMUD: Ashley?

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1 MS. COCKERHAM: A light bulb came on. We  
2 have a SECY paper due in March. If you back up all the  
3 timelines, the October date still stands. It takes a  
4 month or more to get a paper through concurrence. The  
5 paper has to be drafted, and our SECY paper actually  
6 cannot be drafted until this report is submitted and  
7 final and included in it.

8 It is the basis, if you will, of our  
9 paper. We have to provide the ACMUI position and the  
10 staff position. So I'm not sure about this CA note.  
11 That's not ringing a bell right now. But the SECY  
12 paper is due in March, so the October -- mid to early  
13 October date still stands for this Committee report to  
14 be final, voted on by the Committee in a public  
15 meeting.

16 MR. FULLER: Yes, I would -- what I would  
17 like to ask for, if at all possible, I know that  
18 November 4th date is on a Friday. So the previous  
19 Friday I think is October 26th, is that correct?

20 MR. LUEHMAN: 28th.

21 MR. FULLER: 28th? So, I mean, at the very  
22 latest, if we had something that had the endorsement  
23 of the full ACMUI by October 28th, then we would have  
24 -- I know I'm really, really being aggressive, but I  
25 want to give folks the -- you know, the --

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1 MS. COCKERHAM: No, you're not being  
2 aggressive enough.

3 MR. EINBERG: Chris Einberg here. That  
4 won't work.

5 MS. COCKERHAM: The CA note I believe that  
6 you're thinking about is for ACMUI-ACRS best  
7 practices, which was from my pro-con SECY paper.  
8 That's the CA note that we owe in -- but for --

9 MR. FULLER: I know Neelam is getting ready  
10 to make a presentation about the schedule, so it will  
11 become more clear after that. I'm sorry, I just don't  
12 have the dates in front of me.

13 MR. EINBERG: Neelam, can you come to the  
14 microphone, please?

15 MS. COCKERHAM: I'm going to say --  
16 sticking by early to mid October.

17 MS. BHALLA: This is Neelam Bhalla from  
18 NRC. What our CA note to the Commission is looking  
19 for -- and actually that's going to be in my  
20 presentation, but I'll address it right now -- the  
21 Commission asked us that after the workshops give a  
22 note to the Commission that the status -- as to when  
23 can we do this rulemaking and give them a schedule.

24 So it's a chance for us to go back to the  
25 Commission and say, you know, these are the issues,

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1 and we think this is the guideline. We have already  
2 provided a timeline to the Commission in an IP paper,  
3 that SECY-11-0035, and so right now we are planning  
4 and we are hoping that we will stay with that  
5 schedule.

6 But the Commission note -- the CA note in  
7 November will be to let the Commission know if we see  
8 any problems, or would we be able to meet the  
9 schedule. If not, why not? And also, Commission wants  
10 to know what the effect of that schedule would be on  
11 the larger medical community.

12 So we do owe a note to the Commission in  
13 November. The exact date is -- you know, whatever  
14 that date is for us that becomes two weeks prior to  
15 that date because of the way our members move up to  
16 the Commission.

17 So to go back to what this Commission note  
18 is about, the schedule, and basically we will be  
19 giving to the Commission that, yes, we can meet the  
20 schedule that we have right now. But one of the basics  
21 in that report that went out, that for the medical  
22 event we are counting on the ACMUI report, because  
23 that becomes the basis or the starting point for the  
24 technical basis for this medical event definition.  
25 And if we don't have that report on time, it is going

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1 to delay our schedules.

2 CHAIR MALMUD: Thank you. So we would need  
3 a report from the Subcommittee, and then we need a  
4 formal meeting of the Committee, which could be a  
5 telephone conference call. But that would have to be  
6 entered into the Federal Register.

7 MEMBER LANGHORST: Right.

8 CHAIR MALMUD: So what is the timeline for  
9 entering a telephone conference call into the Federal  
10 Register for the ACMUI? How many weeks do we need in  
11 advance?

12 MS. COCKERHAM: We need 15 days.

13 CHAIR MALMUD: Fifteen days. So if we take  
14 15 days from October 30th, that would bring us back to  
15 October 14th or so. Could the Subcommittee have its  
16 report ready for the full Committee before October  
17 14th? Last question is addressed to you, Dr. Welsh,  
18 and members of your Committee.

19 MEMBER WELSH: Dr. Thomadsen has -- is  
20 signaling to me in sign language.

21 CHAIR MALMUD: Dr. Thomadsen is signaling  
22 October 7th. Is that a possibility for the  
23 Subcommittee, October 7th?

24 MEMBER WELSH: As the chair of the  
25 Subcommittee, I can say that since most of what we

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1 will be doing is tweaking rather than rewriting, we  
2 should be able to adhere to an October 7th deadline,  
3 provided that our new members get copies of the  
4 Subcommittee report, the original one that we are  
5 about to amend, as soon as possible. And we can start  
6 working on this and have it finished very quickly,  
7 certainly meeting that deadline.

8 CHAIR MALMUD: So you think you could get  
9 your work done by October 7th, and we could enter the  
10 date for the conference call for the entire ACMUI and  
11 have it before October 30th? Ashley, you're shaking  
12 your head. Not possible?

13 MS. COCKERHAM: The October 7th date is  
14 fine for the Committee report. We can publish a  
15 Federal Register notice. We can draft it next week and  
16 publish it, you know, late next week or early the week  
17 after that, and go ahead and set the date for -- it  
18 could be October 8th, the day after your Subcommittee  
19 reports. That's a little -- I mean --

20 MEMBER LANGHORST: That's a Saturday.

21 MS. COCKERHAM: I am exaggerating. But the  
22 telephone conference could go ahead and be noticed  
23 now, and the Subcommittee would have until the 7th to  
24 do their report and, say, give the Committee a week to  
25 review the reports and already have the teleconference

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1 scheduled for October 14th. I don't know what days  
2 those are. Are we scheduling dates on Saturdays?

3 MR. EINBERG: October 14th is a Friday.

4 MS. COCKERHAM: Okay. Probably not the  
5 best date, but does that seem agreeable?

6 CHAIR MALMUD: October 19th is the  
7 following Wednesday. Is that a good date for the  
8 conference call?

9 MEMBER SULEIMAN: I am in the air --

10 PARTICIPANT: Me, too.

11 CHAIR MALMUD: What day would be preferable  
12 to you?

13 VICE CHAIR THOMADSEN: Tuesday -- would  
14 Tuesday work? Monday or Tuesday, the 17th or 18th,  
15 would that work for --

16 CHAIR MALMUD: Dr. Welsh?

17 MEMBER WELSH: The 17th or 18th, which are  
18 Monday or Tuesday, or the 14th, which is the previous  
19 Friday, would work for me.

