

**Official Transcript of Proceedings**  
**NUCLEAR REGULATORY COMMISSION**

Title: Meeting of the Advisory Committee on the  
Medical Uses of Isotopes

Docket Number: (n/a)

Location: Rockville, Maryland

Date: Friday, March 20, 2015

Work Order No.: NRC-1439

Pages 1-152

**NEAL R. GROSS AND CO., INC.**  
**Court Reporters and Transcribers**  
**1323 Rhode Island Avenue, N.W.**  
**Washington, D.C. 20005**  
**(202) 234-4433**

UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

+ + + + +

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

+ + + + +

PUBLIC MEETING

+ + + + +

FRIDAY,

MARCH 20, 2015

+ + + + +

The meeting was convened in Room T2B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:30 a.m., Bruce R. Thomadsen, Ph.D., ACMUI Chairman, presiding.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

MEMBERS PRESENT:

BRUCE R. THOMADSEN, Ph.D., Chairman

PHILIP O. ALDERSON, M.D., Vice Chairman

FRANCIS M. COSTELLO, Agreement State  
Representative

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

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

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

STEVEN R. MATTMULLER, Nuclear Pharmacist

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

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

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

LAURA M. WEIL, Patients' Rights Advocate

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

Non-Voting: FRED A. METTLER, JR., M.D.

NRC STAFF PRESENT:

PAMELA HENDERSON, Deputy Director, Division of  
Material Safety, State, Tribal and Rulemaking  
Programs

DOUGLAS BOLLOCK, Designated Federal Officer

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

NRC STAFF PRESENT (CONT'D):

SOPHIE HOLIDAY, Alternate Designated Federal  
Officer, ACMUI Coordinator

MARYANN ABOGUNDE, NMSS/MSTR/MSEB

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

JENNIFER BISHOP, RIII/DNMS/MLB

MICHAEL BLAIR, OIG/AIGA/NMWSA

MARCIA CARPENTIER, OGC/GCHEA/AGCNRP

COLLEEN CASEY, RIII/DNMS/MLB

ASHLEY COCKERHAM, NMSS/MSTR/MSEB

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

SARA FORSTER, RIII/DNMS/MLB

CASSANDRA FRAZIER, RIII/DNMS/MLB

SANDRA GABRIEL, Ph.D., NMSS/MSTR/MSEB

JOSEPH GIESSNER, RIII/DRP

LATISCHA HANSON, RIV/DNMS/NMSB-A

MICHELLE HAMMOND, RIV/DNMS/NMSB-B

VINCENT HOLAHAN, Ph.D, NMSS/MSTR

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

CARDELIA MAUPIN, NMSS/MSTR/RPMB

ANGELA McINTOSH, NMSS/MSTR/MSEB

KEVIN NULL, RIII/DNMS/MLB

PATTY PELKE, RIII/DNMS/MLB

SAMI SHERBINI, Ph.D., RES/DSA

TOYE SIMMONS, RIII/DNMS/MLB

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

NRC STAFF PRESENT (CONT'D):

JACLYN STORCH, OIG/AIGA/NMWSA

KATIE TAPP, Ph.D, RES/DSA/RPB

FRANK TRAN, RIII/DNMS/MLB

LESTER TRIPP, RI/DNMS/MB

ALSO PRESENT:

BETTE BLANKENSHIP, American Association for  
Physicists in Medicine

SUE BUNNING, Society of Nuclear Medicine and  
Molecular Imaging

ROBERT DANSEREAU, New York State Department of  
Health

WILLIAM DAVIDSON, University of Pennsylvania

LYNNE FAIROBENT, American Association for  
Physicists in Medicine

CATHERINE GILMORE-LAWLESS, Elekta

PER KJALL, Elekta

CAITLIN KUBLER, Society of Nuclear Medicine and  
Molecular Imaging

RICHARD MARTIN, American Association for  
Physicists in medicine

MICHAEL PETERS, American College of Radiology

DHEREEN PRASAD, Roswell Park Cancer Center

CARA SANTILLO, Elekta

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

ALSO PRESENT (CONT'D):

MICHAEL SHEETZ, University of Pittsburgh

RUTH THOMAS, Environmentalists, Inc.

CINDY TOMLINSON, American Society for Radiation  
Oncology

RICHARD WAHL, Mallinckrodt Institute of  
Radiology

BIN WANG, Walter Reed National Military Medical  
Center

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

	Page
11. Yttrium-90 Microspheres and Radionuclides.....7 in Cadavers - P. Zanzonico, ACMUI	
12. Compatibility Category for Permanent.....35 Brachytherapy Reportable Medical Events F. Costello, ACMUI	
13. Status of Abnormal Occurrence Criteria.....54 K. Tapp, NRC	
14. Perfexion Gamma Knife and AU Physical.....76 Presence - P. Kjall, Elekta	
15. 10 CFR Part 35 Rulemaking Update.....107 J. Danna, NRC	
16. Committee Reporting Structure.....112 S. Holiday, NRC	
17. Open Forum - ACMUI.....130	
18. Administrative Closing.....139 S. Holiday, NRC	

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

(8:32 a.m.)

CHAIR THOMADSEN: Good morning and welcome to our second day. We'll start off with a talk. Dr. Zanzonico will talk to us about yttrium-90 microspheres in cadavers.

MEMBER ZANZONICO: Good morning. As Dr. Thomadsen said, I'll be speaking today about yttrium-90 microspheres and I really broadened the topic to address what I think are really pertinent radionuclides that are encountered wherever unfortunately in cadavers. First slide please. The next slide rather.

So this is outline of my talk. I'll discuss some general considerations, some pertinent critical properties of the radionuclides in question, a to-do list immediately post expiration of the patient with radioactivity; therapeutic amounts of radioactivity on board; final disposition scenarios and there is a number of those obviously; current and past guidance and some concluding marks. Next slide please.

I think something we all intuitively recognize is that fortunately the death of a patient immediately post radionuclide therapy or brachytherapy therapy is really a rare event. These sorts of therapies are rarely used and should rarely be used in

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 moribund patients.

2           And these are some data from Japan. On the  
3 left ordinate axis is plotted the number of I-125  
4 brachytherapy cases in prostate cancer and on the right  
5 ordinate axis the number of cases among those who died  
6 within one year of their implantation. If you do the  
7 arithmetic, you'll see that only about 0.3 percent of  
8 these patients expire within one year with the  
9 treatment.

10           There aren't comparable data, at least that  
11 I could find, for other forms of brachytherapy  
12 radionuclide that would be. But I assume they are very  
13 similar. Again, it's a rare event.

14           As a result, any single mortuary or funeral  
15 home or crematorium is likely to encounter perhaps one  
16 to at most several radioactive cadavers annually. So  
17 it's not a high volume issue. Next slide please.

18           Just some general considerations. Not  
19 surprisingly, general radiation protection principles,  
20 time, distance, shielding, contamination controls,  
21 apply. And I think it's a fair statement that the  
22 radiation risk to personnel and to other individuals are  
23 generally going to be minimal. Next slide please.

24           It should be emphasized that really there's  
25 no special precautions or handling post-diagnostic

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 administrations just because of the levels of activity  
2 typically involved which are much lower.

3 I think it's also noteworthy, although it's  
4 a rare event, that consideration of the patient's  
5 families, the patient themselves and their families,  
6 and their wishes in terms of final disposition perhaps  
7 be addressed pretreatment. I mean if individuals are  
8 insisting and planning on cremation and there's  
9 something that may counter-indicate that, that sort of  
10 thing should be addressed prior rather than after the  
11 fact.

12 And one point I can't emphasize enough is  
13 the guidance of the institutional radiation safety  
14 officer or local radiation protection expert, both in  
15 the hospital or the funeral home or the crematorium,  
16 because the fact this is such a rare event. People may  
17 be unfamiliar with standard for caution in these  
18 scenarios such as they are. It's very important to  
19 enlist the guidance actively and early of your SO. Next  
20 slide please.

21 The first issue is death of a patient  
22 outside a treating facility, outside the hospital,  
23 which might be the most common occurrence. And the  
24 first or foremost thing to do is for whomever is  
25 responsible for the patient, whether it's a family

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 member at home, in a nursing home or other long-term care  
2 facility, that they contact the treating facility  
3 immediately for guidance.

4 As is typically the case for radionuclide  
5 therapy and brachytherapy patients, they should have  
6 some sort of wallet card or documentation which among  
7 other information provides contact information for the  
8 treating institutions, RSO and treating physician.  
9 And those individuals should be contacted immediately.

10 I think a fair general statement, though  
11 not a universal statement, is that for current  
12 outpatients -- in other words, patients who are treated  
13 but based upon either a dosimetric analysis or  
14 radioactivity burden who have deemed "safe" to be  
15 released -- the retained activities at that point likely  
16 would not warrant a radiation precautions or any  
17 excessive or dramatic radiation precautions. Next  
18 slide.

19 This slide has a lot of information on it.  
20 But this is pertinent physical properties of unsealed  
21 sources, sources used for radionuclide therapy. It  
22 includes I-131, yttrium-90, etc. And the point I  
23 really want to emphasize is that for yttrium-90,  
24 phosphorus-32, strontium-89, these are pure beta  
25 emitters. So there's really going to be no significant

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 external hazard which simplifies the radiation  
2 precautions.

3 And even for radium-223, which is an alpha  
4 emitter, the frequency of emissions of gammas is  
5 relatively low, particularly for the low emissive  
6 activities that are used. So there's really a minimal  
7 external hazard.

8 Those commonly used radionuclide therapy  
9 isotopes really are not problematic in terms of external  
10 hazard. The one caveat which I'll discuss is  
11 yttrium-90 because there are several long-lived  
12 radio-contaminants that complicate the picture to  
13 yttrium-90. And I'll discuss that.

14 And, of course, I-131 is both a high energy  
15 beta emitter, but of course it has abundant high energy  
16 gammas that can present a potential external hazard.  
17 So I-131, as is often indicated, might be problematic  
18 and I'll address that isotope as well. Next slide  
19 please.

20 Here are some brachytherapy sources. And  
21 I've divided these into temporary and permanent because  
22 in the case of temporary implants the implants should  
23 be removed postmortem. And of course there should be  
24 no subsequent hazard or special handling then required.

25 For the permanent implants, there is in

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 principal a possible postmortem hazard. But it's  
2 important to note that for the most commonly used  
3 brachytherapy sources, currently I-125 and  
4 palladium-103, these emit very low energy,  
5 non-penetrating gammas. The shielding by the  
6 patient's own body really reduces the x-ray or gamma ray  
7 flux such that any external hazard is minimal. Next  
8 slide.

9 What do you immediately post expiration,  
10 get, notify the RSO. Their guidance for this rare event  
11 is going to be critical. And also notify the nuclear  
12 medicine or other treating physicians in the case of  
13 unsealed source radionuclide therapy or radiation  
14 oncology in the case of brachytherapy.

15 For radionuclide therapy, the cadaver  
16 should be placed in body bag to contain any leaking  
17 fluids which happens post expiration. As always when  
18 working with radioactivity, the isotope, the  
19 administered activity, the date and site of  
20 administration and the treating institution's contact  
21 information should be documented on the body bag as well  
22 as on the cadaver itself, a toe tag kind of arrangement.  
23 Next slide.

24 And the RSO should then perform exposure  
25 rate measurements at contact at 30 centimeters and at

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 one meter. And based on these exposure rate  
2 measurements, the RSO can then formulate a short-term  
3 radiation precaution, admissible procedures such as  
4 embalming and the duration allowable for these  
5 procedures and so forth to maintain doses to personnel  
6 to less than maximum of admissible doses.

7 These data are on this table we're talking  
8 from Kelly Classic's chapter in the handbook of how you  
9 practice. And you see here for several different  
10 isotopes, palladium-103, I-125, I-131 and for different  
11 typical or likely residual activities in a caveat what  
12 the exposure rate in air in millirems per hour at 30  
13 centimeters and one meter from the patient would be.  
14 And most importantly the chart shows the time to reach  
15 a 100 millirem dose to individual around the cadaver and  
16 a 500 millirem dose to individuals around the cadaver.

17 You can see that at 30 centimeters you're  
18 talking of the order of one to several hours for 100  
19 millirem and one to tens of hours for 500 millirem. At  
20 one meter, it's tens to hundreds of hours and even longer  
21 for 500 millirem. The point is that in order to reach  
22 these doses which are the MPDs for general public and  
23 for non-occupationally-exposed individuals, you have  
24 many hours typically before these doses would be  
25 reached.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           Some are performing an autopsy. Some are  
2 embalming the patients and so forth. They could do so  
3 without accruing doses exceeding or in many instances  
4 even approaching MPDs from external radiation. Next  
5 slide please.

6           Continuing post-expiration, for  
7 radioactive solutions or suspensions that are  
8 accessible, an intracavitary therapy, the nuclear  
9 medicine physician should withdraw that fluid to the  
10 extent it's possible with the disposal of the  
11 radioactive liquid down the drain, just like it's doing  
12 with excrement from radionuclide therapy patients.

13           Temporary implants should really be  
14 removed by the radiation oncologist. And I'm  
15 emphasizing who should do these procedures. It should  
16 not be the pathologist or the individual performing who  
17 administered those therapies. They would be less  
18 familiar with the site, with radiation precautions and  
19 so forth.

20           If the cadaver is still radioactive, again  
21 document all the pertinent information on the body bag  
22 and on the cadaver itself, if it hadn't already been  
23 done, and place the cadaver in the posted, isolated area  
24 in the mortuary.

25           Now people sometimes misinterpret that

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 kind of advice to infer that there's some hazard, some  
2 excessive hazard. But it's an indisputable error.  
3 It's a simple, easy thing to do that would further reduce  
4 dose to individuals. That's not to say that there's an  
5 excess or prohibitive hazard associated with the  
6 patient or with the cadaver. If something is simple,  
7 easy, fast, non-disruptive, there's no reason not to do  
8 it. Next slide please.

9 What about final disposition and these are  
10 all the scenarios. Autopsy, organ transplantation  
11 from the cadaver, embalming, a wake, burial and  
12 cremation. Next slide.

13 Autopsy, again as in all of these  
14 scenarios, the RSO should provide guidance. It's  
15 prudent to avoid or consider a limited autopsy unless  
16 there's some compelling reason to do otherwise.  
17 Personal protection equipment, of course, should be  
18 used. There are possible splash hazards, other  
19 contamination hazards. Double disposable gloves  
20 because doubling the gloves can reduce skin exposure  
21 from beta emitters for example. A face shield. A face  
22 mask. And apron especially for radionuclide therapy or  
23 the sources are unsealed. Many of these are used  
24 routinely in autopsy or embalming scenario. Of  
25 course, if you're removing sources or you're having

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 radio-contaminated items, you should shield the  
2 receptacles for those items.

3 And a question is removal of high-activity  
4 organs like for example the liver post yttrium-90  
5 microsphere therapy. And I spoke to the chief of  
6 pathology at Memorial and they were not at all  
7 enthusiastic about that. It had nothing to do with the  
8 radiation.

9 They said a lot of these procedures are time  
10 consuming, take up to one to two hours. They're busy,  
11 so forth and so on. And they're not highly motivated  
12 to undertake such a procedure for a  
13 non-clinically-relevant reason. Generally, removal  
14 of these organs, those case-specific, is generally not  
15 recommended and not necessary frankly. Next slide.

16 Transplantation, some people might find  
17 this surprising that one would transplant organs from  
18 a radioactive patient. They know at the beginning that  
19 transplantation is a life-saving procedure. As we all  
20 know, donor organs are in very limited supply. And  
21 there has to be a very compelling reason for excluding  
22 otherwise useable organs for transplantation.

23 Of course, a targeted or diseased organ,  
24 for example, yttrium-90 microsphere therapy, you  
25 wouldn't transplant that liver in any case independent

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 of the radiation. So that's intuitive.

2 The RSO again should provide guidance in  
3 terms of the radiation dose to the transplanted organ.  
4 And for non-targeted organs, I think it's fair to say,  
5 -- for example, the heart, kidney, liver -- the doses  
6 to those organs from a radionuclide therapy would  
7 generally be sub-toxic. So those organs would remain  
8 functional, usable, transplantable.

9 And I think it would be prudent as well for  
10 the RSO or the dosimetry person to estimate the doses  
11 to the recipient. Again, there would be very few, if  
12 any, scenarios where those estimated doses would be  
13 prohibitive given the life-saving benefit of the  
14 transplanted organ in any case. Next slide.

15 Embalming, follow SO guidance. I've  
16 already identified the PPE, personal protective  
17 equipment. In NCRP Report No. 155, they recommended a  
18 target dose to embalm is less than 25 millirem. And  
19 that's sort of based on the scenario that no single  
20 embalmer would handle more than four radioactive  
21 cadavers a year. If you keep the dose per cadaver to  
22 25 millirem, 25 times 4 is 100. You're below that  
23 limit. But that's just a very soft recommendation.

24 Frankly, if the dose rate at 30 centimeters  
25 is less than 50 millirem per hour, if you integrate that

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 over the various distances an embalmer will actually be  
2 to the cadaver you really don't need any restrictions.

3 Brachytherapy patients, again generally  
4 need no restrictions because these are sealed,  
5 localized sources that generally emit soft betas that  
6 are completely absorbed by the cadaver's tissue.

7 Radionuclide therapy patients, the  
8 embalming fluid should go down the drain, handled no  
9 differently than in the case of patient's fluids,  
10 excrement, so forth, in their homes. Next slide.

11 This is work from my old boss. Some of you  
12 may remember John Laughlin, Chair of the Medical Physics  
13 at Memorial. And here they estimated the radiation  
14 dose for embalming patients who have iridium-198,  
15 gold-198 and I-131. And they've estimated the mean  
16 dose to embalm is per millicurie. It's something to the  
17 order of less than about 1-2 millirem.

18 On the right-hand side of this slide, the  
19 activities on board that would result in a dose to an  
20 embalmer of 100 and 500 millirem. And you can see they  
21 range from hundreds to about a thousand millicuries.

22 And what the graph indicates, this is  
23 plotting the dose rate to embalmer versus the dose rate  
24 measured with a survey meter of about 1 meter. And you  
25 can see the dose rate measurement of 1 meter with a

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 Geiger counter is a very reliable metric of the mean dose  
2 rate to the embalmer.

3 The RSO could then provide very reliable  
4 guidance based on a simple exposure rate measurement  
5 with a Geiger counter at 1 meter in terms of allowable  
6 durations of procedures and so forth. But as the slide  
7 indicates there's really very little hazard involved.  
8 Next slide.

9 Wakes, one could again apply the 500  
10 millirem limit that you would use for radionuclide  
11 therapy patients to family members. It's a  
12 comfortable, emotional situation.

13 Brachytherapy patients, again I-125 and  
14 palladium-123 predominantly which emit very low energy  
15 photons. It really would take tens of hours at less  
16 than 1 meter to accrue dose of 100 millirems. So  
17 there's no restriction for such patients.

18 For radionuclide therapy patients, again  
19 for the pure beta emitters there are no restrictions.  
20 For I-131 it's a bit more problematic because of the high  
21 activities and the penetrating parameters. And of  
22 course you have the issue of compliance. Obviously,  
23 this is a very emotional situation for many people. And  
24 there's no guarantee of compliance even if you were to  
25 recommend precautions. Next slide.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           Burial, there are no restrictions at all  
2 for brachytherapy or radionuclide therapy patients.  
3 There's nothing safer than to bury radioactive sources  
4 deep in the ground and obviously there's no restriction.  
5 Next slide.

6           Cremation is the most problematic  
7 environmental disposition scenario because of the  
8 environmental dispersion of radioactivity. Now modern  
9 cremation is typically done at 2,000 degrees Fahrenheit  
10 with forced air flow of 2,000 cubic feet per minute for  
11 two and a half hours followed by one hour cooling period.  
12 So the total air volume released will be about 11,000  
13 cubic meters.

14           There's a huge dilution factor. You have  
15 up to 10 pounds of ash which will be basically bone ash.  
16 And for other than non-bone localizing radionuclides,  
17 they should not be highly contaminated.

18           Now given the high temperature, you have to  
19 assume that any sealed sources would rupture and the  
20 activity contained in them would be disbursed. Again,  
21 follow the SO guidance at the crematorium with the  
22 appropriate personal protective equipment. Next slide  
23 please.

24           And this is a paper from Japan looking at  
25 cremation of I-125 containing cadavers where a dose

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 calculation was done using a Gaussian Plume Model from  
2 NCRP 123. And you could see all of the assumed  
3 parameters.

4 A key parameter is the dilution of the  
5 activity at the stack and all of these crematoria have  
6 by regulation stacks at fairly high elevations. There's  
7 a thousand-fold dilution typically. And if you make  
8 some conservative assumptions about inhalation added at  
9 a postulated distance of 130 meters from the stack,  
10 you're talking about an effective dose for a cadaver  
11 containing 60 millicuries of less than 1 millirem. So  
12 it's really a pretty insignificant dose.

