

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

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                                  Uses of Isotopes: Open Session

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1 UNITED STATES OF AMERICA

2 NUCLEAR REGULATORY COMMISSION

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4 ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

5 + + + + +

6 OPEN MEETING

7 + + + + +

8 THURSDAY, SEPTEMBER 22, 2011

9 The meeting was convened in the  
10 Commissioners' Hearing Room of One White Flint North,  
11 11555 Rockville Pike, Rockville, Maryland, at 1:30  
12 p.m., Leon S. Malmud, M.D., ACMUI Chairman, presiding.

13  
14 MEMBERS PRESENT:

15 LEON MALMUD, M.D., Chairman

16 BRUCE THOMADSEN, Ph.D, Vice Chair

17 MILTON GUIBERTEAU, M.D., Diagnostic Radiologist

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

19 STEVEN MATTMULLER, Nuclear Pharmacist

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

22 JOHN SUH, M.D., Radiation Oncologist

23 ORHAN SULEIMAN, M.D., FDA Representative

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

25 LAURA WEIL, Patients' Rights Advocate

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1 MEMBERS PRESENT (CONT'D):

2 JAMES WELSH, M.D., Radiation Oncologist

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

4  
5 NRC STAFF PRESENT:

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

8 CHRIS EINBERG, Designated Federal Officer

9 MICHAEL FULLER, Alternate Designated Federal  
10 Officer

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

13 NEELAM BHALLA, FSME/DILR/RB-B

14 SUSAN CHIDAKEL, OGC/GCLR/RMR

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

16 JONATHAN EVANS, FSME/DILR/RB-B

17 SOPHIE HOLIDAY, FSME/DMSSA/LISD/RMSB

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

19 VARUGHESE KURIAN, FSME/DWMEP/DURLD

20 ED LOHR, FSME/DILR/RB-B

21 ANGELA McINTOSH, FSME/DMSSA/LISD/RMSB

22 PATRICIA PELKE, R-III/DNMS/MLB

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

24 DUANE WHITE, FSME/DMSSA/RMSB

25 SHIRLEY XU, FSME/DMSSA/LISD/LB

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1 ALSO PRESENT:

2 ARMIN ANSARI, Ph.D., CDC

3 ART CHANG, CDC

4 WILLIAM DAVIDSON, UNIVERSITY OF PENNSYLVANIA

5 LYNN EVANS, Ph.D., CDC

6 LYNNE FAIROBENT, AAPM

7 ALBERT HYACINTH, CDC

8 FRANCES JENSEN, M.D. CMS/HHS

9 ROBERT JONES, Ph.D., CDC

10 JANETTE MERILL, SNM

11 THALIA MILLS, Ph.D., FDA

12 MICHAEL PETERS, ACR

13 SATISH PILLAI, Ph.D. CDC

14 MICHELLE PODGONIK, CDC

15 DAVID SAUNDERS, CDC

16 JOSEPH SHONKA, Ph.D., CDC

17 CINDY TOMLINSON, ASTRO

18 ANN WARBICK CERONE, MDS NORDION

19 ROBERT WHITCOMB, Ph.D., CDC

20 JENNA WILKES, ASNC

21 GARY E. WILLIAMS, VA NHPP

22  
23  
24  
25  
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## TABLE OF CONTENTS

1		
2	Opening Statements, J. Luehman, NRC	5
3	Old Business, S. Holiday, NRC	13
4	Methods of ACMUI and ACRS Reporting to the	
5	Commission, S. Holiday, NRC	25
6	Status of Commission Paper on Data Collection	
7	Regarding Patient Release, S. Daibes, NRC	43
8	Electronic Signatures, A. Cockerham, NRC	54
9	Comments from Member(s) of the Public	113

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

1:29PM

1  
2  
3 CHAIR MALMUD: In that case, I will  
4 introduce the next item on the agenda, which is Item  
5 7, the opening statements by Mr. Luehman.

6 MR. LUEHMAN: Before I get to that, I guess  
7 I'm going to have to turn it over to Chris as the  
8 Designated Federal Official, and he's going to go  
9 through his opening comments.

10 MR. EINBERG: Okay. Thank you, Mr. Luehman.  
11 As the Designated Federal Officer for this meeting, I  
12 am pleased to welcome you to this public meeting of  
13 the ACMUI.

14 My name is Chris Einberg. I am the Chief  
15 of the Medical Radiation Safety Team of the  
16 Radioactive Materials Safety Branch, and I have been  
17 designated as the Federal Officer for this Advisory  
18 Committee in accordance with 10 CFR Part 7.11.

19 Present today as the alternate Designated  
20 Federal Officers are Mike Fuller, who is the Team  
21 Leader for the Radiation Safety Team, and Ashley  
22 Cockerham, who is also a member of Medical Radiation  
23 Safety Team.

24 This is an announced meeting of the  
25 Committee. The meeting was announced in the September

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1 12<sup>th</sup>, 2011 edition of the Federal Register, Volume 76,  
2 page 17362.

3 The function of the Committee is to advise  
4 the Staff on issues and questions that arise on the  
5 medical use of byproduct material. The Committee  
6 provides counsel to the Staff, but does not determine  
7 or direct the actual decisions of the Staff or the  
8 Commission. The NRC solicits the views of the  
9 Committee and values their opinions.

10 I request that whenever possible we try to  
11 reach a consensus on the procedural issue that we will  
12 discuss today, but I also recognize there may be  
13 minority or dissenting opinions. If you have such  
14 opinions, please allow them to be read into the  
15 record.

16 At this point, I would like to perform a  
17 roll call of the ACMUI members participating today.  
18 Dr. Leon Malmud, ACMUI Chairman.

19 CHAIR MALMUD: Here.

20 MR. EINBERG: Dr. Bruce Thomadsen, Vice  
21 Chairman.

22 VICE CHAIR THOMADSEN: Here.

23 MR. EINBERG: Dr. Mickey Guiberteau,  
24 Diagnostic Radiologist.

25 MEMBER GUIBERTEAU: Here.

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1 MR. EINBERG: Dr. Sue Langhorst, Radiation  
2 Safety Officer.

3 MEMBER LANGHORST: Here.

4 MR. EINBERG: Mr. Steve Mattmuller, Nuclear  
5 Pharmacist.

6 MR. MATTMULLER: Here.

7 MR. EINBERG: Dr. Christopher Palestro,  
8 Nuclear Medicine Physician.

9 MEMBER PALESTRO: Here.

10 MR. EINBERG: Dr. John Suh, Radiation  
11 Oncologist.

12 MEMBER SUH: Here.

13 MR. EINBERG: Dr. Orhan Suleiman, FDA  
14 Representative.

15 DR. SULEIMAN: Here.

16 MR. EINBERG: Dr. William Van Decker,  
17 Nuclear Cardiologist.

18 MEMBER VAN DECKER: Here.

19 MR. EINBERG: Ms. Laura Weil, Patients'  
20 Rights Advocate.

21 MS. WEIL: Here.

22 MR. EINBERG: Dr. James Welsh, Radiation  
23 Oncologist.

24 MEMBER WELSH: Here.

25 MR. EINBERG: Okay. We do have a quorum,

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1 and the meeting can proceed. I now ask oh, did I miss  
2 you? I'm sorry, Dr. Zanzonico and Dr. Zanzonico is  
3 here, as well. I skipped him.

4 MEMBER ZANZONICO: Yes.

5 MR. EINBERG: Anybody else I skipped? Okay.  
6 I now ask NRC Staff members who are presently present  
7 to identify themselves.

8 MS. HOLIDAY: Sophie Holiday.

9 MR. FULLER: Mike Fuller.

10 MR. DAIBES: Said Daibes.

11 MR. EINBERG: We have Dr. Donna-Beth Howe  
12 and Gretchen Rivera-Capella, as well, and Neelam  
13 Bhalla, and Ed Lohr. Anybody else here? And Shirley  
14 Xu.

15 Additionally, a conference line has been  
16 set up to allow interested stakeholders an opportunity  
17 to provide comments during the meeting. The phone  
18 number is (888)677-8203, and the pass code is 55505#.  
19 I'll read that once again, if anybody is watching on  
20 the webcast. The phone number is (888)677-8203, and  
21 the pass code is 55505#.

22 Phone participants should use \*6 to mute  
23 the line when not in use. Individuals who wish to  
24 listen to the meeting and will not be commenting are  
25 encouraged to view the webcast on line at

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1 http://video.nrc.gov.

2 Please note that the ACMUI meeting is  
3 being held in a different room each day. Today the  
4 meeting is held in the Commissioner's Conference Room,  
5 and tomorrow, September 23<sup>rd</sup>, the meeting will be held  
6 in the Two White Flint North Building in T2B3. That's  
7 the room we normally go to.

8 Following a discussion of each agenda  
9 item, the ACMUI Chairperson, Dr. Leon Malmud, at his  
10 option may entertain comments or questions from  
11 members of the public who are participating with us  
12 today.

13 At this point, I'll turn it back over to  
14 Mr. Luehman.

15 MR. LUEHMAN: Thank you, and thank you  
16 members of the Committee. Just a few opening comments  
17 from the Staff.

18 First of all, I just want to formally tell  
19 you of some management changes that have taken place  
20 in FSME, the office to which the Committee reports. As  
21 many of you know, Dr. Charles Miller retired after a  
22 long career at the NRC, and presently his Deputy,  
23 Cynthia Carpenter, is Acting in that position while  
24 Mark Satorius, who is presently the NRC Region III  
25 Administrator is in transition to move into the

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1 position as Director of the office. So, right now  
2 Cindy is the Acting Director, and Mark will be  
3 reporting probably sometime next month to formally  
4 take over as the Office Director.

5 Earlier this morning, you also heard that  
6 from Rob Lewis that he, who is normally the Division  
7 Director, that he would be switching jobs in the  
8 Agency moving on to our Office of Nuclear Security,  
9 and he'll be replaced by Brian McDermott as the  
10 Division Director. In the interim, I am the Acting  
11 Division Director, so those are sort of the  
12 housekeeping on the NRC management changes.

13 Just a couple of other quick notes. The  
14 ACMUI, the paper on the reporting structure, we thank  
15 the Committee for their support on that, on looking at  
16 the reevaluation, potential reevaluation of the  
17 reporting structure for the Committee. That paper went  
18 to the Commission, and the Commission provided an SRM,  
19 which the Staff has responded to. And part of that was  
20 in the budget process, and that has yet to be  
21 finalized.

22 The other paper we thank the Committee for  
23 their support on is the Staff and the Committee's  
24 self-evaluation. That is in the process of making its  
25 way to you, to the Commission for their review and

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1 comment.

2 On today's schedule, the schedule for this  
3 meeting, there's a number of topics that will be  
4 covered. One of them will be an update on our status  
5 of, the Staff's status of responding to an SRM on  
6 direction from the Commission on some activities in  
7 patient release. I would emphasize that that's really  
8 going to be a status briefing. I don't think that  
9 we're going to be talking about the recommendations.  
10 It's just going to be on the status of where we are as  
11 we proceed. There will be a point where the Committee  
12 will discuss that. The Staff will discuss with the  
13 Committee its recommendations in more depth.

14 Also, we'll be hearing today about the  
15 results of the public workshops that we had that were  
16 directed by the Commission on Medical Event Reporting.  
17 Overall, we thank the Committee for their, the members  
18 that supported those meetings, the overall support of  
19 the medical community, as well as other stakeholders.

20 Mike Fuller will be talking more about  
21 those meetings later, but we thought they were very  
22 successful. And we're still evaluating and integrating  
23 all the comments that we got, as we proceed forward.

24 The other issue that we're going to, among  
25 the issues that we're going to discuss this meeting is

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1 going to be a discussion of the strontium breakthrough  
2 on certain medical generators. We've received, I would  
3 just note at this point that we have received  
4 excellent cooperation from the Food and Drug  
5 Administration, who were working closely on that  
6 issue, and from the Agreement States, a number of  
7 obvious -- at this point, most of the identified, or  
8 all of the identified problems with breakthrough  
9 occurred at, with patients that were treated at  
10 medical facilities in Agreement States, not in NRC  
11 states. So, we appreciate that cooperation.

12 Just a couple of other things. I would  
13 like to publicly thank Debbie Gilley for her service  
14 to the Committee. Ms. Gilley has, who was the  
15 Agreement State Representative, has left the  
16 Committee, and has taken an assignment with the  
17 International Atomic Energy Agency. We have posted a  
18 notice to fill the vacancy for an Agreement State  
19 Representative, and that vacancy closes very soon.  
20 And then we'll hopefully have the Committee back up to  
21 full strength.

22 I also would like to publicly thank Dr.  
23 Darrell Fisher for his service to the Committee. Dr.  
24 Fisher has been replaced on the Committee by Laura  
25 Weil, and we appreciate Laura's willingness to add her

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1 voice to the Committee.

2 And I think that just about does it. The  
3 one thing that I'd ask from an administrative  
4 housekeeping standpoint is that if members, people in  
5 the audience would please sign in on the sign-in  
6 sheets, that will help us, especially if you have a  
7 role, you get up and speak, and we have your name and  
8 how to spell it, and that really helps in keeping a  
9 good record of the meeting.

10 So, with that, Dr. Malmud, thank you very  
11 much.

12 CHAIR MALMUD: Thank you, Mr. Luehman. The  
13 next item on the agenda is Item 8, Old Business. And  
14 Ms. Sophie Holiday will review the past ACMUI  
15 recommendations, and provide NRC responses. Sophie.

16 MS. HOLIDAY: Thank you, Dr. Malmud.

17 All right. If you will go in your binders  
18 to Tab 8. All right. So, starting with 2007, we have  
19 no changes, so we'll move along to 2008. Okay. Let me  
20 switch microphones.

21 Okay. Moving on to 2008, Item 5, "NRC  
22 Staff should incorporate the Subcommittee's  
23 recommendations for the Gamma Knife Elekta Perfexion  
24 in future rulemaking." This has changed. I'm sorry.  
25 I'll wait for the slides to fix themselves. Okay, is

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1 that better? All right.

2 Number 5, this has changed to a delayed  
3 status. Revisions to Subpart H for the Use of  
4 Perfexion are not included in the summer 2010  
5 rulemaking due to prioritization, so the use of the  
6 NeoVista device will continue to be regulated under 10  
7 CFR 35.1000 until Subpart F is revised.

8 Are there any questions for number 5?

9 (No response.)

10 CHAIR MALMUD: No questions.

11 MS. HOLIDAY: Okay. Moving on to Item 9,  
12 "NRC Staff should revise the AO criteria to read a  
13 medical event that results in, one: death, or two: a  
14 significant impact on patient health that would result  
15 in permanent functional damage or a significant  
16 adverse health effect that would not have been  
17 expected from the treatment regimen as determined by  
18 NRC or Agreement State designated consultant  
19 physician."

20 This is now pending. What we had on the  
21 chart was that research, the Office of Research, was  
22 planning to revise the AO criteria in 2011. This is a  
23 change from our last update, which was November 2010.  
24 And we'll actually have a presentation on the AO  
25 criteria tomorrow.

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1 Are there any questions for Item 9?

2 (No response.)

3 CHAIR MALMUD: There appear to be no  
4 questions.

5 MS. HOLIDAY: Okay. Moving on to 2009, I  
6 actually have no changes for 2009, as well. So, we can  
7 move on to 2010.

8 Okay. So, on Item 13, I know we mentioned  
9 this at the last meeting, but this is just to closeout  
10 this item. It says, "Steve Mattmuller, Dr. Bruce  
11 Thomadsen, and Dr. Susan Langhorst offered to provide  
12 support to respond to the letter dated October 20<sup>th</sup>,  
13 2010 to Chairman Jaczko from Congressman Markey  
14 regarding patient release." So, I just wanted to go  
15 ahead and mark this as closed, because NRC Staff did  
16 not request ACMUI support to respond to Congressman  
17 Markey.

18 Are there any questions on Item 13?

19 MEMBER ZANZONICO: I have a question.

20 MS. HOLIDAY: Yes?

21 MEMBER ZANZONICO: So, there is no letter,  
22 or there will not be a letter? I don't quite  
23 understand when you say it was closed because NRC  
24 Staff did not request a letter.

25 MS. COCKERHAM: The letter was, this is

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1 Ashley Cockerham. The letter was sent, and it was  
2 addressed to Chairman Jaczko, so Staff was tasked to  
3 respond, so Staff responded. And it just happened to  
4 be that we had a meeting during that time when all of  
5 this came up, and the Committee had offered their  
6 support, and the letter went out before there was a  
7 chance to organize the support and send the letter  
8 out. So, the letter, we did respond to Congressman  
9 Markey, Staff did.

10 CHAIR MALMUD: Any other questions  
11 regarding that item? If not, thank you.

12 MS. HOLIDAY: All right. Moving on to Item  
13 17. "ACMUI will provide a list of action items for NRC  
14 Staff based on the recommendations provided in the  
15 Patient Release Subcommittee report."

16 I need to know if ACMUI would still like  
17 to pursue this, or close this item out?

18 CHAIR MALMUD: I see a question. Sue?

19 MEMBER LANGHORST: This is Sue Langhorst.  
20 I'll kind of poll the Subcommittee here, but I think  
21 that we felt pretty good about the recommendations we  
22 had in our Subcommittee report. And NRC appears to be  
23 following recommendations that we have made, so I'm  
24 not sure that we have anything else to add at this  
25 point. So, I think I would be supportive of closing

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1 that one.

2 MS. HOLIDAY: Okay, so I'll close this item  
3 out.

4 CHAIR MALMUD: There are no other  
5 questions, so the item will be closed out. Thank you.

6 MS. HOLIDAY: Okay. Moving on to 2011. I  
7 didn't mark these first couple of ones, but I will go  
8 over them. For Item 1, "ACMUI endorsed the Draft  
9 Response to NRC comments as reflected in the meeting  
10 handout. ACMUI agreed if NRC believes the release  
11 criteria should be changed from a per-release criteria  
12 to an annual criteria, this change would require new  
13 rulemaking, as stated in Regulatory Issue Summary  
14 2008-07. ACMUI recommended rulemaking to clarify that  
15 the release under 10 CFR 35.75 is per release and not  
16 per year."