20 CHAIR MALMUD: The previous Friday, would  
21 that work for you?

22 VICE CHAIR THOMADSEN: Well, that's --

23 CHAIR MALMUD: Sue, I think --

24 MEMBER LANGHORST: Sue Langhorst. This  
25 would be for the full Committee.

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1 CHAIR MALMUD: Yes.

2 MEMBER LANGHORST: So we need -- I can make  
3 anything work.

4 CHAIR MALMUD: Okay.

5 MS. COCKERHAM: What is the date for  
6 consideration again, really quickly?

7 MEMBER WELSH: We are thinking about the  
8 14th, the 17th, or the 18th. And I guess if anybody  
9 has a problem with those that might be a better way --

10 MS. COCKERHAM: Any time after the 17th  
11 would be good.

12 VICE CHAIR THOMADSEN: After the 17th.

13 MS. COCKERHAM: After the 17th.

14 VICE CHAIR THOMADSEN: That sounds like  
15 the 18th.

16 MR. EINBERG: And that's because of the 15-  
17 day FACA requirement?

18 MS. COCKERHAM: Yes.

19 CHAIR MALMUD: October 18th?

20 MS. COCKERHAM: Sure.

21 PARTICIPANT: It's a Thursday?

22 MS. COCKERHAM: Tuesday.

23 CHAIR MALMUD: Fine. So be it.

24 October 18th.

25 VICE CHAIR THOMADSEN: That day I can do

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1 any time, whatever --

2 CHAIR MALMUD: Dr. Suh, is that good for  
3 you? Dr. Welsh?

4 MEMBER SUH: That's fine.

5 MEMBER WELSH: Yes.

6 CHAIR MALMUD: Dr. Langhorst?

7 MEMBER LANGHORST: I can make anything work  
8 on that day.

9 CHAIR MALMUD: October 18th it is.

10 MEMBER LANGHORST: For the full Committee,  
11 though.

12 CHAIR MALMUD: I just want to do members  
13 of the Committee first. That's why -- I wasn't  
14 ignoring you, Bill. One, two, three, four. So the  
15 four members of the Subcommittee can make it on  
16 October 18th.

17 Thank you. Dr. Van Decker?

18 MEMBER VAN DECKER: I just want to ask a  
19 question, so I'm not reading too much into this.  
20 First of all, I have nothing but the greatest  
21 confidence in the remaining Subcommittee members that  
22 they have a feel for the field, and that this is  
23 working in the right direction, that tweaking this is  
24 fine, and we can do all of this.

25 But I guess this concept of the statement

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1 of we've lost some Subcommittee members makes me just  
2 raise this question and think about it. One of those  
3 Subcommittee members was the representative of the  
4 states, and we just talked about this issue of getting  
5 this through, the proposed rule through the states as  
6 well. So it's got to come out in some fashion where  
7 they feel that they have buy-in to it.

8 So I guess my question is: as far as you  
9 know, Debbie, when she was part of this, was not  
10 expressing a strong minority opinion about something  
11 that we need to know about, have some sense for,  
12 and --

13 VICE CHAIR THOMADSEN: I had very extensive  
14 discussions with Debbie on about three occasions about  
15 the proposals. And I think I know what her take on  
16 that was as far as the states. And I was at the OAS  
17 meeting and heard a bunch from many of the people from  
18 the states about the proposals. So I think that -- I  
19 think I do have an idea of how the state radiation  
20 control people have felt about this.

21 CHAIR MALMUD: Does that answer your  
22 concern, Dr. Van Decker?

23 MEMBER VAN DECKER: Yes. I just don't want  
24 us to set ourselves up for more problems down the  
25 line. But this is --

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1 CHAIR MALMUD: Thank you.

2 MEMBER VAN DECKER: -- where we are, and  
3 that's fine. As long as --

4 CHAIR MALMUD: Mr. Einberg?

5 MR. EINBERG: Because this meeting will be  
6 publicly -- a public teleconference, we could invite  
7 or inform the Agreement States to participate and  
8 perhaps provide them with an advance copy for their  
9 review also to ensure that their views are understood  
10 and heard.

11 CHAIR MALMUD: Thank you. Dr. Welsh, do you  
12 have anything else you want to say to us?

13 MEMBER WELSH: I have said enough.

14 (Laughter.)

15 CHAIR MALMUD: Any questions for Dr. Welsh,  
16 or comments?

17 (No response.)

18 Thank you. It has been a very constructive  
19 session. I think that we are all -- all of us here  
20 have dual -- oh, I'm sorry.

21 MEMBER MATTMULLER: Do we need a time for  
22 our teleconference for Ashley?

23 CHAIR MALMUD: Yes. You'll work that out.  
24 Ashley, do you have a time? Sophie or --

25 MS. COCKERHAM: Yes, now is as good as any.

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1 Do you have your calendars or -- yes? I know we have  
2 people on the west coast, so nothing before 11:00 a.m.

3 Do we have anyone on the west coast now? No?

4 VICE CHAIR THOMADSEN: Well, the state  
5 people, but --

6 MS. COCKERHAM: State people, okay. Let's  
7 consider -- nothing before 11. Okay. Is 11 good?

8 MEMBER LANGHORST: Eleven is perfect. This  
9 is Sue Langhorst. That's perfect for me.

10 MS. COCKERHAM: Okay. 11:00 a.m. Eastern  
11 Time.

12 MR. EINBERG: And how long is the meeting?

13 MS. COCKERHAM: We will probably have --

14 MEMBER LANGHORST: I was thinking Central  
15 Time.

16 VICE CHAIR THOMADSEN: It's Eastern Time,  
17 so what time are you -- 12 is fine.

18 MS. COCKERHAM: 12?

19 CHAIR MALMUD: How is 12?

20 MS. COCKERHAM: Okay. How is 12?

21 VICE CHAIR THOMADSEN: 12 Eastern Time.

22 MS. COCKERHAM: 12 Eastern?

23 MEMBER LANGHORST: yes.

24 MS. COCKERHAM: Okay.

25 PARTICIPANT: And this is the --

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1 CHAIR MALMUD: ACMUI teleconference.