13 Based on this sort of calculation, the body  
14 of I-125 prostate implant patients can really be  
15 cremated safely at any point given these dose estimates.  
16 Next slide please.

17 Yttrium-90 as I said is problematic, not  
18 because of the Yttrium-90 itself for cremation, but  
19 because of two long-lived radiocontaminants,  
20 europium-152 with a 13 year half-life and europium-154  
21 with a nine year half-life. You actually get 10 times  
22 more of the 152 than the 154 because it has a larger cross  
23 section for the n-gamma reaction by which it's produced.  
24 And the best estimate I can find is about 10 microcuries  
25 combined of these two isotopes for yttrium-90

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 treatment.

2 Now Nelson published a paper where he  
3 estimated the effective dose to individuals from the  
4 crematorium effluent of up to 2200 millirems. And I'm  
5 at a loss as to how that was derived. It seems really  
6 excessive. Next slide please.

7 If you just use the ICRP dose conversion  
8 factor for these two isotopes and you assume that a  
9 single individual internalized, inhaled, all of that 10  
10 microcuries from that cadaver, I come up with 1,750  
11 millirem. But that incorporates no dilution, no  
12 dispersion into the environment and again a reasonable  
13 dispersion factor or a dilution factor would be at least  
14 1,000. So you're talking about no more than 2 millirem  
15 in that case.

16 Again, I'm at a loss as to how that previous  
17 estimate was derived.

18 What are the options? One could take the  
19 very conservative estimate and prohibit cremation  
20 between 90 microsphere patients. You could recommend  
21 removing the liver prior to cremation which no one is  
22 enthusiastic about. Or what I would suggest is doing  
23 more realistic dose analysis, actually using the Plume  
24 model, than these ultra conservative assumptions of  
25 simple quantitative incorporation by a single

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 individual. Next slide.

2 There are standards from the National  
3 Bureau of Standards, for example, dating back to 1958.  
4 The NRC in 10 CFR 35, that's a little general  
5 recommendation. CDC says "Do not cremate a decedent  
6 whose body contains man-made radioactive material."  
7 That kind of sweeping kind of non-fact-based  
8 recommendation really seems counterproductive.

9 And the NCRP as I've been emphasizing  
10 recommended RSO guidance for projected dose-based  
11 precautions which to me is always the more scientific,  
12 prudent, etc., approach. Next slide please.

13 Now this emoticon on the right is me because  
14 I'm at a complete loss as to how the Europeans or the  
15 IAEA -- I shouldn't say the Europeans -- came up with  
16 maximum permissible activities per cadaver for  
17 different isotopes. For autopsy and embalming,  
18 they're as low as less than 1 millicurie. For  
19 cremation, likewise, less than 1 millicurie and so  
20 forth.

21 I'm really at a loss as to how these numbers  
22 were derived. They seem arbitrary to me. They seem ad  
23 hoc. Although they have two significant figures.  
24 Maybe they're not as ad hoc as I think. But I can't  
25 follow any rationale.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   In an subsequent IAEA publication in 2014,  
2                   I'd like to think they came to their senses and did not  
3                   include any such MPAs and really largely adopted what  
4                   the NCRP recommended, mainly SO guidance. Next slide.

5                   These are again some European or  
6                   International Standards information. For example,  
7                   unless you remove the prostate, I-125 of brachytherapy  
8                   patients, prostate patients, cannot be cremated for one  
9                   year in Japan and up to three years in France. In  
10                  various other countries, patients cannot be cremated if  
11                  they had tens of millicuries of various isotopes on  
12                  board.

13                  Again, I'm always skeptical of these  
14                  non-dose-based, activity-based recommendations  
15                  because there's a disconnect between activity and dose.  
16                  And it should be dose which is the defining metric rather  
17                  than activity.

18                  And most places where there are such  
19                  recommendations require or recommend that there be ten  
20                  physical half-lives allowed before scattering the ashes  
21                  following cremation. Again, I'm always skeptical of  
22                  that recommendation because ten half-lives following  
23                  with 1 millicurie is very different from 10 half-lives  
24                  with tens of millicuries. Next slide please.

25                  The available guidance is sparse. I think

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 there is a need for regulatory guidance. As I tried to  
2 say, as I've editorialized, much of it is outdated and  
3 contradictory and not based on dose but what appears to  
4 be just ad hoc recommendations.

5 Restrictions and other precautions such as  
6 the appropriate should be based on measurement-derived  
7 projected doses. Again running throughout this whole  
8 paradigm is the critical RSO guidance.

9 Cremation may be problematic, but I think  
10 restrictions if appropriate should be based on  
11 realistic dose models. And the final slide is just the  
12 abbreviations and acronyms. I'd be happy to take any  
13 questions.

14 CHAIR THOMADSEN: Thank you very much, Mr.  
15 Zanzonico. Questions from the Committee? Yes. Mr.  
16 Costello.

17 MEMBER COSTELLO: Dr. Zanzonico, this is  
18 fascinating and very interesting information. You say  
19 there's not much out there. Would it be worthwhile for  
20 us to recommend to the NRC that this be put out there.  
21 I mean the people who are going to be doing this, the  
22 RSOs and so forth and so on, are here today and I'm sure  
23 you could find a way to spread this information.

24 MEMBER ZANZONICO: Yes, absolutely. When  
25 I was tasked with putting this presentation together,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 I was there looking at the literature. And there is  
2 some literature, but as you've seen, a lot of it is very  
3 contradictory. A lot of it is outdated. And a lot of  
4 it is just based on ad hoc pronouncements.

5 So, yes, I think there's a pressing issue  
6 especially with yttrium-90 and the frequency with which  
7 data is done, obviously, I-125, prostate brachytherapy  
8 and so forth. Again, fortunately these are infrequent  
9 occurrences. But in the case of yttrium-90 the  
10 europium contaminant is never going away. There's an  
11 absolute need for such recommendations to be formulated  
12 and distributed.

13 MEMBER COSTELLO: Thank you.

14 CHAIR THOMADSEN: Yes, Dr. Ennis.

15 MEMBER ENNIS: Earlier on, were you  
16 suggesting that post expiration the SO should do a  
17 survey on every cadaver's implant within some period of  
18 time?

19 MEMBER ZANZONICO: Well, I think it would  
20 most commonly be done if they expired in the hospital,  
21 if they were still hospitalized. And let's put it this  
22 way. If they -- In this wallet card or this  
23 documentation, there is some period of time after which  
24 any precautions are no longer deemed necessary.

25 Yes, if a patient expired within that

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 period of time where precautions were still recommended  
2 or where police and other first responders needed to be  
3 aware of an individual radioactive that, yes, service  
4 should be done.

5 MEMBER ENNIS: So then you would suggest  
6 that everyone change their cards to have a line that says  
7 before this date please contact SO.

8 MEMBER ZANZONICO: Something to that  
9 effect, yes. We know that we give patients who have  
10 radiation therapy a wallet card - there's such a thing  
11 as that -- if they go through a radiation detector at  
12 an airport or a train station. And this would be  
13 comparable to that.

14 CHAIR THOMADSEN: Dr. Langhorst.

15 MEMBER LANGHORST: Who will pay for me to  
16 go to France to survey the cadaver that came to my  
17 institution?

18 MEMBER ZANZONICO: That's a very good  
19 question.

20 MEMBER LANGHORST: Now what you're talking  
21 about is a lot of these people have already been released  
22 under 35.75.

23 MEMBER ZANZONICO: Yes.

24 MEMBER LANGHORST: So they are no longer  
25 under NRC regulatory authority.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MEMBER ZANZONICO: Correct.

2 MEMBER LANGHORST: And so then what issues  
3 come up with the SO saying this is what you need to do?  
4 It really is if the crematorium, if the family, whatever  
5 entity, requests help, you can only provide them  
6 guidance.

7 MEMBER ZANZONICO: Yes. Understood. I  
8 was telling someone earlier, thanks to Dr. Thomadsen,  
9 I was contacted by some company which advertises  
10 themselves as the biggest funeral director company in  
11 the country like GM or Sears. And I imagine if there  
12 is a cost involved it becomes part of the cost of the  
13 final arrangements. But that's a consideration.

14 Again, fortunately all of this should be  
15 very rare. But it needs to be considered.

16 MEMBER LANGHORST: But everyone will pass  
17 away eventually.

18 MEMBER ZANZONICO: Yes.

19 MEMBER LANGHORST: So how long?

20 MEMBER ZANZONICO: I think the real  
21 problem, one problem to be aware of, is the yttrium-90.  
22 So I think that needs to become part of the discussion  
23 prior to treatment.

24 The other issue as well is we may find out  
25 that when realistic dose calculations are done these

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 become non-issues. So I think before trying to  
2 stipulate precautions and durations and so forth and so  
3 on we're obligated to look at things with realistic  
4 dosimetric models. And I think a lot of issues will  
5 disappear.

6 MEMBER LANGHORST: One more. Would that  
7 be more of an appropriate review to be done by NRC maybe  
8 with NRC funding, but to have that kind of analysis done  
9 and recommendation?

10 MEMBER ZANZONICO: I would think so.  
11 Obviously, NCRP reports have a certain cachet.

12 CHAIR THOMADSEN: Dr. Howe.

13 DR. HOWE: I just wanted to reiterate that  
14 the NRC does get calls every once and a while for a  
15 patient that has passed away. We don't get the calls  
16 that they pass away in the hospital that treats them  
17 because the SO is responsible.

18 We get the calls when they pass away or they  
19 end up in a different hospital from where they're  
20 treated and they die. And they want to know what to do  
21 at the crematorium.

22 What we always tell them to do is go back  
23 and have the local SO wherever they are that's closest  
24 to them. And hopefully that SO will be a good neighbor  
25 and will assist the crematorium and will assist the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 family.

2 A lot of times we get strange requests where  
3 people think we've got to put the body in the cold  
4 storage for six months. And we try to discourage that.  
5 We try to tell them "No, you've got to pay attention to  
6 what the family wants. If there really is a hazard, go  
7 ahead and do what you need to do."

8 But generally it is we're recommending  
9 people to be good neighbors and assist the crematorium  
10 -- they don't have RSOs -- and assist the hospitals that  
11 don't have radioactive material that end up with these  
12 patients.

13 CHAIR THOMADSEN: There goes your trip to  
14 France.

15 MEMBER LANGHORST: I know.

16 CHAIR THOMADSEN: Dr. Alderson.

17 VICE CHAIR ALDERSON: That was a great  
18 presentation. I hadn't really thought about this  
19 particular area. So it's more of a question than a  
20 comment as Dr. Langhorst and Dr. Ennis had comments.

21 As we're sitting around the table and  
22 talking about this, we all understand logically what  
23 you're saying, what the risks are. But that isn't how  
24 the general public necessarily would relate to this.

25 And it makes me think of the way that nurses

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 in the ICUs relate to the fact that there may be patients  
2 on their service who have had a nuclear cardiology study  
3 and they're absolutely panicked despite the fact that  
4 you do a large study. Two or three years when that study  
5 has been forgotten you have to do it again because of  
6 a new group. So the public is very concerned.

7 I wonder in academic medical center space  
8 -- I can only speak to that -- in our medical center,  
9 we have techs who work the MAR. And they're intimately  
10 involved with the bodies. And I believe that they as  
11 members of the general public knew that perhaps there  
12 was a radiation hazard they hadn't been told about there  
13 could certainly be a social/political response. It  
14 might not be as logical and well-thought out as  
15 something we would do. But it could be here.

16 It made me wonder in all hospitals when you  
17 dispose of your radioactive material. I mean every one  
18 of the places where your garbage goes out has those  
19 detectors. If somebody missed and something that's  
20 radioactive is headed out in general waste, the alarm  
21 goes off.

22 I don't know what those things cost. It  
23 made me wonder should we have them in our academic  
24 medical center MAR. When a body comes in there's at  
25 least an alarm and if there's something wrong it goes

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 off. And then the SO comes in.

2 Does that make any sense? Or is that too  
3 expensive or just not reasonable to do?

4 MEMBER ZANZONICO: Dr. Langhorst could  
5 give her impression. But what I would think is it's a  
6 different scenario. In the case of regulated waste,  
7 you're trying to detect something that you may not be  
8 aware of. Somehow radioactivity guys did the general  
9 waste stream.

10 Here all the parties involved should know  
11 based on the patient's clinical history, the chart  
12 information, so forth and so on that they had gotten  
13 radioactivity. So they should be cognizant of that.  
14 It is expensive.

15 VICE CHAIR ALDERSON: My fundamental  
16 assumption is that they won't have communicated with one  
17 another and they won't know. That's my fundamental  
18 assumption.

19 CHAIR THOMADSEN: We just had almost that  
20 similar condition where we had a patient show up who  
21 wasn't treated in our facility who was radioactive and  
22 was only found by accident much later on. And we've  
23 started putting detectors at our doors. It's not that  
24 expensive.

25 VICE CHAIR ALDERSON: It's not.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIR THOMADSEN: Only a few hundred  
2 dollars.

3 MEMBER ZANZONICO: What I'm thinking I  
4 mean sort of split the difference. If you get a thin  
5 crystal survey meter, it would be less than a minute to  
6 survey every cadaver. I mean it doesn't take any more  
7 kind of training to have someone do that as an  
8 alternative to fixed detective frame. That's  
9 something to consider I think.

10 VICE CHAIR ALDERSON: Okay. Thank you.

11 CHAIR THOMADSEN: Dr. Mettler.

12 DR. METTLER: This effluent from the stack  
13 with the long lived stuff, does the EPA or the States  
14 regulate any of that stuff?

15 MEMBER ZANZONICO: That's the question.  
16 They probably do. Yes, I'm sure they do. These  
17 specifications of how high the stack should be and what  
18 the force flow rate should be, I think that's all by  
19 regulation.

20 DR. METTLER: So maybe there is some EPA  
21 thing that makes this prohibitive right from the get-go.  
22 I don't know.

23 MEMBER ZANZONICO: There may be. I  
24 haven't encountered it yet, but that's not to say it  
25 doesn't exist.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIR THOMADSEN: Maybe what we should do  
2 and I don't think we need a motion for this, but make  
3 a recommendation to the NCRP that they pick up this as  
4 an extension to the question of radioactive patients  
5 which you were involved with. And that could become a  
6 basis for regulatory guidance or for just anybody.  
7 Does that seem like a reasonable approach?

8 MEMBER ZANZONICO: Yes, absolutely.

9 CHAIR THOMADSEN: And I think that would be  
10 what we might -- Yes, Ashley.

11 MS. COCKERHAM: I just wanted to provide a  
12 general comment since mine is on the guidance.

13 I'm frequently the one that gets phone  
14 calls related to Y-90. And I regularly get phone calls  
15 asking about the information. I just got one last week.  
16 They're typically from the Agreement States which makes  
17 sense as far as that's usually where the work is being  
18 done. I do get those phone calls regularly.

19 DR. METTLER: What do you tell them?

20 (Laughter)

21 MS. COCKERHAM: What Donna-Beth explained  
22 that we don't -- they ask if there are any other NRC  
23 regulations. And we don't do Y-90 microspheres in the  
24 regs. It's in guidance space. And we don't  
25 specifically address cremation.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           A lot of the times it's more of a  
2 conversation about the long-lived isotopes and the  
3 europium and if there are other things that they need  
4 to consider along with isotopes. And it's the good  
5 neighbor principle.

6           CHAIR THOMADSEN:     Fine.     Any other  
7 questions or comments?

8           (No response)

9           Very nice report. Thank you.

10          And Mr. Costello, you are up talking about  
11 compatibility.

12          While you're coming up, I'd just say we used  
13 to have a lot of problems with radioactive bodies  
14 treating for abdominal perfusions in ovarian cases with  
15 G-32 who frequently would die in a couple of days of  
16 treatment. Those who practiced in the '60s and '70s  
17 will remember that.

18          MEMBER COSTELLO:    Good morning. This  
19 presentation changed radically during development. I  
20 created a set of slides that I thought were okay and I  
21 talked to Dr. Langhorst. She very bluntly told me they  
22 were awful.

23          MEMBER LANGHORST:   No, I did not.

24          (Laughter)

25          MEMBER COSTELLO:    No, you were very

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 polite. You didn't say words like that, but your  
2 comments were so good that I concluded that my slides  
3 were awful. It was just a judgment call. In fact the  
4 whole point I was trying to make was awful.

5 (Laughter)

6 I changed the whole thrust of presentation  
7 based on your very polite, not saying that they are  
8 awful.

9 Before we get started, if you all could turn  
10 this book here, we have the 2013 recommendations from  
11 the ACMUI. And if you could turn to the first page of  
12 this. Okay. And just keep it open there and I'll get  
13 back to that. You won't have to flip through each page.  
14 Just hold on to that. I think I have a book. I'm pretty  
15 sure.

16 Okay. Just as a clue as to the value the  
17 Dr. Langhorst gave me, the whole title of this changed  
18 based on her comments. So if you ever want to have  
19 somebody provide really good comments, I suggest going  
20 to Dr. Langhorst because she's really good and really  
21 fast. I guess she just has good slides.

22 The original version of this, the first  
23 thing I sent it, was Compatibility for Permanent  
24 Brachytherapy Event Reporting. And that was my first  
25 slide. I sent it to Dr. Langhorst and she went through

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 the whole presentation. She pointed out that other  
2 than the title I never mentioned permanent  
3 brachytherapy reporting. It was nowhere to be seen.

4 So my presentation wasn't about that even  
5 though I thought it was about that. It was really about  
6 medical event reporting in general. Next slide.

7 Now about a year ago before I was on the  
8 Committee, the ACMUI comments on the proposed Part 35.  
9 And if you look at this here, it says "The ACMUI and its  
10 Rulemaking Subcommittee recommend that the draft rule  
11 redefining medical events in permanent implant  
12 brachytherapy be designated as Compatibility Category  
13 B. This recommendation was approved by the ACMUI with  
14 one dissenting vote" who I suspect is probably my  
15 predecessor. I don't know, but I'm pretty sure that is  
16 true. Next slide.

17 Basically, what went up to the Commission  
18 was that the staff recommended -- and by staff I really  
19 mean the standing committee of compatibility because  
20 that's the NRC's way normally for rules to determine  
21 compatibility of a particular rule. So the paper went  
22 up there, recommending Compatibility C. Next slide  
23 please.

24 And the Commission by a four-to-one vote  
25 adopted the ACMUI's view. But if you note in the first

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 check, it says a vote of four to one to change  
2 compatibility category for reportable medical events.  
3 It doesn't say reportable permanent implant events. It  
4 says reportable medical events.

5 And Chairman MacFarlane who is no longer  
6 the Chairman, she wrote that she was going to set the  
7 medical event definition as a trans-boundary issue  
8 where it has to be the same every year. Next slide  
9 please.

10 Now what will I do here? One of the things  
11 I do is I try to bring issues from the Agreement States'  
12 attention to the NRC and I was trying to guess when I  
13 was discussing patient intervention and certainly  
14 valuing compatibility of regulations. Next slide  
15 please.

16 Now there's another process in place and  
17 doesn't really rely on my position in the ACMUI for just  
18 compatibility and that's a Standing Committee on  
19 Compatibility. However, ACMUI also provides advice to  
20 the NRC on compatibility. And I reached out to the  
21 States and to OAS to have them given me advice on what  
22 position I should take.

23 Now I listened to them like the NRC listens  
24 to you. And eventually I make my own decision of what  
25 I'm going to say. But I certainly do listen to them.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 Next slide.

2 This is probably hard to read, but these are  
3 compatibility categories. Can you all read them? At  
4 least on the paper. Basically, A is a basic standard  
5 of what's around.

6 B basically says that these things have to  
7 do it pretty much identically with the NRC.

8 C says you have essential objectives which  
9 should be adopted by the State, conflicts, duplications  
10 and gaps. And how they do it doesn't have to be exactly  
11 the same as the NRC provided the essential objectives  
12 are met.

13 D means the States can do what they want.  
14 It's not required for compatibility. The other two  
15 aren't relevant here. Next slide please.

16 This is how the current situation is. I  
17 didn't list them all, but I think this is some of the  
18 real important ones. If you notice, there are only two  
19 B's there. Lost materials aren't B. Dose of materials  
20 are not B. And at the current time, medical events are  
21 not B.

22 The only thing under B are things  
23 associated with national security, National Source  
24 Tracking System reporting and loss of large sources  
25 during shipment under Part 37. All other reporting

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 requirements that the States are required to do are C  
2 or very small sources of D. Next slide please.

3 This includes both medical events and  
4 notice of a dose to an embryo/fetus or a nursing child.  
5 Got that. The States have a lot of reports that they  
6 have to pass along to the NRC that require the licensees.  
7 Every single one of them is Compatibility C except for  
8 national security. I think we all can agree that  
9 medical event reporting is not a matter of national  
10 security. Next slide please.