17 The comment is that this particular topic  
18 is not included in the current expanded Part 35  
19 rulemaking, and is not being considered for inclusion  
20 in it. Staff will have or consider ACMUI comments for  
21 future rulemaking.

22 Are there any questions for Item 1?

23 CHAIR MALMUD: I see no questions.

24 MS. HOLIDAY: All right. Moving on to Item  
25 3. "ACMUI endorsed the Draft Comments on proposed 10

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1 CFR Part 37, as reflected in the meeting handout."  
2 The comment I have about this is that Staff addressed  
3 the ACMUI comments in the Federal Register Notice  
4 which was provided to the Committee on September 6,  
5 2011.

6 Are there any questions about Item 3?

7 CHAIR MALMUD: I see no questions.

8 MS. HOLIDAY: All right. Moving on to Item  
9 5. "ACMUI recommended NRC Staff maintain the current  
10 reporting structure for the ACMUI with enhancements in  
11 communication, as described in FSME Policy and  
12 Procedure 2-5, an increased technical and  
13 administrative support staff."

14 So, just to reflect on what Jim said  
15 earlier, the NRC Staff provided this recommendation to  
16 the Commission as part of SECY-11-0049. The Commission  
17 approved Staff's recommendation for ACMUI to maintain  
18 its current reporting structure.

19 Are there any questions for Item 5?

20 CHAIR MALMUD: I see no questions.

21 MS. HOLIDAY: Okay. Moving on to Item 7.  
22 "Dr. Malmud will serve as a reviewer to screen iodine-  
23 131 cases for the ACMUI Medical Event Subcommittee."  
24 I'm moving to leave this as open, but there's no NRC  
25 action on this.

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1 Are there any questions?

2 CHAIR MALMUD: Are there any questions? I  
3 see none.

4 MS. HOLIDAY: Thank you. Moving on to Item  
5 8. "ACMUI recommended to reserve some time at the fall  
6 ACMUI meeting for public stakeholders to discuss items  
7 for the Part 35 public workshops." This item is now  
8 considered closed, and there is no NRC action as this  
9 did not pass at the last meeting.

10 Are there any questions for Item 8?

11 CHAIR MALMUD: I see no questions.

12 MS. HOLIDAY: All right. Moving on Item 9,  
13 "ACMUI recommended a three-month minimum notice for  
14 future public stakeholder workshop meetings." This was  
15 in respect to when we were trying to hold a public  
16 workshop meeting in June, and July, if I'm correct,  
17 Mike, originally. Originally, we had two workshops  
18 scheduled for June. In response, NRC moved one of  
19 those medical rulemaking workshops from June to August  
20 in response to this recommendation.

21 In the future, Staff will work hard to  
22 schedule public workshops and publish an FRN at least  
23 three months in advance of the public meeting.

24 Are there any questions on Item 9?

25 CHAIR MALMUD: Dr. Van Decker has a

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1 question.

2 MEMBER VAN DECKER: Not to steal from what  
3 will probably be questions tomorrow afternoon, but  
4 just a matter of interest, what was your turnout for  
5 the Houston meeting? Was it as large as the New York  
6 City meeting, and feedback was okay for the timing for  
7 it to happen?

8 MR. FULLER: Yes, we had a very similar  
9 turnout to the Houston workshop that we had for the  
10 New York, somewhere in the neighborhood of 80 or so  
11 participants. And we'll go over it some more tomorrow,  
12 but a very highly successful workshop.

13 CHAIR MALMUD: Thank you. There are no  
14 other questions on that item.

15 MS. HOLIDAY: Okay. Item 10, "ACMUI  
16 recommends NRC Staff hold a second public stakeholder  
17 workshop in August in order to accommodate all public  
18 stakeholders with the caveat that the ACMUI Permanent  
19 Implant Brachytherapy Subcommittee report be finalized  
20 by the fall ACMUI meeting."

21 So, just to reiterate, we did hold that  
22 second Part 35 workshop in Houston in August, and the  
23 ACMUI is currently in the process of finalizing that  
24 Permanent Implant Brachytherapy Subcommittee report.

25 Are there any questions for Item 10?

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1 CHAIR MALMUD: I see no questions.

2 MS. HOLIDAY: Okay. Moving on to Item 12.  
3 This is actually supposed to be Item 11, my  
4 apologizes. Number one, "ACMUI feels ASTRO's approach  
5 to permanent implant brachytherapy is the correct  
6 approach for patient welfare. And the ACMUI recommends  
7 that the NRC require post-implant dosimetry following  
8 brachytherapy treatment. ACMUI believes that prostate  
9 brachytherapy is a unique subset of brachytherapy and  
10 should, therefore, require a separate set of rules  
11 from non-prostate brachytherapy."

12 ACMUI's recommendation and the ASTRO  
13 position will be considered in the regulatory basis  
14 developed for the Part 35 rulemaking.

15 Are there any questions to Item 11?

16 CHAIR MALMUD: I see no questions. I stand  
17 corrected. Dr. Welsh has a question.

18 MEMBER WELSH: I have no question on the  
19 current topic, but I was wondering if I could go back  
20 to a question from an item from 2010. Specifically,  
21 Item 13 regarding the letter from Chairman Jaczko to  
22 Congressman Markey. Is that letter available to us or  
23 to the public at this point?

24 MS. COCKERHAM: It would have been sent to  
25 you. I can resend, if needed.

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1 MEMBER WELSH: Thank you.

2 CHAIR MALMUD: The question was, is the  
3 letter available? And your response was, it is?

4 MS. COCKERHAM: Yes.

5 CHAIR MALMUD: Thank you. And can that be  
6 distributed to the members of the Committee?

7 MS. COCKERHAM: It would have been  
8 previously distributed, but I can absolutely send it  
9 again.

10 CHAIR MALMUD: Thank you.

11 MS. HOLIDAY: Okay. So, moving on to Item  
12 12, the real Item 12, "ACMUI has planned to hold the  
13 fall 2011 ACMUI meeting on September 22<sup>nd</sup> through 23<sup>rd</sup>,  
14 2011. The backup dates were October 27<sup>th</sup> through the  
15 28<sup>th</sup>, or October 31<sup>st</sup> and November 1<sup>st</sup>." This item is  
16 closed as we are in session now.

17 Are there any questions to Item 12?

18 CHAIR MALMUD: I see none.

19 MS. HOLIDAY: Okay. Moving on to Item 13.  
20 "ACMUI recommends to eliminate the written attestation  
21 for board certification pathway regardless of date of  
22 certification."

23 The ACMUI's recommendation will be  
24 considered in the review of the regulatory basis that  
25 was developed for the Part 35 rulemaking. An amended

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1 regulatory basis will be developed, if needed.

2 Are there any questions to Item 13?

3 CHAIR MALMUD: I see no questions.

4 MS. HOLIDAY: Okay. Moving on to Item 14.

5 "ACMUI recommends the attestation to be revised to say  
6 has received the requisite training and experience in  
7 order to fulfill the radiation safety duties required  
8 by the licensee."

9 Again, ACMUI's recommendation will be  
10 considered in the review of the regulatory basis that  
11 was developed for the Part 35 rulemaking. An amended  
12 regulatory basis will be developed, if needed.

13 Are there any questions to Item 14?

14 CHAIR MALMUD: I see no questions.

15 MS. HOLIDAY: Okay. Moving on to Item 15,

16 "ACMUI supports the statement that residency program  
17 directors can sign attestation letters representing  
18 consensus of residency program faculties if at least  
19 one member of the faculty is an AU in the same  
20 category designated by the applicant seeking  
21 authorized status, and that AU did not disagree with  
22 the approval."

23 Same goes for this, "ACMUI's  
24 recommendation will be considered in the review of the  
25 regulatory basis that was developed for the Part 35

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1 rulemaking. An amended regulatory basis will be  
2 developed, if needed."

3 Are there any questions?

4 CHAIR MALMUD: I see no questions.

5 MS. HOLIDAY: Okay. Moving on to Item 16,  
6 "ACMUI continues to assert that the current  
7 regulations are based on a per-release limit. ACMUI  
8 does not recommend any change to the regulation, and  
9 does not recommend NRC consider this topic during the  
10 current rulemaking process, as there is no clinical  
11 advantage or advantage to members of the public for  
12 using an annual limit."

13 This topic is not included in the current  
14 expanded Part 35 rulemaking, and is not being  
15 considered for inclusion. Staff will, however,  
16 consider ACMUI comments for future rulemaking.

17 Are there any questions?

18 CHAIR MALMUD: I see no questions.

19 MS. HOLIDAY: Thank you. I'm finished with  
20 Presentation 8.

21 CHAIR MALMUD: Thank you. Are there any  
22 questions for Ms. Holiday?

23 (No response.)

24 CHAIR MALMUD: I see none. Thank you very  
25 much, Sophie.

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1 MS. HOLIDAY: All right.

2 CHAIR MALMUD: We are a bit ahead of our  
3 schedule. The next item on the agenda is the Methods  
4 of the ACMUI and ACRS reporting to the Commission.  
5 May we move ahead with that, or do you wish to stay to  
6 the agenda timing for the members of the public?

7 MS. HOLIDAY: If we could wait a few  
8 minutes, please.

9 CHAIR MALMUD: We will.

10 MS. HOLIDAY: Thank you.

11 CHAIR MALMUD: In that case, we'll take a  
12 brief break, five minutes.

13 MS. HOLIDAY: Thank you.

14 CHAIR MALMUD: Thank you.

15 (Whereupon, the proceedings went off the  
16 record at 2:00:17 p.m., and went back on the record at  
17 2:11:38 p.m.)

18 CHAIR MALMUD: The next item on the agenda  
19 is Item 9, the methods of the ACMUI and ACRS reporting  
20 to the Commission. And Sophie Holiday will handle this  
21 for us, as well. Sophie.

22 MS. HOLIDAY: Thank you, Dr. Malmud.

23 Okay. So, this is Tab 9 in your binders,  
24 "Methods of ACMUI and ACRS reporting." For those of  
25 you who don't know, ACRS is the Advisory Committee on

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1 Reactor Safeguards.

2           Okay. All right. So, here we have SRM-  
3 SECY-11-0049 dated April 28<sup>th</sup>, 2011. I mentioned this  
4 in my last presentation, but this is the SRM titled,  
5 "Advisory Committee on the Medical Uses of Isotopes  
6 Reporting Structure, Options, Analysis and Proposed  
7 Implementation Plans."

8           In this SRM, Staff Requirements  
9 Memorandum, the Commission directed Staff to consult  
10 with the ACRS Staff to determine, as appropriate, for  
11 example, ACMUI could formally document its  
12 conclusions, its recommendations and findings in a  
13 letter report to the MSSA Director in FSME with a copy  
14 to the Commission. And this SRM requires that we  
15 provide our response to the EDO by November 30, 2011.

16           So, in other words, we were told that we  
17 needed to consult with ACRS to see where our  
18 similarities and our differences were so that we can  
19 compare them and figure out the best reporting  
20 structure, and way to interact with the ACMUI in  
21 respects to our Staff.

22           So, as part of the SRM, on June 30<sup>th</sup>,  
23 myself, Ashley Cockerham, Michael Fuller, and Chris  
24 Einberg met with the ACRS Branch Chief, Cayetano  
25 Santos, or Tanny, to discuss the ACRS procedures and

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1 their best practices. During this meeting, we were  
2 able to gain a better perspective on the ACRS  
3 proceedings and their practices.

4 Okay. So here, I would like to point out  
5 two major differences. The ACRS is a Commission-level  
6 Advisory Committee, so they report directly to the  
7 Commission, as was mandated by the Atomic Energy Act  
8 of 1954.

9 The ACMUI, however, reports to the  
10 Materials Safety and State Agreements Director, who is  
11 currently Jim Luehman, but will be replaced by Brian  
12 McDermott come next month.

13 The ACMUI is an advisory committee to the  
14 Staff and, therefore, advises the Office of Federal  
15 and State Materials and Environmental Management  
16 Programs, FSME.

17 Okay. Another important difference to note  
18 is that the ACRS has 10 full committee meetings per  
19 year. They meet every month with the exception of  
20 January and August where they have their breaks off.  
21 These meetings are held at headquarters, and all  
22 members are expected to be present. These meetings are  
23 typically three days long, and during these meetings  
24 they generate letter reports which are topical area-  
25 specific. And these letter reports are then given to

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1 the EDO, but only represents the ACRS' position, not  
2 the Staff's position. As a result of these letter  
3 reports, Staff then typically receives a ticket to  
4 respond to those letter reports.

5 Also, another thing to point out is that  
6 they have 60 plus Subcommittee meetings per year, and  
7 these are the meetings that are outside of the full  
8 ACRS meetings that happen 10 times a year. And, as I  
9 said, they generate letter reports.

10 So, in comparison to ACMUI, we have two  
11 full committee meetings per year, once in the fall and  
12 once in the spring, and teleconferences are scheduled  
13 as needed. Staff understands the demanding schedules  
14 of the ACMUI members, and recognizes it is reasonable  
15 to only meet two times per year. Subcommittee meetings  
16 for the ACMUI do not take place at headquarters, and  
17 are arranged amongst the Subcommittee members.

18 The ACMUI Subcommittees meet informally  
19 and typically via teleconference on their own, as  
20 needed. ACMUI does not generate letter reports, but  
21 Subcommittee reports instead. And these Subcommittee  
22 reports are drafted during the Subcommittee meetings  
23 and discussions, and then brought to the full ACMUI  
24 Committee for comments and vote.

25 Okay. The ACRS meets with the Commission

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1 twice a year. This is a regular practice for them.  
2 There may be times when the schedule may have to be  
3 changed, but they are pretty much guaranteed a slot  
4 twice a year with the Commission.

5 The ACRS Chairman is allowed to attend  
6 periodic meetings or one-on-one meetings with the  
7 individual Commissioners. This is done in conjunction  
8 with the ACRS Executive Director's periodic meetings  
9 with the Commissioners.

10 With the ACRS, I'm sorry, with the ACMUI,  
11 we have no dedicated annual meeting with the  
12 Commission. The last ACMUI meeting with the Commission  
13 took place in 2010, but this was a combined meeting  
14 with NRC Staff and stakeholders. So, it's been over  
15 two years since the last solo ACMUI Commission  
16 meeting.

17 From time to time, the ACMUI Chairman may  
18 be invited to drop-in or have a one-on-one meeting  
19 with one or more of the Commissioners. Dr. Malmud did  
20 a drop-in with some of the Commissioners last year.  
21 ACMUI also has the ability to request a drop-in for a  
22 specific issue on an as-needed basis.

23 Okay. ACRS has consultants for specific  
24 issues. So, basically, the ACRS as a Committee chooses  
25 consultants or subject matter experts, as needed, for

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1 specific issues. In addition to this, ACRS is  
2 supported by approximately 30 dedicated NRC Staff.

3 The difference between ACMUI and ACRS is  
4 that our division, the Materials Safety and State  
5 Agreements Division hires medical consultants for  
6 specific issues, like reviewing medical events. ACMUI  
7 members may also serve as medical consultants, but  
8 ACMUI does not currently utilize consultants in the  
9 same way and manner that ACRS does.

10 And also very important to note, ACMUI is  
11 supported by approximately two staff members in FSME,  
12 Ashley and myself. And in addition to supporting  
13 ACMUI, we also have other duties to perform for our  
14 jobs under NRC's medical program.

15 All right. Enhancements. FSME Policy and  
16 Procedures P&P 2-5. On January 12<sup>th</sup>, 2011, the ACMUI  
17 recommended the FSME NRC Staff maintain the current  
18 reporting structure for the ACMUI with enhancements in  
19 communication as described in FSME P&P 2-5. The ACMUI  
20 will be given at least 60 days to complete its review  
21 and provide comments for a major policy issue that may  
22 affect medical uses of radioactive materials other  
23 than rulemaking, that the Material Safety and State  
24 Agreements Division intends to take to the Commission  
25 for review, such as a Commission Paper on a specific

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1 issue, or significant licensing or inspection guidance  
2 revision for medical use licensees. ACMUI must be  
3 given 90 days to review and provide comments for  
4 proposed and final rules that are considered major  
5 medical policy.

6 Another enhancement that we recently made  
7 was naming an additional Designated Federal Officer,  
8 DFO. So, in reviewing ACRS' Best Practices, as  
9 directed by the Commission, Staff noted that the ACRS  
10 office uses multiple DFOs to support the Committee. It  
11 has been FSME's practice to only name one DFO, Chris  
12 Einberg, and one alternate, Michael Fuller, which  
13 corresponded with the Branch Chief and the Medical  
14 Team Leader positions.

15 However, Ashley Cockerham has been added  
16 as an alternate DFO to better reflect the support that  
17 she provides to the Committee and the role that she  
18 plays in insuring that Staff and ACMUI adhere to FACA  
19 policy. Should Chris or Mike be unavailable, Ashley  
20 would be able to open and close a meeting, or conduct  
21 a meeting in absence of the ACMUI Chair or Vice Chair.

22 And our last bullet says "transmit meeting  
23 summary to Commission." At the conclusion of each  
24 ACMUI meeting, Staff could transmit a Commissioner's  
25 Assistants Note with the meeting summary as an

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1 enclosure or the Subcommittee report, if available.  
2 And this is seen as the best route of communication to  
3 the Commission in comparison to the ACRS letter  
4 reports, as those letter reports are generated at the  
5 end of every ACRS full meeting and passed on to the  
6 EDO and the Commission.