2 PARTICIPANT: And how long did we say?

3 PARTICIPANT: Approximately two hours or  
4 less.

5 MR. HAGAN: Can I make a comment from the  
6 public?

7 CHAIR MALMUD: Oh, a comment from the  
8 public, who is invited. Absolutely. Please introduce  
9 yourself.

10 MR. HAGAN: I'm Mike Hagan. I'm the  
11 National Director for the VA for radiation oncology,  
12 hired in the wake of Philadelphia brachytherapy issues  
13 that you have mentioned several times today.

14 A comment and a request. The comment is  
15 imaging was done in Philadelphia. Imaging is available  
16 now in all of those patients, save seven that couldn't  
17 be found in archives, but 107 patients. And clearly  
18 the imaging was done -- or was not done as any quality  
19 assessment.

20 So no metric at all was applied, not from  
21 a clinical standpoint, not from a regulatory  
22 standpoint. And so when the VA had to design and then  
23 apply a metric to evaluate those cases  
24 retrospectively, they opined and then selected an  
25 absorbed dose metric.

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1 Absorbed dose metric, as you have heard  
2 through the workshops, is very problematic, and you  
3 have moved away from that. In fact, you moved away  
4 from that in 2005, and now you are, with good  
5 confidence and with good support from the professional  
6 societies, move away from an absorbed dose metric to  
7 an activity metric.

8 The point that I would make is that an  
9 activity or a source strength metric is entirely in  
10 keeping with your current language for Part 35. The  
11 definition of "dose" for manual brachytherapy has two  
12 parts, and one of those parts is activity times time  
13 equals dose.

14 So the application of the 20 percent  
15 standard for a source strength based metric fulfills  
16 your current regulatory requirement. So I think it  
17 would be quite helpful, because several practitioners  
18 of national repute have indicated that the confused  
19 regulatory environment now has caused them to stop  
20 practicing this procedure.

21 So the idea of perhaps suggesting or  
22 requesting NRC to issue guidance that the application  
23 of an activity metric for regulatory evaluation is  
24 appropriate during the interim period when new  
25 language is being proposed may be helpful not only to

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1 the practice but to the issue of reducing some of the  
2 regulatory confusion that exists today.

3 CHAIR MALMUD: Thank you. Dr. Welsh, do you  
4 care to address the comment?

5 MEMBER WELSH: Well, I think Dr. Hagan's  
6 input is always appreciated and the point is an  
7 important and valid point, an important point that  
8 although we are saying that we are shying away from a  
9 dose-based metric and this could be a little bit  
10 difficult for someone -- NRC to accept or to really  
11 endorse.

12 We are implicitly using dose by the  
13 definition of activity times time gives you dose. So  
14 I'm -- for the most part, I concur with Dr. Hagan's  
15 input.

16 CHAIR MALMUD: Thank you. And having heard  
17 your concern, Dr. Hagan, the Subcommittee will come to  
18 a resolution that will incorporate, to the extent  
19 possible, your concern.

20 What I was about to say earlier was that  
21 there are a number of therapies available toward  
22 treating prostate cancer. This has been a very  
23 valuable member of that armamentarium. It has been  
24 damaged not by anything that the NRC did, but it has  
25 been damaged. And as soon as we can assist in

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1 establishing, with the specialty groups, guidelines  
2 which will restore both physician and the public's  
3 confidence in the technique, the more rapidly it will  
4 resume its important role in the treatment of prostate  
5 cancer.

6 Thank you. We will move on to the next  
7 item on the agenda. And I want to thank, again, Dr.  
8 Suh, you have -- we have now volunteered you for two  
9 Subcommittees, and you have accepted both.

10 MEMBER SUH: That's right. That's what I'm  
11 here for, so --

12 (Laughter.)

13 CHAIR MALMUD: We are now up to the Part 35  
14 rulemaking update, and that will be presented by Dr.  
15 -- Bhalla and Lohr from the NRC. Ms. Bhalla and Mr.  
16 Lohr will provide an update to NRC Part 35 rulemaking  
17 activities.

18 MS. BHALLA: Good afternoon, Dr. Malmud and  
19 members of the ACMUI, and, of course, the members of  
20 the public. This -- we are going to give a very, very  
21 quick update basically on the status of the expanded  
22 rulemaking Part 35.

23 I am Neelam Bhalla. This is Ed Lohr. We  
24 are both from Rulemaking, Division of Rulemaking, and  
25 from the FSME.

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1           Basically, we just wanted to bring back to  
2 your attention that the proposed rule, the current  
3 schedule is December -- it's due to the Commission  
4 December of 2012, and then the final rule is due to  
5 the Commission October of 2014. And this schedule we  
6 have previously presented at the last ACMUI meeting.

7           Based on that schedule, we plan to give  
8 the draft FRN to the ACMUI for their review, for your  
9 review, in July of next year. And as agreed upon --  
10 and it is also in our procedure manual now -- that we  
11 would be -- that you will have the full 90 days for  
12 that review.

13           That means that we should be receiving  
14 your review and doing our comments on those -- our  
15 resolution of those comments in September/October  
16 timeframe of next year.

17           In an SRM to SECY-11-0035 -- that's the  
18 one I previously mentioned also a few minutes ago --  
19 in this SRM the Commission asked us to, after the  
20 workshops, the staff is to provide the Commission by  
21 November 2011 two things. One is an estimate of the  
22 overall schedule to complete the rulemaking, and,  
23 secondly, any potential impacts the schedule may have  
24 on the medical industry at large.

25           So on potential impacts of this schedule,

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1 we believe the proposed amendments would make  
2 clarifications to the rule, consider attestation  
3 requirements, and address issues raised in the  
4 Ritenour petition. Staff believes that the amendments  
5 would make the regulations more effective, efficient,  
6 and also enhance safety in certain areas.

7           Going into a little bit of discussion of  
8 that, staff believes that this schedule will have  
9 minimal impact, because staff is developing inspection  
10 guidance for permanent brachy procedures for the  
11 current rule.

12           And NRC has not heard any instances where  
13 licensees indicated shortages of authorized  
14 individuals, and those authorized individuals include  
15 the authorized users, RSOs, AMPs, ANPs, and so on, due  
16 to regulatory constraints. And so at this time, we  
17 would like to get ACMUI's comments on the schedule  
18 impact.

19           And just to go back, or just to elaborate,  
20 that if we get -- our schedule is based on, you know,  
21 we are working on two parts of the rulemaking. One is  
22 to do the medical event definition, and then  
23 everything else we are calling it as expanded  
24 rulemaking. So we are working on the expanded  
25 rulemaking, but, as you know, that the medical event

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1 definition was rejected by the Commission last year.  
2 And we were asked to go and get that done with the  
3 help of the ACMUI.