11 The previous rule and the thing referred to  
12 yesterday I think that Dr. Yeager mentioned was from  
13 1992 also specified that medical reporting at that time  
14 in the administration for C. So we almost have a  
15 quarter century of history of requiring States under  
16 Compatibility C to have those reported to C rather than  
17 B.

18 I'm not aware and I don't think the  
19 Committee is aware when they were thinking about this  
20 of this ever causing a single problem. It raises the  
21 question of what was broken. Next slide please.

22 With Compatibility C, we must meet the  
23 essential objective. It's just some flexibility  
24 sometimes and sometimes these requirements might be  
25 already state requirements for reporting any medical

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 event to the Department of Health or elsewhere. Next  
2 slide please.

3 With that said, now turn back to wherever  
4 you were before to these 2013. Save that spot. The  
5 recommendation of the Committee was that reporting of  
6 permanent brachytherapy events be Compatibility B.  
7 And I believe when the Commission discussed this and in  
8 their votes they talked about permanent brachytherapy.

9 And I don't know if the Committee even knows  
10 this, but this was applied to all modalities. All  
11 modalities. And I don't know whoever discussed this  
12 being a good idea.

13 I assume you took very seriously your  
14 discussions about permanent brachytherapy requiring to  
15 be B. You talked about training of doctors and  
16 confusion for the facilities that work cross boundaries  
17 and such. And I understand that.

18 Did you consider how this should be applied  
19 for HDRs? For I-130? For I-131 therapy or I-223  
20 therapy or any other therapy now or in the future? I  
21 suspect not.

22 And I'm just saying from a good guy in  
23 supporting you that such a sweeping change in the  
24 compatibility designation, albeit it's been there since  
25 Ronald Reagan was President, should require at least a

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 little discussion and transparency before this decision  
2 was made. Next slide please.

3 I have a recommendation. Subcommittee at  
4 least look into this. Now my preference is to roll back  
5 everything, including permanent brachytherapy.

6 But I realize that some of you weren't on the  
7 Committee at the time. But a lot of consideration was  
8 given to this for permanent brachytherapy. And if you  
9 want to decide that despite my pointing out that it's  
10 not about national security. That's the only thing in  
11 Compatibility B.

12 For those of you who are thinking that it  
13 retained a dose-based requirement, I'm not sure that  
14 could be done in Compatibility C anyway. I mean you  
15 could talk to the NRC about that, but I don't think it  
16 could be done in Compatibility C anyway.

17 Now that would have to be discussed between  
18 the individual States if they were to adopt that. But  
19 to be blunt I think we were fixing a non-problem. I  
20 don't think that the States could do a dose-based role  
21 under Compatibility C.

22 But if you want to keep that anyway in B,  
23 at least consider whether the other modalities that were  
24 never discussed by the ACMUI and which have been  
25 Compatibility C for almost a quarter century should stay

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 Compatibility C because there is no compelling argument  
2 that for HDRs we should change the reporting requirement  
3 from C to B.

4 Is that my last slide? Okay. Who has the  
5 first question? I was giving a talk at OAS or someplace  
6 and they said people never ask questions. So if you  
7 want to get questions, ask who has the first question.

8 CHAIR THOMADSEN: Thank you very much for  
9 your comments. And usually I would go to the Committee  
10 for their comments before giving any of mine. But I  
11 think that for those new members on the Committee, there  
12 is some background that we should clarify.

13 And the first is the question of why fix  
14 something that's not broken. The Committee did feel  
15 that there was something broken dealing with the  
16 permanent brachytherapy reporting criteria which is why  
17 we proposed change which has been for the most part put  
18 into the new Part 35.

19 The reason that the ACMUI did recommend  
20 Compatibility B was for three reasons that I can  
21 identify. One is that many practitioners had practices  
22 across State lines. And if they were going to be  
23 practicing in States which did not adopt the new  
24 definitions and in States that were NRC that had adopted  
25 that this could cause confusion in trying to establish

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 what should be reported, what shouldn't be reported in  
2 given practices.

3 The second is that if we're looking at data  
4 in the reporting databases if different States have  
5 different criteria for what are events and what are not  
6 events it would be very difficult to establish what may  
7 be dangerous and hazardous situations if we have a  
8 mixture of incidents reported some of which are  
9 considered serious and some of which we have decided are  
10 not considered serious.

11 And thirdly the main reason that the whole  
12 issue came up was the great number of incidents that have  
13 been reported as events which should not have been  
14 reported in events. But because of the definitions  
15 they did qualify as events. But most experts in the  
16 field felt were perfectly fine in implants.

17 That's what led to the change in the  
18 definition. And that's what led to the recommendation  
19 of this body that they should be Compatibility B. I was  
20 not aware that we had been voting on making  
21 Compatibility B for all medical event definitions.  
22 That is news to me right now. I think that was an  
23 inadvertent effect of what we had done.

24 With that, I will open up --

25 MEMBER COSTELLO: Can I respond to each of

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 those three thoughts?

2 CHAIR THOMADSEN: Please do.

3 MEMBER COSTELLO: First of all, I don't  
4 believe that Compatibility C will allow States to retain  
5 the dose-based definition for permanent brachytherapy.  
6 And your third point about the large number of events  
7 which maybe upon further review didn't look like events,  
8 the most prominent of those, that could happen in a green  
9 room space. Right. That happened with the  
10 Philadelphia VA.

11 CHAIR THOMADSEN: Actually, I was thinking  
12 of Wisconsin.

13 MEMBER COSTELLO: And I understand that,  
14 too. Wisconsin, thank you for that. Philadelphia VA  
15 I think started a lot of interest in this unfortunately.  
16 Wisconsin was very aggressive on looking at the Y-90 and  
17 that was the be all and end all of medical events. I  
18 spoke to them there about that.

19 I don't believe they can continue what they  
20 were doing if the NRC changed the rule. That would be  
21 between the NRC when they did their rule review and any  
22 State including Wisconsin. I don't think  
23 Compatibility C would allow them simply to do dose-based  
24 on the rules set on activity-based.

25 CHAIR THOMADSEN: I have talked to several

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 State regulators from several States who have expressed  
2 the opinion that if it's Compatibility C they plan on  
3 maintaining the current definitions. That is between  
4 them and the NRC.

5 MEMBER COSTELLO: Right.

6 CHAIR THOMADSEN: But that is their plan.  
7 If we're done exchanging, I'll open this up to the floor.

8 MEMBER COSTELLO: Yes, I'm done.

9 CHAIR THOMADSEN: Dr. Ennis.

10 MEMBER ENNIS: So I was not involved in the  
11 prior discussions, but I've heard about the issue. And  
12 as someone new who practices a lot of brachytherapy, I  
13 think I should share.

14 I have no doubt that if I'm doing seed  
15 implants in different locations or I'm training someone  
16 who's going to another location and it is not uniform,  
17 there will be events and mistakes. Brachytherapy is  
18 not an easy procedure. It's got to be done carefully.  
19 And like most things in medicine, you need a process,  
20 you need a procedure and you need to do the same thing  
21 every time.

22 If I have to remember where I'm doing the  
23 case and how I have to prescribe and how I have to record,  
24 there will be events that are not events. And it will  
25 interfere with people's interest and ability to do the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 seed implant procedure. It's a phenomenal procedure  
2 for prostate cancer focusing on that aspect for now.

3 But there are alternatives. There are  
4 alternatives for the radiation oncologists, which are  
5 frankly easier and more financially rewarding.

6 If we create a barrier, doctors hate  
7 regulatory barriers. And if we are going to create  
8 another level of barrier, it's just going to go -- forget  
9 it. All I need is for a city to come in and declare a  
10 medical event. And I have to tell my hospital and I have  
11 to tell the patient. I have to tell the referring.  
12 I've got to worry about getting more patients from this  
13 referring. It's not going to happen. Forget it.

14 The patient doesn't know any different.  
15 I'll give him the other treatment even if I think seeds  
16 are better. I won't do it because it's just too much  
17 of a hassle. We've got to make it for the patient's  
18 benefit. And for the patient's benefit, it's got to be  
19 smooth and easy and accurate and reproducible every  
20 time.

21 Anything we can do to make sure that's the  
22 case across the country, across state boundaries, I work  
23 in New York, New Jersey. These are two different  
24 regulatory. There are so many centers across the  
25 country right now that are transboundary. Hospitals

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 are amalgamating. Many of these departments are  
2 practicing in multiple States at this time for  
3 regulations.

4 So to me whatever it was in the past, we had  
5 a problem. We identified the problem. This is the  
6 solution to the problem that will allow the procedure  
7 to continue to be used effectively, safely, by people.

8 Whether this should be expanded to other  
9 medical events, I mean I can see the same argument  
10 applying to them. But frankly I don't know enough about  
11 all those other treatments to know whether the same  
12 issues apply. Although in theory, just in my thinking,  
13 it would be similar. But again, whether that was  
14 discussed before or whether it's inadvertent, those  
15 aren't really things I can weigh in on.

16 CHAIR THOMADSEN: Thank you. Dr. Howe.

17 DR. HOWE: This is just to address Frank's  
18 comment that he believes if it's Compatibility C that  
19 the Agreement States will have to adopt and record.  
20 When I do the medical event reports for you every year  
21 I scan my medical events. And I ended up this year with  
22 over 60 medical events.

23 I read each one of them to see if it complies  
24 with NRC's definition of a medical event. And the big  
25 one that I'm drawing a lot out on is back in 1972, not

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 '72, '92 or '94, we changed the definition for medical  
2 event for nuclear medicine to have to exceed 5 rem whole  
3 body, 50 rem to an organ. So that eliminates almost one  
4 biomedical that's in diagnostic.

5 I'm still getting 20-30 medical events a  
6 year from the Agreement States for the wrong patient,  
7 the wrong drug and they don't exceed the dose limits.  
8 So the seed does give them more flexibility. I don't  
9 know if it's not looking at things closely in IMPEP  
10 space, but I do think it is MedEX for flexibility.

11 MEMBER COSTELLO: Would you comment on  
12 whether or not speaking about prostate and permanent  
13 brachytherapy seed would allow them to retain the role  
14 as is as it does in this rule?

15 DR. HOWE: It appears as if some of the  
16 Agreement States have retained the pre '92-'94 rule.

17 MEMBER COSTELLO: Okay. Thank you.

18 CHAIR THOMADSEN: Thank you, Dr. Howe.  
19 Other comments? Dr. Zanzonico.

20 MEMBER ZANZONICO: I just have a question.  
21 What's the down side of making it B rather than C?

22 MEMBER COSTELLO: Good question. I'm  
23 tempted to say what's the positive side because remember  
24 this rule has been place for almost 25 years. And as  
25 far as I know for other modalities, no one has ever even

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 suggested that for HDRs or I-131 you should fix  
2 something and that it would be going from C to B.

3 But it's really the purpose of B and C.  
4 It's hard to say that a BCR patient, but this is a  
5 transboundary issue. And B is supposed to be for  
6 transboundary issues and it's not.

7 Now in fact I think C, I don't know if any  
8 State has a different definition for HDRs or I-131. You  
9 do see it for diagnostic because it's still retain both.  
10 Some of this might be caused of State law that would  
11 require that.

12 Medicine is probably more regulated by the  
13 States. I suspect there might be some variety in other  
14 ways from State to State. You would know that better  
15 than I would.

16 Some of our protection programs are under  
17 the Department of Health which regulates medicine in its  
18 own way. But basically it's to recognize that the  
19 States are the regulators here. So long as they follow  
20 the basic achievements and the goals of rule, then they  
21 can have some flexibility.

22 In fact, I remember yesterday we were  
23 talking about gallium and germanium. Well, if State  
24 had flexibility there, perhaps it's 35.1000 which I  
25 believe is C. Maybe the States could, some State could

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 try something different and not require DFPs for that.

2 Many of our regulations started with the  
3 States doing something different, not in this area here,  
4 but in the two person rule for the radiography and  
5 certifying radiographers. Many of these things  
6 started with States being sort of elaborate for  
7 innovation or regulation. That's some reason to do it.  
8 The purpose of the Agreement State is to allow States  
9 to vary a little bit, while still achieving the basic  
10 goals.

11 But the main thing I wanted by having the  
12 working group is I think something happened that went  
13 beyond our decision. And I think if you read the  
14 Commission's discussion on this, I don't think they ever  
15 talked about doing every modality. It would be a much  
16 different discussion.

17 And maybe if the Committee discussed that  
18 and said for the reasons you're talking about it should  
19 apply to every modality. That would be much better at  
20 least from a process point of view. Does that answer  
21 your question?

22 MEMBER ZANZONICO: I wouldn't agree, but  
23 it answered the question.

24 CHAIR THOMADSEN: Can I get a sense of the  
25 Committee? Did the Committee think when it made the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 recommendations to the Commission that we were making  
2 a recommendation for all medical events or just dealing  
3 with permanent implants? Yes, Dr. Langhorst.

4 MEMBER LANGHORST: My recollection was we  
5 were limited to the permanent implant.

6 CHAIR THOMADSEN: Is there anybody who had  
7 a different opinion on what happened? Sorry for the  
8 people who weren't involved though. Maybe what we  
9 should do as a Committee is I can draft a letter to the  
10 Commission explaining that we think that the vote that  
11 they took was just misworded from the intention of both  
12 this Committee and the Commissioners and needs to be  
13 clarified.

14 MEMBER COSTELLO: That's even better than  
15 to the subcommittee.

16 CHAIR THOMADSEN: And if there's no  
17 dissension in this Committee I will do that. Yes, Dr.  
18 Ennis.

19 MEMBER ENNIS: Will you say that the ACMUI  
20 does not agree with what the letters are or just say that  
21 it's not what we said?

22 CHAIR THOMADSEN: No, I will reiterate  
23 that our intention was for permanent implants, that the  
24 new definitions would be Compatibility B and we did not  
25 discuss other forms of medical events. I was planning

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 on in our next open discussion bringing up the other  
2 topic and this has been a good introduction for that.

3 Thanks very much, Mr. Costello for alerting  
4 us to the situation. Dr. Alderson.

5 MEMBER COSTELLO: Thank Dr. Langhorst. I  
6 would never have found it without her.

7 CHAIR THOMADSEN: She reads every letter  
8 very carefully.

9 VICE CHAIR ALDERSON: I just need a point  
10 of clarification and there are a number of us here, among  
11 them I am, who weren't here when this happened. So on  
12 page two of the slides, a short history lesson, reading  
13 the words there, I'm going to make sure I'm interpreting  
14 this the correct way. So the Commission initially  
15 voted four to one to change the category to B. But then  
16 the next long paragraph says that the Chairman stated  
17 that she didn't agree with that.

18 MEMBER COSTELLO: Yes.

19 VICE CHAIR ALDERSON: And so it didn't  
20 change to B is what I'm understanding.

21 MEMBER COSTELLO: No, the Chairman didn't  
22 agree, but she was the one in the four to one vote.

23 VICE CHAIR ALDERSON: So she doesn't have  
24 the power to offset all the others.

25 MEMBER COSTELLO: No.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 VICE CHAIR ALDERSON: So it is changed to  
2 B.

3 MEMBER COSTELLO: Right now, it's still C.  
4 It's still a proposed rule. Goes for comment until  
5 December. So as we sit here today, is Compatibility C  
6 across the country? And I would just suggest that the  
7 sun will come up again tomorrow anyway.

8 VICE CHAIR ALDERSON: Thank you very much.

9 CHAIR THOMADSEN: With that, there are no  
10 other comments. We'll move to the Status of Abnormal  
11 Occurrence Criteria from the NRC staff.

12 DR. TAPP: Good morning. I'm here today  
13 to give an update on the status of the proposed abnormal  
14 occurrence for the medical events. Next slide please.

15 First, I wanted to start with the  
16 background. Just so everyone is aware, abnormal  
17 occurrences are defined as an unscheduled incident or  
18 event that the NRC determines to be significant from a  
19 standpoint of public health and safety. I think it's  
20 good to highlight that word "significant" from the  
21 standpoint of public health and safety.

22 AOs are required by Section 209 of the  
23 Energy Reorganization Act of 1974 that the NRC reports  
24 these events to Congress that they deemed that are  
25 significant. The criteria was initially created in

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 1977, but has been updated periodically as the staff  
2 finds out new information. Next slide please.

3 For the current proposed abnormal events  
4 that we're going through right now, I wanted to provide  
5 a little history. The NRC established a working group  
6 back in 2011 to evaluate changes to the Abnormal  
7 Occurrence Criteria.

8 The NRC presented in 2012 to the ACMUI their  
9 current proposed AO criteria. You guys provided  
10 recommendations back to the staff on April 15, 2013.

11 In October the staff revised their AO  
12 criteria and provided that revision to the Agreement  
13 States for their comments. We received comments back  
14 from that and we did a little more revision to the  
15 Abnormal Occurrence Criteria. Now we have finalized  
16 the proposed criteria that is going to be sent out to  
17 the Commission. Next slide please.

18 I wanted to go over the actual criteria  
19 changes. First, the medical event criteria which is  
20 III.C. The first change was to the title. The current  
21 title is just For Medical Licensees. The staff's  
22 proposed title change is events involving the medical  
23 use of radioactive materials in patients or human  
24 research subjects criteria. This revision was based on  
25 recommendation from the ACMUI with a slight editorial

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 change to fit the other criteria.

2 We additionally added a footnote pointing  
3 that Criteria III.A.2, A.3 and A.4 also apply to medical  
4 licensees. This criteria has always applied to medical  
5 licensees, but we're just highlighting the fact it is  
6 still applicable to them since they have their own  
7 criteria.

8 For the rest of the slides I do want to point  
9 the blue font highlights are the new changes to the AO  
10 criteria. Next slide please.

11 I point on III.A just to highlight what that  
12 footnote was showing. These are more generic trends or  
13 large nationwide impacts or a large deficiency or event  
14 that could be reported but don't actually meet the III.C  
15 criteria.

16 I think the fourth one really highlights it  
17 could be a generic trend which is a series of events,  
18 occurrences, incidents which have implications for  
19 similar facilities that raise a major safety concern.  
20 But they don't actually meet the III.C criteria by  
21 themselves. Next slide please.

22 The actual proposed new medical criteria on  
23 III.C stays similar to the old criteria where it had a  
24 dose criteria to start and then a cause, a reason why  
25 it was an event. But in addition to that, the new

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 proposed criteria now will require an actual side effect  
2 to occur before it is reported. That makes it a  
3 significant impact to public health and safety.

4 The ACMUI did not recommend to keep the dose  
5 criteria, the reason criteria. But the staff would  
6 like to keep that criteria as a screening criteria.  
7 When we generally get notification of events, we do not  
8 have enough information to know at the time if the  
9 patients are going to have an adverse effect. So this  
10 criteria knows when we do need to send out a medical  
11 consultant to look further into this information.

12 For the dose criteria, there are slight  
13 changes as you see on this slide. The first thing is  
14 we're highlighting a medical event as defined in  
15 regulations. The NRC is 10 CFR 35.3045. It will not  
16 be a medical event in a different term. It has to be  
17 current to that regulation.

18 In addition, we are changing the dose  
19 criteria to other organs or tissues that has to exceed  
20 by 10 gray the expected dose. This will change from  
21 events that had been reported in the past where there  
22 was an event but it didn't actually exceed 10 gray. It  
23 just was 10 gray even though that might have been what  
24 the wanted dose was. Next slide please.

25 This is cause criteria. There are no

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 changes to this. It's very similar to the past. Next  
2 slide please.

3 This is a new criteria which is the adverse  
4 effects that have to be included as an "and." So you  
5 have to have the dose, the cause and the adverse effect  
6 before it is going to be proposed as an abnormal  
7 occurrence. The criteria is very similar to what was  
8 recommended in 2013. And it states "that results in one  
9 or more of the following as determined by an independent  
10 physician deemed qualified by the NRC or an Agreement  
11 State." It has to have either an unintended or  
12 unexpected permanent functional damage to an organ or  
13 physiological system or a significant unexpected  
14 adverse health effect or death.

15 The slight change in wording from the  
16 recommendation is we have now changed it from consultant  
17 physician to independent physician just because some  
18 States would like the use of an independent physician  
19 maybe on their staff or not part of actual consultants.

20 But the independent physician has to be not  
21 directly involved in the care of the patient as well as  
22 it has to be determined to be qualified by the Agreement  
23 State or the NRC. Next slide please.

24 Now going back to Criteria I.A which is for  
25 all human exposures, there's been some slight changes

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 for this criteria as well. The new criteria, there's  
2 a new criterion as part of I.A.4 which states that these  
3 criteria in Section I.A do not apply to medical events  
4 as those were covered in III.C. Addition made is  
5 there's going to be footnote added to the title of I.A  
6 to make sure that medical patients are excluded from  
7 this criterion. We really want to highlight that I.A  
8 is for exposures not related to medical patients. Next  
9 slide please.