7 Okay. Do we have any questions for me?

8 CHAIR MALMUD: Thank you for an excellent  
9 summary, Sophie. We've not seen these comparable data  
10 before, and we appreciate your work, and Ashley's work  
11 in preparing that.

12 There must be some questions or comments.  
13 Yes, Dr. Zanzonico.

14 MEMBER ZANZONICO: Pat Zanzonico. I have  
15 some, one question I have is, what's the size of the  
16 membership of the ACRS?

17 MS. HOLIDAY: I'm not sure of the numbers  
18 exactly, but I believe that their Committee is  
19 substantially larger. Is it larger than ours? No.  
20 Fifteen members, I apologize. Fifteen members, so  
21 roughly the same size, but they meet here more  
22 frequently.

23 MEMBER ZANZONICO: The other question is,  
24 what exactly is the difference between a letter report  
25 and a Subcommittee report? Does that imply that every

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1 report is generated by the entire Committee?

2 MS. HOLIDAY: Yes, the letter reports are  
3 generated by the entire full Committee of the ACRS, so  
4 it's, when it's submitted, it reflects the entire  
5 Committee's position. Whereas, the Subcommittee  
6 reports are first formulated from the Subcommittee's  
7 standpoint, and then voted on and commented by the  
8 full Committee. And then after everyone provides their  
9 comments, then we incorporate those comments into the  
10 Subcommittee reports, and those are then sent up.

11 CHAIR MALMUD: Other questions or comments?  
12 Dr. Welsh.

13 MEMBER WELSH: I'm just curious given the  
14 huge responsibilities that ACRS has with 10 full  
15 Committee meetings, and 80 Subcommittee meetings per  
16 year, do they qualify, do they meet the definition of  
17 SGOs, or do they exceed the 130 days per year?

18 MS. COCKERHAM: I don't know the answer to  
19 your question.

20 MS. WEIL: Laura

21 MS. COCKERHAM: We could find out, if you  
22 would like.

23 MS. WEIL: Laura Weil. Is there a  
24 difference in the time frame when letter reports and  
25 Subcommittee reports are made public?

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1 MS. HOLIDAY: To our knowledge, there's not  
2 a difference in time of when those reports are  
3 released. It's after they are, yes, it would just be a  
4 standard process.

5 MS. COCKERHAM: I guess for the letter  
6 reports, this is Ashley. They're drafted by the  
7 Committee and sent typically to the Chairman directly.  
8 So, I guess as long as it wasn't anything classified  
9 or sensitive that it would be released to the public,  
10 just like any other public document within our agency.  
11 Once the document was finalized by the Committee, it  
12 would go into our ADAMS system, and be publicly  
13 available at that point. Our Subcommittee reports  
14 would be the same way. Once they're finalized and  
15 voted on by the Committee, they're submitted to Staff.  
16 We would process them into ADAMS, and they would be  
17 released to the public in the same way.

18 MR. EINBERG: This is Chris Einberg. Just  
19 to add to the letter reports, the letter reports were  
20 written at the Committee meetings there, and they have  
21 these marathon letter-writing sessions, so these are  
22 not pre-drafted letters. So, the Committee sits down  
23 and hashes out these letters, and sometimes even on  
24 Saturdays. So, they have these marathon sessions to  
25 write these letter reports.

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1           Since these are Committee reports, under  
2 FACA if the Committee deliberates on them, they have  
3 to be made publicly available, so the FACA rules  
4 require any deliberation on products to be made  
5 publicly available. So, I would suspect that these  
6 letter reports are made publicly available as soon as  
7 they have been finalized.

8           MS. HOLIDAY: One thing to point out is  
9 that when ACRS has their letter report writing  
10 portion, that portion is actually open to members of  
11 the public. Some of NRC Staff are present, but that's  
12 not for them to weigh in and give their opinion, but  
13 to provide assistance if they need some type of  
14 technical language assistance with writing the report.

15           CHAIR MALMUD: Thank you. Are there other  
16 questions regarding this item? Comments?

17           MR. MATTMULLER: Comment, question. Steve  
18 Mattmuller. Since we're one of two Committees that the  
19 NRC has, and I noticed on the Home Page in the  
20 organizational chart there is a spot for the ACRS.  
21 Would it be possible for a spot to be created at least  
22 on the FSME organizational chart of where we fit into  
23 this whole group? And by chance we have a picture  
24 taken today.

25           MR. EINBERG: Chris Einberg. I think that's

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1 an excellent suggestion, and we'll take that as an  
2 action item.

3 CHAIR MALMUD: Thank you. Dr. Van Decker.

4 MEMBER VAN DECKER: Two questions, if I  
5 may. I guess question number one is just to give us a  
6 sense of size. Can you give us some feel in gross  
7 terms for the size of your medical consultant program  
8 with MSSA, and the size of the consultant program  
9 that's going on with ACRS, and what you see as the  
10 need for these consultants, and what kind of expertise  
11 is being brought in? That's question one.

12 I'll ask question two, too, so you can  
13 think about that. I guess question two is, I'm getting  
14 older these days, I know because my kids are starting  
15 to go to college, and so I forget a little bit. Can  
16 you refresh my memory again on what the discussion had  
17 been about some more formal mechanism for some  
18 Committee-Commissioner interaction in the future? I  
19 think that those of us who have been around for a  
20 little bit have found occasional interaction with the  
21 Commission to be a positive factor for being able to  
22 face-to-face express a few concepts.

23 I mean, obviously, that's pressure on the  
24 Committee to be doing positive things that need a  
25 discussion, but that's obviously a piece of a vetting

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1 process. I forget what our discussion about that was,  
2 so that was question two.

3 CHAIR MALMUD: Who on NRC Staff wishes to  
4 address the question, Mike?

5 MR. FULLER: This is Mike Fuller. I'll take  
6 the first question that had to do with the medical  
7 consultant program.

8 Currently, we only have four physicians  
9 that serve as medical consultants, other than folks  
10 that serve here as well on the ACMUI. And I think if I  
11 recall, your question was what sort of services they  
12 provide, or what do they actually do?

13 When medical events, I guess when we first  
14 started this, a little bit of a short history. When  
15 we first started this program, probably 15 or so years  
16 ago, and we had a need to assess the clinical  
17 consequences or the medical consequences of any of the  
18 misadministrations, or what we now call medical  
19 events, we needed that medical expertise, obviously,  
20 because we don't have that on our staff, the clinical  
21 expertise on our staff.

22 Over the course of the years, again, this  
23 is something that's prompted by the regions. When they  
24 need, when they feel they need a medical consultant,  
25 then they will contact us, and we provide that

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1 information and sort of coordinate between the regions  
2 and the medical consultants.

3 What has sort of happened over the years  
4 is there have been a number of medical events where  
5 there's been an understanding amongst the staff in the  
6 regions that a need for a medical consultant is not  
7 necessary. They understand the situation, and so  
8 forth. So it's only those when they are not certain  
9 that they would call in a medical consultant.

10 That being said, the whole program at this  
11 point in time is being, we're beginning a review of  
12 that and see if there are ways that we can improve  
13 that program as we move forward. And, also, we do  
14 recognize at this point in time that we need  
15 additional resources, additional medical consultants.  
16 So, I hope that answered your question.

17 CHAIR MALMUD: Dr. Van Decker, did that  
18 address your question?

19 MEMBER VAN DECKER: That's adequate for my  
20 simple mind. Second part of the question I guess?  
21 Yes?

22 MR. EINBERG: This is Chris Einberg, and  
23 I'll try to take the second part of the question,  
24 which was pertaining to the interactions with the  
25 Commission, and the desire to have interactions with

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1 the Commission.

2 We have communicated the ACMUI's desire to  
3 have at least some annual interaction with the  
4 Commission. There are agenda planning sessions with  
5 SECY, which is the Office of the Commission, and we've  
6 tried to get onto the agenda planning sessions there  
7 to put a placeholder for an annual meeting with the  
8 ACMUI.

9 CHAIR MALMUD: This is Malmud. Are you  
10 telling us that you're currently requesting that there  
11 be an assured opportunity annually to have a meeting  
12 with the Commissioners?

13 MR. EINBERG: That's correct.

14 CHAIR MALMUD: Thank you. Susan.

15 MEMBER LANGHORST: Sue Langhorst. There's  
16 been a lot of great history work done in this  
17 exercise, so one thing I would suggest is that we be  
18 able to have some of that history that's been written  
19 in these documents on the ACMUI web site. I think that  
20 would be very helpful to public understanding the  
21 history of the organization. And like the ACRS, I  
22 would really like to see a history of who the members  
23 of ACMUI have been. All we have right now are current  
24 membership, but I think it would be very helpful to  
25 know who in the past has been, served on this

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1 Committee, too. And the ACRS membership goes back to  
2 1957, so I'm not saying you have to go back that far,  
3 but I think if you would use some similar models as  
4 what they have on their web site, I think that would  
5 be very helpful.

6 CHAIR MALMUD: Could that accommodation be  
7 made?

8 MS. HOLIDAY: I can't promise anything but  
9 I can look into that, because we don't necessarily  
10 have the resources as ACRS does. But we can certainly  
11 look into it.

12 MR. EINBERG: Chris Einberg. We'll look  
13 into it, and if we have the resources, I know there  
14 are some things that may have been written in the  
15 past, and we can do a search for that. And if we can  
16 polish that a little bit, we'll put something on the  
17 web site.

18 CHAIR MALMUD: Is there another question?  
19 Sue?

20 MEMBER LANGHORST: Sue Langhorst. I don't  
21 think you have to go back to 1957, but I'd just say,  
22 if at the very least you start building that history  
23 document, I think that would be very helpful to  
24 understand that. And I know you can build that from  
25 past transcripts, but it does take time. And I

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1 appreciate that, so anything you could lend to that I  
2 think would be great. Thank you.

3 CHAIR MALMUD: In addressing the request,  
4 we certainly could produce data for the last 10 or 20  
5 years without difficulty. Certainly, for the last 10  
6 years. I say that because that's almost the amount of  
7 time that I've been around here, and I can fill you  
8 in, if there are any gaps.

9 What did concern me is, again, that you  
10 raised the issue of having the Staff to do it. And  
11 that's one of the concerns that the members of the  
12 Committee have had all along. It isn't that we  
13 necessarily need to have the same status or staffing  
14 as the ACRS, but we certainly do feel that we need  
15 additional staff.

16 We've been very fortunate in having  
17 extraordinary people who have done the work of more  
18 than -- each of them have done the work of more than  
19 one person. However, we feel that the process would be  
20 more efficient if we had a little bit more staff  
21 development, developed for us than we have now. And  
22 that's the point that we made when we began this  
23 discussion about ACMUI organization in comparison to  
24 ACRS.

25 I don't think that we're equal bodies in

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1 terms of responsibilities, but we certainly do feel  
2 that handling the things that we handle could be made  
3 somewhat more efficient with additional staffing. I  
4 think I speak for the Committee in saying that. I see  
5 heads nodding affirmatively, so I'll assume that I  
6 speak for the Committee. Thank you.

7 MR. EINBERG: Dr. Malmud, Chris Einberg.  
8 We have requested additional resources in this regard.

9 CHAIR MALMUD: Yes, I know that you have.  
10 We're waiting to hear the response.

11 MR. EINBERG: At this point, it's not  
12 publicly available.

13 CHAIR MALMUD: Thank you. We will look  
14 forward eagerly to the response. And optimistically,  
15 as well.

16 Are there any other items anyone wishes to  
17 discuss with regard to the item on the agenda right  
18 now? If not, I thank you, Sophie.

19 MS. HOLIDAY: Thank you.

20 CHAIR MALMUD: And it looks as if we are  
21 due for a break. If we may, we'll be back here  
22 promptly at 3:15. Thank you.

23 (Whereupon, the proceedings went off the  
24 record at 2:37:01 p.m., and went back on the record at  
25 3:12:20 p.m.)

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1 CHAIR MALMUD: Welcome back to the second  
2 session. The first item on the agenda this afternoon  
3 will be Dr. Daibes, the status of the Commission Paper  
4 on data collection regarding patient release. Said.

5 DR. DAIBES: Well, thank you very much.  
6 First of all, thank you everybody for your time. My  
7 title, Status of Commission Paper on Patient Release.  
8 First slide.

9 Our purpose today is actually to provide  
10 ACMUI with the status of the completion of paths  
11 provided to the Staff on the SRM provided to the  
12 Commission, and that's COMGBJ-11-0003 with the title,  
13 "Data Collection Regarding Patient Release." Again,  
14 our specific purpose will be to provide that status.  
15 Second slide.

16 Let me provide you some background on what  
17 was provided to our Staff with respect to this SRM.  
18 Our first task that was provided was to evaluate  
19 whether there are gaps in the available data on doses  
20 received by members of the public from release of  
21 patients treated with medical isotopes, task number  
22 one.

23 Task number two was how the Agency could  
24 go about collecting additional data, if needed, if  
25 indeed gaps were identified. Task number three, a

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1 recommendation as an alternative option on the  
2 feasibility of revisiting the dose assessment used to  
3 support the 1997 Patient Release Rulemaking. Next  
4 slide.

5 In its role as to the SRM was actually  
6 focusing on the Staff's recommended approach on the  
7 use of expert elicitation, again, if needed. Next  
8 slide.

9 So our current status right now. Staff has  
10 completed the data gap analysis and provided this gap  
11 analysis to research, the Office of Research, we're  
12 working in very close collaboration with them.  
13 Research is developing options for addressing tasks  
14 two and three at this moment. Next slide.

15 At this moment, our next steps will be NRC  
16 concurrence on the SECY Paper, and recommendations  
17 Staff has provided. ACMUI review, which we envision  
18 here in the next month or so. And after that, to  
19 transmit those recommendations in the paper directly  
20 to the Commission. And we envisioning that happening  
21 on January 2012. Next slide. Questions?

22 CHAIR MALMUD: Are there any questions from  
23 members of the Committee? Dr. Zanzonico.

24 MEMBER ZANZONICO: Yes, thank you for that  
25 update. I have two questions.

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1 DR. DAIBES: Yes, sir.

2 MEMBER ZANZONICO: One is, is one of the  
3 possible alternatives for providing this missing or  
4 gap information extramural funding, meaning something  
5 the equivalent of research grants or contracts to  
6 either academic institutions or professional  
7 societies, or some such thing as that, or would it be  
8 strictly an intramural effort, if it's deemed needed?

9 DR. DAIBES: Well, first of all, that's a  
10 very good question, and we're not aware if that's a  
11 component right now, so I don't have that information.  
12 In the SRM, all we have right now is the SRM. It was  
13 just basically saying let's do the following tasks,  
14 and we don't have that information, if that's a  
15 component with that.

16 MEMBER ZANZONICO: And my second question,  
17 I don't know if it's appropriate at the time, or if  
18 it's outside the scope of this session, but is it  
19 possible to summarize what the gaps in pertinent  
20 knowledge are that you identified?

21 DR. DAIBES: That's another very good  
22 question. However, we, by providing that, we will  
23 compromise the paper. It's not public yet. As soon as  
24 that's public, that information will become available.

25 MR. FULLER: Dr. Zanzonico, this is Mike

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1 Fuller. One thing I might add, sort of where we are in  
2 the process. If the Commission actually directs the  
3 Staff to conduct research in this area, the Office of  
4 Research at that point in time would look and see  
5 exactly what we were directed to do. And they may have  
6 a number of options available to them.

7 They may do some or all in-house, they may  
8 contract out for some of this, in which case there may  
9 be opportunities for, like you had mentioned, academic  
10 institutions or something to participate. But all of  
11 that will have to be, will have to come after a  
12 decision is made on whether or not to go forward with  
13 this.

14 CHAIR MALMUD: Thank you. Are there other  
15 comments from members of the Committee, or NRC Staff?  
16 Dr. Welsh.

17 MEMBER WELSH: My question is to Mr.  
18 Fuller. Should the Commission direct the Staff to move  
19 in this direction, would it be possible for ACMUI  
20 involvement relatively early on so that you could get  
21 some feedback and advice as to which directions to  
22 follow in terms of any potential research?

23 MR. FULLER: Again, assuming that we have  
24 some direction to pursue research, or the Staff has  
25 that direction, I'm confident that the ACMUI at that

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1 point in time will have an opportunity to weigh in on  
2 the approach, direction, and so forth. However, it  
3 will be limited to be within the confines of what the  
4 Commission has directed the Staff to do with regards  
5 to that sort of research. So, we'll have to wait and  
6 see what we're told, and then, but this would be  
7 considered major medical policy-type of work, so we  
8 would definitely have ample opportunity for folks that  
9 are involved to make presentations to the ACMUI and  
10 get that feedback and so forth, like we normally do  
11 with all of our issues. So, again, we'll just have to  
12 wait and see what we're asked to do, or directed to  
13 do, I should say.

14 MR. EINBERG: Yes, Dr. Welsh. Chris Einberg  
15 here. Just to expand on what Mike Fuller said. We're  
16 doing the gap analysis to see if there is new gaps in  
17 the existing research. And if it is found to be that  
18 there are gaps, then when we provide this paper to the  
19 ACMUI for review, you'll have an opportunity to review  
20 the various options that Research puts forth for  
21 collecting this additional data. So, you will have an  
22 opportunity to review what's being proposed by  
23 Research, if gaps are found.

24 MR. FULLER: And that will be in the  
25 paper.

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1 MR. EINBERG: And that's anticipated to be  
2 provided to the ACMUI, as Dr. Daibes indicated, in the  
3 next month or so.

4 CHAIR MALMUD: Does that address your  
5 question?

6 MEMBER WELSH: Yes, for the most part it  
7 does. I'm very appreciative of the fact that a gap  
8 analysis is being conducted, and I look forward to the  
9 results of that analysis. As my personal opinion has  
10 been that there is a gap, but I have no evidence to  
11 support that hypothesis, so I look forward to the  
12 results of your in-depth analysis.