4 And, therefore, I have mentioned that -- a  
5 few minutes ago that we are counting on that report,  
6 so that the staff can use that report, along with the  
7 other information they have, to come up with a  
8 technical basis for the medical event definition.

9 So when we go back to the Commission in  
10 November, which is, you know, coming up, with our CA  
11 note, which is informing the Commission about that --  
12 can we stay with this schedule, or do we need to move  
13 our schedule in some other, you know, direction -- so  
14 right now we think we can stay with this schedule  
15 provided we have that report, so that a technical  
16 basis can be developed in a timely fashion.

17 So having said that, we are just going to  
18 note from the ACMUI we are -- we are asking you what  
19 you think this schedule of, let's say, the final rule  
20 to be in October of 2014, how would that impact  
21 license community overall?

22 CHAIR MALMUD: Thank you. Any comments?

23 (No response.)

24 From our experience, we should be able to  
25 meet the deadline for the final rule, which is October

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1 of '14. The concern, I understand, is about possible  
2 impact on the restrictions of access to AUs for  
3 institutions that may be deficient in having them now.  
4 Is that what you were addressing?

5 MS. BHALLA: Yes. We believe that the  
6 schedule -- clearly, the sooner rulemaking can be  
7 accomplished, the better it is. But we believe that  
8 this schedule is not impacting or is not impacting the  
9 licensees, because we have not heard that there are  
10 any shortages per se.

11 For example, we have the Ritenour  
12 petition, which is also included in this rulemaking.  
13 And we believe that although, you know, those RSOs and  
14 ANPs, they would like to be recognized and not have to  
15 go through the alternate pathway, but we do believe  
16 that that pathway is available right now. Although we  
17 recognize that it is onerous on the applicant,  
18 nonetheless, it is available out there.

19 So that's what we meant by that we have  
20 not heard any instances where there are shortages  
21 per se because of this rulemaking, you know, it's not  
22 done.

23 CHAIR MALMUD: Thank you. Has anyone heard  
24 of an instance in which there was an actual shortage?  
25 Anyone on the Committee? So we -- oh, Sue Langhorst.

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1 MEMBER LANGHORST: Sue Langhorst. I know  
2 that there are shortages of radiation safety officers,  
3 and we have talked about that in past meetings. But I  
4 don't know -- I mean, yes, we would like to have  
5 changes done right away, but I think their schedule  
6 can't be compressed. I mean, we can say, yes, we need  
7 it changed, but this is as fast as we can go on the  
8 logistics of what the processes are for rulemaking.  
9 Is that correct?

10 MS. BHALLA: That is correct. I mean, this  
11 is -- because rulemaking I think we have -- we have  
12 expressed that before, too, it's a process, it's a  
13 process by -- we are required to notice for comment,  
14 and more complex a rulemaking is -- you need to give  
15 that much more time, and now we need to also include  
16 this additional time for the ACMUI review.

17 So not only that we will be getting your  
18 review or your comments, then the staff needs to  
19 resolve those comments, just like we do for Agreement  
20 States or we also do for members of the public. So --

21 MEMBER LANGHORST: Dr. Malmud?

22 MS. BHALLA: So it is going to --

23 CHAIR MALMUD: Dr. Van Decker?

24 MEMBER LANGHORST: Oh, I'm sorry. Can I  
25 follow up, just real quickly?

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1 CHAIR MALMUD: Please do.

2 MEMBER LANGHORST: I'm sorry.

3 CHAIR MALMUD: Dr. Langhorst.

4 MEMBER LANGHORST: Sue Langhorst. I think  
5 you see our commitment in how the Subcommittee is  
6 willing to go quickly on this report, and the ACMUI  
7 not hold you up in regard to getting you that final  
8 approval of a final document. So I think you have our  
9 commitment to work as quickly as we can on this.  
10 So --

11 MS. BHALLA: Thank you. Ed, do you want to  
12 add something?

13 MR. LOHR: I just wanted to point out, so  
14 it doesn't get lost, that the idea of why we need --  
15 the medical event report is crucial is because in our  
16 schedule we have already sent to the Commission we are  
17 merging that particular rulemaking into the expanded.  
18 And that may not be clear as we were presenting that,  
19 and I just want to make that point clear.

20 They merged together, and they are  
21 supposed to be released together. And so that's what  
22 makes it so crucial for us to get this in the  
23 rulemaking process in a very timely manner.

24 CHAIR MALMUD: Thank you, Mr. Lohr. Dr. Van  
25 Decker?

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1           MEMBER VAN DECKER: Well, first, I think we  
2 are all appreciative of that, because at one point we  
3 heard that couldn't happen. So that's good. But,  
4 number two, you know, at the risk of harping on the  
5 same subject for a long time, you know, recognize that  
6 pragmatically in the trenches 2014 sounds great.

7           But we are really talking 2017, because  
8 that has been my experience from the last rulemaking  
9 that started in '97, because the states have up to  
10 three years to implement what they see. And many of  
11 them took until the last moment on the last go-round,  
12 so this is really a long process, and I think the  
13 medical event definition, you know, is a pretty big  
14 deal.

15           When you're thinking about it being out  
16 there by 2017, depending on the state, that -- so your  
17 timeline, I think we are all fine with. The timeline  
18 after that on what you could do about that -- that  
19 that's what the process is -- is probably going to end  
20 up being more frustrating.

21           There will be states that won't pick up  
22 the medical event change until 2017, I promise you.

23           MS. BHALLA: This is Neelam again. As we  
24 said, we are working at the guidance document, and  
25 hopefully the guidance document it should help.

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1 CHAIR MALMUD: I was just checking with Dr.  
2 Howe. I recall that in the past there was an emergency  
3 situation where there was one individual available to  
4 be, in terms of AU or RSO --

5 DR. HOWE: AMP.

6 CHAIR MALMUD: -- and -- AMP?

7 DR. HOWE: AMP.

8 CHAIR MALMUD: And we were able to achieve  
9 an exemption by going directly to the district and  
10 then to the NRC. So we have not heard of an immediate  
11 emergency, but if there were one it could be dealt  
12 with. The process is there. It's not pleasant. It's a  
13 bit tedious, but it's there, and the exemption can be  
14 made in the interim. So we are hopeful that the need  
15 won't arise. But if it does, it will not meet a stone  
16 wall.

17 And we, therefore, support what you are  
18 doing, and we will try and meet the target. We will  
19 assure you we will meet the target that you require.