10 In addition, the staff is not recommending  
11 the removal of the embryo/fetus criterion in I.A.2 as  
12 this criterion is used for all regulated entities.  
13 There could be an overexposed, pregnant worker.

14 Generally it has been in the past a medical  
15 patient who had a baby at the time has been reported.  
16 But it is still possible of someone who is a radiation  
17 worker who is pregnant could have this exposure. We  
18 wanted to keep this criterion there to make sure we would  
19 capture those events.

20 We are also not recommending new criterion  
21 to I.C.3 regarding accidental embryo/fetus as we have  
22 it here. Next slide please.

23 The next steps are we are sending this up  
24 to the Commission, the staff's recommendation, the  
25 input from the Agreement States as well as the ACMUI's

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 recommendation. They're going to have a chance to  
2 review and vote on this.

3 If they approve it for a vote, we then send  
4 it through the Federal Register for a public comment  
5 period of 90 days. The staff will incorporate  
6 comments, send it back around for more comments and  
7 review.

8 Then the Commission will have another  
9 chance for review, final approval. And it will not go  
10 final or will not be able to use it until it's published  
11 in the Federal Register at the end. Next slide please.

12 That's my last slide. I'll open it up for  
13 any questions.

14 CHAIR THOMADSEN: Thank you very much.  
15 Any questions? Dr. Zanzonico.

16 MEMBER ZANZONICO: I just want to clarify  
17 things in my own mind. So these criteria III, these are  
18 all "ands."

19 DR. TAPP: They're all "ands."

20 MEMBER ZANZONICO: So all of those  
21 criteria have to be met for an abnormal occurrence. So  
22 a medical event -- an abnormal occurrence has to be a  
23 medical event, but not the other way around. A medical  
24 event is not necessarily an abnormal occurrence.

25 DR. TAPP: That's true.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MEMBER ZANZONICO: Thank you.

2 CHAIR THOMADSEN: Thank you very much.

3 Dr. Langhorst.

4 MEMBER LANGHORST: I think you guys have  
5 done a wonderful job of taking our recommendations.  
6 And I really appreciate the considerations that you did  
7 because I know you look at this at a much wider space  
8 than just medical use.

9 I have a question concerning the  
10 embryo/fetus criterion. If kept as you have it here  
11 proposed, every patient who later finds out they're  
12 pregnant and has unintended dose no matter whether it  
13 caused no problem at all that will be an abnormal  
14 occurrence that will be reported to Congress. Correct?

15 DR. TAPP: As it is written and proposed,  
16 it will be reported to Congress.

17 MEMBER LANGHORST: Would it be possible in  
18 your -- if we could go to your slide about the new  
19 criterion in I.A. I think that's slide nine. Would it  
20 be possible to say that these criteria in I.A do not  
21 apply to medical events defined in 10 CFR 35.3045 and  
22 in the 10 CFR 35.3047 which is where we deal with an event  
23 for unintended dose to an embryo, fetus or nursing  
24 child?

25 I'm concerned that these types of issues

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 arise and they don't arise very often. But they're just  
2 automatically catapulted into a Congressional report.  
3 And I don't think that it's appropriate.

4 DR. TAPP: That recommendation could be  
5 made. This is actually proposed and up to the  
6 Commission. But that could be a comment or something  
7 they could see. But it's not currently in the proposed.

8 MEMBER LANGHORST: I'll say one thing. I  
9 totally understand that you need to keep that criterion  
10 for exactly what you're talking about like a radiation  
11 work order or other members of the public and that sort  
12 of thing. But in the medical arena, I really think that  
13 35.3047 needs to be included in that exclusion.

14 DR. TAPP: Thank you.

15 CHAIR THOMADSEN: That was going to my  
16 comment, too, except I would disagree. I think that is  
17 something that actually happens not that uncommonly  
18 when you find out that a patient was pregnant without  
19 knowing and happened after you started radiation and  
20 haven't done any pregnancy test. You aren't going to  
21 do a pregnancy test before each fraction.

22 MEMBER LANGHORST: And, Dr. Thomadsen, I'm  
23 not arguing that it shouldn't be a medical event.

24 CHAIR THOMADSEN: Yes.

25 MEMBER LANGHORST: It just does it then

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 automatically catapult it an abnormal occurrence.

2 CHAIR THOMADSEN: Exactly. Mr.  
3 Mattmuller.

4 MEMBER MATTMULLER: Behind you.

5 CHAIR THOMADSEN: Oh, I'm sorry.

6 MS. FAIROBENT: That's okay, Dr.  
7 Thomadsen. Lynne Fairobent with AAPM. I actually  
8 really second Sue's last comment. And part of the  
9 reason is if we had a similar situation caused by machine  
10 producing radiation, say, somebody getting a CT scan or  
11 being treated on a LINAC, those events would not be  
12 reported to Congress.

13 They would be reported hopefully to the  
14 State in which it occurred. But they would not be  
15 triggered to an abnormal occurrence event. To me  
16 that's a disconnect. Why should it be in one case?

17 And if you go back and you look at the  
18 abnormal occurrences that are reported to Congress by  
19 far the majority are medical-related which is why this  
20 whole topic got initially surfaced a number of years  
21 ago. So I really do think Sue has hit a very good point.  
22 I think we ought to consider that.

23 CHAIR THOMADSEN: Thank you very much.  
24 Would you care to make a motion?

25 MEMBER LANGHORST: I would move that we

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 recommend the new criterion in I.A be amended to include  
2 reference to 10 CFR 35.3047. And if there is harm as  
3 noted in medical event, I think that just like your  
4 proposing in III.C that should be raised to an abnormal  
5 occurrence.

6 CHAIR THOMADSEN: Okay.

7 MEMBER LANGHORST: Does that make sense?  
8 For those of you who are new, this is all very confusing  
9 I know.

10 DR. METTLER: What do you mean by harm?

11 MEMBER LANGHORST: As defined in the  
12 medical event.

13 DR. METTLER: Permanent.

14 MEMBER LANGHORST: Right. That an  
15 independent or consultant physician would judge.

16 CHAIR THOMADSEN: Do we have a second.

17 MEMBER ZANZONICO: I'm still not clear  
18 what the motion is?

19 CHAIR THOMADSEN: Can you --

20 MEMBER LANGHORST: I wanted it added to  
21 I.A, but I'm not sure if it's included back here in the  
22 III.C. You do reference 35.3045.

23 DR. TAPP: Yes.

24 MEMBER LANGHORST: I think it should be  
25 referenced in both places. I'm sorry. Let me redo my

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 motion before we go any further.

2 CHAIR THOMADSEN: Yes.

3 MEMBER LANGHORST: I would move that 10 CFR  
4 35.3047 be included in the proposed changes for III.C  
5 that was on slide six of your presentation and in the  
6 proposed criterion I.A. That's slide nine of the  
7 presentation to be part of the two reportable medical  
8 incidents of Part 35.

9 CHAIR THOMADSEN: Thank you very much.

10 VICE CHAIR ALDERSON: I'm sorry to ask for  
11 more clarification. But having said that now, what  
12 would be the functional significance of what you just  
13 said? What does that amount to?

14 MEMBER LANGHORST: Essentially, if it  
15 stays as is, every occurrence -- and it's not a medical  
16 event. It's reported under 35.3047 -- every one of  
17 those incidents is an abnormal occurrence. And that  
18 would probably be the only abnormal occurrence that get  
19 reported to Congress.

20 VICE CHAIR ALDERSON: So you're trying to  
21 exclude that by adding this as an exclusion.

22 MEMBER LANGHORST: That's right.

23 CHAIR THOMADSEN: Now can we get a second  
24 so we can discuss this?

25 MEMBER COSTELLO: Second.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIR THOMADSEN: We have a second. Now  
2 discussion on the motion please.

3 MEMBER COSTELLO: I just have a question as  
4 to timing of the motion. I agree with all the content  
5 of the motion. Right now this is before the Commission.

6 DR. TAPP: It's in a process going to the  
7 Commission. It will be there by next week.

8 MEMBER COSTELLO: Okay. How would a  
9 recommendation affect a process since it's already  
10 going to the Commission? Would we be better off waiting  
11 until it came down from the Commission and we had another  
12 shot at it?

13 DR. TAPP: I did want to make one comment.  
14 The staff's recommendation is different from the  
15 previous ACMUI's recommendation in 2013. The previous  
16 ACMUI recommendation was to take out that criterion and  
17 move it.

18 This is slightly different way to do it.  
19 But as you said, the Commission will have both the  
20 staff's recommendation and ACMUI's recommendation at  
21 the time of their vote. So we do not know which way it  
22 will come back from them yet.

23 MEMBER COSTELLO: And I think the  
24 Commission already has this recommendation.

25 CHAIR THOMADSEN: Was this in the previous

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 ACMUI recommendation or is this both --

2 DR. TAPP: Not the exact wording.

3 CHAIR THOMADSEN: I think this has only  
4 come up because of the changes that have been made.

5 DR. TAPP: Yes.

6 CHAIR THOMADSEN: Dr. Langhorst.

7 MEMBER LANGHORST: We included this  
8 concept in our recommendations, not knowing how to  
9 structure your abnormal occurrence policy.

10 DR. TAPP: Sure.

11 MEMBER LANGHORST: I totally understand  
12 that your need to have that criterion still stay in there  
13 for these non-medical events. I understand that.

14 So I think our intent of making that  
15 recommendation in our report and that report is listed  
16 under our website in 2013 is to add that reporting  
17 section of .3047 in with .3045 in both those places.  
18 And if there's a significant adverse health impact to  
19 the embryo, fetus or child, then that gets moved forward  
20 as an abnormal occurrence. Sorry, I get confused  
21 there.

22 CHAIR THOMADSEN: Dr. Mettler.

23 DR. METTLER: If I was on the Commission,  
24 I would say tell me the rationale why you want to reports  
25 from a nuclear power reactor but not medicine if it's

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 an effect or an exposure to a fetus. Why are you  
2 reporting from this set but not that set?

3 MEMBER LANGHORST: Well, why aren't we  
4 reporting all medical events? Because we were saying  
5 some shouldn't raise to the level of abnormal  
6 occurrence. And I can't remember the definition of  
7 abnormal occurrence but it's in the Atomic Energy Act  
8 that NRC is required to report these to Congress.

9 DR. METTLER: Right. But the question is  
10 it's the same pregnancy here, pregnancy there. The  
11 same dose. Same whatever. Different sources. And if  
12 I was a Commissioner I would say "Tell me the rationale  
13 why this should be sent this way and this one shouldn't."  
14 All I'm saying is as you send forward your suggestion  
15 you might send forward the reason for it.

16 MEMBER LANGHORST: And I think we did and  
17 I'd have to look at the report again. But we did make  
18 that rationale. And if the Committee wants to change  
19 that, that's fine.

20 CHAIR THOMADSEN: Dr. Zanzonico.

21 MEMBER ZANZONICO: If I could take a stab  
22 at answering that question. The criterion is  
23 unintended which does not necessarily mean unknown. In  
24 other words, there may be some medical scenario where  
25 you're aware a patient is pregnant, you're aware the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 embryo or fetus may get a dose, but it's medically  
2 justified. And I think that's the distinction.

3 I mean it's never justified in an  
4 occupational exposure scenario to have an excessive  
5 fetal dose. But there can be scenarios in the medical  
6 context where although it's undesirable it could be  
7 justified.

8 DR. METTLER: But that's intended.

9 MEMBER ZANZONICO: No, the dose to the  
10 fetus is not intended. It's unintended but it's  
11 incidental.

12 DR. METTLER: All I'm saying is if you just  
13 say we want to take this out but not this, they probably  
14 need a little bit higher --

15 MEMBER LANGHORST: I will point you to our  
16 report.

17 DR. METTLER: Okay.

18 MEMBER LANGHORST: And I think it's the  
19 logistics of how you do that. I think we suggested that  
20 this criteria I.A for the unintended radiation exposure  
21 to the embryo/fetus wasn't intended to totally go away.  
22 We intended it not to be applied in the case of a  
23 reporting event of 35.3047.

24 Now I'll say, Dr. Zanzonico, that is not a  
25 reportable event if you decide that the doctor says

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 "Yes, we do want to do that." That's not going to be  
2 reported under that .3047 because they involve that if  
3 the physician says "We know this and we are going to  
4 treat this patient anyway."

5 CHAIR THOMADSEN: Other comments?

6 MEMBER COSTELLO: Can we get in our  
7 recommendation to the Commission in time to have an  
8 impact since they're getting it next week?

9 DR. TAPP: I do not know how long the vote  
10 will take. We do not know how long that process takes  
11 once it gets up there.

12 MEMBER COSTELLO: I'll move in favor of the  
13 motion. I just didn't know if the timing of this would  
14 work out.

15 CHAIR THOMADSEN: Any other discussion?

16 VICE CHAIR ALDERSON: I think that the  
17 motion should be repeated before we vote just so we're  
18 all clear of what we're doing here.

19 CHAIR THOMADSEN: Yes. Good point. Dr.  
20 Langhorst.

21 MEMBER LANGHORST: I would recommend --  
22 Can we pull it up? Yes, thank you. I would recommend  
23 that on Item 1 there when we have 10 CFR 35.3045 I would  
24 say "and 3047." I would add that.

25 CHAIR THOMADSEN: I think that that would

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 cover it, would it not?

2 MEMBER LANGHORST: Yes. Dr. Howe does  
3 bring up a point that it's not a medical event for the  
4 embryo/fetus/nursing child. That term is not used  
5 there. Maybe if we say -- I mean I guess you could say  
6 a medical -- I don't know what you want to call it.

7 MEMBER COSTELLO: It's a reportable event.

8 MEMBER LANGHORST: A reportable event.

9 CHAIR THOMADSEN: Why don't we at this  
10 moment -- Yes.

11 MS. COCKERHAM: Can I make a suggestion  
12 here? I think if the Committee made a recommendation  
13 to capture their intent that things reported to us under  
14 35.3047 or that it's to things that are.

15 MEMBER LANGHORST: Yes.

16 MS. COCKERHAM: Okay. So things that are  
17 reported to the NRC under 35.3047 not be reportable to  
18 Congress in the AO criteria. That is your intent.

19 MEMBER LANGHORST: Right.

20 MS. COCKERHAM: Will unless there's harm.

21 MEMBER LANGHORST: Right.

22 MS. COCKERHAM: Then if the Committee  
23 wants to make that recommendation I wouldn't worry so  
24 much about the actual wording of the criteria because  
25 that's the message you want to send to the Commission,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 right? We do not want to report things that would come  
2 to us under 35.3045 that do not result in harm to an  
3 embryo or fetus.

4 DR. TAPP: 07.

5 MS. COCKERHAM: .3047, I'm sorry. I  
6 misspoke, to Congress. That's the Committee's  
7 intention. I think that that's good enough and from a  
8 process perspective I can't promise this is what we  
9 would do, but just thinking about our processes.  
10 You're saying "How do we get this recommendation to the  
11 Commission?" You advise staff. Staff has ways to  
12 communicate with the Commission. We could send up a  
13 simple CA note that goes to them saying "We had a  
14 significant conversation that is pertaining to a paper  
15 that is coming to you."

16 Our CA note from the Office of NMSS could  
17 go up and coincide with a SECY paper that's coming up  
18 from Research. They will get all of the information  
19 at the same time. Or maybe they get the CA note ahead  
20 of time. We're able to brief their assistants and say  
21 "This is technical information that you're going to need  
22 to make a decision on a paper that's coming to you."

23 We have processes for that. Does that  
24 help?

25 MEMBER LANGHORST: It helps me.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MEMBER COSTELLO: Yes, a lot.

2 CHAIR THOMADSEN: Do we have a motion?

3 MEMBER LANGHORST: I will repeat that  
4 motion.

5 (Laughter)

6 I don't know that I can because we already  
7 had a motion.

8 CHAIR THOMADSEN: Will you withdraw your  
9 motion?

10 MEMBER LANGHORST: I will withdraw that  
11 first one.

12 CHAIR THOMADSEN: And the seconder? Who  
13 was the seconder?

14 MEMBER COSTELLO: I was the second.

15 CHAIR THOMADSEN: Will you withdraw your  
16 second?

17 MEMBER COSTELLO: Yes.

18 CHAIR THOMADSEN: Okay. Now you can make  
19 a new motion to whatever Ashley just said.

20 MEMBER COSTELLO: Maybe Ashley should.

21 MS. COCKERHAM: Would you like me to  
22 rephrase it again?

23 CHAIR THOMADSEN: Please.

24 MS. COCKERHAM: So the Committee's intent  
25 is that events reported to NRC under 35.3047 that do not

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 result in harm to an embryo or fetus are not included  
2 as AO capturable and reported to Congress.

3 MEMBER LANGHORST: Yes. And I would just  
4 add or nursing child.

5 MS. COCKERHAM: Okay. Or nursing child.

6 CHAIR THOMADSEN: Do you want to second  
7 that one?

8 MEMBER COSTELLO: I second that one, too.

9 CHAIR THOMADSEN: Excellent. Any  
10 discussion on the new motion?

11 (Vote)

12 MEMBER ENNIS: Abstain. I don't really  
13 understand.

14 (Laughter)

15 CHAIR THOMADSEN: All right. And I will  
16 have to admit that the abnormal event criteria --

17 MEMBER LANGHORST: Abnormal occurrence.

18 CHAIR THOMADSEN: I'm sorry. Thank you.  
19 Abnormal occurrence criteria is actually a lot more  
20 convoluted than it seems like it should be. So it's  
21 quite understandable. This is your first.

22 MEMBER ENNIS: Never heard of the concept  
23 before.

24 CHAIR THOMADSEN: Yes, it wouldn't be  
25 clear. But it passes anyway. Thank you very much.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 DR. TAPP: Thank you.

2 CHAIR THOMADSEN: And with that we are up  
3 to a break until 10:30 a.m. Off the record.

4 (Whereupon, the above-entitled matter went  
5 off the record at 10:11 a.m. and resumed at 10:33 a.m.)

6 CHAIRMAN THOMADSEN: Let us resume. We  
7 now have a guest to talk with us from Elekta talking  
8 about Perfexion and Gamma Knife authorized user  
9 physical presence. And welcome to our meeting.

10 DR. KJALL: Thank you and thank you for  
11 inviting us to give this presentation, which as I see  
12 it is sort of a continuation or extension of the  
13 presentation given in the last meeting.

14 Before I start I'm here representing Elekta  
15 only. I'm not representing our users, at least not in  
16 a formal sense. However, everything I'm going to talk  
17 about today is of course based on our discussions during  
18 the years about this particular issue, which many users  
19 find some problematic.

20 So to be honest from the beginning, this is  
21 why I'm here. I'm here to ask for your support of a  
22 change to the licensing guidance concerning the  
23 physical presence requirements.

24 I'm going to use three arguments. I  
25 mention this from the beginning in order for you to sort

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 of detect when I gather momentum with the arguments.  
2 I'm going to talk about the design of the Perfexion  
3 system. I'm concentrating on Leksell Gamma Knife  
4 Perfexion. The design and the safety features of  
5 Perfexion. I'm going to talk about incident rates. I  
6 have data on incidents. I will define incidents later  
7 on. And I'm also going to talk about comparative safety  
8 analysis; a very simple one, but very telling. And in  
9 order to sort of assess the reasonableness of the  
10 arguments and the suggestion that we propose I'm going  
11 to show data on how patient safety is managed outside  
12 U.S.

13 One slide about who we are. I hope most of  
14 you already know that. Then Leksell Gamma Knife from  
15 various perspectives, how it works. Patient safety  
16 again from various perspectives. And then finally of  
17 course the recommended change.

18 I hope you can see the pictures there.  
19 Elekta has during many years been in the center of modern  
20 cancer care. The images show from left to right the  
21 system we're going to talk about today. Elekta Gamma  
22 Knife Perfexion system. There is a brachytherapy  
23 system, one of many. We have a range of software  
24 solutions from patient management all the way across  
25 treatment planning. And also a range of neural

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 accelerators. And you see a couple of numbers there  
2 representing how many patients actually deal with  
3 Elekta equipment per year and per day.

4 This is the primary focus of the  
5 presentation. Leksell Gamma Knife, past, present,  
6 future. The concept has always been cross-firing a  
7 large number of beams. The beams meet in a small volume  
8 and essentially this volume is thinner than the  
9 isocenter. The parameters you have at your disposal  
10 when you perform this treatment and when you plan the  
11 treatment is of course the irradiation time, the width  
12 of the beams. For Perfexion, we have three widths: 4,  
13 8 and 16 millimeter. That is very narrow beams. And  
14 of course the number of beams. We can selectively lock  
15 beams strung from different directions. We move around  
16 the patient in order to position the isocenter in  
17 various parts of the target, of course.