13 Should it prove true that there is a gap,  
14 I think you'll find no shortage of ideas from members  
15 of this Committee on how to solve this particular  
16 problem, and look forward to possibly participating,  
17 should there be a need.

18 CHAIR MALMUD: Thank you, Dr. Welsh. Are  
19 there other comments from members of the Committee or  
20 NRC Staff? If not, are there comments from members of  
21 the public present today? Excuse me, Dr. Zanzonico.

22 MEMBER ZANZONICO: Can you give us some  
23 insight -- and I know this it's not a clearly stated  
24 question, but what are the criteria, if there are any  
25 formal criteria, for deciding whether significant

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1 knowledge gaps exist or not, because two fair-minded  
2 people can look at the same set of data, or the same  
3 set of studies, and one decide that the data are  
4 convincing and compelling, and the other decide that  
5 they're not. Is there some objective set of criteria  
6 for making that decision in a regulatory context?

7 MR. EINBERG: The simple answer is no, that  
8 there is not. Basically, the approach that was taken  
9 has been a review of the literature to see if there is  
10 existing gaps in the literature. And if there is  
11 existing gaps in the literature, then they'll be  
12 culled out within the paper to the Commission.

13 CHAIR MALMUD: Did that answer your  
14 question, Dr. Zanzonico?

15 (No response.)

16 CHAIR MALMUD: I'd like to see if there are  
17 any questions from members of the public who are  
18 present today with regard to this issue?

19 (No response.)

20 CHAIR MALMUD: Are there comments from  
21 members of the public who are tuned in with us today?

22 (No response.)

23 CHAIR MALMUD: I hear no response.

24 MR. EINBERG: Can we get confirmation that  
25 the phone line is on and working from the Audio/Visual

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1 people? Okay, thank you.

2 CHAIR MALMUD: We have confirmation that  
3 the phone line is working. Is there anyone on the  
4 phone line who wishes to make comments at this point?  
5 You're invited to do so.

6 (No response.)

7 CHAIR MALMUD: Hearing no response, I will  
8 assume the answer is no.

9 We've had some communications by mail,  
10 have we not, with regard to this issue? I'm asking  
11 that question of NRC Staff. And would it be  
12 appropriate for that to be circulated to the members  
13 of the Committee and attached as a document?

14 MR. EINBERG: That's correct, Dr. Malmud.  
15 Chris Einberg here, again. We have received some  
16 comments from a member of the public, from a Mr. Peter  
17 Crane. That was circulated to the Committee in an  
18 email, as an attachment to an email. We can make that  
19 an attachment to the written transcript at your  
20 discretion, Dr. Malmud.

21 CHAIR MALMUD: Thank you. That was my goal,  
22 to make certain that the statement was entered into  
23 the Minutes, and that the document will be available  
24 for those who have not yet seen it. Thank you.

25 Are there any other items to discuss with

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1 respect to this issue? And the issue is the status of  
2 the Commission Paper on Data Collection Regarding  
3 Patient Release. Dr. Zanzonico.

4 MEMBER ZANZONICO: Just one more question.  
5 Gaps presumably have been identified, and I understand  
6 that it's premature to disclose or discuss those at  
7 the moment. But is the potential scope of work of the  
8 NRC in addressing those gaps itself restricted to  
9 further literature review? I presume the answer is no,  
10 but I just would like to clarify it, or can it involve  
11 data collection, actual measurements among real  
12 patients and other contexts, and so forth?

13 MR. EINBERG: Chris Einberg once again.  
14 The answer is yes. Research is looking at various  
15 options, in addition to literature search that has  
16 already been completed, how to go about collecting  
17 empirical data, as well. And that would be, if gaps  
18 are identified, they're looking at whether it's  
19 practical, and how much it would cost to do so. And  
20 that would be part of the, included in the paper.

21 MEMBER ZANZONICO: I don't want to belabor  
22 the point, but I do want to try to clarify what the  
23 end game may be, because in my experience, NRC and  
24 other regulators, their work product, so to speak, say  
25 at hospitals and other licensees is largely a review

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1 of records and so forth. And I wasn't aware that the  
2 NRC had the resources or the legal standing, for lack  
3 of a better term, to independently collect data,  
4 implying making measurements on patients, going into  
5 patient homes, perhaps doing surveys and a wipe test  
6 for contamination, et cetera, et cetera. So, is that  
7 kind of action within the scope of what the NRC does  
8 do on occasion?

9 MR. EINBERG: If you recall the, Chris  
10 Einberg. If you recall, the SRM indicated to look into  
11 the feasibility of collecting data, and the paper will  
12 address that.

13 CHAIR MALMUD: Sue Langhorst?

14 MEMBER LANGHORST: Yes, I had a question  
15 since we are lacking our Agreement State  
16 Representative on the Committee at this point in time,  
17 how will, will there be any Agreement State  
18 involvement in reviewing what all is being put  
19 together?

20 MR. EINBERG: Chris Einberg. The plan is  
21 to share this with the OAS Board for review.

22 CHAIR MALMUD: Thank you. So, to put this  
23 in clear language, if I may attempt to do so. If gaps  
24 are found, then there, the NRC would assist in  
25 assuming the responsibility for filling those gaps

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1 either by internal investigation, research, or by  
2 issuing contracts or that data to be collected to  
3 close the gap. Is that a fair summary?

4 MR. EINBERG: That's a fair summary.

5 CHAIR MALMUD: Thank you.

6 MR. EINBERG: Mr. Fuller here clarified, if  
7 it's not too expensive.

8 (Laughter.)

9 CHAIR MALMUD: Well, we would hope that it  
10 would not be too expensive. However, if the gap  
11 exists, we do have a responsibility to fill in the  
12 data somehow, if it's not available in the literature,  
13 so that might mean that some agency, perhaps not the  
14 NRC, but hopefully the NRC, would find some modest  
15 source of funds to do a study to fill the gap, even in  
16 these times of fiscal constraint.

17 Any other questions with regard to this  
18 agenda item? If not, we will move on to the next  
19 agenda item, which I believe can be covered because it  
20 actually is here, and this is not an item which the  
21 public would necessarily participate in. Am I correct?  
22 Because we're ahead of our agenda, that's why I'm  
23 raising the issue. So, we could move ahead of our  
24 agenda without offense to anyone? Ashley, would that  
25 be okay?

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1 MS. COCKERHAM: Yes.

2 CHAIR MALMUD: Thank you. The next topic  
3 will be electronic signatures. Ashley Cockerham will  
4 be discussing it, and she'll provide a discussion for  
5 the medical record.

6 MS. COCKERHAM: So, for the summary, we're  
7 talking about electronic signatures, and just a  
8 summary of the issue; that more and more documents are  
9 developed and stored electronically. And NRC does  
10 permit the use of electronic media to produce and  
11 store records that are inspected at the licensee's  
12 facilities. So, for example, a licensee can create a  
13 document on a computer and scan or save the document  
14 to the computer.

15 10 CFR Part 35 is silent on the topic of  
16 electronic signatures. Documents that require  
17 signatures by specific individuals can be signed  
18 electronically. For example, an authorized user or  
19 radiation safety officer, or licensee management can  
20 sign documents electronically.

21 So, to be clear, for this presentation  
22 we're not talking about documents that are submitted  
23 to NRC, we're only talking about documents that are  
24 retained at licensee's facilities under NRC  
25 regulations, so license amendments would not be

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1 applicable for this discussion. Examples of documents  
2 we are covering include written directives,  
3 calibration reports, periodic spot checks, and  
4 radiation surveys, just to name a few.

5 Digital signatures are accepted on certain  
6 documents that are submitted to NRC. A digital  
7 signature would be considered the gold standard, and  
8 it involves digital ID certificates issued by the NRC.  
9 NRC uses Verisign to establish secure, encrypted  
10 communications; however, Staff is not expecting  
11 licensees to follow the strict protocols for digital  
12 signatures for documents that are maintained at the  
13 licensee sites. So, although a digital signature could  
14 be -- so, a digital signature could be used as an  
15 acceptable form of an electronic signature, although  
16 that's not quite where we're trying to take it at this  
17 point. And here I've listed the web site that talks  
18 about NRC's digital signatures, just for reference.

19 Go the next slide. Here's a list of all of  
20 the regulations in 10 CFR Part 35. They are medical  
21 licensee record requirements. And I've listed all of  
22 them here mainly just for reference, 35.40 we see in  
23 here a lot about. That's the written directive  
24 portion. And there are many others that talk about  
25 calibration records, and spot checks, and all those

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1 sorts of things.

2 So, now I'm going to talk a little bit how  
3 written signatures function. For unique  
4 identification, it's a person's signature or name can  
5 identify them as an individual. For electronic  
6 signature, this could mean a typed name or initials,  
7 or biometrics like a thumb print. So, for example, AMC  
8 typed on a document would uniquely identify me versus  
9 SJH for Sophie.

10 For the next authentication, a person's  
11 real signature can be compared against that person's  
12 handwriting. For electronic signatures, this could  
13 mean a password or, again, biometrics like a thumb  
14 print to insure the person's signature is being added  
15 to the document by that person.

16 For the third bullet, non-repudiation,  
17 means that you cannot deny that you signed. So, again,  
18 for an electronic signature, a password or biometric  
19 identifier would insure that someone else could not  
20 sign your name, assuming you do not share your  
21 password.

22 Other considerations, data integrity  
23 assurance means that data can't be tampered with, so  
24 the document shouldn't be editable after it is signed.  
25 It should be locked. Also, the individual signing must

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1 know that he or she is signing something like a  
2 password or a checkbox, I agree to these terms and  
3 conditions. We see that on many websites, so you know  
4 you are, in fact, agreeing to what you're signing. So,  
5 merely opening or closing the document, or reviewing  
6 the document doesn't mean that the person approved it  
7 or signed it.

8 We want there to be a concise process so  
9 the same individual that initiates it concludes it.  
10 If an authorized user opens a written directive on a  
11 computer and the computer, we would want the computer  
12 to lock out or timeout so that another individual  
13 could not come along and sign that document just  
14 because the authorized user had opened it.

15 For the last one, inspection. The  
16 inspector must be able to see an electronic audit of  
17 the document, and the electronic signature process  
18 since the last inspection to insure the completeness  
19 and accuracy of the document. For example, revisions  
20 to written directives should create a new written  
21 directive, and not overwrite the original; or the  
22 inspector should be able to see where the document was  
23 revised and signed again.

24 Okay. So, the NRC solicited for public  
25 comments in a Federal Register Notice on October 20<sup>th</sup>.

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1 And in the Federal Register, NRC asked several  
2 questions which I've listed on the next six or so  
3 slides, so I'm just going to go through those  
4 questions briefly.

5 What standards for electronic signatures  
6 in medical records are in use or under development?  
7 How do these standards address the principles of  
8 authentication, non-repudiation, data integrity, and  
9 access for inspection? And do these standards consider  
10 any additional key principles? For software  
11 applications currently in use, how does the licensee  
12 assure that the signature process is uniquely tied to  
13 the individual whose signature is required? What  
14 provisions does the licensee use to inform persons  
15 electronically signing documents that they are  
16 entering their signature? How does the licensee assure  
17 that the document is being signed electronically and  
18 cannot be changed after it is signed? How does the  
19 licensee assure that subsequent changes to the  
20 document require a new electronic signature and cannot  
21 overwrite the previous versions? How does a licensee  
22 assure that the electronic signature process affixes  
23 the date and time to each electronic signature? How  
24 does a licensee assure that electronically signed  
25 documents and all revisions to the documents are

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1 accessible for inspection? How does a licensee assure  
2 that electronically signed documents and all revisions  
3 to the documents are retained for three years? Are  
4 any improvements needed for current commercially  
5 available software applications to adequately meet  
6 existing standards and principles?

7 And in response to all of those questions  
8 that I just read, we received five submissions from  
9 the public. And the first comment we received was to  
10 coordinate with other regulatory agencies and  
11 accreditation organizations for consistency and  
12 compatibility. And other regulatory agencies that were  
13 mentioned were the Department of Health and Human  
14 Services, the Centers for Medicare and Medicaid  
15 Services or CMS, the Joint Commission, and the State  
16 Board of Medicine, and also the State Board of  
17 Pharmacy.

18 There were also concerns about unnecessary  
19 burdens on health care providers. Another comment was  
20 to accept electronic signatures if the issues raised  
21 by NRC are addressed and state laws do not prohibit  
22 actions. In the context of this, these were from the  
23 Agreement States. And Agreement States also  
24 recommended that NRC poll each state to determine if  
25 laws would prohibit any of the actions.

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1 Another commenter stated that PDFs have  
2 been standard in the information technology community  
3 for over a decade with regards to electronic document  
4 standards and digital signing. They can prevent  
5 revisions or edits, can be digitally signed in  
6 conjunction with public key signer through one of  
7 Adobe's partners, which allows for complete security.  
8 And PDFs are globally accepted, and the Worldwide Web  
9 Consortium is an accepted international web standards  
10 group, also uses PDF documents.

11 We also received comments from the  
12 Department of Veterans Affairs. And they stated that  
13 the VA electronic health record system currently uses  
14 a proprietary electronic, it's not a digital, but it  
15 is an electronic system signature in nuclear medicine,  
16 as well as other applications. It does not adhere to  
17 any specific standard, and it cannot be validated  
18 outside of VA's electronic health record.

19 The VA's approach to electronic signatures  
20 is changing since they must comply with the NIST  
21 standards, which implements the Homeland Security  
22 Presidential Directive, which is HSPD-12, which is  
23 what made us get all of the same looking little  
24 badges. And use of Personal Identity Verification or  
25 PIV cards, which are the badges that we have now.

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1           So, as I mentioned in the previous slide,  
2 the VA is moving away from their own system to comply  
3 with HSPD-12, and the most recent draft of the NIST  
4 FIPS 201 was published March 8<sup>th</sup>, 2011 in response to  
5 HSPD-12. So, NIST FIPS 201 is the Federal Information  
6 Processing Standards publication. It talks about  
7 Personal Identity Verification of federal employees  
8 and contractors.

9           The goal is to achieve appropriate  
10 security assurance for multiple applications by  
11 efficiently verifying the claimed identity of  
12 individuals seeking physical access to federally-  
13 controlled government facilities and electronic access  
14 to government information systems.

15           Federal government is using Personal  
16 Identity Verification cards, or PIV cards to comply  
17 with HSPD-12, and NIST FIPS 201. The cards include the  
18 capability to digitally sign documents using federally  
19 approved Public Key Infrastructure, or PKI.

20           Currently, the VA is transitioning to  
21 electronic prescribing for all substances to PKI  
22 digital signatures. This can used outside of the VA,  
23 and can be independently verified by the recipient.  
24 This electronic signature addresses all the principles  
25 of authentication, non-repudiation, data integrity,

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1 and access for inspection.

2 So, the request to ACMUI today, NRC is  
3 seeking information for a benchmark, or for current  
4 practices for the use of electronic signatures for  
5 medical records. And NRC is seeking recommendations  
6 from the ACMUI on acceptable criteria for using  
7 electronic signatures. And here I have listed all of  
8 the acronyms that were contained in the presentation.  
9 And that concludes my presentation, if there are any  
10 questions?

11 CHAIR MALMUD: Thank you, Ashley. Are there  
12 questions for Ashley? Dr. Zanzonico.

13 MEMBER ZANZONICO: This is more of a  
14 comment than a question, but it strikes me; all of the  
15 characteristics you've identified for an acceptable  
16 electronic signature paradigm, I don't think anyone  
17 could argue with them, authentication, non-  
18 repudiation, et cetera, et cetera, but it strikes me  
19 that those criteria that we're now applying to  
20 electronic signatures are actually much more stringent  
21 in practice than are applied to traditional paper  
22 records. I mean, you can easily imagine if you have a  
23 multi-page document where someone signs the final  
24 page, one could easily have the remaining pages  
25 without the signature easily doctored. So, I guess

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1 that falls under non-authentication.

2 So, my question is, or comments, or semi-  
3 question is, how do these criteria jive, so to speak,  
4 with existing criteria, if any, for paper documents?  
5 In other words, will this impose additional or  
6 different restrictions on paper documents and  
7 signatures on such documents, or will they strictly  
8 apply just to electronic records?

9 CHAIR MALMUD: Thank you for that question,  
10 Dr. Zanzonico. Do you wish to address it, Ashley, or a  
11 member of Staff? It would seem to me as an observer  
12 that the new system would be more thorough than the  
13 old, and that that would be an advance. Transitioning  
14 from a written record to a computerized record, if you  
15 will, has been very traumatic for all of us who are  
16 old enough to have gone from the old system to the  
17 new. But once in the new system, it actually functions  
18 more smoothly and allows us to retrieve the data more  
19 rapidly. So, from my personal experience, I think the  
20 new system is better than the old. However, I'm  
21 certain that NRC would like to comment on that rather  
22 than myself.

23 MR. FULLER: Yes, this is Mike Fuller. And  
24 I think you hit one of the nails on the head, so to  
25 speak.

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1           One of the things that Staff has been  
2 struggling with on this issue is how do we envision,  
3 or how do we go about explaining to licensees what our  
4 expectations are for electronic signatures without  
5 making them much more onerous than what we currently  
6 require, or currently assume when we think about a  
7 paper-based record system? And that's why when Ashley  
8 talked about it, currently our rules do not prohibit  
9 electronic signatures. We have seen the technology,  
10 just like everyone else has in the hospitals and  
11 amongst our licensees, and folks have been doing  
12 various things.

13           The one thing that we have simply stressed  
14 to the inspectors, even though they've been really  
15 clamoring at us in headquarters for a more clear cut  
16 policy on this, is that as long as the records and the  
17 approach seems to be reasonable, then we've been  
18 accepting those things. On occasion, we get case-by-  
19 case things where people ask questions.