20 Thank you. Thank you, both. Oh, I'm sorry.  
21 More comments?

22 MEMBER MATTMULLER: More comments, yes.

23 CHAIR MALMUD: Okay.

24 MEMBER MATTMULLER: Hi.

25 CHAIR MALMUD: Steve Mattmuller.

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1                   MEMBER   MATTMULLER:   Steve   Mattmuller.  
2   Thinking about what Dr. Hagan spoke -- and I think he  
3   was alluding to this, but unfortunately he has left --  
4   but I -- is it possible for the NRC to put out a  
5   guidance sooner rather than later in terms of how to  
6   define a medical event for brachytherapy, specifically  
7   prostate, that is based on activity?

8                   And then, this guidance would accomplish  
9   -- because one -- as I think our new future state  
10  representative has pointed out, that 2007 team for the  
11  current process is when all of this becomes effective.  
12  So if we could get guidance out sooner in regards to  
13  how this is going to be defined, that that would be  
14  helpful for getting more uniform acceptance or  
15  interpretation. That's a better word -- interpretation  
16  -- of how these -- especially since if it were to be  
17  on activity, that's, as I understand it, consistent  
18  with the current regulations.

19                  MR. EINBERG: Yes. Chris Einberg here. The  
20  NRC recognizes the need for guidance for the existing  
21  rule. So do the Agreement States. And there is a  
22  joint NRC-Agreement State working group, and it is  
23  addressing the issue right now. It is co-chaired by  
24  both the NRC and the Agreement States.

25                  The NRC representative on that working

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1 group is Ron Zelac, and the Agreement State  
2 representative or co-chair is Chris Timmerman. And so  
3 they are actively working on developing something  
4 right now, and it is for the existing rule. And their  
5 target is to have something drafted by the end of this  
6 year. So there are efforts underway right now.

7 CHAIR MALMUD: Okay. Is there another  
8 question, or was it the same question?

9 MEMBER WELSH: It was the same question.

10 CHAIR MALMUD: Thank you. It has been  
11 addressed satisfactorily for you? Thank you.

12 MEMBER WELSH: Yes. I'll just say that if  
13 guidance can accelerate the whole thing for all  
14 parties involved that the Subcommittee report will  
15 probably have a sentence or two formally recommending  
16 that.

17 CHAIR MALMUD: Thank you. Again -- oh.

18 MEMBER MATTMULLER: I'm sorry. One more  
19 comment. You mentioned the complexity of the  
20 rulemaking or the extent of the rulemaking helps  
21 determine the speed of how quickly it goes. And I'm  
22 thinking of in regards to the moly-99 potential  
23 requirement changes, that since in some ways that is  
24 already required by the FDA package insert  
25 information, would it be helpful to perhaps cut that

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1 part of the rulemaking out, save it for a later time,  
2 if it's deemed necessary? Would that help expedite the  
3 other concerns or expedite the rulemaking process?

4 MR. LOHR: Removing one item from the mount  
5 of items that we are considering in this rulemaking  
6 would make very little difference.

7 MEMBER MATTMULLER: Okay.

8 MR. LOHR: Unless it was one of the very,  
9 very major pieces, such as medical event. That might  
10 help, but we are not advocating that, but -- and not  
11 to downplay the moly, it is very important. But it  
12 would make little difference.

13 MEMBER MATTMULLER: Okay.

14 CHAIR MALMUD: Thank you. Any other  
15 questions for Mr. Lohr or Ms. Bhalla?

16 MS. BHALLA: Go ahead. Yes, this is Neelam  
17 again. Earlier I think there was a question about the  
18 public meetings or before we do the final rule after  
19 the proposed rule. And it is in our plan right now to  
20 have at least one meeting, if not two, before we go  
21 for the final rule. So I just thought I will just  
22 mention it.

23 CHAIR MALMUD: And that would be  
24 calendar '12 or '13?

25 MS. BHALLA: 2013.

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1 CHAIR MALMUD: '13, thank you. Thank you,  
2 again, both.

3 And if we may, we'll move on to the last  
4 item on the agenda, and that is usually handled by NRC  
5 staff. And today Sophie Holiday will address it.

6 MEMBER GUIBERTEAU: Dr. Malmud?

7 CHAIR MALMUD: Oh, yes. Excuse me.

8 MEMBER GUIBERTEAU: Do we have an issue on  
9 the table?

10 PARTICIPANT: We do.

11 CHAIR MALMUD: We do have an issue on the  
12 table? All right. Please remind me. Sorry.

13 MEMBER GUIBERTEAU: It was regarding the  
14 abnormal event -- occurrences, abnormal occurrences,  
15 the wording of abnormal occurrence.

16 CHAIR MALMUD: Yes.

17 MS. HOLIDAY: I'll address that in my  
18 portion.

19 CHAIR MALMUD: Sophie will address that,  
20 she said. Thank you. Thanks for reminding me, Dr.  
21 Guiberteau.

22 MS. HOLIDAY: So coming around to you guys  
23 is the recommendation and action items table. So we  
24 can go ahead and go to page 2.

25 All right. Item Number 17. Dr. Welsh, you

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1 asked NRC staff if ACRS members are considered SGEs or  
2 SGOs. And, if so, given the number of their Committee  
3 and Subcommittee meetings, how many days and hours do  
4 they work a year in order to meet those criteria, such  
5 as our Advisory Committee?

6 So we took that as an NRC action, and the  
7 answer to your question is that all ACRS members are  
8 special government employees. Although they meet much  
9 more frequently than the ACMUI does, none of the  
10 members exceed that 130-day per year limit. The ACRS  
11 staff keeps tabs on the members' days, so that they do  
12 not go over that limit, even though they meet so  
13 frequently.

14 However, if a special government employee  
15 does exceed those 130 days, the Director of Human  
16 Resources has the authority to grant a waiver if there  
17 were exceptional circumstances that caused that to  
18 happen. However, before that special government  
19 employee is reappointed, the office using that special  
20 government employee's services should make a  
21 determination that that SGE will not exceed the 130-  
22 day limit in the subsequent year. Does that clearly  
23 answer your question?

24 MEMBER WELSH: Thank you.

25 MS. HOLIDAY: You're welcome. Does anybody

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1 have any questions about Item 17?

2 (No response.)

3 CHAIR MALMUD: There are no other questions  
4 about Item 17.

5 MS. HOLIDAY: All right. Moving on to Item  
6 18, Dr. Langhorst, you asked that NRC staff provide  
7 the ACMUI with Congressman -- or, sorry, provide ACMUI  
8 with NRC's response to Congressman Markey's letter  
9 regarding patient relief.