18 During the '50s and '60s the field of  
19 stereotactic radiosurgery was established by merging  
20 the fields of open stereotactic surgery and radiation  
21 therapy. A platform was created. Prototypes on the  
22 platforms started to evolve during the years and the  
23 evolution has been in terms of patient comfort, the  
24 number of different collimators that you can use, of  
25 course patient safety. But the principle has always

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 remained the same, cross-firing a large number of beams  
2 in a small volume.

3 The latest system is, the latest released  
4 system is the Leksell Gamma Knife Perfexion system.  
5 And it's interesting to note that the Leksell Gamma  
6 Knife is still the intracranial system that all other  
7 solutions measure themselves against when it comes to  
8 accuracy and precision after all these years.

9 So this is what it looks like. The  
10 treatment process. Since it's a system based on  
11 stereotactic principles, the first thing you have to do  
12 is of course is to attach the stereotactic system to the  
13 patient; in this case the Leksell G Frame. On this  
14 frame you've put what we call the fiducial box. It's  
15 a box that contains markers that enables you to define  
16 the stereotactic space in the diagnostic image set,  
17 which can be based on a MR, CT, MU or PETs.

18 This information is then fed into the  
19 treatment planning system where you of course locate  
20 defined targets, you simulate your dose delivery, you  
21 calculate a large number of statistics in order to  
22 assess the quality of your plan, and then finally you  
23 of course treat the patient.

24 So what makes the Perfexion system  
25 different from the other systems? The first and the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 primary difference is that when you initiate treatments  
2 you can move the patient into the treatment position  
3 without having the beams on. You stopped the  
4 treatment. Can you see them? Yes, you can see the  
5 beams. And then you can in between isocenters; that is  
6 when you move the patient -- you can turn the beams off.  
7 And you restart the treatment. And if there is an  
8 incident, something happens, you can emergency move or  
9 turn off the beams.

10 And this ability is designed in such a way  
11 that sources are placed on moveable mechanical  
12 structures that we call sectors. And each one of these  
13 sectors can be in a number of different positions. Two  
14 of these positions are such that the patient is shielded  
15 from the primary radiation from the sources. And the  
16 shielding thickness is between 15 and 20 half-value  
17 layers, which means that in practice the dose rates in  
18 the isocenter is almost, from a clinical point of view,  
19 zero.

20 And we have this system installed all over  
21 the world; around 120 here in the U.S. of which 80 to  
22 90 is the system I'm talking about, the Perfexion  
23 system. Three hundred plus something in the world out  
24 of which two hundred are Perfexion systems. Two years  
25 ago almost 800,000 patients had been treated with this

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 system, with the Leksell Gamma Knife in general. Out  
2 of these 800,000 around 300,000 were treated with the  
3 Perfexion system.

4 Now I'm moving over to patient safety in  
5 general not related specifically or uniquely to the  
6 Perfexion system per se. And I'm sorry about sort of  
7 the linguistic proximity of medical incidents I have  
8 here with medical events. I'm not talking about  
9 medical events now. Sorry about that.

10 And incident can be the medical or a system  
11 failure. Medical, I'm talking about vomiting, nausea,  
12 pain, etcetera. System failure, hardware,  
13 software-related or a mix, of course.

14 The required actions to manage an incident  
15 is to of course first recognize it and then to respond  
16 appropriately. To recognize medical incident you of  
17 course need some medical clinical competence. To  
18 respond to a medical incident you need to know how the  
19 system works. That is, you need to have system  
20 competence. For system failure, on the other hand, you  
21 need more of a technical background for system  
22 competence. And as you see I've included knowing the  
23 risks and characteristics of a radiation in system  
24 competence.

25 What is a medical incident? It takes a

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 certain amount of time to recognize that something is  
2 happening or has happened. And these are numbers I've  
3 assumed are reasonable. To recognize a medical  
4 incident you need somewhere between 0 and 30 seconds if  
5 you are looking at the patient of course through the  
6 patient surveillance system.

7 To respond I've defined here as turning the  
8 beams off. And all systems on the market, regardless  
9 of manufacturer, can turn the beams off in a matter of  
10 seconds.

11 A system failure on the other hand may take  
12 since now the system has actually failed, may take a  
13 longer time to respond to. And during this response  
14 time there is of course a risk to be exposed to unwanted  
15 dose.

16 This is a graphical illustration of medical  
17 incidents. All the green bars represent dose delivered  
18 to the correct position and in the correct amount. At  
19  $t$  equal  $t_1$  there is a medical incident. It takes a  
20 certain amount of time to recognize it and to respond  
21 to it. At the end of the response time the beams are  
22 off and the incident is resolved. And then you restart  
23 the treatment again. No extra dose to patient, no extra  
24 dose to user.

25 The competencies needed here are medical;

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 I talked about that on the previous slide, for instance  
2 a nurse. And it has to be remembered that acute medical  
3 emergencies caused by the treatment itself during Gamma  
4 Knife treatments are extremely rare.

5 The same kind of graphical illustration but  
6 for a system failure. Anything up to  $t$  equal  $t_1$  is  
7 according to plan. Dose delivered to the correct  
8 position and the correct amount.  $t$  equal  $t_1$ , something  
9 happens. And all systems on the market are designed to  
10 turn beams off if there is a system failure. However,  
11 the system has failed. So there is an uncertainty as  
12 to the state of the system.

13 And then of course the maximum risk is if  
14 the beams are still on. So this area of uncertainty or  
15 this dose to the patient, this uncertain dose to the  
16 patient is of course bounded from below by zero dose rate  
17 and from above by the maximum dose rate the system is  
18 able deliver. And this is sort of a fundamental  
19 principle of radiation therapy, and of course also  
20 radiosurgery. And that is that the maximum patient  
21 risk is predicated on the maximum dose rate of the system  
22 and not on the total dose planned to be delivered to the  
23 patient during the treatment. And the competencies  
24 needed here in order to manage this kind of incident,  
25 again I repeat from the previous slide, technical

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 radiation safety, for instance the competencies of a  
2 radiation therapist.

3 If we now use this principle, as I called  
4 it, that maximum patient risk is predicated on the  
5 maximum dose rates and we compare a number of different  
6 systems available on the market for the moment. LINAC  
7 is a generic LINAC. Cyber Knife you know is also a LINAC  
8 technology. ViewRay is a system based on cobalt.  
9 Gamma Knife is a system based on cobalt as well. And  
10 if we assume now a reaction time -- reaction time I  
11 define as the time it takes to recognize that there is  
12 an incident and the time to respond. If we assume that  
13 this reaction time now is the same for all these systems,  
14 I don't think that the exact number of seconds is  
15 important.

16 Then of course we see that the potential  
17 maximum dose delivered to the patient during this  
18 incident is of course directly proportional to the  
19 maximum dose rate. And from this point of view we see  
20 that the Leksell Gamma Knife is actually in all of the  
21 systems the safest one. And now I am talking about  
22 Leksell Gamma Knife Perfexion.

23 Okay. We receive reports continuously  
24 about things that have happened to our systems, and of  
25 course the Leksell Gamma Knife is not an exception.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 During this nine-year period I counted 2,000 customer  
2 feedback reports about Gamma Knife. Out of these 17  
3 reports were incidents where the users had to enter the  
4 treatment room to manually extract the patient and close  
5 the shielding doors. And this is the incident I'm going  
6 to use in the incident rate later on, and we call it  
7 manual un-docking. Out of these 17 reports 12 were for  
8 Perfexion. During the same nine-year period around  
9 300,000 patients were treated with the Perfexion  
10 system.

11 So we have a situation where the incident  
12 rate is 12 incidents per 300,000 treatments, which gives  
13 an incident rate of 1 per 25,000. And I'm fully aware  
14 that there are unreported events or incidents, but we  
15 can only speculate about the number of unreported  
16 incidents. And the number given by Dr. Suh in his  
17 presentation during the last meeting had a -- there was  
18 an attempt at estimating this number of unreported  
19 incidents. And that's why he reported a lower -- or a  
20 higher incident rate. Sorry. Five to ten thousand.  
21 But these are the real numbers. Two of these twelve are  
22 from U.S. here in the NRC event reporting database. And  
23 during the same period of time in U.S. around 40 to  
24 50,000 patients were treated with the Perfexion system.  
25 And again, so we end up with 1 in 20-25,000 treatments,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 which I will say is a very, very low incident rate.

2 So how is patient safety managed outside  
3 U.S.? I fully understand that this is not an argument  
4 to change anything, but at least let's have a look and  
5 see to get this perspective. We asked two very simple  
6 questions: At your site who must be present at the  
7 console for the duration of the treatment, and why? And  
8 the other question was what additional personnel must  
9 be reasonably close to the console during the  
10 treatments?

11 The answers to the first question indicate  
12 that most sites actually want to have  
13 nurse/technologist; that is, radiation therapist at the  
14 console during the treatments. Not so many sites  
15 answered that they wanted to have a radiation oncologist  
16 at the console. But if we rephrased the question so  
17 that it reads, "Do you think that a radiation oncologist  
18 can contribute or is able to contribute the maximum  
19 amount of patient safety by staying at the console," and  
20 then the answer then clearly no. The answers to  
21 question No. 2 indicate that now there is a desire to  
22 have more clinically-proficient personnel in the  
23 vicinity of the treatment area in case something  
24 happens. And I state two examples at the bottom there  
25 of answers to question No. 1 from Canada and U.K.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           So in the present licensing guidance there  
2           is a reference to this physical presence requirement,  
3           and it's very clear of course. There must be an AU and  
4           an AMP physically present, where physically present  
5           means within hearing distance of normal voice. For the  
6           other systems I've talked about there is no such thing  
7           as a physical presence requirement during LINAC  
8           treatments. There is one for ViewRay treatments, but  
9           it's much more relaxed. And the one about Gamma Knife  
10          I just mentioned.

11           If we now put this into perspective and  
12          summarize what I've just talked about, the design of the  
13          Perfexion system is, I would say, inherently safe  
14          because we can move the source out of the way from the  
15          collimators. Data on safety indicates that there is a  
16          very low incident rate, and a comparative safety  
17          analysis indicates that the Gamma Knife Perfexion  
18          system is actually one of the safest systems. And due  
19          to the clarity and the safeness of which the system is  
20          designed, it is the case that any one of the existing  
21          team can actually be trained to manage the system and  
22          to manage an incident appropriately.

23           So this is our suggestion: The first part  
24          is to have an AU and an AMP physically present during  
25          the initiation of the treatment. And now I would like

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 to say that physical presence should not mean within  
2 hearing distance of normal voice. It should actually  
3 be physically present in the treatment room or at the  
4 console. So maybe physically present needs to be  
5 qualified. Whereas when the treatment has started  
6 there should be an AU or an AMP physically present  
7 somewhere in the department. And this is very similar  
8 to the ViewRay requirements.

9 So who has the first question?

10 (Laughter)

11 CHAIRMAN THOMADSEN: Thank you very much,  
12 Dr. Kjall. Yes?

13 VICE CHAIR ALDERSON: Are you aware of the  
14 requirements for Cyber Knife? What are they, do you  
15 know?

16 DR. KJALL: There's no such thing as  
17 physical presence requirements for Cyber --

18 VICE CHAIR ALDERSON: Cyber Knife?

19 DR. KJALL: Yes.

20 VICE CHAIR ALDERSON: Thank you.

21 MEMBER COSTELLO: I apologize for asking a  
22 question you might have answered when I was out of the  
23 room, but what about the -- and I do apologize if you've  
24 already answered this question. What about Perfexion  
25 is different than other Gamma Knives where they would

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 be required to have a physical presence and Perfexion  
2 wouldn't?

3 DR. KJALL: The other Gamma Knives are out  
4 of sales, so we are only now talking about Perfexion  
5 systems.

6 MEMBER COSTELLO: Right. What I'm saying  
7 is why is a Perfexion system so different that it  
8 wouldn't require the physical presence and the other one  
9 do?

10 DR. KJALL: The other ones do as well.  
11 They are required to have --

12 (Simultaneous speaking)

13 MEMBER COSTELLO: So your proposal would  
14 basically to modify the physical presence requirements  
15 for the Perfexion?

16 DR. KJALL: Right.

17 MEMBER COSTELLO: But leave in place --

18 DR. KJALL: Yes.

19 MEMBER COSTELLO: -- the physical presence  
20 requirements --

21 DR. KJALL: For the other Gamma Knives.

22 MEMBER COSTELLO: -- for the other Gamma  
23 Knives, too.

24 DR. KJALL: Yes.

25 CHAIRMAN THOMADSEN: As a follow-up can

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 you answer his question as to why is the Perfexion  
2 different from the Gamma Knife in that context?

3 MEMBER COSTELLO: Yes. Thank you.

4 DR. KJALL: In this context it's different  
5 because you can turn the beams off. In a matter of  
6 seconds you can shield the patient from the primary  
7 radiation by moving the sources away from --

8 MEMBER COSTELLO: Thank you. You've  
9 answered my question. Thank you.

10 DR. KJALL: -- the collimators. Okay.

11 MEMBER COSTELLO: Thank you.

12 DR. KJALL: I'm sorry.

13 CHAIRMAN THOMADSEN: Thank you. Dr. Suh.

14 MEMBER SUH: So, thanks for a very  
15 comprehensive overview about Perfexion. So I've been  
16 a very long-time user of the Gamma, actually for over  
17 18 years now. I've used the Perfexion since 2007.  
18 There is no question that from the design standpoint and  
19 the safety feature standpoint there is definitely an  
20 improvement over the model B, the model C, the model 4C,  
21 which I have used.

22 Because of the changes that have occurred  
23 with the machine, I think because of the current  
24 requirements that have been required as a result of  
25 having an authorized user present during treatment the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 safety record for the Gamma Knife Perfexion is  
2 incredibly good. No one around this table would argue  
3 that the safety record isn't very good.

4 So one of my contentions is because it is  
5 so good and we make a change and all of a sudden things  
6 are not as good, have we -- is that the right -- because  
7 right now you're saying this incidence is between one  
8 to 5,000 and one to 25,000, which I would argue that's  
9 a very high bar. And right now in terms of, in my view,  
10 having an authorized user present in the console area  
11 to do a treatment, especially when you're treating  
12 benign conditions like arteriovenous malformations,  
13 acoustic neuromas, tremors, or if you miss -- and as we  
14 heard yesterday we had situations where the wrong  
15 patient was treated, the wrong site got treated, and  
16 ultimately the physician, who I believe is the  
17 authorized user, has to take responsibility.

18 So in terms of the treatment and I think in  
19 terms of the integrity you set up, any medical issues  
20 that occur during treatment, any issues that may occur  
21 with the machine, I think ultimately the authorized user  
22 is responsible. Now, you're arguing in terms of what  
23 happens in Canada, outside of the United States. As you  
24 know, it's practiced very differently outside the  
25 United States. And I would say that one is better than

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 the other, but it practices very differently and it's  
2 very much -- you're a surgery-driven versus here in the  
3 United States we really have equal balance between what  
4 medical physics does, what radiation oncologists do,  
5 what neurosurgeons do as well.

6 DR. KJALL: Yes, I understand your  
7 concern. One response is of course that the -- as I  
8 shared, the incident rate outside U.S. and in U.S. are  
9 almost identical based on the statistics here. So by  
10 relaxing the rules here moving towards the situation  
11 outside U.S. apparently the incident rate doesn't  
12 change.

13 When you mention the wrong site being  
14 treated, even wrong patient being treated and so on, I  
15 think that is something that happens much earlier in the  
16 work flow and there is an error being made during  
17 planning. And that will not be captured unless the  
18 authorized user and the AMP are there during the  
19 initiation of the treatment. And that is what we  
20 suggest. So I think the errors being made upstreams can  
21 be captured. I'm not saying they are captured, because  
22 if it's the same person selecting the trigeminal on the  
23 wrong side, then of course nothing would change even  
24 though you will sit and look at the patients for hours.

25 So, but at least set up errors, obvious

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 errors and maybe having another pair of eyes looking at  
2 the patients during set up and initiation will prevent  
3 some of these incidents.

4 CHAIRMAN THOMADSEN: We have a member of  
5 the public. Please?

6 DR. PRASAD: Yes, I'm Dr. Prasad. I'm the  
7 Medical Director of Radiation Medicine at Roswell Park,  
8 and I must say I'm a poster child for the NRC because  
9 when the rules changed from neurosurgeons to radiation  
10 oncologists being the prime driver of this technology  
11 at the console, I actually went back and trained as a  
12 radiation oncologist to keep up with the rules. So I've  
13 been doing it just like John from 1992, nearly 9,000  
14 patients, all models except the very first one. And  
15 there has been a distinct change in the Perfexion  
16 technology from the user point of view. There is a very  
17 high level of record and a very high level of ongoing  
18 supervision during delivery from an engineering  
19 standpoint, which is what this discussion --

20 I support what Per is saying. Up to the  
21 point of planning and setting a patient up there is no  
22 disagreement that the parties involved in neurosurgery,  
23 radiation oncology, medical physics, everyone has to be  
24 involved in the writing and prescribing of the written  
25 directive and positioning of the patient. And

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 hopefully at that point existing rules and  
2 double-checks and cross-checks have prevented the  
3 errors you discussed yesterday.

4 But at that point Per is right, if you have  
5 committed to treating the wrong side and none of the  
6 three in the group have picked it up, then that error  
7 will occur. And the system can't catch that. So that  
8 leaves us with the actual delivery piece, which I agree  
9 with John there's a wide variety of indications. It's  
10 one of the few technologies that crosses over from  
11 functional, like epilepsy, trigeminal, to benign  
12 conditions like benign tumors which are traditionally  
13 not radiated to actual cancer. The mix, however, has  
14 changed as you saw in the utilization curve. The number  
15 of patients with malignant tumors, especially multiple  
16 tumors, being treated has gone up.

17 And what it's done is that for that subset  
18 of patients its continued utilization and the clinical  
19 benefit which it unquestionably brings to our patients  
20 is going to ultimately get time-limited by the physical  
21 presence of a person. And the question is who has the  
22 competence to look at the console, be patient-focused  
23 and really pick up an early event like a seizure or  
24 vomiting or anything of those? And I personally feel,  
25 despite being a physician, I'm not necessarily the most

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 competent in picking that up. I think a trained nurse  
2 has a much more directed portfolio.

3 I am, despite being physically present at  
4 the console, under much more pressure in a system. And  
5 I'm being very honest. I can get paged, I can get  
6 called. That is not necessarily the case with a  
7 technician and a nurse. In my opinion if we're moving  
8 towards safety, fragmentation of responsibility is an  
9 organizational strategy that medicine doesn't adopt  
10 very quickly. And I totally support every rule coming  
11 out of this office and we've followed them to the letter.

12 I think the rules need to re-look at where  
13 the technology is at, how it's being deployed, and I  
14 think we can provide exceptional patient safety going  
15 forward in the American context with a qualified nurse  
16 and a therapist or two, if the States require it, be at  
17 the console.

18 Just to give you a clear idea, currently in  
19 my institution we have a physicist, a nurse, a radiation  
20 oncologist and a neurosurgeon, all four, at the console  
21 for every treatment we do. So we have not taken any  
22 -- we can't give you statistics on how it would change  
23 if one of us wasn't there. And I think John's point is  
24 valid that it's a great safety record. Do we want to  
25 mess with it? But I feel that the kind of patient that

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 we treat today, especially being a cancer hospital -- I  
2 think it would help. The technology would remain much  
3 more palatable.

4 To speak to Dr. Ennis' point, sometimes  
5 regulation can take choices away. And I feel that we  
6 are getting to that point where the physical presence  
7 barrier does take certain clinics out of using the Gamma  
8 Knife for what it is really designed to do, and more and  
9 more data is coming out to show that it has become a very,  
10 very -- a big step away from whole brain radiation, which  
11 is not a discussion here, but I feel we can do this safely  
12 with the right people. And my nurse has a call button  
13 right next to her for additional support and code. So  
14 if an event occurs, like anywhere else in a radiation  
15 therapy department during any procedure, she could call  
16 for help.

17 CHAIRMAN THOMADSEN: Thank you very much,  
18 Dr. Prasad. Yes, Dr. Ennis?

19 MEMBER ENNIS: Actually, I would like to be  
20 able to ask the question to the prior speaker.

21 CHAIRMAN THOMADSEN: Oh, sure. Sorry.

22 MEMBER ENNIS: So, I don't know a whole lot  
23 about the regulations for this because I'm new to the  
24 Committee, but is a neurosurgeon required to be at the  
25 console? And if not, why does he choose to stay?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   MEMBER PRASAD: So, we are an Agreement  
2 State. And we were one of the first Gamma Knives in the  
3 State and our medical physics group was advising the  
4 State in writing those regulations. And so, it was  
5 stipulated and so it has been. I think there is some  
6 flexibility. The absolute mandate is AU and AMP. The  
7 neurosurgeon is only at our institution more of our  
8 guideline. And I think the State of New York does not  
9 require at all the other centers. So that's changed  
10 back. But I was just giving you context as to how many  
11 full-time man hours we invest in keeping the procedure  
12 the way we do it.