20           But back to your original point, we don't  
21 want to require, come up with new requirements. We  
22 don't want to go to rulemaking if we don't have to.  
23 What we would like to do is to be able to provide  
24 guidance that says, that recognizes where technology  
25 is, and where it's been since we changed the rules, or

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1 where we've come from since we changed the rules, and  
2 just explain what's reasonable, and what's acceptable.

3 And that's why we finally decided that  
4 what we'd really like to do is ask those of you who  
5 work day in and day out in the real world in the  
6 medical community, what are the current standards, and  
7 what are people doing now that we could just simply  
8 say these are the types, and if we find all that to  
9 meet our needs, then we could simply go out and  
10 communicate that these are the types of things that we  
11 are aware of, and that we find acceptable. And I'll  
12 give one example, and then I'll be quiet.

13 We had heard years ago that requiring  
14 biometrics was just way out of line, that that is just  
15 way too burdensome, expensive, so much more onerous  
16 than somebody scribbling their initials on a piece of  
17 paper. But now I am hearing that many medical  
18 professionals prefer it because it's so much easier  
19 than remembering a password. And, in fact, the  
20 technology has become very, very inexpensive.

21 So, anyway, that's why we would like for  
22 -- we would like to hear from the members of the  
23 ACMUI, or from the ACMUI some recommendations, some  
24 ideas, some advice, if you will.

25 MEMBER ZANZONICO: So, just to follow-up.

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1 So, you know the NRC doesn't envision that whatever  
2 recommendations, guidance, whatever is recommended for  
3 electronic signatures would, necessarily, impact  
4 traditional paper-based records.

5 MR. FULLER: No, you are correct. If  
6 someone chooses to use a traditional paper-based  
7 system, our rules certainly, in fact, that's  
8 what those areas where we require a signature, the  
9 assumption at the time was that those rules were  
10 written that it was something that people actually  
11 signed with a writing instrument on a piece of paper.  
12 So, yes, those will be acceptable. We're not requiring  
13 anyone to move into some other technology-based  
14 process.

15 CHAIR MALMUD: Thank you. I have a  
16 question, and that is that Slide 12 indicates that the  
17 electronic signed documents and all revisions would be  
18 retained for three years. And then later on it talks  
19 about 10 years for the PDF, Portable Document File.  
20 What was the basis for the three and the ten, or is  
21 that something that needs, that's passed on from  
22 another agency?

23 MS. COCKERHAM: I can tell you the basis  
24 for the three years is a regulatory requirement in 10  
25 CFR Part 35. The ten-year, let me look and see.

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1 CHAIR MALMUD: Slide 15.

2 MS. COCKERHAM: Oh. This is just an example  
3 of (--) a commenter provider this information and said  
4 that PDFs have been standard in the IT community for  
5 over a decade. So, that 10 years is just saying that  
6 PDFs have been around.

7 CHAIR MALMUD: Oh, they've been around for  
8 10 years.

9 MS. COCKERHAM: For a long time, yes.

10 CHAIR MALMUD: Thank you for clarifying  
11 that.

12 MS. COCKERHAM: Yes.

13 CHAIR MALMUD: Questions? Comments? Steve  
14 Mattmuller.

15 MEMBER MATTMULLER: Hi, Steve Mattmuller. I  
16 was looking through your list of examples of medical  
17 license records requiring signature. And only really  
18 number four jumped out at me as, these are, I would  
19 say, records performed at a medical license, but I  
20 wouldn't necessarily call them medical records. And  
21 really, the only one that jumped out at me as a  
22 medical record is the written directive.

23 In our facility, in our hospital  
24 networking we've just recently, or over the past  
25 several months converted to electronic medical record

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1 system, but even for our own written directives, it's  
2 still paper. In fact, it doesn't even get scanned and  
3 then attached as a PDF file to the patient's medical  
4 record because the pertinent data within, as far as  
5 the need for the treatment, the dose and such is  
6 elsewhere in the medical record, so it's somewhat  
7 superfluous to add the written directive information  
8 to it. So, it's kept separate. So, that's my comment.

9 So, my question is, do you get many  
10 records submitted to you now with an electronic  
11 signature, because I really had trouble thinking of  
12 records that would actually be sent to you that would  
13 have electronic signatures, or you're just looking  
14 down the road when this might happen?

15 MR. FULLER: No. And, again, the focus of  
16 this is not for things that are submitted to the NRC.  
17 These are things that are required to be signed, and  
18 then the records maintained by the licensee. So,  
19 they're inspected, perhaps, but none of these are  
20 required to be submitted to us. If they were required  
21 to be submitted to us, then we do have a standard for  
22 a digital signature, and that's sort of a different  
23 topic.

24 But, yes, what we are talking about here  
25 are only those records that are required to be

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1 maintained by the licensee, and would then be  
2 inspected during inspection. And you're exactly right,  
3 we need to be careful that we don't say medical  
4 records. We are talking about records that are  
5 required to be produced and maintained by our medical  
6 licensees, but I don't want anybody and if we say  
7 medical records, please point it out to us, because we  
8 should be careful. We're not talking about medical  
9 records here, we're talking about, again, records that  
10 we require to be created and maintained, and so forth,  
11 by our medical licensees.

12 CHAIR MALMUD: Did that answer your  
13 question, Steve?

14 MEMBER MATTMULLER: Yes.

15 CHAIR MALMUD: I don't know what other  
16 departments are doing, but what we do is to have a  
17 Written Directive then scanned into the medical  
18 record, but there's also a log book of doses which  
19 have been calibrated and administered, which is kept  
20 in the Hot Lab. The two should correspond exactly.

21 The medical record, itself, which includes  
22 the scanned copy of the written directive, which is  
23 jargon for a radioactive prescription, is maintained  
24 permanently since it's now part of the medical record.  
25 Though technically, I assume, not a requirement of the

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1 NRC, it's an internal requirement that we've  
2 established, that it be part of the medical record in  
3 addition to the log book which indicates that the dose  
4 was administered. It's an assumption on my part.

5 I don't know how other departments handle  
6 it. Chris, do you want to comment on that?

7 MEMBER PALESTRO: Yes, Chris Palestro.  
8 That's exactly how we handle it, the same way. The  
9 Written Directive is scanned in as part of the patient  
10 record into the PACS system.

11 CHAIR MALMUD: And it's never been  
12 requested of us by the NRC to review the written  
13 directives, but our own Radiation Safety Officer makes  
14 certain that these records are complete at the time of  
15 the administration of the radiopharmaceuticals.

16 MEMBER ZANZONICO: Yes. Just to your point,  
17 as far as I know, ultimately, it's a handwritten  
18 document, whether it's a Hot Lab log book or even the  
19 requisition. It's ultimately a traditional  
20 handwritten, hand, well, hand-signed document that may  
21 be scanned into some HIS system, Hospital Information  
22 System, or a PACS system. But I'm not really aware  
23 that on any large-scale basis, if at all, at least in  
24 our institution, that that's been replaced in any way  
25 with a fully electronic signature system.

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1 CHAIR MALMUD: I'm not aware of its having  
2 been replaced either. However, in physicians writing  
3 prescriptions for patients, they often now do an  
4 immediate electronic entry, and it wouldn't be  
5 unreasonable to assume that this may some day  
6 incorporate radiopharmaceuticals, as well. Dr.  
7 Thomadsen.

8 VICE CHAIR THOMADSEN: Well, we are in the  
9 process of switching over to completely electronic  
10 prescriptions. We've done it for the linear  
11 accelerators. We're doing it for the brachytherapy  
12 right now, so there will not be any paper to scan in.  
13 The characteristics I don't think quite satisfy  
14 everything that Ms. Cockerham listed at the moment.  
15 We are trying to work with the manufacturer to tighten  
16 things up a bit on that. But it is a commercial  
17 system, so we can't do exactly what we want to do  
18 quite yet.

19 CHAIR MALMUD: Dr. Van Decker.

20 MEMBER VAN DECKER: I guess just try to  
21 place this into a broader context, and this is a  
22 little bit thinking off my head. I think it's  
23 important when you say medical record, making a  
24 distinction of what we're really talking about here.  
25 I mean, if you look at most large health systems right

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1 now that are going to medical records because there's  
2 incentivization to try to create more electronics  
3 because of wide variety of stuff that this helps.  
4 Those systems are not infinite. They, essentially,  
5 have been clearing-housed through other government  
6 agencies that are attempting to create standardization  
7 for how that is tracked and all.

8 And you can be sure no large health  
9 system, and even no practice is going to go out and  
10 invest in a system that hasn't been vetted and kind of  
11 approved that it does what it does, because nobody  
12 wants to be on the side of, and there are options out  
13 there right now as far as these large systems go,  
14 but the options are not infinite.

15 And I'm not in the therapy realm, but I  
16 could see Written Directives becoming a piece of this,  
17 because I know how it goes for general drugs and all.  
18 The majority of those systems right now, as far as  
19 their requirements for signing off on meds, has  
20 basically been password-driven, because that's been  
21 the easiest thing to drive for large health systems  
22 and everything around; although, I think your  
23 philosophical tenets up there are not unreasonable.  
24 And I'm not sure how the HIT downtown here has dealt  
25 with that when it vets these systems as potential

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1 options for purchasers to look at.

2 I guess the last piece of this, which I  
3 guess I need a little clarification on in my own mind  
4 is obviously the record keeping; that is, the  
5 regulatory isotope handling record keeping that is not  
6 part of the clinical care of the patient.

7 Most of these systems are not that far in  
8 depth as far as what they're trying to accomplish, and  
9 what their vetting has been. As a matter of fact,  
10 there's a subjective statement most of them have been  
11 really set up to kind of coordinate the primary care  
12 piece of it, and even a specialty piece getting in,  
13 has had some rough edges to it. But they have not  
14 thought in depth about other little pieces of the  
15 system, so I don't think that part of these vetted  
16 systems have been developed to that degree.

17 The other question, obviously, is  
18 electronics makes the world easier, and it's obviously  
19 enough to do. And if there's people wishing to buy,  
20 I'm sure there's products out there, and there are  
21 probably software products available for some of this  
22 other stuff. Whether those have been vetted so, if  
23 that comes up, if somebody says well, I want to do the  
24 piece of this electronically, does that mean that you  
25 want to know whether that system has been vetted as a

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1 piece of it so that somebody does use something that's  
2 not going to meet your philosophical tenets, or are  
3 you going to let somebody purchase something that as  
4 long as it fits your guidance on your philosophical  
5 tenets and the purchaser can defend those saying look,  
6 we wanted to go this way. We're trying to do this  
7 piece of our puzzle better, and it meets your  
8 guidance. And then the onus is on us to the onus is  
9 on that person to say that person to say that what  
10 they're using fits those guidance pieces, or whether  
11 you're going to vet the products first.

12 I mean, it starts to become much more  
13 complicated than it sounds right off the bat, because  
14 I think that, as was pointed out, the majority of  
15 those other functions right now are probably still  
16 being performed handwritten because that's the state  
17 of where the art is developing so far. But it's an  
18 interesting question.

19 CHAIR MALMUD: Thank you. Dr. Guiberteau.

20 MEMBER GUIBERTEAU: Mickey Guiberteau. I'm  
21 just curious to know if there is a particular incident  
22 or reason why the NRC is exploring a benchmark for  
23 electronic signatures, when there are a number of  
24 available benchmarks, I mean, over and above the  
25 password protected signature, which is pretty much the

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1 standard for documents that need to be signed  
2 electronically.

3 Holographic documents for prescriptions  
4 are pretty much gone in most large institutions. And  
5 my worry here is that if we become admittedly, in  
6 nuclear medicine and in some areas the written  
7 documents scanned in are pretty common, but I think  
8 we're going pretty quickly on these, at least in some  
9 of our institutions, to go to electronic instruments  
10 that can be signed with a password. And my worry here  
11 is that if there's not a good reason, are we being too  
12 premature and being too restrictive on this because  
13 there may not be development of the standards to  
14 comply with what we may want.

15 MR. FULLER: I can respond to the first  
16 part of that. When you asked if there was anything  
17 that prompted this, for a number of years, we've had  
18 occasional questions come in from the region, someone  
19 is out doing an inspection, they see where a licensee  
20 has done something maybe a little bit unique or what  
21 have you, so they'll come in and say is this  
22 reasonable? Should we cite this as a violation,  
23 because it wasn't really signed? There's been a  
24 learning curve.

25 We actually got a request from one of our

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1 regions to actually develop a policy on what is  
2 acceptable as far as an electronic signature goes. So,  
3 that coupled with just simply a recognition that there  
4 are now directives that require medical certain  
5 medical institutions and entities to move to medical  
6 records, or electronic I'm sorry, electronic medical  
7 records, so we just recognize that. And then we also  
8 recognize that technology is moving forward and so  
9 forth, and what we don't want to do, I mean, there is  
10 absolutely no reason, or no expectation that if  
11 someone wants to have a piece of paper and sign it,  
12 that is going to be in compliance. We have no  
13 expectations or no plans to change that.

14 All we're trying to do is make sure that  
15 if we -- when we are ready to finally provide some  
16 guidance, which we hope would be sooner rather than  
17 later, to tell our licensees what is acceptable, that  
18 it not be more onerous than what they currently do  
19 with a paper system, nor would it be outside of what  
20 would be considered sort of the state-of-the-art. In  
21 other words, that's why we're looking for some  
22 feedback and bench marking-type feedback so we can  
23 learn what is out there, what is reasonable, what  
24 works for other regulatory agencies and other agencies  
25 have found to be acceptable.

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1           In other words, we don't want to go and  
2 reinvent the wheel. We don't want to create a  
3 situation where it becomes a problem, problematic for  
4 our licensees to comply. At the same time, we don't  
5 want to put a -- in other words, so now today this  
6 works, but then it might not work tomorrow. So, we're  
7 looking.. the bottom line is we're just, we're looking  
8 for advice. We want to do it correctly and properly,  
9 and we don't want to go to rulemaking, if we don't  
10 have to. And I don't at this point in time, we don't  
11 see any need to have to do that.

12           MEMBER GUIBERTEAU: Again, my concern is  
13 that when we talk about these things, there are  
14 designations, such as usual and customary, standard  
15 and state-of-the-art, and that we have all of those  
16 right now out in the community. Even though electronic  
17 records are encouraged and they're coming pretty  
18 quickly, they're not going to be it's going to be very  
19 heterogeneous, because it's very expensive to do. And  
20 as technology changes, many departments who could  
21 barely afford it the first time, are now having  
22 trouble updating to the current state-of-the-art.

23           So, my question is, is there any  
24 consideration in the interim for consideration to  
25 allow electronic signatures, if there is a policy in

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1 place at institutions that define electronic  
2 signature. And that, as has been mentioned, is the  
3 case in most of our institutions.

4 I mean, you have a system in place. It is  
5 an electronic signature, and that is what is the  
6 standard for an electronic signature within that  
7 practice. But, to me, because of the changes that are  
8 going forward, rather than the edict coming down,  
9 perhaps we should wait before that happens from the  
10 NRC, to allow those people who are transitioning and  
11 actually improving their records to have their  
12 variability in terms of what their standards are.

13 MR. EINBERG: Chris Einberg. Let me try it  
14 a little differently, a different approach than Mike  
15 had.

16 Basically, we have requirements in our  
17 regulations that require a signature. We're seeking  
18 advice from the Committee here on how medical  
19 institutions can meet the requirements that are  
20 comparable to paper signature, or hard copy signature.  
21 So, we want to know what are the, I guess at a de-  
22 minimus level, what are those requirements? I mean, we  
23 have inspectors that need to go out and they're going  
24 out and seeing these electronic signatures. And from  
25 what I've gathered, there is a wide variety of

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1 standard practice out there. Some are going to be more  
2 advanced, some are not going to be. But we have to be  
3 able to able to provide guidance to our inspectors,  
4 and also to the medical community as to what is  
5 adequate and sufficient. So, we're seeking advice from  
6 the Committee as to what is adequate and sufficient to  
7 meet our regulatory requirements.

8 CHAIR MALMUD: I think I understand the  
9 question. If I were to answer the question today as a  
10 practitioner, I would say it's either a written  
11 directive, or it's a written directive signed  
12 electronically in the same fashion that I would sign a  
13 prescription, and a prescription for any other drug  
14 that I'm dispensing.

15 MR. EINBERG: And that's exactly the kind  
16 of guidance we're looking for. You say electronic  
17 signature for a prescription, what does that entail?  
18 We're looking for advice as to what is that. We've  
19 heard also that Drug Enforcement Agency has guidance  
20 out there for controlled substances. What do they  
21 require for electronic signatures for prescriptions?  
22 Could that be used for written directives? So, that's  
23 the type of advice we're looking for.

24 CHAIR MALMUD: Thank you. My understanding  
25 is that they accept the same electronic signature that

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1 the hospital accepts for writing a prescription,  
2 discharge prescriptions, for example, outpatient  
3 prescriptions for our patients which is an electronic  
4 signature known only to the holder of the signature.  
5 And when writing for a controlled substance, it  
6 includes listing our medical, our state license  
7 number, as well as our number for the controlled  
8 substances. So, it's the same material, one presented  
9 in writing, one presented electronically. But the key  
10 is that the electronic signature is known only to the  
11 holder of the signature, and no one else, it's to be  
12 shared with no one else, and never to be breached. It  
13 would be equivalent to giving your electronic  
14 signature to a stranger to access your bank account.