10 Just to verify, Ashley Cockerham resent  
11 that email. The email was originally dated January 25,  
12 2011, which contained the NRC's response to  
13 Congressman Markey dated January 12th to the ACMUI.  
14 And she sent that yesterday evening, on September 22,  
15 2011.

16 MEMBER LANGHORST: This is Sue Langhorst.  
17 I don't think I was the one that asked that, but I  
18 very much appreciate that you sent that out. And so  
19 thank you. I saw that also.

20 MS. HOLIDAY: Okay. Great. So I assume  
21 there is no question on Item 18.

22 We can move on to Item 19. Steve  
23 Mattmuller asked that NRC staff add ACMUI to the  
24 organizational chart on the FSME website, as ACRS is  
25 reflected on the NRC website. NRC staff will look into

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1 this.

2 Are there any questions for Item 19?

3 CHAIR MALMUD: I see none.

4 MS. HOLIDAY: All right. Moving on to Item  
5 20, Dr. Langhorst, you requested that NRC staff place  
6 historical documents on the ACMUI website, so that  
7 viewers could have a better perspective and  
8 understanding of the ACMUI's organization.

9 And in addition to that, you asked that we  
10 place past ACMUI members' biographies on the internet,  
11 so that people can have a better understanding of who  
12 was here before and how we've gotten to here now. So,  
13 again, we will also look into this request.

14 Are there any questions for Item 20?

15 CHAIR MALMUD: Dr. Langhorst?

16 MEMBER LANGHORST: I have just one comment.  
17 You don't necessarily have to put the biographies on,  
18 but it would be nice to name them and what institution  
19 -- well, what institution they were from, at least  
20 that point in time. So I wasn't asking for a full  
21 biography of all --

22 VICE CHAIR THOMADSEN: And what position  
23 they --

24 MEMBER LANGHORST: Yes, and what ACMUI  
25 position they held. That would be very helpful, too.

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1 MS. HOLIDAY: Okay.

2 DR. HOWE: Do you want that to go back to  
3 the very beginning?

4 MEMBER LANGHORST: This is Sue Langhorst  
5 again. The question was whether it went back to the  
6 very beginning. Gosh, that would be great, but I know  
7 there is limited resources. So, you know, the past 10  
8 years would be nice to have. It would be nice to have  
9 a little bit more than that, but I fully understand  
10 that is -- that could be a very time-consuming effort.  
11 And whatever you could provide, even just going  
12 forward, would be great.

13 MS. HOLIDAY: All right. Thank you.

14 All right. Moving on to Item 21, Dr.  
15 Malmud, you created a subcommittee to address the  
16 electronic signatures for documents that licensees are  
17 required to retain in accordance with 10 CFR Part 35.  
18 I have the Subcommittee members as Dr. Thomadsen, Dr.  
19 Suh, Dr. Palestro, and Dr. Welsh. I will need to know  
20 who is chairing that Subcommittee.

21 CHAIR MALMUD: I believe it is Dr.  
22 Thomadsen.

23 MS. HOLIDAY: All right.

24 CHAIR MALMUD: That's the danger of sitting  
25 next to me.

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1 (Laughter.)

2 MS. HOLIDAY: Are there any questions for  
3 Item 21?

4 (No response.)

5 Okay. Moving on to Item 22, Dr.  
6 Guiberteau, I believe you just mentioned this. So we  
7 had a previous recommendation on the table, but Steve  
8 Mattmuller and Dr. Langhorst agreed that we should  
9 table the discussion on the changes to the AO criteria  
10 once we are able to present you with all of the  
11 information and facts that you need from the 2008  
12 ACMUI's recommendations.

13 And at this time, I would like to turn it  
14 over to Chris Einberg.

15 CHAIR MALMUD: Chris Einberg?

16 MR. EINBERG: Yes. My recommendation is  
17 that we combine it with one of the upcoming two  
18 telecons that we just agreed to, the telecon for  
19 prostate brachytherapy medical events.

20 We could add this discussion to that  
21 telecon, where once you receive the patient release  
22 SECY paper and review that and provide your comments,  
23 we could -- we will need to have a separate telecon  
24 for that. And we could add that to -- this topic to  
25 that teleconference. So it's at the discretion of the

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1 ACMUI, which would work better.

2 CHAIR MALMUD: I think adding it to the  
3 existing telecon -- how many hours shall we put aside  
4 for the telecon?

5 MR. EINBERG: Currently, we have two hours  
6 scheduled.

7 CHAIR MALMUD: Will that be sufficient?  
8 Dr. Langhorst?

9 MEMBER LANGHORST: I had a question. I  
10 didn't understand -- there are two telecons that are  
11 coming up? And so that's where I was confused.

12 MR. EINBERG: We have not scheduled the  
13 second teleconference. We will be providing the ACMUI  
14 with our SECY paper on research for patient release  
15 within the next month or so. The ACMUI will be asked  
16 to review that paper, after which they will need to  
17 have a public telecon to receive the ACMUI's views on  
18 that paper.

19 MEMBER LANGHORST: This is Sue Langhorst  
20 again. I think it would be good to maybe combine it  
21 with that telecon, so that our permanent implant  
22 discussions can be pretty succinct.

23 CHAIR MALMUD: So we will combine them, and  
24 we should set aside two hours. Would that be  
25 sufficient?

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1 MR. EINBERG: For the -- we are going to  
2 combine the AO discussion with the patient release  
3 conference call. I believe that that time -- two hours  
4 -- probably would be sufficient.

5 CHAIR MALMUD: We will put aside two hours.  
6 When you contract with the telephone carrier, I would  
7 book a little extra time if necessary.

8 MR. EINBERG: Yes, okay. The patient  
9 release discussion may require the full two hours, so,  
10 yes, maybe three hours would be --

11 CHAIR MALMUD: All right.

12 MR. EINBERG: -- better.

13 CHAIR MALMUD: If you would, though -- we  
14 will be on the telecon, we anticipate, possibly three  
15 hours. And the time of the meeting will be at noon.  
16 Is it not noon?

17 MS. HOLIDAY: I believe what we are asking  
18 is to combine the AO criteria discussion with the  
19 patient release SECY paper, which is a separate --

20 CHAIR MALMUD: All right.

21 MS. HOLIDAY: -- teleconference. Correct.  
22 We did not schedule that as --

23 MR. EINBERG: And that will not -- Chris  
24 Einberg. And that will not be scheduled until we  
25 provide you the paper.

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1 CHAIR MALMUD: Thank you.