13                   Just to echo what John said, that I think  
14 center of excellence models are a great base to look at  
15 things, but sometimes when you're deploying a  
16 technology and technology evolves, maybe a readdressing  
17 of what should be the bare minimum mandated is well worth  
18 consideration primarily to maintain acceptance and  
19 deployment of a technology that has great social value.  
20 That's my point.

21                   MEMBER ENNIS: And that's just what I was  
22 trying to get at. Doesn't the fact that the  
23 neurosurgeon chooses, even though not required, to be  
24 there belie the notion that you don't need a  
25 physician/authorized user present? I would think the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 neurosurgeon would say, oh, no, I'm not needed here.  
2 Once the treatment is going I'm going to go do my next  
3 case.

4 PARTICIPANT: They have to be there to  
5 bill.

6 PARTICIPANT: That's true.

7 DR. PRASAD: And we absolutely do feel that  
8 none of this should ever allow an escape hatch for  
9 somebody to sort of abdicate their responsibility.  
10 That is not the intent of this discussion. All I'm  
11 saying is that the intent of the ruling is to get the  
12 patient safety front and center. So I'm being more of  
13 a patient advocate from a safety point of view, how I  
14 do my job, and be -- deployment and utilization of  
15 technology is a patient advocacy issue, too. Because  
16 if we kind of end up not using it as often because it's  
17 onerous to fulfill the requirements, we are actually  
18 seeing a negative in social terms. I mean, these are  
19 expensive technologies. They take a lot of stuff to get  
20 together and put in a building. if you don't use them  
21 enough -- we don't have to over-use them, right? And  
22 using enough might be an issue, just like the brachy  
23 considerations you were raising earlier.

24 CHAIRMAN THOMADSEN: Thank you again.  
25 Dr. Mettler?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 DR. METTLER: Two questions: The first  
2 one is how long do these treatments take?

3 DR. KJALL: For a newly loaded Gamma Knife  
4 it takes maybe -- depends on the treatment itself, but  
5 between 15 minutes and up to maybe 2 hours. If the plan  
6 contains many metastases, of course you have to assign  
7 the treatment for each one of those. Dr. Suh, I think  
8 you mentioned up to two hours. Fifteen minutes up to  
9 two hours.

10 MEMBER SUH: It varies on the source  
11 strength, how big the lesion is, what you're trying to  
12 target, what you're trying to shield, but a -- I'd say  
13 a functional case like trigeminal neuralgia, depending  
14 on how hot the source is, you're probably looking at  
15 about 38 minutes, 50 minutes, something like that.

16 DR. METTLER: The second question. So if  
17 you would like to have the regulations relaxed because  
18 you can turn the beam off and the other guys can't, how  
19 does the radiation therapist being there or not being  
20 there have any -- what is the reason? I don't get that  
21 the radiation therapist is going to be able to do  
22 something different --

23 CHAIRMAN THOMADSEN: Do you mean --

24 DR. METTLER: -- because the beam is  
25 not --

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN THOMADSEN: -- radiation  
2 oncologist?

3 DR. METTLER: Sorry. Radiation  
4 oncologist.

5 CHAIRMAN THOMADSEN: Yes.

6 DR. METTLER: Yes. But I don't see that  
7 whether you can turn the beam off or not, that that makes  
8 the difference about whether the radiation oncologist  
9 needs to be there.

10 DR. KJALL: No, not that single fact, but  
11 what I wanted to share was that the system is safe from  
12 that point of view. And I also added the incident rates  
13 and the comparative safety analysis. And from these  
14 three points, or these three arguments I think they  
15 clearly show that the competence is needed at the  
16 console or well-filled by a nurse and the radiation  
17 therapist.

18 DR. METTLER: Well, I guess you're  
19 advocating that the other manufacturers don't get  
20 relaxed requirements. Just your company. And I don't  
21 see the reason for that.

22 DR. KJALL: Do you mean for instance the  
23 LINAC manufacturers? They don't have this  
24 requirement, so they don't need to be there.

25 DR. METTLER: The other people who make

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 similar machines to yours?

2 DR. KJALL: Yes. Yes, they don't have  
3 these.

4 DR. METTLER: I thought they did.

5 MEMBER COSTELLO: I think he means the  
6 other Gamma Knives.

7 DR. METTLER: Yes.

8 DR. KJALL: Oh, you mean the Gamma Knives  
9 that is now out of sales, the old -- what we call the  
10 old Gamma Knives?

11 DR. METTLER: Well, there are other  
12 manufacturers besides your company?

13 DR. KJALL: No. No.

14 DR. METTLER: Yours is the only one?

15 MEMBER ENNIS: You're talking about  
16 previous generations of the equipment versus the  
17 current generation.

18 DR. METTLER: But the question is still a  
19 good one, I think. Why not from your perspective  
20 relax regulations for all Gamma Knives? Why just for  
21 Perfexion? Because maybe the -- I don't really kind of  
22 get why it matters.

23 DR. KJALL: I think the safety record and  
24 the fact that you have -- as we talked about earlier,  
25 the fact that you have the ability to turn the beams off

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 very quickly and the design of the system makes it safer  
2 than the other systems. So in case -- older Gamma Knife  
3 is -- if there is an incident occurring on an older Gamma  
4 Knife, we have to enter the treatment room. The beams  
5 are still on.

6 DR. METTLER: But how does that reflect on  
7 whether radiation oncologists are at the console or not?  
8 It's a riskier thing to deal with, but again it has  
9 nothing to do with whether a radiation oncologist is  
10 there or not. So I don't get the connection.

11 DR. KJALL: Yes, we just have rather few  
12 old systems out, so they would be gradually replaced.  
13 So we are aiming at changing the licensing guidance for  
14 Perfexion only. There is no other sort of reason why.  
15 They will be replaced, thank God.

16 CHAIRMAN THOMADSEN: Dr. Langhorst?

17 MEMBER LANGHORST: I am hesitant to speak  
18 because I do have a license amendment in with our region  
19 to change our AU physical presence requirement for  
20 Perfexion, but I do want to clarify why talking about  
21 Perfexion and not the older units. Perfexion is  
22 licensed under 35.1000. And so the requirements of  
23 that use are in licensing guidance which is relatively  
24 easy to change. The old units are under 35.600. That  
25 would require rulemaking, and plan on about 15 to 20

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 years.

2 CHAIRMAN THOMADSEN: Thank you, Dr.  
3 Langhorst. Dr. Zanzonico?

4 MEMBER ZANZONICO: I have a question. You  
5 mentioned that outside the U.S. where the physical  
6 presence requirement is not as extreme, for lack of a  
7 better term, the error rate, as far as you can tell, is  
8 comparable to what is in the U.S.

9 DR. KJALL: Right.

10 MEMBER ZANZONICO: I don't know if these  
11 data are available or not, but is the response rate in  
12 the event of an error comparable. I've heard that the  
13 times you were referring to were basically assumed. In  
14 other words, they weren't based on measurements.

15 DR. KJALL: The 45 seconds that I --

16 MEMBER ZANZONICO: Yes. Right.

17 DR. KJALL: No, I said that doesn't really  
18 matter because it's proportional to the maximum dose  
19 rate. So it could be 15 seconds or 50 seconds.  
20 Response rate? Do you mean the --

21 (Simultaneous speaking)

22 MEMBER ZANZONICO: Well, it seems to me  
23 that the physical presence of physician/radiation  
24 oncologists as opposed to a tech plus a nurse -- I think  
25 as most people are suggesting, wouldn't improve things

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 in terms of a recognition of an event, that the radiation  
2 technologist can be adequately trained to recognize and  
3 respond to a technical event, and a nurse, as has been  
4 suggested, would perhaps even be better in recognizing  
5 a medical event. The question is it seems then is the  
6 timed response. In other words, would those  
7 individuals respond as quickly and therefore limit the  
8 potential damage from an event? And my question is are  
9 there any data on that?

10 DR. KJALL: No.

11 MEMBER ZANZONICO: Okay.

12 CHAIRMAN THOMADSEN: Okay. Thank you  
13 very much. Dr. Ennis?

14 MEMBER ENNIS: It just seems worth noting  
15 that although it may not be required in Europe -- well,  
16 I guess this is kind of similar to my previous comment.  
17 A high proportion of European patients who are being  
18 treated with a neurosurgeon or radiation oncologist  
19 present, so that high-level kind of observation is  
20 occurring in Europe, at least in the majority of cases  
21 as well. So it's not as though in Europe and U.K. it's  
22 just always a nurse and therapist treating the patient.  
23 That's not the reality there.

24 DR. KJALL: In U.K. it actually is.

25 MEMBER ENNIS: Oh, it could be in U.K., but

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 certainly it wasn't for the rest.

2 DR. KJALL: No. The most common answer  
3 was actually a radiation therapist alone, followed by  
4 a neurosurgeon alone, followed by radiation therapist  
5 and a nurse and the neurosurgeon, in that order. So a  
6 lot of sites they only have a radiation therapist and  
7 a nurse at the console.

8 MEMBER ENNIS: I mean, it was over 50  
9 percent where there was a neurosurgeon present.

10 DR. KJALL: Yes.

11 MEMBER ENNIS: So that's not most.

12 DR. KJALL: There is a wide variety of sort  
13 or constellations. And I think that it's interesting  
14 to note that the incident rate doesn't really vary that  
15 much even though the data is of course maybe not that  
16 sensitive to this. But the incident rate doesn't vary  
17 with the constellations you have at the console. So  
18 it's more important to talk about the competencies there  
19 than actually job descriptions and types. And one  
20 country even reported that when they had got rid of the  
21 radiation oncologist, patient satisfaction went  
22 through the roof.

23 MEMBER ENNIS: So, I'm going to -- so let  
24 me -- Dr. Suh, in response to that?

25 MEMBER SUH: So, I can just tell you I have

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1       been involved with several thousand cases now. I think  
2       the patients and their family members are very reassured  
3       when they know that I'm at the console. So I think the  
4       last statement that you made is probably not an  
5       appropriate statement.

6                   CHAIRMAN THOMADSEN: Ms. Weil?

7                   MEMBER WEIL: How many of the older Gamma  
8       Knives are out there in proportion to the Perfexions?

9                   DR. KJALL: Globally or here? About  
10       two-thirds are Perfexion globally.

11                   MEMBER WEIL: Yes.

12                   DR. KJALL: Eighty, ninety out of hundred  
13       and twenty something here are Perfexion.

14                   MEMBER WEIL: And what's the life span of  
15       those existing older units? Are they nearing the need  
16       the need to be replaced by Perfexion units, or will they  
17       be functional for a long period of time if they facility  
18       chose to keep them?

19                   DR. KJALL: Oh, I really don't know. I  
20       think they are -- my own interpretation, are being  
21       replaced continuously right now.

22                   MEMBER WEIL: What is - does a Perfexion  
23       cost?

24                   DR. KJALL: That is --

25                   (Laughter)

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           MEMBER WEIL: It just seems to me that it  
2 would be very advantageous to an institution who wants  
3 to use the unit more without having -- it would be an  
4 incentive to replace the unit if the requirements for  
5 people at the console were changed.

6           DR. KJALL: Yes, that would be a driving  
7 force, of course.

8           CHAIRMAN THOMADSEN: Any other comments?  
9 Hearing none, I will thank you for the presentation.

10          DR. KJALL: Thank you.

11          CHAIRMAN THOMADSEN: And that bring us to  
12 a discussion of 10 CFR Part 35 rulemaking. Mr. Danna,  
13 are you alone or is Neelam --

14          MR. DANNA: I'm alone. Well, actually no,  
15 someone's on the phone, hopefully.

16          CHAIRMAN THOMADSEN: Okay.

17          MR. DANNA: Okay. Good morning. My name  
18 is Jim Danna. I'm the Branch Chief for Rulemaking in  
19 the Office of Nuclear Material Safety and Safeguards,  
20 and this morning I will provide you an update of the  
21 status of the Part 35 medical rulemaking.

22                 Giving today's presentation will be Neelam  
23 Bhalla, who should be on the phone.

24                 Neelam, are you there?

25          MEMBER COSTELLO: Someone is there.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MS. HOLIDAY: Neelam, are you on the line?

2 MS. BHALLA: Yes, Jim, I am.

3 MR. DANNA: Because this might be  
4 confusing, I'll go through the presentation. And,  
5 Neelam, if you can hear me, if you have anything to add,  
6 you can do so at the end. And there are several others  
7 in the room that can answer questions.

8 Neelam is the project manager. She knows  
9 the ins and outs of the rulemaking. So I'll do my best.

10 Okay. As you're aware, the Part 35  
11 rulemaking amends the regulations related to the  
12 medical use of byproduct material. The NRC published  
13 a proposed rule for comment on July 21st. It was  
14 available for public comment for four months and the  
15 comment period closed on November 18th, 2014.

16 The NRC received approximately 47 comment  
17 letters. Those comment letters were parsed into  
18 several hundred individual comments. The Rulemaking  
19 Working Group is currently getting those comments into  
20 topical areas and summarizing those comments and  
21 developing responses. Now once they finish evaluating  
22 those comments, they'll then make modifications to the  
23 proposed rule, prepare the final rule package. And  
24 that will be delivered to the Commission in December of  
25 this year.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           What we wanted to do is just summarize who  
2 we've received comments from and the nature of those  
3 comments, and this is just a summary. The staff is  
4 still in the process of evaluating the comments.

5           We did include comments from professional  
6 societies, the Organization of Agreement States, the  
7 CRCPD States, individual States, practicing  
8 physicians, medical physicists, radiation safety  
9 officers, nuclear pharmacists, as well as individual  
10 members of the public. Recently we also had an inquiry  
11 from Congressman Heck from Nevada. We arranged a call  
12 with the Congressman. He has a medical background. He  
13 had some interest in this rule on training requirements.  
14 He followed it up with a letter to the NRC, which we also  
15 included in the docket as an additional comment. We  
16 received that, I think it was last week.

17           And to summarize the comment, just key  
18 areas -- and actually maybe I'll turn to Donna-Beth or  
19 Sandy Gabriel. Could you summarize the commentaries?  
20 You could probably do a better job than I could.

21           DR. HOWE: Because we've got a new  
22 individual identified as the associate radiation safety  
23 officer we got a lot of comments on how we added them  
24 into the regulation and our requirements on them. So  
25 we got a lot of comments on the associate radiation

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 safety officer.

2 The medical event definition in permanent  
3 implant brachytherapy, that certainly is a major part  
4 of the rule, so we had a lot of comments on what we had  
5 proposed for specific requirements and also for written  
6 directives and the program to assure that  
7 administrations are in accordance with the intended  
8 written directive.

9 Agreement State compatibility from B to C  
10 was certainly a major topic, and we got comments from  
11 the Agreement States and individual States on that.  
12 And also got comments from individuals, members of the  
13 public on that.

14 We had a number of comments on the alpha and  
15 beta emitters, and we'll be working those.

16 We had comments on reporting of failed  
17 generators. And that would be the molybdenum-99m,  
18 technetium-99m and the strontium-rubidium generators.  
19 So we got comments on reporting and other issues with  
20 that.

21 And we got a lot of positive comments on the  
22 attestation requirements for board-certified  
23 individuals, both the new people coming in as  
24 board-certified and the grandfathered board-certified  
25 individuals.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MR. DANNA: Okay. Thanks, Donna-Beth.  
2 As I said earlier, the working group is in the process  
3 of evaluating those comments, summarizing them and  
4 developing responses. The working group will then make  
5 any modifications as appropriate from the proposed  
6 rule. I believe Neelam scheduled calls for having a  
7 revised rule package sometime in the May or June time  
8 frame, and I believe at that time the Committee will  
9 receive a copy of the proposed [final] rule for comment  
10 as they did the -- a copy of the final rule for comment  
11 as you did the proposed rule. And it's due to the  
12 Commission with a summary of those comments in December.

13 Any questions?

14 CHAIRMAN THOMADSEN: Thank you very much.  
15 Dr. Zanzonico?

16 MEMBER ZANZONICO: I'd just like to point  
17 out the ACMUI had submitted a detailed report on the  
18 proposed rulemaking. The ACMUI isn't listed among the  
19 commenters.

20 MR. DANNA: Yes, you're right. That's a  
21 good point.

22 MEMBER ZANZONICO: I presume --  
23 (Simultaneous speaking)

24 MR. DANNA: Yes, you're right. Yes, we  
25 need to include those in the comments. But, yes, those

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 are being included along with the other comments.  
2 Thank you.

3 CHAIRMAN THOMADSEN: Thank you. Any  
4 other comments or questions?

5 (No response)

6 CHAIRMAN THOMADSEN: In that case thank  
7 you very much.

8 MR. DANNA: Okay. Great. Thank you.

9 CHAIRMAN THOMADSEN: Ms. Holiday? Our  
10 next topic is our reporting structure.

11 MS. HOLIDAY: I didn't bring my tent. I  
12 hope you guys know who I am by now.

13 (Laughter)

14 MS. HOLIDAY: So today I'm here to talk to  
15 you about our annual reporting structure. So of course  
16 I'm going to talk about what the current reporting  
17 structure is, talk about the annual review that the  
18 Committee requested that I make, discuss our meetings  
19 in terms of how often the Committee meets, and then open  
20 it up for discussion. Thank you.

21 So this is a chart that should look very  
22 familiar to the Committee, or not so familiar to our new  
23 individuals, but the way that the hierarchy works is  
24 that ACMUI does not report to Sophie, although it may  
25 seem like that sometimes.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 (Laughter)

2 MS. HOLIDAY: But ACMUI does not report to  
3 Douglas. In fact, the ACMUI reports to the division  
4 director of the Division of Material Safety, State,  
5 Tribal and Rulemaking Programs. I know last time we met  
6 we had a different division name, and the names never  
7 get any better.

8 (Laughter)

9 MS. HOLIDAY: And of course we are now  
10 under the director of the Officer of Nuclear Material  
11 Safety and Safeguards, NMSS. I believe you all met  
12 Catherine Haney last time and Scott Moore. They are our  
13 director and deputy officer director. And then of  
14 course NMSS reports to the EDO, Mark Satorius. And then  
15 the EDO goes up to the channel for the Commission.

16 So our branch -- oh, yes. I'm sorry.

17 MEMBER ENNIS: I'm sorry, but EDO stands  
18 for?

19 MS. HOLIDAY: Executive Director for  
20 Operations. Yes. So he is like the voice of all the  
21 offices in NRC.

22 And so our branch, MSEB, Medical Safety and  
23 Events Assessment Branch, we are in charge of overseeing  
24 the day-to-day operations for the ACMUI. So again,  
25 that's why you probably think I am in charge of you,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 because I'm the one that is in charge of overseeing the  
2 Committee.

3 Okay. So now we're at the current  
4 reporting structure. This all came about because in  
5 January of 2011 the ACMUI held a public teleconference  
6 where they discussed the current reporting structure,  
7 which was what I just described in the previous slide,  
8 and the Committee made the recommendation unanimously  
9 to continue reporting to our division director. This  
10 was then captured in what we call a SECY paper, a paper  
11 that's sent up to the Commission where the Commission  
12 approves the Committee's recommendation to retain their  
13 current reporting structure.

14 Okay. So in the subsequent teleconference  
15 that happened a week later, January 12th of 2011, the  
16 Committee requested that we continue to review this  
17 reporting structure on an annual basis to make sure that  
18 you're still happy with my interactions with you, your  
19 interactions with our branch, with our division through  
20 the office versus going straight to the Commission  
21 because there's been a comparison between the ACMUI and  
22 ACRS, which is our Advisory Committee on Reactor  
23 Safeguards. They report to the Commission versus the  
24 ACMUI, which reports to staff.

25 So since then we have had an annual review

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 in September of 2012, September 2013, and in May of 2014.  
2 And so I brought this up here so I could quote something.  
3 At the May 2014 ACMUI meeting Dr. Zanzonico presented  
4 the ACMUI Bylaw Subcommittee report. And one of the  
5 tasks that the ACMUI was charged with was reviewing your  
6 reporting structure and informing staff if they  
7 preferred continuing this reporting structure and if  
8 they wanted to change the frequency of meetings, so on  
9 and so forth.

10 So I thought that it was befitting for me  
11 to quote something directly out of that report, in which  
12 it says, "The working relationship between the NRC and  
13 the ACMUI remains excellent. The reporting structure  
14 through NRC staff continues to function effectively and  
15 the associated logistical overhead associated with  
16 direct reporting to the Commission; e.g., the need for  
17 more frequent meetings, did not and does not now justify  
18 any change in the ACMUI's reporting structure. This  
19 recommendation is predicated on the annual Commission  
20 briefing by the ACMUI and the annual review of its  
21 reporting structure remaining in place." And that  
22 report of course was endorsed by the Full Committee.