15 MR. EINBERG: And when you say electronic  
16 signature that's unique to you, do you mean a  
17 password?

18 CHAIR MALMUD: Exactly. Dr. Van Decker.

19 MEMBER VAN DECKER: I was going to say  
20 we're probably missing, Dr. Suleiman, would be helpful  
21 here because he probably knows all the government  
22 acronyms for all these other agencies that are  
23 controlling all of this on a national basis right now.  
24 But, obviously, there are federal standards for e-  
25 Prescribing, because these large vendors, of which

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1 there are 15 or 20 of them, didn't go out and  
2 manufacture a system to come to sell and didn't go to  
3 get it vetted so that they could get it sold unless  
4 they were fulfilling those requirements. So, I'm sure  
5 we could find what the e-Prescribing regulations are.  
6 And then, obviously, there's this agency that's  
7 vetting health information technology that has been  
8 the funding source for incentivizing some of this to  
9 go on. And they are the group that is actually vetting  
10 these vendors as approvable within the realms of what  
11 they're trying to accomplish for meaningful use.

12           And one of the meaningful use criteria of  
13 electronic medical records is prescribing,  
14 essentially. So, there are standards out there for  
15 prescribing, and there are agencies that are clearing  
16 vendors prescribing. So, that part of it is easy. And  
17 then, obviously, whether you decide to go from paper  
18 or not right now, as opposed to a few years from now,  
19 it may be more pushed. It's obvious, I think I would  
20 agree with Dr. Guiberteau, you've got to leave room  
21 for the motion of things as they are going. But the e-  
22 Prescribing stuff, and where you could see written  
23 directive fitting into, and isotope use fitting into  
24 is not going to be the same thing as regulatory  
25 documentation in departments, because these systems

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1 have not gone that far. But you could say that the  
2 requirements that they're using for signing off on  
3 something should be relatively universal, and then the  
4 only question really comes on your part, do you take  
5 those principles, make them universal as a guidance  
6 piece of it, as we want to be consistent with the  
7 guidance going on, or do you really see yourself as  
8 vetting software vendors who say well, you know, your  
9 e-Record which does all this five billion things  
10 doesn't do this little piece of the puzzle, and we're  
11 going to give you an interface add-on that's going to  
12 do that piece of a puzzle. And do you really look at  
13 all of those and decide which ones it is, or is it the  
14 buyer beware, if you're going to use, buy a sub-piece  
15 system to add in that's going to do some of this other  
16 stuff for you, you have to be able to justify that it  
17 fulfills some philosophical tenets, or not. That's a  
18 decision that go a variety of ways.

19 CHAIR MALMUD: Thank you, Dr. Van Decker.  
20 I like to think in simple terms. To me, writing a  
21 written directive is the same thing as writing a  
22 prescription. And a written directive is the name that  
23 the NRC uses for a prescription for a radioactive  
24 drug.

25 We have a system in place at our

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1 institution which I'm sure we purchased from some  
2 major vendor, and other hospitals have similar systems  
3 in place where we can write prescriptions  
4 electronically. That system can be extrapolated to  
5 handle the radiopharmaceuticals, as well, instead of  
6 going to the local pharmacy, because these  
7 prescriptions can be emailed immediately to a pharmacy  
8 at a distance from the hospital. It goes to the  
9 radiopharmacy, which has already has a computer in it  
10 for maintaining records. And it's as simple as  
11 that.

12 If I understand your question, it is how  
13 can we transition this smoothly so that there's no  
14 danger of lapse in the interim. Is that the basis of  
15 the question?

16 MR. FULLER: Well, that's part of it. The  
17 other thing we wanted to know was, again, what would  
18 be well, I think for prescriptions we have a pretty  
19 good idea, but if you wanted to make a recommendation  
20 along those lines, that would be very helpful to us.  
21 But there are other records that we require to be  
22 signed that are not prescriptions so, for instance, if  
23 you're the Radiation Safety Officer, there are certain  
24 things you're required to periodically review and then  
25 sign off on and things like that. So, we wanted to

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1 make sure that whatever our expectations were, or  
2 whatever we communicated that would be acceptable  
3 were, I guess, wide-ranging enough that it would be  
4 good for everything.

5 Now, as I listen, I'm thinking well, maybe  
6 we need to say one thing about written directives, and  
7 then maybe have another discussion, perhaps, about  
8 some of the other stuff. But, again, we don't want to  
9 prescribe something, or to describe something in our  
10 guidance that would cause someone a great deal of  
11 burden as they moved forward (--) assuming that  
12 somebody wanted to move to a paperless system for  
13 everything in their facility, then we want to be able  
14 to give them reasonable guidance so that if it's  
15 something as simple as a PDF that you put in your  
16 password for, if that would not be considered to be a  
17 problem again, anyone who chooses to maintain a paper  
18 system is going to be fine. We just wanted to be able  
19 to communicate in sort of a generic way the types of  
20 systems that we have seen and been made aware of that  
21 we find acceptable. That's all.

22 CHAIR MALMUD: Thank you. I... is there a  
23 comment?

24 (No response.)

25 CHAIR MALMUD: I think that the systems

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1 already exist. What we could do is set up a small  
2 Subcommittee to think if there are issues that they  
3 believe cannot be adequately dealt with, with the  
4 electronic signature. I doubt that they'll find any  
5 but, nevertheless, a small working group can come up  
6 with some potential areas of concern. Because  
7 currently, all of us who are practicing are using our  
8 electronic signature on everything, on office notes,  
9 on written directives, prescriptions, comments,  
10 follow-up visits. We don't sign anything by pen any  
11 longer with some exceptions, and when we do sign it by  
12 pen it's then scanned into the electronic record  
13 anyway.

14 So, I don't think that there's I don't  
15 think that there will be a problem. And as long as  
16 paper records are able to be maintained as an  
17 alternative in a small office, some remote office in a  
18 lightly populated part of the country where they don't  
19 have the electronics, or they choose not to have them,  
20 then the paper record will be maintained as it was  
21 before.

22 So, I don't see an issue, but just because  
23 I don't see it doesn't mean it's not there. So, we  
24 could set up a small Subcommittee of the ACMUI and let  
25 them brainstorm and try and create issues that might

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1 theoretically occur, which is I'm sure what you're  
2 concerned about, and reassure us that we are okay. Dr.  
3 Welsh.

4 MEMBER WELSH: Yes. While I agree that  
5 having a small Subcommittee is not an unreasonable  
6 idea, I do anticipate one potential problem that just  
7 entered my mind. I'll stay in the way of background  
8 that I've worked with various organizations over the  
9 past several years in varying levels of maturity of  
10 their electronic paperless systems ranging from  
11 customary, acceptable, standard to state-of-the-art.  
12 And I would ask NRC if they have identified any  
13 deficiencies with any of the commercial vendors of  
14 paperless systems. I think that would be a first step,  
15 to see if any of the commercially available electronic  
16 signature approaches that we all use now, as Dr.  
17 Malmud has said, have any deficiencies from the NRC's  
18 perspective.

19 I suspect that you will find none. And as  
20 far as the question of switching over to an electronic  
21 record being overly burdensome or onerous, I would say  
22 the answer is clearly not, because as has been  
23 mentioned, for the majority of what we do we already  
24 are completely paperless.

25 However, I think all of us who are

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1 familiar with dictations and paperless systems are  
2 aware of one significant weakness, and that is when we  
3 dictate our notes, it depends on the transcriptionist  
4 on the other end, maybe with the Dragon Dictation  
5 system or something electronic, this will no longer be  
6 a problem, but the reality is that somebody has to  
7 type that up, and sometimes it can be a day or two, or  
8 longer. And, therefore, there is a time period between  
9 the dictation of a written directive or some type of  
10 note. And I'm assuming that we could move to a  
11 dictated Written Directive, maybe using a template,  
12 but typing in or dictating some specifics. But then  
13 there could be a time interval between the actual  
14 signature. And I'm wondering if that could pose a  
15 challenge for NRC.

16 CHAIR MALMUD: This is Malmud again. But,  
17 Jim, isn't that an existing issue with the handwritten  
18 system? With an electronic record, we are already on  
19 voice dictation, so when we dictate we're the ones who  
20 do any correcting of the dictation because it's on the  
21 screen immediately. It's equivalent to the public's  
22 commercial Dragon system, but it's tuned into medical  
23 terminology so that we are our own secretaries now.  
24 And I won't editorialize on that.

25 (Laughter.)

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1 CHAIR MALMUD: The magnificence of  
2 electronics has replaced a secretary at one-tenth the  
3 salary that the physician is paid to do the same work  
4 and slow down his process, or her process.  
5 Nevertheless, this is the future. And I think that the  
6 issue that you're raising is a valid one, but it's  
7 more relevant to what was past than what's coming.

8 MEMBER WELSH: If I might reply, that's why  
9 I prefaced my statement by saying that I've seen  
10 various levels of maturity ranging to state-of-the-  
11 art. But more facilities that I've been at are still  
12 using the older approach, where a tape goes to a  
13 transcriptionist who then types it, and then gets it  
14 back to us the next day if we are lucky. But what if  
15 it is not the next day, or the day after, then there  
16 could be a potential lag between the...

17 CHAIR MALMUD: Absolutely.

18 MEMBER WELSH: ...procedure and the  
19 signature. And I'm wondering if that could pose a...

20 CHAIR MALMUD: You're absolutely correct.  
21 And that's one of the other advantages of the  
22 electronic system, because when you dictate something  
23 electronically, the time that you dictate it is also  
24 entered. And, therefore, should you wind up in  
25 litigation about the timeliness of a note, the note is

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1 timed and cannot be challenged in the same fashion  
2 that it could possibly be challenged currently. So,  
3 we're moving into an era in which it's an additional  
4 burden for us, but it carries some benefit. But that's  
5 not to ignore your correct comment about the lag  
6 between dictation and typing in some instances.

7 I had the unpleasant experience when I was  
8 Vice President of the University of reviewing every  
9 case, every claim against the University's faculty and  
10 hospitals for potential negligence, and the  
11 timeliness, the contemporaneous value of a note was  
12 extraordinary, so that if there was proof that the  
13 note was dictated before the complaint was registered,  
14 and if the note indicated that the information had  
15 been transmitted, it in most cases resolved the issue.  
16 And that is done automatically with the electronic  
17 system, so it does have distinct advantages.

18 We're also required to change our  
19 signature periodically. The computer will tell us the  
20 signature is expiring, and that we have to put a new  
21 signature in. And this occurs about what, every 90  
22 days at Temple, Bill? Approximately every 90 days  
23 we're required to change our electronic signature.  
24 And that's out of concern that someone may have  
25 discovered it, although I'm not aware of any such

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1 instance. So, that I think the future will offer us  
2 some benefits, though at the expense of some  
3 additional paperwork, not paperwork but additional  
4 effort on behalf of the professional in what used to  
5 be handled by a secretary or a clerk.

6 Are there any other questions or issues to  
7 be presented, (--) yes, Dr. Palestro.

8 MEMBER PALESTRO: Chris Palestro. Just a  
9 question regarding the real-time transcription and  
10 reviewing the report a day or two later. If it's being  
11 transcribed, then I assume there's no electronic  
12 medical record. It's being signed by hand. Correct?

13 MEMBER WELSH: Jim Welsh. To answer your  
14 question, at the facility that I was thinking of,  
15 there were still no handwritten notes, everything was  
16 typed and electronically signed. But there was that  
17 interval where things were in the cyber cloud.

18 CHAIR MALMUD: Sue?

19 MEMBER LANGHORST: Sue Langhorst. I wanted  
20 to also look at it from the perspective of how you  
21 inspect upon those types of records. So, I know that  
22 NRC, much like my Staff, is interested in knowing how  
23 best to inspect upon electronic records, because with  
24 a paper record you could set an inspector down, they  
25 could go through the paper record and do that. You

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1 don't, necessarily, especially for an outside  
2 inspector give them their own password to go into your  
3 electronic system, so there's the perspective of how  
4 you inspect upon those records. Is printing it out and  
5 showing the electronic signature, is that adequate, or  
6 do they have to look at the electronic system and have  
7 someone there helping them?

8 So, that's a perspective I know that we  
9 look at as we evaluate our own electronic  
10 documentation systems, and I think NRC is looking for  
11 some guidance in that regard, too, from that  
12 perspective. And that can be a little more tricky as  
13 you have to inspect upon a program like that. So, I  
14 just wanted to raise that issue, too, and that  
15 perspective.

16 CHAIR MALMUD: Thank you for that  
17 clarification of what perhaps NRC Staff was trying to  
18 transmit to us.

19 So, then there would be some virtue in  
20 setting up a small Subcommittee to look at this?  
21 You've identified a problem right here, a potential  
22 problem, or an area of concern.

23 MEMBER LANGHORST: I wouldn't say, I'd just  
24 say it's a different perspective on how you provide  
25 guidance to inspection protocols, on how you look at

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1 these things, and what makes sense as far as was that  
2 a real signature of that authorized user. That's part  
3 of the inspection part of things, so I'm not raising a  
4 concern. I'm just looking at it from that perspective,  
5 also.

6 CHAIR MALMUD: I'm sure that all of our  
7 systems work in a similar fashion, and that is if I  
8 sign a note electronically, it's in the medical  
9 record. If someone is going to audit the medical  
10 record, they don't have access to my electronic  
11 signature, but they have permission through another  
12 channel to enter the system and look at the medical  
13 records; which are, of course, otherwise highly  
14 protected. But they would not need to have access to  
15 my signature, but they would see my name there, and  
16 that meant that I signed it electronically.

17 Other questions? Ashley?

18 MS. COCKERHAM: I just wanted to add one  
19 comment. And I think several people have mentioned  
20 this. For the bullets that I have listed about unique  
21 identification, authentication, things like that, the  
22 guidance definitely has not been developed. This is  
23 not the guidance. These are not the criteria that  
24 we're setting. I just wanted to, at least, give some  
25 ideas of things to think about so when you're looking

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1 at your system and you're saying oh, it's a password.  
2 Okay, that's unique to me. You're thinking about these  
3 types of things.

4 So, please don't look at any of the  
5 bullets on Slide 6 or 7 about -- there are seven  
6 bullet there, don't think that that's an exhaustive  
7 list, or that that is a regulatory requirement that  
8 we've already set. That was just me brainstorming,  
9 looking at documents that we already had, information  
10 that I had gathered from other staffers, and tried to  
11 just have some idea so I didn't just come to you with  
12 a blank presentation saying hey, what do you guys do?  
13 But it's like what do you do, and how could it apply  
14 to these types of things, and how would we develop  
15 guidance based on that. So, it's very, very early on  
16 in the process. We do not have guidance developed, and  
17 no preconceived ideas here. I'm open to hear your  
18 opinions.

19 CHAIR MALMUD: The problem that I'm having,  
20 Ashley, is that I don't see the problem, because to me  
21 writing a prescription for a radiopharmaceutical is  
22 the same process as writing a prescription for a non-  
23 radioactive pharmaceutical. Writing a note relevant to  
24 treatment of a patient with radioactivity is no  
25 different from writing a note without, so I don't see

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1 an issue. But I'm in a large institution, as is Sue  
2 and others here, and there's a whole IT infrastructure  
3 that maintains the security of these systems,  
4 maintains the security of our passwords, and warns us  
5 of all kinds of possible threats, and reminds us of  
6 these things electronically all the time.

7           However, I think that the point that Dr.  
8 Welsh is making is that not everyone is as fortunate  
9 as we may be in being large institutions with large IT  
10 departments, and there are existing issues, and there  
11 may be issues in the future.

12           Therefore, with the concerns raised, does  
13 the Committee feel that we need a Subcommittee to look  
14 at this issue, or do we feel it's really not an issue?  
15 I don't want to be the nihilist and say it's not an  
16 issue, because it's not an issue that I see at my  
17 institution. But it may be an issue that the NRC  
18 correctly is identifying as existing in other  
19 institutions and offices in the United States. Dr. Van  
20 Decker?

21           MEMBER VAN DECKER: At the risk of saying  
22 too much, it's something that's probably not my horse.  
23 I think the question really becomes how much of the  
24 issue you guys see as the Written Directive piece,  
25 which is really something that fits into all e-

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1 Prescribing stuff. And how much of this issue that  
2 you're kind of alluding to is really other things that  
3 are not part of the mainstream electronic medical  
4 record as we understand it for record keeping for  
5 regulatory basis. And that may need some thought.

6 MR. FULLER: I guess to sort of bring it  
7 back to where we started, we've had inspectors in the  
8 regions ask us what's acceptable, and what's not  
9 acceptable. We recognize that the IT world, or the  
10 technology is advancing, and more and more of our  
11 licensees are doing things electronically vice the  
12 more traditional paper-based process.

13 Left to our own devices to come up with  
14 some guidance for our inspectors on what's acceptable  
15 and what's not acceptable, I'm concerned that we end  
16 up somewhere where we find out after-the-fact when we  
17 have licensees that come in who have been cited for  
18 various things, that we overstepped or we became too  
19 prescriptive, or we made mistakes. So, the reason I  
20 asked for this to be put on the agenda, and it was at  
21 my request, is because I wanted to get advice from  
22 people who are already doing this that would tell us  
23 what we should do or shouldn't do as we think about  
24 developing guidance for our inspectors both in our  
25 regions and in Agreement States.

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1           So, that's the whole impetus for this.  
2           And, again, if we go off and do it ourselves, we'll do  
3           something. I just want to make sure we don't do  
4           damage, put it that way.

5           CHAIR MALMUD: Ashley?

6           MS. COCKERHAM: To give you an example, if  
7           you had a system where you entered one password and  
8           that was, suffice to say that you had signed the  
9           document, and NRC writes guidance that says you know,  
10          you entered your password when you signed this, but we  
11          really want you to double check that you signed this.  
12          Like we want you to check a box and put a password. Is  
13          that too much? Is a double password too much?

14          You know, we don't want to go too far.  
15          And I've seen a couple of systems, but there were  
16          holes here, and then there were some things that we  
17          were like yes, that's too much. We wouldn't  
18          necessarily want that for everyone, like you said  
19          everyone is at different levels. So, just to give a  
20          concrete example of entering your password twice might  
21          be too much. We don't want to come out with guidance  
22          that says two passwords are required for all systems,  
23          when the Committee says no, medical practice we do it  
24          this way and it works just fine. We want to hear  
25          what's the just fine.