2 MS. HOLIDAY: Okay. Are there any questions  
3 on Item 22?

4 CHAIR MALMUD: I see none.

5 MS. HOLIDAY: All right. Moving on to Item  
6 23, Dr. Malmud added Dr. Suh and Ms. Weil to the  
7 Permanent Implant Brachytherapy Subcommittee.  
8 Existing Subcommittee members include Dr. Welsh, the  
9 chair, Dr. Langhorst, and Dr. Thomadsen.

10 I understand that, as you have added Ms.  
11 Weil to the Subcommittee, she will not be --

12 CHAIR MALMUD: We have not added Ms. Weil  
13 to the Permanent Implant Brachytherapy Subcommittee.

14 MS. HOLIDAY: Okay. I will correct that on  
15 the table. So we just added Dr. Suh.

16 CHAIR MALMUD: That's correct.

17 MS. HOLIDAY: All right. Do we have any  
18 questions for Item 23?

19 CHAIR MALMUD: I see none.

20 MS. HOLIDAY: All right. Item 24, the  
21 Permanent Implant Brachytherapy Subcommittee will  
22 revise their Subcommittee report and distribute it to  
23 the full Committee for review by October 7, 2011.

24 CHAIR MALMUD: That's correct. They have  
25 made that commitment, for which we are very grateful.

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1 MS. HOLIDAY: All right. Thank you.

2 Item 25, I have that the ACMUI has planned  
3 a teleconference for October 18, 2011, from 12:00 p.m.  
4 to 2:00 p.m. Eastern Time to discuss and finalize the  
5 Permanent Implant Brachytherapy Subcommittee report.

6 Do I have any questions for Item 25?

7 CHAIR MALMUD: I see none.

8 MS. HOLIDAY: Okay. And last item, this is  
9 an NRC action item. NRC staff has agreed to provide an  
10 advance copy of the Permanent Implant Brachytherapy  
11 Subcommittee report to the Agreement States prior to  
12 our October 18th teleconference call, and invite them  
13 to participate in the teleconference call.

14 CHAIR MALMUD: That's correct. Thank you.  
15 Any comments about that?

16 (No response.)

17 We're okay with that.

18 MS. HOLIDAY: All right. So now we will  
19 move on to planning our spring meeting. If you will  
20 turn to Tab 19 in your binders. All right. My first  
21 set of proposed dates are April 12th and 13th. That's  
22 a Thursday and Friday. Does anybody have conflicts  
23 with April 12th and 13th?

24 MEMBER PALESTRO: I do.

25 MS. HOLIDAY: Yes, okay. All right. The

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1 next set of proposed dates are the 16th and the 17th.  
2 Are there any conflicts for the 16th and 17th? That's  
3 a Monday and Tuesday.

4 CHAIR MALMUD: April 16th/17th. Going once,  
5 going twice? Sold the whole Committee on April 16th  
6 and 17th.

7 MEMBER MATTMULLER: Just a reminder that  
8 everyone has to have their income tax done on the  
9 16th, too.

10 (Laughter.)

11 MS. HOLIDAY: All right.

12 MEMBER MATTMULLER: Bring our checks here  
13 and drop them off.

14 CHAIR MALMUD: Just send in an extension  
15 form.

16 (Laughter.)

17 MEMBER ZANZONICO: That's my wedding  
18 anniversary, but that's okay.

19 CHAIR MALMUD: Oh.

20 (Laughter.)

21 MEMBER ZANZONICO: My wife has given up on  
22 those.

23 (Laughter.)

24 MS. HOLIDAY: Okay. My next set of possible  
25 dates for backup, April 23rd and 24th, also a Monday

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1 and Tuesday.

2 MS. FAIROBENT: That's ACR's annual  
3 meeting.

4 CHAIR MALMUD: There's a conflict.

5 MS. HOLIDAY: All right. So that marks that  
6 off. How about April 30th and May 1st, another Monday  
7 and Tuesday?

8 (No response.)

9 CHAIR MALMUD: It looks like there is no  
10 objection to it.

11 VICE CHAIR THOMADSEN: May 1st is not the  
12 best. As a backup, I guess it's okay.

13 MS. FAIROBENT: That's the Roentgen Ray  
14 Society's annual meeting dates. I don't know if anyone  
15 here is going.

16 CHAIR MALMUD: Roentgen Ray, May 1st?

17 MS. FAIROBENT: Yes.

18 CHAIR MALMUD: It looks like April 16th/  
19 17th is ideal.

20 MS. HOLIDAY: Okay. But I'd like to have a  
21 backup date just in case.

22 CHAIR MALMUD: All right.

23 MEMBER WELSH: Can I ask --

24 CHAIR MALMUD: 30th and the 1st. Just --

25 MEMBER WELSH: Can I ask a question of

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1 the --

2 CHAIR MALMUD: Of course.

3 MEMBER WELSH: -- of the members of the  
4 Committee? This Thursday/Friday combination seems to  
5 work out better for me personally, because I have  
6 found that Delta Airlines doesn't have late afternoon  
7 flights that it used to have. And so I'm going to have  
8 to leave tomorrow morning.

9 But if it's a Monday and Tuesday, I either  
10 would have to leave the next day and then miss a third  
11 day of work, or miss part of the meeting. And since I  
12 was presenting late in the afternoon, it could have  
13 been a problem. So I'm wondering if Thursdays and  
14 Fridays is working out better for most of us for the  
15 same reason, or Monday and Tuesdays in general is --

16 MEMBER ZANZONICO: The only thing I would  
17 point out is that, don't you miss part of the day  
18 traveling Wednesday? This way you would be traveling  
19 Sunday. If that kind of balances it out.

20 MS. COCKERHAM: Dr. Malmud?

21 CHAIR MALMUD: Yes.

22 MS. COCKERHAM: Just to make a comment --  
23 the reason we were shooting for the Monday/Tuesday  
24 dates, we have requested -- and it has still not been  
25 finalized -- we are hoping for an ACMUI-Commission

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1 briefing. In the past, they have taken place on a  
2 Tuesday. So if it was possible to have a  
3 Monday/Tuesday meeting, that was the push for -- there  
4 is the potential to meet with the Commission.

5 CHAIR MALMUD: So Monday/Tuesday is better  
6 for that purpose.

7 MS. COCKERHAM: I believe the Commission  
8 meetings have been on Tuesdays. That has been their  
9 preferred dates for those particular meetings. They  
10 may come back and say no meeting. They may come back  
11 and say, "Hey, we want to meet on a Thursday," and  
12 everything I just said goes out the door. But I -- you  
13 are welcome to --

14 CHAIR MALMUD: Is this room available?

15 MS. COCKERHAM: Is this room available?

16 CHAIR MALMUD: Maybe.

17 MS. COCKERHAM: It should be. The first  
18 week -- it's the first week of the month that ACRS  
19 typically has this room. And we are out -- well  
20 outside of that.