23 So then that brings me to the frequency of  
24 our meetings. As you all know, we meet here at NRC  
25 headquarters in this room twice a year, once for the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 spring and once in the fall. Previously our spring  
2 meetings were April-May, but we've moved them to  
3 March-April. And our fall meetings are between  
4 September and October. Then we have public  
5 teleconferences on an as-needed basis, which I will  
6 cover at our administrative closing because it looks  
7 like we have quite a busy summer this year.

8 Okay. So now that brings me to our  
9 discussion portion. This is my time to ask you are you  
10 still satisfied with our current reporting structure or  
11 do you want to report directly to the Commission? Do  
12 you agree with the frequency of these meetings? Is two  
13 in-person meetings enough or should there be three or  
14 should there be four? What other changes do you want?  
15 Thank you.

16 CHAIRMAN THOMADSEN: Comments from the  
17 Committee? Dr. Zanzonico?

18 MEMBER ZANZONICO: Having been involved  
19 with the Bylaws Committee and --

20 CHAIRMAN THOMADSEN: I'm sorry.

21 MEMBER ZANZONICO: I said having been  
22 involved with the Bylaws Committee and generating the  
23 verbiage that Sophie just quoted, I don't feel that  
24 there's been any change, at least personally, in my  
25 perception of how the Committee, the ACMUI is

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 functioning and so forth. So I don't see any compelling  
2 or really any need to change or reporting structure or  
3 frequency of meetings. I don't have the impression  
4 that there are unaddressed issues that would be better  
5 addressed or addressed at all in there were more  
6 frequent meetings. I mean, I think the teleconference  
7 mechanism is fine in addressing issues that may arise  
8 or require attention between meetings. But my point is  
9 I think the current reporting structure is perfectly  
10 adequate.

11 CHAIRMAN THOMADSEN: Dr. Alderson?

12 VICE CHAIR ALDERSON: Yes, I would agree  
13 with that comment. What I wanted to know about was  
14 where the other people that we see a lot around the  
15 tables like Sophie, you, Dr. Howe, Ashley, where do all  
16 those people belong on this chart? Are you under  
17 Material Safety?

18 MS. HOLIDAY: Under the block that says  
19 MSEB.

20 VICE CHAIR ALDERSON: MSEB?

21 MS. HOLIDAY: MSEB is the acronym for our  
22 branch. And so, Ms. Cockerham, Dr. Daibes, Ms.  
23 Abogunde, Dr. Gabriel, Dr. Howe. There are other  
24 individuals in our branch. We're all a part of that  
25 branch. And Douglas Bollock is our branch chief, who

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 is the new branch chief as Laura Dudes mentioned  
2 earlier. So he is actually now your new designated  
3 federal officer as well.

4 VICE CHAIR ALDERSON: Okay.

5 CHAIRMAN THOMADSEN: Thank you for the  
6 clarification.

7 MS. HOLIDAY: You're welcome.

8 CHAIRMAN THOMADSEN: Mr. Costello?

9 MEMBER COSTELLO: And I agree I don't think  
10 there's any change. I just do have a question based on  
11 something we discussed over lunch. Is there a  
12 provision if the ACMUI did want to communicate directly  
13 to the Commission for something that they felt was so  
14 important that they'd want to do that? Can that be  
15 done?

16 MS. HOLIDAY: Absolutely. I know you  
17 weren't here before when we discussed this, but our  
18 Commission has an open-door policy. They've always had  
19 the door open for the ACMUI Chairman or any other  
20 individuals on this Committee to come up and have a  
21 discussion with them. But since you report to staff,  
22 we just want to be made aware that you're coming. Not  
23 that you have to tell us what you're talking about. It  
24 would just be nice to know that you're in town.

25 MEMBER COSTELLO: Good neighbor policy?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MS. HOLIDAY: That's right.

2 (Laughter)

3 CHAIRMAN THOMADSEN: Ms. Cockerham, were  
4 you going to say something?

5 MS. COCKERHAM: I was just going to point  
6 out to Dr. Alderson that we're on the bottom right. I  
7 had the chart brought up. All of staff falls --

8 VICE CHAIR ALDERSON: Under MSEB?

9 MS. COCKERHAM: Yes.

10 VICE CHAIR ALDERSON: Okay. Great.  
11 Thank you.

12 CHAIRMAN THOMADSEN: Dr. Zanzonico?

13 MEMBER ZANZONICO: Just a technical  
14 suggestion.

15 MS. HOLIDAY: Sure.

16 MEMBER ZANZONICO: I think it would be  
17 helpful if there could be a secure server established,  
18 something analogous to Google Docs or some such thing  
19 as that where Committee members could deposit and access  
20 documents, working documents and so forth, rather than  
21 having to go constantly through email. It seems like  
22 we're a step behind the times in terms of remote access  
23 networks. And I know there are all kinds of security  
24 issues. We can't get Internet service here, so forth  
25 and so on, but I imagine that could be done.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN THOMADSEN: There is also some  
2 open record issues with that. Just as we can't on email  
3 have a discussion with the whole Committee, we would  
4 have to have particular rules with --

5 (Simultaneous speaking)

6 MS. HOLIDAY: To respond to your request,  
7 do you know how every fall we have required annual  
8 trainings, and you know how onerous and burdensome those  
9 trainings can be? If we were to give you access to some  
10 internal stuff, that would open up a whole other can of  
11 worms. More training. NRC would monitor your  
12 computers, things like that, things that happen for us.

13 MEMBER ZANZONICO: So let's take that off  
14 the table.

15 (Laughter)

16 MEMBER ZANZONICO: But what about the  
17 possibility still of a server specifically for the  
18 ACMUI? In other words, a mechanism other than email for  
19 reviewing documents and so forth?

20 MS. HOLIDAY: I think the only response  
21 that I could probably make is I'll look into it and get  
22 back to you, but I wouldn't be surprised if my answer  
23 changes much differently.

24 MEMBER ZANZONICO: Okay.

25 CHAIRMAN THOMADSEN: Oh, Ms. Cockerham?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MS. COCKERHAM: This is Ashley, and  
2 Sophie's right, it opens up another can of worms  
3 specifically with regard to training. There would be  
4 multiple courses that would be required and also the  
5 computer monitoring. Anything that we provide would  
6 have to be on the NRC servers and therefore you would  
7 be subject to all of the requirements that we deal with  
8 internally with documents.

9 MEMBER ZANZONICO: But we all come from  
10 institutions where there are HIPAA and other laws and  
11 all sorts of firewalls and so forth. I don't understand  
12 the fundamental difference why a server couldn't be  
13 firewalled from the rest of NRC's computer --

14 (Simultaneous speaking)

15 MS. COCKERHAM: We would have to look back  
16 at all of the exemption memos that we initially wrote,  
17 because we provided very specific justifications for  
18 exempting you from training. And our whole premise is  
19 that you do not have access to the NRC network. Opening  
20 up your computers to the NRC network, it presents  
21 difficulties.

22 CHAIRMAN THOMADSEN: Mr. Costello?

23 MEMBER COSTELLO: Currently I notice on  
24 the Web site we have subcommittee reports there, we have  
25 agendas there, many ACMUI documents there. I assume

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 those are all on NRC servers. Right?

2 MS. HOLIDAY: Those are publically  
3 available and captured into our Agency-wide Document  
4 -- ADAMS. It's captured in our publically-available  
5 ADAMS system.

6 MEMBER COSTELLO: Understood. But would  
7 it be possible for us to give to the NRC to put on their  
8 server something that could be password protected or  
9 something that we won't be placing there, right, but we  
10 could have access to it?

11 MS. HOLIDAY: Anything on our public Web  
12 site must be publically --

13 MEMBER COSTELLO: I'm not saying that. It  
14 doesn't have to be identical to the way that we currently  
15 do ACMUI documents. I think the ACMUI documents are on  
16 the NRC server and we have access to them. The public  
17 has access to them. Could there be other documents on  
18 the NRC server that we give to them to place on the server  
19 which could potentially then give access to and which  
20 would not be publically available?

21 MS. COCKERHAM: In that case we would be  
22 giving you access to internal NRC servers, and therefore  
23 you would be subject to --

24 MEMBER COSTELLO: Okay.

25 MS. COCKERHAM: -- all of the security

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 requirements.

2 MEMBER COSTELLO: In other words, no?

3 MS. COCKERHAM: This is something I've  
4 looked into extensively. I think for those of you that  
5 have been around, you know I'm a make-it-happen-type  
6 person. And I wrote numerous memos to sort of make  
7 these things happen. And this was one of those where  
8 -- like Dr. Zanzonico said, okay, never mind I take it  
9 back, to just get back into that space. It doesn't mean  
10 Sophie can't look into it again.

11 MEMBER COSTELLO: Our sister committee has  
12 access, don't they?

13 MS. COCKERHAM: It's different.

14 MEMBER COSTELLO: But they have access,  
15 the other --

16 (Simultaneous speaking)

17 MS. COCKERHAM: But they come here.

18 MEMBER COSTELLO: Okay.

19 MR. BOLLOCK: That's something we can look  
20 into like an information exchange. I mean, I know there  
21 are restrictions for what we as the NRC staff have -- we  
22 have our internal SharePoint sites and things like that.  
23 But we can look into something that would maybe be  
24 accessible to you and us for that information exchange.  
25 So that's something we can look into.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN THOMADSEN: Thank you very much.  
2 Dr. Alderson?

3 VICE CHAIR ALDERSON: Just a comment about  
4 the structure as it sits up there on the screen. And  
5 now from the questions I understand that all of the  
6 people who support us and with whom we work here are in  
7 MSEB. The diagram itself, I would submit, doesn't  
8 imply to anyone else that we communicate with one  
9 another. I mean, ACMUI is over there and MSEB is over  
10 there. It would seem like on a lot of TOs you have a  
11 little dotted line or you have other ways that show that  
12 these two groups actually work together. It's just a  
13 minor comment.

14 MS. HOLIDAY: Understood.

15 CHAIRMAN THOMADSEN: Dr. Mettler?

16 DR. METTLER: Yes, I'm not sure this is  
17 exactly in relation to what you're asking, but when I  
18 was looking into this Committee to begin with, I went  
19 on the Web pages and looked all around back for about  
20 three years. And a curious thing that I ran into was  
21 it said support for this Committee is 1.3 FTE and  
22 \$300,000. And I thought to myself that can't be. I  
23 don't know, do you guys have any input into saying,  
24 excuse me, they actually need more money than that or  
25 something? I mean --

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 (Laughter)

2 DR. METTLER: I don't know, maybe you guys  
3 could talk about it, but it just was strange.

4 CHAIRMAN THOMADSEN: There have been  
5 occasions when we've discussed things such as the  
6 additional topical meetings, and the expenses that may  
7 be incurred in order to have those occur. For the most  
8 part I think we've found that when we want to have  
9 something happen it does. I don't think we've been  
10 starved for resources.

11 DR. METTLER: No, and apparently you get  
12 the resources.

13 CHAIRMAN THOMADSEN: Yes.

14 DR. METTLER: I just don't know why it was  
15 on the site like that and --

16 CHAIRMAN THOMADSEN: No, I have not --

17 DR. METTLER: -- whether that -- if  
18 somebody decides to cut a budget somewhere, that this  
19 is an issue.

20 CHAIRMAN THOMADSEN: Yes.

21 MR. BOLLOCK: I think it's just the  
22 transparency. This is how much effort and money we put  
23 towards this committee on a yearly basis.

24 MS. COCKERHAM: Yes, FACA requires that to  
25 be a part of the information provided.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MR. BOLLOCK: Right. We have to report  
2 that information annually.

3 DR. METTLER: If that's what you're doing  
4 it with, this is the best deal the taxpayers have.

5 (Laughter)

6 MS. HOLIDAY: I will say that what you  
7 bring up is something that has been brought up by this  
8 Committee before where they felt that just Sophie in  
9 this position -- because ACMUI is not my only duties,  
10 although it course seems like it, isn't enough.

11 (Laughter)

12 MS. HOLIDAY: It's just a matter of how our  
13 budget is formulated from year to year. And the numbers  
14 that you see on the Web site, as Mr. Bollock indicated,  
15 every year we are required to submit a publically  
16 available report to GSA every year because this is a  
17 federal advisory committee. And so the numbers, the  
18 dollar signs that you see there are calculated based on  
19 what we pay for your hours of work and for your travel  
20 here and for when staff does work that's related to this  
21 Committee.

22 So some years it's higher. Like for  
23 example, when we had the rulemaking year, that was a  
24 very, very busy year. 2013 was pretty high for those  
25 reasons. But then there are other years where there

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 aren't as many pressing matters and the money for that  
2 year is just not as high because there aren't as many  
3 hours or efforts put towards certain topics. So that's  
4 where the money dollar signs come from.

5 CHAIRMAN THOMADSEN: Mr. Costello?

6 MEMBER COSTELLO: On the previous question  
7 about can we go to the Commission if we really need to,  
8 and you said yes. Anybody can go to the Commission.

9 MS. HOLIDAY: Absolutely.

10 MEMBER COSTELLO: I was thinking a little  
11 more than that. But would there be a value  
12 -- can the chart have a dotted line to the Commission  
13 to indicate that if a situation requires it,  
14 particularly a chairman could talk to them?

15 MS. HOLIDAY: So I'll be honest with you  
16 guys, this is just a chart that Sophie put together.  
17 So if there are no dotted lines or solid lines, that's  
18 because Sophie didn't --

19 (Laughter)

20 MS. HOLIDAY: So if it would please you, I  
21 can add the dotted lines.

22 (Laughter)

23 MEMBER COSTELLO: Well, it says something.  
24 It says something.

25 MS. HOLIDAY: Understood.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MEMBER COSTELLO: In a lot of places you go  
2 you'll see an RSO will be reporting -- the RSO will have  
3 access to the highest levels of the institution.

4 MS. HOLIDAY: Sure.

5 MEMBER COSTELLO: And I think that to say  
6 that we do is not a trivial matter.

7 MS. HOLIDAY: Sure.

8 MEMBER COSTELLO: Okay? Depending what  
9 the issue is.

10 CHAIRMAN THOMADSEN: Ms. Weil?

11 MEMBER WEIL: In response to that comment,  
12 I think we tried to address that in the Bylaws  
13 Subcommittee by changing some of the wording in our  
14 reporting relationship. It originally said we report  
15 to staff, and we changed it to say we report to the  
16 Commission through staff --

17 MS. HOLIDAY: Through staff.

18 MEMBER WEIL: -- or something similar.

19 MS. HOLIDAY: Yes.

20 MEMBER WEIL: So it's there.

21 CHAIRMAN THOMADSEN: Mr. Mattmuller?

22 MEMBER MATTMULLER: A question, a comment,  
23 and a question. Can we turn off the public record for  
24 a while?

25 (Laughter)

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MEMBER MATTMULLER: Sophie, it's okay if  
2 you're in charge. We're happy with that.

3 (Laughter)

4 MEMBER MATTMULLER: But my real question  
5 is this is my sixth-and-a-half year on the Committee and  
6 we're now on our fourth director of MSTR. And is that  
7 typical for NRC positions, or are we that challenging  
8 for a director?

9 (Laughter)

10 MS. HOLIDAY: Oh, no.

11 MS. HENDERSON: No, no, it has nothing to  
12 do with ACMUI.

13 (Laughter)

14 MS. HENDERSON: And it has been a little  
15 unusual. Hopefully it will settle down.

16 MEMBER MATTMULLER: Settle down. Because  
17 my concern would be with that rapid turnover that that  
18 might dilute or interfere with the continuity of our  
19 message to the Commissioners. So I wish you a long  
20 tenure, Doug.

21 MS. HENDERSON: Thank you. So do I.

22 MS. HOLIDAY: I would like to add that  
23 -- I know we said this at the last meeting when we changed  
24 from FSME to NMSS that our new office director; not so  
25 new anymore, and deputy office director originally came

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 from Materials. So they know medical. And your new,  
2 soon-to-be division director was a medical physicist.  
3 So I would think that that's major progress in what this  
4 Committee would like to see happen.

5 CHAIRMAN THOMADSEN: Any other comments of  
6 questions from the Committee?

7 (No response)

8 CHAIRMAN THOMADSEN: I think we're set.  
9 Which brings us to the open forum again. Just as we  
10 opened, we'll close with that. And I'll ask the  
11 Committee do you have comments, items you would like to  
12 consider? Mr. Costello?

13 MEMBER COSTELLO: Can I raise a logistical  
14 issue rather than medical topic of interest?

15 CHAIRMAN THOMADSEN: Yes.

16 MEMBER COSTELLO: This is purely  
17 logistical. I think it may still be snowing out there  
18 and I have a long drive back. Could we shorten our lunch  
19 a little bit?

20 CHAIRMAN THOMADSEN: Yes, that would be  
21 fine. If we can get through -- why don't we set the time  
22 once we're done with everything and -- I see no problem  
23 with doing that. Yes, I think we'd all like to do that.

24 Other issues that are coming up? Mr.  
25 Mattmuller?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MEMBER MATTMULLER: Well, I suppose I need  
2 clarification as to what our pathway is for germanium-68  
3 and the DFP issue.

4 CHAIRMAN THOMADSEN: That's a very good  
5 question. Sophie, can you answer that?

6 MS. HOLIDAY: You want to know what options  
7 you have or what the charge is or the task for the  
8 Subcommittee going forward? Or maybe I should say  
9 that's something we can talk about outside of this piece  
10 since I'm the staff resource person for that.

11 MEMBER MATTMULLER: Okay.

12 MS. HOLIDAY: So I will be working very  
13 closely with the Subcommittee to discuss different  
14 avenues for pursuing that.

15 MEMBER COSTELLO: Can I venture a possible  
16 answer to that?

17 CHAIRMAN THOMADSEN: Yes, please.

18 MEMBER COSTELLO: It is to come up with the  
19 most expeditious how.

20 MS. HOLIDAY: Yes.

21 MEMBER COSTELLO: And I don't think the  
22 Subcommittee has to discuss anymore why this is a good  
23 idea because I don't think there are any dissenters, and  
24 the "what" and the "why" I think are clear. I think it  
25 should just simply be a logistical question using the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 NRC processes, whatever they may be, to get this done  
2 as quickly as possible.

3 CHAIRMAN THOMADSEN: Thank you. Ah, a  
4 member of the public.

5 MS. FAIROBENT: Dr. Thomadsen, we've been  
6 having some --

7 CHAIRMAN THOMADSEN: This is Lynne --

8 MS. FAIROBENT: Lynne Fairobent with AAPM.  
9 Sorry. We've been having some difficulty hearing in  
10 the back and I just wondered if I may have missed what  
11 action the Committee is thinking of taking based on the  
12 Elekta presentation. I didn't hear if there was any  
13 follow-up, if there's a Subcommittee or just sort of  
14 -- from what I could hear it seemed to be hanging. So  
15 that's my question.

16 CHAIRMAN THOMADSEN: And I think that  
17 that's exactly the case. There was no motion that was  
18 raised following that presentation. We may pick up the  
19 topic in the future if somebody on the Committee decides  
20 to raise that.

21 MS. FAIROBENT: Thank you.

22 CHAIRMAN THOMADSEN: You're welcome. Did  
23 somebody else have their hand up? No. Yes.

24 MEMBER LANGHORST: Go ahead.

25 CHAIRMAN THOMADSEN: Anyways, in response

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 to your question, Mr. Mattmuller, I think your  
2 subcommittee's charged -- not to belittle exactly that  
3 we've -- we have been very convinced that there is a  
4 problem that needs to be addressed. I think in the  
5 addressing of it, it probably will be useful to have a  
6 document that very clearly and concisely describes the  
7 problem and probably its origin. But, right, your  
8 subcommittee will work --

9 MEMBER MATTMULLER: Okay.

10 CHAIRMAN THOMADSEN: -- off-line would the  
11 --

12 MEMBER MATTMULLER: Okay.

13 CHAIRMAN THOMADSEN: -- NRC staff to come  
14 up with what documentation is necessary and the most  
15 expedient remedial action.

16 Yes, Dr. Langhorst. Sorry.

17 MEMBER LANGHORST: I think a question that  
18 came up that we may want to explore; this was during Mr.  
19 Costello's talk, is the compatibility B, and maybe  
20 exploring what this means, program elements with  
21 significant direct trans-boundary implications, what  
22 that means in medical practice across different states  
23 and so on. That seemed to be a question that Dr. Ennis  
24 raised.

25 CHAIRMAN THOMADSEN: Yes.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   MEMBER LANGHORST:   And I don't know if that  
2 would be worth a look at from the Committee's point of  
3 view on that.