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1 CHAIR MALMUD: Dr. Guiberteau?

2 MEMBER GUIBERTEAU: You know, I really  
3 think this would be an unreasonable burden for the NRC  
4 to come up with its own definition of electronic  
5 signature when they're already out there. I mean, we  
6 have a very good system in place. We can't sign  
7 documents unless we use a unique password. It can't be  
8 the password we go on to the main IT system with in  
9 order to sign things.

10 We have a security system. We have an IT  
11 department, and IT security that overlooks this. My  
12 feeling is that if this works for our electronic  
13 records, for our prescribing, for our notes and our  
14 charts, for the JCAHO, the Joint Commission, that  
15 these should be acceptable locally. But if now I have  
16 to go back and say well, wait a minute, guys, we have  
17 to get another system or add on to this one where I  
18 have to check a box, I have to put in my password  
19 twice, they're going to say mmm, maybe we shouldn't be  
20 doing I-31 therapies. I mean, what's the issue here?  
21 Maybe you should just be writing them all yourself.

22 And at some point I think you know, I do  
23 understand what you're up against, and I'm not opposed  
24 to it, but just listening to this conversation, I  
25 mean, we have nobody here is doing it exactly the same

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1 or on the same system. So, we have to have something  
2 that is going to be broad enough so that it doesn't  
3 disenfranchise some people from writing a written  
4 directive electronically.

5 CHAIR MALMUD: Thank you. I think what Dr.  
6 Guiberteau is saying in a different way is the same  
7 thing that I'm saying, which is I don't see a problem.  
8 In fact, the introduction of the electronic record is  
9 reducing potential problems.

10 May I ask you a question, and that is, do  
11 workers in nuclear power plants have to have  
12 passwords, unique signatures, electronic signatures?  
13 I would assume that they do, or are they still using  
14 paper?

15 MR. EINBERG: I can't really speak to that.  
16 We can get the answer to that, but unless Mike or  
17 anybody else here knows.

18 CHAIR MALMUD: Because what we're dealing  
19 with is fractional, and it's just what we do every  
20 day. And we do it with care, we do it with concern,  
21 and our electronic signature is as sacred as our  
22 handwritten signature, but actually is even better  
23 because it enters the time of the entry.

24 MR. EINBERG: Chris Einberg again. I think  
25 we're all saying the same thing, but we don't know

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1 what that electronic signature is. So, please help us  
2 with that. So, we agree we're not in disagreement  
3 here.

4 I think we need to know what the Joint,  
5 JCAHO requires, or your institution, and what are you  
6 using for electronic signatures? We've talked about e-  
7 Prescriptions, but we here don't know what that means.

8 CHAIR MALMUD: Okay.

9 MR. FULLER: Yes, just to say -- and I  
10 know, Sue, you've been dying to talk. None of us work  
11 in medical institutions, so we can only theorize about  
12 what you're talking about. So, we're getting a lot of  
13 good advice, and a lot of good recommendations as we  
14 sit here and go through this discussion. This is very  
15 helpful to us. If we could actually get something  
16 written down that basically reflects all of the  
17 discussion we're hearing today, we could then take  
18 that and move forward and develop some guidance, and  
19 bring it back to you, and give you the opportunity to  
20 review it and make further revisions.

21 In other words, all we're looking for is  
22 something that we can get out to our inspectors that  
23 says these are the types of things that we all agree  
24 are very reasonable. That's all.

25 CHAIR MALMUD: Now, I understand. You're

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1 looking for documentation of the integrity of the IT  
2 system. Sue?

3 MEMBER LANGHORST: Sue Langhorst. That's  
4 exactly what they're asking for, and I commend them  
5 for asking for this because it is difficult to know is  
6 this okay? I see on the computer screen it says  
7 electronically signed by this person. Okay?

8 Now, in my system this is a letter. It  
9 wasn't written directive. When I print out that  
10 letter, there's no indication that there's an  
11 electronic signature, or that wording of electronic  
12 signature, so I just get a memo with no signature at  
13 all. So, I know my medical groups say well, Sue, I  
14 electronically signed it. I said, "But I'm going into  
15 paper documents on my end," so I need a signature that  
16 will print on a piece of paper.

17 I know that's just an example of what we  
18 face in trying to document and trying to go in between  
19 systems. Now, is it okay for an Agreement State  
20 Inspector to come look at a screen and see it's  
21 electronically signed, or do they need to print out  
22 that piece of paper and show that it was  
23 electronically signed?

24 It's how do those inspectors look at  
25 things to make sure they do understand the integrity

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1 of the documentation, which is all they're asking.

2 MS. COCKERHAM: Dr. Malmud?

3 CHAIR MALMUD: Yes, please, Ashley?

4 MS. COCKERHAM: To add to that, I think our  
5 goal is to develop guidance that is broad enough that  
6 encompasses all of what is used out there to not be  
7 overly prescriptive. And that's why we need this  
8 information. It will help us develop the guidance. It  
9 will be the basis for the development of it.

10 CHAIR MALMUD: Thank you. I can only speak  
11 from personal experience, and that is that there is an  
12 individual at our institution who is knowledgeable  
13 about the entire system, how it's set up and its  
14 controls and security system. He could answer the  
15 question adequately for you, I can't.

16 My suggestion would be that we contact IT  
17 people who have this responsibility for a major  
18 medical institution and they could answer your  
19 question, and offer the NRC the reassurance that's  
20 necessary. That would be my response, that we know the  
21 system works, but we don't know the details of how the  
22 security is monitored other than the requirements that  
23 are made of us. We really need I think we would  
24 benefit from the input of an IT person.

25 Yes, Laura Weil?

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1 MS. WEIL: This is Laura Weil. I think in  
2 addition to speaking to IT folks are large academic  
3 medical centers, it might make sense to speak to IT  
4 folks at small community institutions, as well.

5 CHAIR MALMUD: Thank you. I agree. Dr.  
6 Palestro.

7 MEMBER PALESTRO: It might also be useful  
8 to see what standards the JCAHO has set in place for  
9 electronic medical records, assuming that they have.

10 CHAIR MALMUD: I'm sure that they do. We  
11 can look into that. All right. I'm sorry. Who, oh, we  
12 have a member of the public. Steve, did you want to  
13 say something, or were you...

14 (Off mic comment.)

15 CHAIR MALMUD: Would you please introduce  
16 yourself. I know you.

17 MS. FAIROBENT: Thank you, Dr. Malmud.  
18 Lynne Fairobent with the American Association of  
19 Physicists in Medicine.

20 I just wanted to point out that AAPM in  
21 2010 did a briefing at the Conference of Radiation  
22 Control Program Directors that looked at this very  
23 issue that you all are discussing. And I would be  
24 happy to make that briefing available both to ACMUI  
25 and to NRC. It just so happens that it is one of the

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1 briefings that we did capture that year for our  
2 virtual library, so we do have it electronically  
3 captured. And we would be happy to, as you go forward  
4 with this issue, if there's anything we can do to help  
5 elaborate on what we had done with CRCPD in 2010 on  
6 this topic, we would be happy to sit down with NRC or  
7 the ACMUI and go over that briefing and to update it.

8 CHAIR MALMUD: Thank you.

9 MS. FAIROBENT: You're welcome.

10 CHAIR MALMUD: Would that be addressed to  
11 Chris, or to Mike?

12 MR. EINBERG: Thank you, Lynne. If you  
13 could actually please send that to either myself, or  
14 Sophie, or one of our staff members. Thank you. And  
15 we'll get it to the ACMUI.

16 CHAIR MALMUD: Someone else had his or her  
17 hand, I'm sorry. Who? Steve?

18 MR. MATTMULLER: Steve Mattmuller. Possibly  
19 a correction and a comment. I'm sure earlier our  
20 Chairman when he said secretary meant to say  
21 administrative assistance or transcriptionist. But the  
22 comment would be flexibility in that, while the Joint  
23 Commission looms large over a large number of  
24 institutions, there are also other accreditation  
25 groups out there, such as HFAP, which our group, our

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1 hospital network recently changed over to. So,  
2 standards could be different between those.

3 And, also, flexibility between states,  
4 because I believe in Ohio we have some of the more  
5 restrictive requirements for an electronic system, and  
6 that all of our staff have a RFID device that they  
7 use, and they tap onto the computer screen, in  
8 addition. I mean, first they sign in with their  
9 password, and then when they add data to the record  
10 they also have to sign off with their little RFID  
11 device to tap in and tap out. But I believe, I mean, I  
12 know it happens in Ohio. I don't know about other  
13 states, but I'd hate to see the guidance say yes, you  
14 must have this because we saw it in Ohio, but Ohio  
15 might be unique in that regard.

16 CHAIR MALMUD: Thank you. Sue?

17 MEMBER LANGHORST: Sue Langhorst. Just one  
18 more comment. As you look at other standards, it may  
19 be good to look at how those accreditation agencies or  
20 whatever, what their standards are for how, what's  
21 acceptable on inspecting on that electronic  
22 documentation, because I think that's really the point  
23 that NRC staff is asking is, what do we tell our  
24 inspectors is acceptable. And if it's looking at a  
25 screen and seeing the electronic signature, is that

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1 good enough?

2 CHAIR MALMUD: Bruce?

3 VICE CHAIR THOMADSEN: Bruce Thomadsen. The  
4 Staff is asking for our input, and I think we would be  
5 lacking not to give that. We've also been saying we  
6 aren't, necessarily, the best people to give this  
7 input, and we've cited that there probably are well, I  
8 think we know that there are standards out there  
9 somewhere. And Lynne has pointed out that there's been  
10 groups who have reported on this.

11 Maybe what we might do, I could make this  
12 as a motion, is that rather than making a Subcommittee  
13 to provide the guidance, make a Subcommittee that can  
14 provide some guidance for how they can develop the  
15 guidance; not necessarily give them the guidance, but  
16 help them through finding what guidance to develop.  
17 So, maybe a Subcommittee to provide guidance for  
18 forming a group that could give them the guidance that  
19 they need.

20 CHAIR MALMUD: Sounds like an excellent  
21 idea. Any support for that from the Committee?  
22 Mickey?

23 MEMBER GUIBERTEAU: Yes, I do support that,  
24 but I actually had my hand up for another reason.

25 CHAIR MALMUD: Okay.

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1           MEMBER GUIBERTEAU: Since Sue has brought  
2 this up three times, I have to respond to this. And I  
3 would be a little bit stronger than the way you've  
4 left it on the table, because this bothers me a great  
5 deal. And my feeling that absolutely and unequivocally  
6 that an electronic signature should be accepted by the  
7 NRC as entered within a system that we, in the system  
8 in which it was allowed to be entered, and not on a  
9 separate media that may be required by the NRC or any  
10 inspector, simply because all you have to do is try to  
11 convert a PDF to a text file, and then into Word, and  
12 you find out there's plenty lost in translation.

13           My feeling is if whatever definition, or  
14 whatever guidance that is provided, that that  
15 signature is acceptable in the, if the way they're  
16 doing it is acceptable, then the signature should be  
17 acceptable within the confines of the system that was  
18 used, and in no other media.

19           MR. EINBERG: I think that's an excellent  
20 point. But just bear in mind that the inspector has to  
21 be able to verify that signature. So, he or she needs  
22 to have access to the system to verify that signature.

23           MEMBER GUIBERTEAU: Well, that would be  
24 attendant upon the licensee. And I don't think that's  
25 unreasonable.

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1 CHAIR MALMUD: It sounds as if we should  
2 set up a Subcommittee for the purpose described  
3 eloquently by Dr. Thomadsen. Since you described it  
4 eloquently, would you be willing to participate in  
5 that Subcommittee?

6 VICE CHAIR THOMADSEN: Certainly.

7 CHAIR MALMUD: Do we have other volunteers  
8 for that Subcommittee?

9 MEMBER SUH: So, I'll volunteer, at our  
10 institution we've been using electronic medical  
11 records for a very long time. And, in fact, in  
12 radiation oncology all of our scripts are put in  
13 electronically, so our written record is actually put  
14 on a template, signed off at radiation oncology before  
15 actually proceeding with treatment. So, we actually  
16 have had a fair amount of experience using this. And  
17 one of the things we can do, as well, is kind of give  
18 some institutional guidelines in terms of how we set  
19 up our EMR program. It's fairly robust.

20 CHAIR MALMUD: Was your positive statement  
21 a volunteering to...

22 MEMBER SUH: Yes, I will help the effort.

23 CHAIR MALMUD: Thank you. That was Dr. Suh,  
24 S-U-H. And Dr. Palestro?

25 MEMBER PALESTRO: Yes.

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1 CHAIR MALMUD: All right. So, I think three  
2 should be an adequate Subcommittee. Now, Laura  
3 mentioned that we might want a small institution to  
4 have some input to this, as well, so that we don't  
5 assume that everyone has the wealth and breadth of a  
6 large institution. But none of us, as far as I know,  
7 represents a small institution. With which  
8 organization are you currently working, Laura?

9 MS. WEIL: With an academic institution,  
10 which has a...

11 CHAIR MALMUD: Small or large?

12 MS. WEIL: Small, which has electronic  
13 signatures for academic issues, but not medical ones.

14 CHAIR MALMUD: Would you like to  
15 participate in this, or do you feel that this is  
16 really out of your realm? The truth is that an  
17 electronic signature is an electronic signature,  
18 regardless of what we're signing. But I don't want to  
19 draft you into it. This is, perhaps we'll need to get  
20 a I think what we need is to augment is an IT  
21 specialist, which one of you or all of you would speak  
22 to at your own institutions. Would that be helpful?  
23 Sure, Bruce?

24 VICE CHAIR THOMADSEN: As I said, I don't  
25 see that this Subcommittee is going to define the

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1 answer. What they're going to try to do is define how  
2 to find that answer, so I don't think right now we  
3 need on the Subcommittee an IT person, but we need to  
4 know how to get the IT people, and get the information  
5 from them that will be useful. So, I think you just  
6 need a core from this Subcommittee, which will then  
7 try to reach out to find what not only in the IT  
8 community what's available, but in the accreditation  
9 community, what's accepted standards, and from  
10 commercial vendors what's possible, if that answers...

11 CHAIR MALMUD: It does. Still remain  
12 concerned about Laura's concern that we not overlook  
13 the needs of a...

14 VICE CHAIR THOMADSEN: I agree fully. The  
15 person who has spoken to that with some experience has  
16 been Dr. Welsh.

17 (Laughter.)

18 CHAIR MALMUD: Dr. Welsh, would you be  
19 willing to participate in the Subcommittee? We've  
20 asked you for so many things in the past, and being  
21 from Louisiana, I know that you've been flooded with  
22 material.

23 MEMBER WELSH: Well, I might reluctantly  
24 have to accept. I say reluctantly in part because  
25 going back to your original question about whether

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1 there's an issue at all, still is in the back of my  
2 mind, and are we going overboard by having a  
3 Subcommittee that's going to involve IT and community  
4 hospitals to answer a problem that doesn't really  
5 exist? Having said that, if there is a decision to  
6 have a Subcommittee, I will volunteer.

7 CHAIR MALMUD: Thank you. All right, we  
8 have our Subcommittee. And I agree with you, I just  
9 didn't comprehend sufficiently that those of us who  
10 are not practicing physicians or physicists are not  
11 familiar with the electronic signatures used in  
12 medical institutions. And the NRC has the honesty and  
13 the concern to tell us that, and to ask us for our  
14 advice, and that's what we're here for, so that's what  
15 we'll do. Thank you.

16 Having said that, are there any other  
17 questions or issues today? Sophie?

18 MS. HOLIDAY: I just wanted to verify. So,  
19 the motion was made by Dr. Thomadsen and seconded by  
20 Dr. Guiberteau, or were you just agreeing that...

21 CHAIR MALMUD: He seconded the motion.

22 MS. HOLIDAY: Okay. And the Subcommittee,  
23 as I recall, is Dr. Thomadsen, Dr. Palestro, and Dr.  
24 Welsh, and Dr. Suh.

25 MS. HOLIDAY: Okay.

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1 CHAIR MALMUD: I detected a hesitancy, and  
2 this is not a draft I don't draft people in the  
3 Subcommittees. And, also, you're just starting with  
4 us. Let's give you some time to get in harness. Okay?  
5 I apologize for attempting to draft you into it.

6 (Laughter.)

7 CHAIR MALMUD: But you raised the issue,  
8 and it's a good issue, because sometimes we in big  
9 well-staffed institutions forget about the needs of  
10 smaller offices and so on. We will address the issue  
11 that you have raised. Thank you. So, Sophie, do you  
12 have the information that you need?

13 MS. HOLIDAY: I do. Thank you.

14 CHAIR MALMUD: Okay, thank you. Any other  
15 items for today on the agenda? If they're not on the  
16 agenda, anything that we need other than to point out  
17 that it's four minutes before 5:00, and we actually  
18 will have ended the meeting in a timely fashion.

19 MS. COCKERHAM: Please take your name tags  
20 off.

21 CHAIR MALMUD: I beg your pardon?

22 MS. COCKERHAM: Please take your name tags  
23 off.

24 CHAIR MALMUD: Oh, please take your  
25 name tags now, we'll not be in this room tomorrow.

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1 We're going to be in the room that we usually are in,  
2 which is in Building Two. Today we're in Building One.  
3 So, you want the name tags returned to you. You'll  
4 take care of this stuff here, and all we have to do is  
5 show up tomorrow at 8:00 a.m. in the other building in  
6 the room where we usually meet.

7 Now, does everyone now on the Committee  
8 have their ID? Ahh, you don't know how fortunate you  
9 are, Laura. It took me about half a year to get that.

10 MR. FULLER: I was just going to make sure  
11 that everyone understood it's T2-B3. So, that's Two  
12 White Flint, second floor, Room B3.