21 CHAIR MALMUD: All right.

22 MS. COCKERHAM: If you schedule  
23 Thursday/Friday, I totally --

24 CHAIR MALMUD: Do you want a backup of a  
25 Thursday/Friday? Thursdays are dreadful for me, but

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1 it's six months, I guess I could change things. Are  
2 you proposing April 19th/20th or no?

3 MS. COCKERHAM: Is that that same week?

4 MS. HOLIDAY: Yes, it's the same week.

5 CHAIR MALMUD: Our backup April 19th/20th?

6 MEMBER SULEIMAN: That's my birthday, so  
7 that should be factored into it.

8 (Laughter.)

9 CHAIR MALMUD: All right.

10 MS. COCKERHAM: So what did we decide?

11 CHAIR MALMUD: And if I have a conflict on  
12 the 19th and 20th?

13 MS. HOLIDAY: I just wanted to throw  
14 something else in there. ACRS, they meet on the first  
15 and third week of the month, so this would actually be  
16 the third week, but they usually have their meeting I  
17 believe Wednesday, Thursday, and Friday.

18 CHAIR MALMUD: So Monday/Tuesday is better.

19 MS. HOLIDAY: The Monday/Tuesday, if we  
20 were to choose this week, the 16th and 17th would be  
21 ideal. But the 19th and the 20th would not be for  
22 that particular week.

23 CHAIR MALMUD: Sorry, Jim.

24 MS. COCKERHAM: There are two rooms, so not  
25 -- I don't know that they would be taking up both

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1 rooms, but there is going to be a higher probability  
2 that both rooms may be taken.

3 MEMBER WEIL: What about 26th/27th?

4 MS. HOLIDAY: Is the ACR meeting the entire  
5 week of the 23rd?

6 MS. FAIROBENT: The 23rd through the 25th.

7 MS. HOLIDAY: Okay.

8 CHAIR MALMUD: It looks like 16/17 is the  
9 best. Jim? I heard another voice. Did you want to say  
10 that for the record?

11 PARTICIPANT: No.

12 CHAIR MALMUD: It was off the record.  
13 Okay. The 16th and 17th.

14 MS. HOLIDAY: Okay. So is our backup date  
15 still the 30th and the 1st of May, or is May 1st --

16 CHAIR MALMUD: Backup the 30th and the 1st.

17 MS. COCKERHAM: I think Ms. Weil had  
18 suggested the 26th and 27th, if we were going to do a  
19 Thursday/Friday, as a backup.

20 MS. HOLIDAY: But the ACR meeting is the --

21 MS. COCKERHAM: Until the 25th.

22 MS. HOLIDAY: -- until the 25th, so it  
23 might be kind of tight.

24 MS. COCKERHAM: That would be tight  
25 schedules for how many individuals?

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1 CHAIR MALMUD: Well, that must be SCAR and  
2 the ACR. They usually meet together, right?

3 MEMBER GUIBERTEAU: No.

4 CHAIR MALMUD: No? Separate now?

5 MEMBER GUIBERTEAU: Yes. SCAR is meeting  
6 now.

7 MS. COCKERHAM: Would that be tight travels  
8 for you, Dr. Guiberteau?

9 MEMBER GUIBERTEAU: Pardon?

10 MS. COCKERHAM: To have the meeting on the  
11 26th and 27th, if you are coming out ACR on the 25th?

12 MEMBER GUIBERTEAU: Well, the meeting is  
13 here in Washington, so that would --

14 MS. COCKERHAM: Oh, okay.

15 MEMBER GUIBERTEAU: -- that would work.

16 MS. COCKERHAM: Okay. So there is your  
17 Thursday/Friday backup week?

18 CHAIR MALMUD: Gone the whole week?

19 MEMBER GUIBERTEAU: Well, it's not the  
20 best, but I'm trying to be -- if you want a  
21 Thursday -- we're not going into May, is that what I'm  
22 -- okay.

23 MS. HOLIDAY: We are trying to avoid May.

24 MEMBER GUIBERTEAU: Well, I think of all  
25 those, then the 26th or 27th seems to be the one that

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1 fits with your first and third week of the other  
2 meeting.

3 MS. HOLIDAY: Okay. So does anybody have  
4 conflicts with the 26th and 27th?

5 CHAIR MALMUD: No. I will adjust my  
6 schedule.

7 MS. HOLIDAY: Okay.

8 MEMBER LANGHORST: And that is the backup.

9 CHAIR MALMUD: That's the backup, yes,  
10 26th/27th. So 16th/17th or 26th/27th.

11 MS. HOLIDAY: Very good. Okay. That  
12 concludes the presentation part.

13 Now, just particularly speaking to the  
14 Committee, you were given your Form 450, which is a  
15 financial disclosure form. I will need that from you  
16 at the conclusion of this meeting. However, if you  
17 choose to take it home and fill it out, you can mail  
18 it to John Szabo, and I will be happy to provide you  
19 with his mailing address. But I will need a promise  
20 that you will mail it to him.

21 In addition to that, earlier I distributed  
22 your 148 forms for your time and attendance. That is  
23 due today, as this is the last day of the pay period.  
24 So I will definitely need that today.

25 VICE CHAIR THOMADSEN: So the periods are

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1 from when to when?

2 MS. HOLIDAY: Last week was -- yes,  
3 September 11th through --

4 VICE CHAIR THOMADSEN: It's through today  
5 or tomorrow?

6 MS. HOLIDAY: Tomorrow, the 24th.

7 And, as always, I will email you your  
8 Form 64 for your travel vouchers. You can complete  
9 those and mail those back to me. All of your  
10 instructions will be in my email.

11 And that concludes my portion, Dr. Malmud.

12 CHAIR MALMUD: Thank you. I would like to  
13 thank all of -- oh, excuse me.

14 MEMBER WEIL: Before you do, my contact  
15 information is a bit old, so I have some business  
16 cards I would like to distribute.

17 CHAIR MALMUD: Thank you.

18 MS. HOLIDAY: Okay. Great.

19 CHAIR MALMUD: And I want to thank all the  
20 members of the Committee for their effort, talent,  
21 contributions, and the members of the NRC staff who  
22 have been so accommodating for us.

23 Thank you all. Have a safe trip home.

24 (Whereupon, at 4:25 p.m., the proceedings in the  
25 foregoing matter were concluded.)

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