4                   CHAIRMAN THOMADSEN:   Thank you.   Probably  
5 so.   If there are no others, I would raise an issue that  
6 became clear to me when I was involved with a discussion  
7 at the University of Wisconsin dealing with a medical  
8 event on a linear accelerator, which turned out not  
9 being a medical event, but it was clear that the  
10 definition of "medical event" contained some  
11 ambiguities that we had tended to clarify in the  
12 permanent implant cases.   And I think an issue for us  
13 to consider in the future is the definition of a medical  
14 event outside of permanent implants to clarify some  
15 ambiguities that exist in there.

16                  DR. METTLER:   What were the ambiguities  
17 specifically?

18                  CHAIRMAN THOMADSEN:   The question  
19 surrounded exactly the issues that we dealt with in  
20 permanent implants; that is, was the dose in excess to  
21 a point exactly what should be the issue under judgment?  
22 And the definitions for the medical event in Wisconsin  
23 statutes which governed the linear accelerator were I  
24 think exactly the same as in Part 35 for medical events  
25 other than permanent implants in dealing with

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 radioactive materials.

2 Which leads us to the question -- I now have  
3 an incredibly long list of items that have been raised  
4 here which all are very good and what to do with this  
5 all? I would propose that I will try to come up with  
6 some priority for addressing these issues, send it to  
7 the Committee. I don't think that this is something  
8 that we have to worry about open records since this is  
9 just our scheduling issues.

10 MEMBER MATTMULLER: There's one item I'd  
11 like to add to your list, if possible.

12 CHAIRMAN THOMADSEN: Sure.

13 MEMBER MATTMULLER: And that is with the  
14 new NorthStar technetium-99m generator system that's  
15 undergoing FDA review right now that it might be  
16 beneficial to contact the NorthStar people for them to  
17 give a presentation on how it works, because it is  
18 significantly different from a standard technetium-99m  
19 generator.

20 CHAIRMAN THOMADSEN: Thank you for  
21 alerting us to that fact.

22 MEMBER ZANZONICO: Pat Zanzonico. That  
23 actually raises an issue that since we have had industry  
24 representatives here, relative to my presentation on  
25 the cadaver issue, it's been very difficult to try and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 get from the manufacturers of -- the producers of  
2 yttrium-90 what their -- the actual radionuclide  
3 composition is. I mean, they're not anxious to  
4 publicize the radio-contaminants that may create  
5 logistical and other problems. Perhaps in terms of  
6 inviting an industry rep you might want to invite the  
7 manufacturer --

8 MS. HOLIDAY: Dr. Thomadsen?

9 CHAIRMAN THOMADSEN: Yes, Ms. Cockerham?

10 MS. HOLIDAY: That's information that  
11 staff will be able to provide to you.

12 CHAIRMAN THOMADSEN: I'm sorry.

13 MS. COCKERHAM: This is Ashley Cockerham.  
14 I can get in touch with you, Dr. Zanzonico --

15 MEMBER ZANZONICO: Okay.

16 MS. COCKERHAM: -- if we want to talk,  
17 because I have additional questions for you following  
18 your presentation.

19 MEMBER ZANZONICO: Okay.

20 CHAIRMAN THOMADSEN: Okay. Thank you.  
21 Dr. Alderson?

22 VICE CHAIR ALDERSON: I have a comment on  
23 that issue, and it's just a general concern. When we  
24 invite, and when any federal committee, but when this  
25 Committee invites industrial representatives to come to

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 speak before us, we have to think about the entire  
2 industry because we are in fact potentially giving a  
3 benefit to one particular seller of a product over the  
4 others. So the more that you open up the door to  
5 industry people coming here and talking to us, you're  
6 going to have to keep opening it wider and wider and  
7 wider or you're be accused of favoritism. So I just  
8 throw that out there as the Committee thinks about  
9 industrial reps.

10 CHAIRMAN THOMADSEN: Thank you for keeping  
11 that foremost in our minds. Oh, yes, Dr. Howe.

12 DR. HOWE: As I was giving my presentation  
13 on medical events I was realizing that in the past we've  
14 had two presentations to the ACMUI. One was the medical  
15 events and the other was the reportable events coming  
16 from medical use licensees. And that kind of dropped  
17 off the table. And I don't know whether the ACMUI would  
18 like to consider adding that back in.

19 CHAIRMAN THOMADSEN: I'm sorry, I wasn't  
20 hearing you very well at all. What have we lost?

21 DR. HOWE: You've lost the presentation  
22 that Ralph Lieto used to present, which was the  
23 reportable events from medical use licensees that were  
24 not medical events. They were more the radiation  
25 safety issues. And I don't know whether the ACMUI wants

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 to go back and add those or not.

2 CHAIRMAN THOMADSEN: I think when we added  
3 Dr. Langhorst to the Medical Event Subcommittee that she  
4 would probably be assigned to pick up on those types of  
5 issues that Mr. Lieto did.

6 MEMBER LANGHORST: And sorry, I've never  
7 been told that.

8 CHAIRMAN THOMADSEN: Well, we'll talk  
9 about that.

10 (Laughter)

11 MEMBER LANGHORST: Sounds great.

12 CHAIRMAN THOMADSEN: But thank you for  
13 bringing that up. And since discussion has terminated  
14 on this -- oh, do you have something else to say, Dr.  
15 Langhorst?

16 MEMBER LANGHORST: Well, I just wondered  
17 if you might share with us your list.

18 CHAIRMAN THOMADSEN: Oh, yes, I'll be  
19 happy to. Source security assessment, potential Part  
20 20, Part 35 comments, the mirrored alpha dose tracking  
21 through the National Academy's report, regulatory dose  
22 limits, radioactive cadavers, continued  
23 nanotechnologies, licensing guidances, older, and  
24 reviewing those. That's from you. Security of  
25 sources, further on the germanium/gallium situation,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 and NorthStar's technetium-99m generator,  
2 compatibility implications that we've discussed so far.  
3 And I apologize for those being just shorthand parts of  
4 my list, but they will be filled of course in what I send  
5 out.

6 MEMBER LANGHORST: Thank you.

7 CHAIRMAN THOMADSEN: All right. In that  
8 case it's time for summaries. And now we're [going to]  
9 find out if we actually did something this meeting.

10 (Laughter)

11 MS. HOLIDAY: And I will provide a hard  
12 copy to the Committee after this.

13 So the first recommendation -- or for those  
14 of you in the audience or our new members, at the end  
15 of every meeting we go over the current recommendation  
16 action chart which captures all of the items that either  
17 the Committee said that they would do, or a  
18 Subcommittee, or that they requested staff do.

19 So yesterday Dr. Langhorst committed for  
20 herself and Mr. Costello to distribute questions to the  
21 Committee regarding the proper platform, their expected  
22 and necessary participants, and the feasibility in  
23 conducting this additional medical meeting. So that's  
24 an ACMUI action. Are there any questions on that one?

25 (No response)

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MS. HOLIDAY: Okay. Moving on to the  
2 second item, Dr. Thomadsen formed a subcommittee to  
3 review and evaluate the phrase "patient intervention."  
4 Members include Dr. Dilsizian as the chair, Dr.  
5 Alderson, Mr. Costello, Dr. Ennis, Dr. Suh and Ms. Laura  
6 Weil. The staff resource person is Dr. Gabriel.

7 Okay. The third item is that Dr. Thomadsen  
8 formed another subcommittee to review the existing 10  
9 CFR 35.1000 guidance for the radioactive seed  
10 localization. That was the guidance that Mr. Sheetz  
11 presented yesterday. The subcommittee was tasked with  
12 making their recommendations to revisions to that  
13 guidance. Members of that subcommittee include Dr.  
14 Ennis as the chair, Dr. Alderson, Mr. Costello, Dr.  
15 Zanzonico and Dr. Mettler pending security clearance.  
16 A public teleconference will be held with the next  
17 several months. We'll do that planning after I get  
18 through this list. And your staff resource person will  
19 be myself as I am the co-chair for the NRC Agreement  
20 State Working Group that's been put together for this.

21 The next item is that because we've had  
22 members that rotate off the Committee and we have new  
23 members now this is simply to state that we have added  
24 Dr. Ennis, Dr. O'Hara and Dr. Zanzonico to the Standing  
25 Medical Events Subcommittee. So for the full

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 membership -- and I wasn't sure if we wanted to make Dr.  
2 Ennis the chair of that subcommittee. I was just  
3 thinking that Dr. Welsh was the chair last time, so  
4 that's a call for you, Dr. Thomadsen.

5 CHAIRMAN THOMADSEN: Are you comfortable  
6 with that, Dr. Ennis?

7 MEMBER ENNIS: I don't really know what's  
8 involved, so it would be hard to speak to that.

9 (Laughter)

10 CHAIRMAN THOMADSEN: It sounds like you  
11 don't have an objection then.

12 (Laughter)

13 MEMBER ENNIS: I learned a lot of lessons  
14 today.

15 (Laughter)

16 MS. HOLIDAY: And so the other members of  
17 that subcommittee are Dr. Langhorst, Mr. Mattmuller,  
18 Dr. O'Hara, Dr. Palestro, Dr. Suh, Dr. Thomadsen and Dr.  
19 Zanzonico. While this is 8 members out of 13, this is  
20 a subcommittee that simply reports on the previous  
21 year's fiscal year's medical events, so this doesn't  
22 violate any of the rules because there are no  
23 recommendations or actions that come out of this report.

24 Next item is that Dr. Thomadsen has tasked  
25 the existing Germanium/Gallium-68 Subcommittee with:

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 (1) estimating the number of potential gallium-68  
2 generator licensees; and (2) making a recommendation to  
3 the Full Committee on which route of action it believes  
4 NRC should pursue to address the decommissioning  
5 funding plan issue. The subcommittee should plan to  
6 hold a public teleconference again within the next  
7 several months. Just to recap, members of that  
8 subcommittee include Mr. Mattmuller as the chair, Mr.  
9 Costello, Dr. Langhorst, Dr. Palestro and Dr.  
10 Zanzonico. And again that staff resource person is  
11 myself.

12 Are there any comments or issues on that  
13 one?

14 MEMBER LANGHORST: I'm not sure that the  
15 subcommittee was going to have a public --

16 MS. HOLIDAY: I think --

17 MEMBER LANGHORST: I think it's the  
18 Committee.

19 CHAIRMAN THOMADSEN: No, the ACMUI will  
20 have --

21 MEMBER LANGHORST: Right.

22 MS. HOLIDAY: Yes. I'm sorry.

23 MEMBER LANGHORST: I thought you said the  
24 subcommittee would. And so I just wanted to clarify  
25 that.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN THOMADSEN: Right.

2 MS. HOLIDAY: Oh, yes. I'm sorry.

3 That's the ACMUI will hold a public teleconference to  
4 discuss what the --

5 MEMBER LANGHORST: The subcommittee's --

6 MS. HOLIDAY: -- subcommittee will have  
7 that --

8 MEMBER LANGHORST: Yes.

9 MS. HOLIDAY: -- report. Thank you.

10 The next is an item that Dr. Thomadsen said  
11 he would do. He will draft a letter to the Commission  
12 addressing the miswording of the intention of ACMUI's  
13 recommendation that they made for rulemaking where the  
14 intent was a compatibility category B for permanent  
15 implant brachytherapy only and not across all  
16 modalities.

17 Are there any issues or comments on that?

18 (No response)

19 MS. HOLIDAY: Thank you. I think this is  
20 the last item, is that the ACMUI recommended -- and this  
21 was during Dr. Tapp's presentation on the AO criteria  
22 -- recommended that events reportable under 10 CFR  
23 35.347, which is the embryo/fetus/nursing child  
24 category, that do not result in harm to the embryo, fetus  
25 or nursing child not be captured as AOs reported to

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 Congress.

2 Are there any comments, questions or issues  
3 on that?

4 (No response)

5 MS. HOLIDAY: Thank you. Okay. Said, if  
6 you would switch to the Word document?

7 Okay. This is the part where we have to  
8 plan for our fall meeting. I think we should do this  
9 one before we tackle the teleconferences.

10 As always, I sent out the meeting wizard to  
11 pulse the Committee on their availability. There are  
12 a couple of people that didn't respond. I'm afraid I  
13 didn't include you, Dr. Mettler. Based on this -- Said,  
14 if we could go to the October calendar? I have here  
15 October 8th and 9th highlighted in green because that  
16 was a day that all 10 persons that responded had no  
17 issues. So does still remain as the ideal date for the  
18 Committee to hold its fall meeting? October 8th and  
19 9th.

20 Dr. Mettler, Dr. Ennis, Dr. O'Hara, is this  
21 an issue with either three of you?

22 DR. METTLER: I don't think so. I don't  
23 have my schedule.

24 MS. HOLIDAY: Okay.

25 MEMBER ENNIS: I don't think so.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MS. HOLIDAY: Okay. No? Okay. I take  
2 it from no objections perhaps this should be our first  
3 choice for the fall meeting, October 8th and 9th. All  
4 the days marked after that are not available because  
5 this will be our Chairman's last meeting, and we need  
6 him to be here. So we would not want to schedule a  
7 meeting after that date.

8 Okay. So then of course we like to pick up  
9 an alternative date just in case October 8th and 9th does  
10 not work.

11 So if you would scroll back up to September  
12 for me, Said?

13 There were two sets of dates where only one  
14 person out of the 10 who responded said they weren't  
15 available for the 3rd and 4th, and then for the 10th and  
16 11th. So I guess are there any other persons who are  
17 unavailable for September 3rd and 4th? Dr. Palestro?

18 MS. COCKERHAM: This is Ashley. I would  
19 just note that that's Labor Day weekend.

20 MS. HOLIDAY: Is it?

21 MS. COCKERHAM: The 7th is Labor Day, so  
22 you're coming up on --

23 MS. HOLIDAY: Okay.

24 MS. COCKERHAM: If you're going to leave on  
25 Friday to go to something Labor Day weekend.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MS. HOLIDAY: Thank you. Okay. Then  
2 let's look at September 10th and 11th. Are there any  
3 persons outside of Mr. Mattmuller who have issues with  
4 those two dates?

5 MEMBER ZANZONICO: Well, we have our  
6 institutional Committee on Radiation meetings the  
7 second Thursday of every month, so I can miss one, not  
8 two, since I chair the meetings.

9 MS. HOLIDAY: Understood. So hearing  
10 that, the only person other than Mr. Mattmuller is Dr.  
11 Zanzonico. It looks like we have two people who have  
12 issues with both sets of dates, so it's really a toss  
13 of do you want your backup date to be the two days before  
14 Labor Day weekend or would you prefer that they be  
15 September 10th and 11th? And 9 times out of 10 we never  
16 even go to our backup date, just to throw that out there.

17 CHAIRMAN THOMADSEN: I would suggest the  
18 10 and 11.

19 MS. HOLIDAY: Ten and eleven? So I have  
20 our first choice for the fall 2015 meeting to occur here  
21 in 2 White Flint North, Room 2B3 to be October 8th and  
22 9th with a backup date of September 10th and 11th. Is  
23 that amenable to the Committee?

24 (No response)

25 MS. HOLIDAY: Thank you. Okay. So we

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 have quite a bit of topics for discussion during the time  
2 frame before the next fall meeting, so I pulled up  
3 between June and August.

4 Said, if you would scroll down to June?

5 I would like to note that we have several  
6 topics to discuss, one being the Germanium/Gallium-68  
7 Subcommittee report. The Working Group for the  
8 Radioactive seed Localization. And also there was a  
9 request made Spectrum Pharmaceuticals to make a  
10 presentation to the Committee on the training and  
11 experience for alpha and beta emitters.

12 I was thinking that, for our new members,  
13 our public teleconferences are usually between two and  
14 three hours apiece, so we like to conduct those using  
15 GoToMeeting or GoToWebinar so you're able to see the  
16 slides in real time on the screen. But you do not have  
17 to physically leave your office, so it makes it a little  
18 bit more convenient for members to participate.

19 So I was looking at the month of June, and  
20 these are the only days that I have marked off. So I  
21 guess my question is which month is easier? And I want  
22 the Radioactive Seed Localization subcommittee and the  
23 Spectrum Pharmaceuticals teleconference together, to  
24 have both topics together, and that would be our long  
25 teleconference for three hours. So is there a month

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 that is not good for anyone and we can just start with  
2 that?

3 MEMBER COSTELLO: July is terrible for me.

4 MS. HOLIDAY: July is terrible? I believe  
5 July is terrible for quite a lot of people.

6 MEMBER COSTELLO: Actually July is  
7 wonderful for me, but it's not good for meetings.

8 (Laughter)

9 CHAIRMAN THOMADSEN: How about between the  
10 15th or the 26th?

11 MS. HOLIDAY: Fifteenth or twenty-sixth?

12 MEMBER ZANZONICO: Also the Society of  
13 Nuclear Medicine and Molecular Imaging meeting is --

14 CHAIRMAN THOMADSEN: Is what?

15 MEMBER ZANZONICO: Is in June.

16 PARTICIPANT: It's the 5th through the  
17 10th.

18 MS. HOLIDAY: Fifth through the tenth?

19 MEMBER ZANZONICO: Yes. And, Dr. Suh, you  
20 are on travel when?

21 MEMBER SUH: Fifteenth to the  
22 twenty-sixth.

23 MS. HOLIDAY: Okay.

24 MEMBER SUH: I mean, I could try to calling  
25 from the other side of the world, but --

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MS. HOLIDAY: Okay.

2 CHAIRMAN THOMADSEN: Actually, we have  
3 GoToMeeting. It doesn't make any difference other than  
4 when you're awake.

5 MEMBER WEIL: Yes, that's the trick.

6 MS. HOLIDAY: I would also like to note as  
7 part of our bylaws discussion that we had and when we  
8 finalized the bylaws in November the Committee was very  
9 adamant on the amount of membership that should be  
10 present. Of course you know in order to have a meeting,  
11 you must meet a quorum, which means in a case by then  
12 we will have 13 members. So we would have to have at  
13 least seven members. But I believe we also need to have  
14 a quorum in order to pass a major recommendation by the  
15 Committee. So I think that means we need at least maybe  
16 nine members to make a recommendation. And to  
17 be honest, it may be that we want to discuss dates for  
18 a public teleconference off-line because these are  
19 three months that we're polling from. So what I could  
20 do is I could send out another MeetingWizard and that  
21 would be the most efficient way to go about picking dates  
22 for teleconferences, if that would be acceptable to the  
23 Chair.

24 CHAIRMAN THOMADSEN: That's very  
25 acceptable.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MS. HOLIDAY: Thank you. Okay. So I will  
2 just go on the record and say that the ACMUI will plan  
3 to hold two public teleconferences this summer, one for  
4 three hours to discuss the Radioactive Seed Working  
5 Group's report, as well as the presentation from  
6 Spectrum Pharmaceuticals. And the second public  
7 teleconference should be about an hour-and-a-half, two  
8 hours to discuss the Germanium/Gallium-68 Subcommittee  
9 report and its recommendations.

10 MEMBER LANGHORST: I would strongly  
11 recommend you schedule two hours --

12 MS. HOLIDAY: Sure.

13 MEMBER LANGHORST: -- and if you're done  
14 early, that's great.

15 CHAIRMAN THOMADSEN: Right.

16 MS. HOLIDAY: Absolutely.

17 CHAIRMAN THOMADSEN: Yes.

18 MS. HOLIDAY: Absolutely. Okay?

19 CHAIRMAN THOMADSEN: Sounds good.

20 MS. HOLIDAY: Thank you. I think that's  
21 all that we have on our side for administrative closing.  
22 As always, take your name tags off because I don't want  
23 to have to make them over. And I'm finished with my  
24 portion of the meeting.

25 CHAIRMAN THOMADSEN: We will be adjourning

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 for lunch shortly and returning for a closed working  
2 session. The question was raised before whether we can  
3 shorten lunch and get back to work more quickly. Right  
4 now we're scheduled to come back at 1:45. It's 12:15  
5 right now. I would think we should be able to get back  
6 by 1:15. Is that good by everybody?

7 VICE CHAIR ALDERSON: I have to go to my  
8 hotel down in Bethesda and check out and get back, so  
9 I don't know. I mean, it was supposed to be an  
10 hour-and-a-half and that's how I planned it.

11 CHAIRMAN THOMADSEN: That's correct. You  
12 are correct.

13 VICE CHAIR ALDERSON: Yes.

14 CHAIRMAN THOMADSEN: Why don't we try for  
15 1:30?

16 VICE CHAIR ALDERSON: That's fine. Thank  
17 you.

18 CHAIRMAN THOMADSEN: And we'll see who's  
19 here at that point. With that we will close the open  
20 meeting. Thank you all for attending.

21 (Whereupon, the above-entitled matter was  
22 adjourned at 12:15 p.m.)

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701