13 CHAIR MALMUD: Thank you all.

14 (Whereupon, the proceedings went off the  
15 record at 4:52:57 p.m.)  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

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## COMMENTS FROM MEMBER(S) OF THE PUBLIC

**STATEMENT OF PETER CRANE**

NRC Counsel for Special Projects (Retired)

to the

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

(Meeting of September 22/23, 2011)

Submitted September 19, 2011

**I. Introduction**

In a press announcement issued July 13, 2011 (news release No. 11-128), the Commission directed the staff "to examine feasibility and need of study on radiation doses to public from nuclear medicine." On September 12, 2011, when the NRC issued the news release (No. 11-171) announcing the ACMUI meeting of September 22/23, 2011, the status of the resulting staff paper was one of the agenda items. The same news release announced that any statements from the public must relate to an agenda item and be submitted within four days - that is, by September 16, 2011.

The meeting summary of the ACMUI meeting of April 11/12, 2001, is available online, and it shows that the date for the September meeting was chosen five months ago. The tardy notice inevitably serves to keep away interested persons who might have attended, and a four-day window for comment is utterly inadequate, given the complexity of the subjects that the ACMUI deals with. Why did the ACMUI wait until the last minute to give notice of the meeting, and why did it set a four-day deadline for submissions? There are only two possible explanations, neither flattering to the Committee: either it was deliberately trying to prevent public participation or it was so oblivious to the need to accommodate the public that the inadequacy of these time periods never crossed its mind.

As I emphasized in a brief memo to the Commissioners, emailed on September 18, 2011, what is at stake here is not the merits of the patient release issue or any other substantive matter. Rather; it is a question of process: of the fairness, openness, and integrity of the ACMUI's consideration of issues. The actions of the ACMUI reflect not only on the Committee itself; they also reflect, for good or ill, on the agency as a whole. In this case, they can only foster skepticism about the genuineness of the NRC's declared commitment to public involvement.

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1 The Committee should therefore reschedule the meeting to a  
2 later date, alter the time for submission of statements,  
3 and in the future pay greater attention to the need to  
4 accommodate the public meaningfully. In submitting a  
5 statement after the September 16 deadline, I do so in the  
6 full expectation that it will be accepted as a valid  
7 submittal and considered. But how many others are there  
8 who will have been foreclosed from making filings by these  
9 patently unrealistic deadlines? If the ACMUI does not  
10 feel conscience-bound to reconsider its original dates and  
11 deadlines, I trust that the Commissioners will intervene  
12 and set things right.

13  
14 I will outline my substantive concerns in a nutshell. The  
15 Staff Requirements Memo referred to in the June 13 news  
16 release says: "The staff should assume that existing  
17 guidance provided to the patients is being followed  
18 appropriately, **including the additional guidance provided**  
19 **recently to the licensees regarding the use of hotels."**  
20 [Emphasis added.] The problem is that this guidance is  
21 not being followed appropriately. Irrefutable evidence of  
22 this comes from the licensee community itself - most  
23 notably, from a March 2011 article in the online  
24 publication ASCO Post, a journal for endocrinologists, as  
25 I will describe below.

26  
27 If the Commission has been told otherwise, it has been  
28 misinformed, and not for the first time. I think it worth  
29 explaining this in some detail, in order to put the  
30 Commission on full notice of the risk that exists of being  
31 misled in this area.

## 32 33 **II. Misinformation about the release of radioactive** 34 **patients**

35  
36 The subject of the release of radioactive patients seems  
37 all too often to produce serious factual errors from  
38 sources of whom one would expect better. Let me give  
39 three recent examples, the first of which the Commission  
40 had an opportunity to witness first-hand. I assure you  
41 that this list is not exhaustive, and I can readily  
42 produce more such instances, though probably none so  
43 glaring as the following.

### 44 45 **A. The Advisory Committee on the Medical Uses of** 46 **Isotopes (ACMUI) Briefs the Commission, October 20, 2010.**

47  
48 The Commission's October 20, 2010, briefing on medical  
49 issues included a presentation by Dr. Susan Langhorst, who  
50 chaired a subcommittee that included most of the  
51 membership of the Advisory Committee on the Medical Uses  
52 of Isotopes (ACMUI). Dr. Langhorst assured the

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1 Commission, on behalf of the subcommittee, that its  
2 regulations on radioactive patients were just fine as is,  
3 needing no revision or fine-tuning to deal with  
4 radioactive patients in hotels or anything else. They  
5 were, she said, consistent with international standards:  
6 500 millirems for adult caregivers, 100 millirems for  
7 children and members of the public. (See her slide #11.)  
8 The group's bottom line (see her slide #15) was that "10  
9 CFR 35.75 should not be changed."

10  
11 Minutes later, Jim Luehman of the NRC staff took over the  
12 microphone, and the Commission learned from him that in  
13 fact the NRC does **not** follow the 500mr/100mr split  
14 standard that the International Commission on Radiation  
15 Protection and the National Commission on Radiation  
16 Protection recommend. Instead, it has a standard of 500  
17 millirems for everyone, including children and pregnant  
18 women. Indeed, the 500/100 split standard was expressly  
19 rejected by the NRC in 2008, when the NRC staff denied my  
20 petition for rulemaking. (Since the Commission did not  
21 involve itself in the matter, leaving it entirely to the  
22 staff, the Commissioners may have been unaware of this at  
23 the time.) It was apparent to all those watching that  
24 this information, which directly contradicted what Dr.  
25 Langhorst had told the Commission, took her utterly by  
26 surprise.

27  
28 10 CFR 35.75 is short and crystal clear.<sup>1</sup> (See Appendix B,  
29 where it is reproduced in full.) It would have been  
30 completely impossible for the subcommittee members to have  
31 misunderstood it - *if they had read it*. Plainly, during  
32 their five months of effort, handsomely compensated from  
33 NRC funds, none had thought to do so.<sup>1</sup> In an ideal world,  
34 Dr. Langhorst and her subcommittee would have apologized  
35 to the Commission for the inadequacy of their work and  
36 returned the money NRC paid them for it.<sup>2</sup>

---

<sup>1</sup> Dr. Langhorst incorrectly assured the Commission (see her slide #11) that the current release criteria were "Consistent with national and international recommendations in principle/practice," with "5 mSv/episode for caregivers/relatives" and "1 mSv/y for child/pregnant woman/public," and that the criteria "apply to single releases - not annual limit." Not only are NRC standards much looser, but international standards also make clear that this is an annual limit, not the per-release standard that the ACMUI so passionately advocates.

<sup>2</sup>The inevitable question is: what or whom were they relying on? Plainly they had not read the staff's 2008 denial of my petition, nor the petition itself, and if they had consulted Jim Luehman or other knowledgeable staff personnel, they would have been set right immediately. Nor, evidently, had they read ICRP 94, whose authors reported that the NRC standard was 5 mSv for everyone.

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1  
2           **B. Article in "Thyroid," April 2011, by Dr. James**  
3 **Sisson, et al.**  
4

5 The embarrassment suffered by the ACMUI subcommittee was  
6 minor, however, compared to that of Dr. James Sisson and  
7 fourteen co-authors, whose study of the patient release  
8 issue was the lead article in the April 2011 issue of  
9 "Thyroid," the journal of the American Thyroid  
10 Association. Whereas Dr. Langhorst and her colleagues  
11 spent five months on the ACMUI study, Dr. Sisson and his  
12 team spent three years studying the issue, and their work  
13 product went through extensive review within the ATA.  
14 Somehow, however, they did not even become aware of the  
15 existence of 10 CFR 35.75 until after they published their  
16 results, when they were set straight by Dr. Avenel Joseph  
17 of Congressman Markey's office and me. Until then, they  
18 had been under the mistaken impression that 10 CFR Part 20  
19 governed the release of patients.  
20

21 The June issue of "Thyroid" therefore includes a lengthy  
22 correction notice, and the following gracious statement:  
23

24           The authors deeply regret these errors and  
25 oversights, and express their gratitude to  
26 Peter Crane, J.D. (retired, Nuclear Regulatory  
27 Commission) and Avenel Joseph, M.S., Ph.D.  
28 (Office of Edward Markey, U.S. Congress) for  
29 bringing our attention to the errors needing  
30 correction.  
31

32 The moral of the story, I believe, is that whether you get  
33 reliable information depends less on the degrees and other  
34 credentials of those providing it than on their diligence  
35 and competence, and on whether their judgment is clouded  
36 by a particular agenda. Years ago, Dr. Carol Marcus wrote  
37 to the Commission urging that as a non-doctor, I was unfit  
38 to comment on matters pertaining to patient release, which  
39 should be left entirely to experts in the field. I did  
40 not agree then, and after what I have seen from the  
41 supposed experts, I agree even less today. Indeed, I  
42 would argue that even a high school student, if  
43 conscientious in doing research and open-minded in  
44 following it where it leads, may sometimes be a better  
45 source of information than doctors and scientists with  
46 impressive resumés but also a fixed determination to reach  
47 a particular conclusion.  
48

49           **C. The NRC's Brief to the Ninth Circuit Court of**  
50 **Appeals**  
51

52 In March 2011, the Commissioners received a report from

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1 the Office of Inspector General on its investigation of  
2 the discrepancy between what NRC headquarters told Region  
3 I in June 2008, on the permissibility of sending newly  
4 treated I-131 patients to hotels, and what the NRC's  
5 lawyers told the Ninth Circuit Court of Appeals in  
6 November of the same year.

7  
8 I don't want to rehash this matter at length. Suffice it  
9 to say that the Region was told that this practice was  
10 permissible under NRC regulations, that it was not  
11 uncommon, and that the agency intended to issue safety  
12 guidance dealing with the issue. The Court of Appeals, on  
13 the other hand, was sent a brief, five months later, that  
14 included a section headed, "NRC's rule does not permit or  
15 encourage doctors to send treated patients to hotels."  
16 Congressman Markey, whose letter to NRC had caused the  
17 memo to the Region to become known, asked the Office of  
18 Inspector General to investigate the matter.

19  
20 Charlie Miller, according to the report, told OIG that:  
21 "he disagreed with the November 2008 OGC legal brief  
22 subtitle, *NRC's rule does not permit or encourage doctors*  
23 *to send treated patients to hotels.*" He said that 10 CFR  
24 Part 35.75 does not state that doctors are not permitted  
25 to send patients to hotels, and it neither encourages nor  
26 discourages doctors from sending patients to a hotel."  
27  
28

29 Charlie had it right on the money.

30  
31 The OGC attorney who wrote the brief told OIG in his first  
32 interview that the word "permit" should have been replaced  
33 with the word "prohibit." He too was absolutely correct.  
34 His admission was significant, given that "permit" and  
35 "prohibit" are antonyms.<sup>3</sup>  
36

37 Strangely, however, the attorney quickly reversed himself  
38 180 degrees. In his subsequent OIG interviews, in the  
39 words of the report, he "said he stood by the language in  
40 his brief and said that replacing the word 'permit' with  
41 'prohibit' would not have been a correct reflection of his  
42 viewpoint." What caused him to recant between his first  
43 and later interviews with OIG is not stated in the report.  
44 OIG does not seem to have thought to ask.

---

<sup>3</sup>When the NRC uses the phrase "does not permit" in giving guidance to licensees, it means that something is forbidden or precluded. See, e.g., Regulatory Guide 1.193, Rev. 3, in October 2010, in which it wrote, "The NRC does not permit the use of rupture disk devices in spent nuclear fuel storage canister designs." Many such examples could be cited, as a simple Google search makes clear. Likewise, when the Ninth Circuit and the Supreme Court use the term in their decisions, there is no doubt that it means "precludes."

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1  
2 Whether or not there was actual wrongdoing involved,  
3 something clearly went awry here. In my 21 years in NRC's  
4 Office of General Counsel, defending the agency in  
5 appellate courts, an absolutely essential part of my job  
6 was to work closely with the technical staff to be sure I  
7 had my facts straight before making representations on  
8 behalf of the NRC and the U.S. Government. For example,  
9 when I was defending the Commission's approach to  
10 licensing dry cask storage in *Kelley v. Selin*, in the  
11 Sixth Circuit - a case I am happy to say that I briefed,  
12 argued, and won, and where I believed firmly that we were  
13 achieving something valuable for this country - I spent  
14 countless hours conferring with Charley Haughney of the  
15 NRC's technical staff. We needed to make completely sure  
16 that everything I wrote and said was scrupulously  
17 accurate. In those days, moreover, it was normal for the  
18 relevant staff to attend the moot courts in which lawyers  
19 prepared for oral argument, in part to make sure that we  
20 had an accurate understanding of the facts. If OGC's  
21 standards and practices have changed since then, I am  
22 sorry to hear it.

23  
24 Here, where the issue of whether radioactive patients were  
25 going to hotels was centrally important to the case, the  
26 NRC staff knew full well that this practice **was** occurring,  
27 and that it presented safety issues that needed to be  
28 dealt with. A single phone call from the lawyers to a  
29 knowledgeable staff official, such as Cindy Flannery, Jim  
30 Luehman, or Charlie Miller, would have revealed that fact,  
31 and ensured that the NRC gave the Ninth Circuit  
32 information that was accurate, complete, and unambiguous.  
33 Even under the most charitable view of the lawyers'  
34 actions, there was thus a failure to coordinate properly  
35 with the staff.

36  
37 I should make very clear that the lawyers' misinformation  
38 to the court did not, as far as we can tell, play any part  
39 in the disposition of the case. I lost the case, and the  
40 NRC lawyers won it, not on the merits, which the court did  
41 not reach, but on "standing" - a threshold jurisdictional  
42 question that asks whether the person bringing suit has  
43 the right to be in court at all. The NRC argued, and the  
44 court agreed, that my own I-131 treatments for thyroid  
45 cancer occurred too long ago for me to be sufficiently  
46 affected by the present rules to challenge them in court.<sup>4</sup>

---

<sup>4</sup> What we can never know, of course, is whether the court would necessarily have taken so restrictive a view of standing if the NRC's lawyers, instead of giving the court to understand that the issue of radioactive patients in hotels was my fabrication, had said this: "Yes, radioactive patients are going to hotels in significant numbers; no, nothing in the NRC's rules prohibits this; yes, the petitioner and a number of commenters

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1 Thus the court had no occasion to decide whether patients  
2 were going to hotels, or any other substantive issue in  
3 the case. The other side of that coin, however, is that  
4 the court's decision did not "uphold the NRC's rules on  
5 patient release," as some may imagine; rather, it ruled  
6 that in a lawsuit brought by me alone, it lacked  
7 jurisdiction to hear the case, and therefore had no  
8 authority to render judgment pro or con on the NRC's  
9 rules.

10  
11 At a meeting at NRC in 2010, Chris Einberg of the staff  
12 explained the delay in acting on the 2008 commitment to  
13 issue guidance on radioactive patients in hotels by saying  
14 that the staff had been advised - he didn't say by whom -  
15 to wait until the lawsuit was resolved. If his  
16 recollection was accurate, that is evidence of a shocking  
17 failure on someone's part to keep the agency's priorities  
18 straight. Protecting the public from harm must always  
19 take precedence over perceived advantages in litigation.  
20

21 As noted above, there would have been no need for an RIS  
22 in 2011 if it were true that NRC's rule "does not permit"  
23 radioactive patients to be sent to hotels. What seems so  
24 regrettable and tragic and inexcusable in all this is that  
25 I first raised this issue with NRC in **January 2006**. It  
26 took five years for an RIS to be issued - five years in  
27 which we have no way of knowing what harm may have been  
28 done to hotel staff and guests, and of that harm, how much  
29 might have been averted by a timelier warning. If there  
30 is just one case of mental retardation or thyroid cancer  
31 in a child who was in the womb of a hotel housekeeper when  
32 she cleaned a room contaminated with I-131, and if that  
33 case could have been prevented by an RIS issued in 2006 or  
34 2008, it will be one case too many.

### 35 36 **III. The Commission's July 13 Directive to the Staff**

37  
38 The Commission's July 13 directive tells the staff to  
39 proceed on the assumption that its guidance, including  
40 that on radioactive patients in hotels, is being followed.  
41 In fact, there is irrefutable evidence that licensees are  
42 not following the NRC's non-binding guidance on the use of  
43 hotels. In March 2011, in an article in ASCO Post, an  
44 online journal serving endocrinologists, Dr. R. Michael  
45 Tuttle of New York City's celebrated Sloan-Kettering

---

raised this point; no, we said nothing about it in the denial  
of the petition; yes, safety issues are raised, which we will  
eventually address with guidance of some kind; but you, the  
Court, still have no right to hear this case, because the  
petitioner's last I-131 treatment occurred in 1991, and what  
the NRC does and doesn't do with respect to radioactive  
patients therefore doesn't affect him."

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1 Memorial Cancer Center was quoted as saying that "many  
2 patients don't have a choice [about staying in a hotel]  
3 because they are flying in for their treatments." "We are  
4 absolutely comfortable that it is safe for these patients  
5 to be in a hotel," he said. (A copy of the full article,  
6 converted into Word format, is attached as an appendix.)  
7

8 It is worth noting that New York City's Department of  
9 Health issued a notice in 2009 that included the words,  
10 "Do **NOT** advise patients to go to hotels." [Emphasis in the  
11 original.] If Sloan-Kettering is not deterred by that  
12 directive, it certainly will not be influenced now by  
13 NRC's toothless plea for voluntary compliance.<sup>5</sup>  
14

15 Some explanation may be needed of Dr. Tuttle's statement  
16 that "many patients don't have a choice." The problem for  
17 patients "flying in" for treatment is that at the same  
18 time that the NRC was deregulating I-131, Europe was  
19 tightening its restrictions, based on data from Chernobyl  
20 on the danger to others. Today, if you are a thyroid  
21 cancer patient treated in Europe, you will be hospitalized  
22 for an I-131 dose as low as 8 millicuries (in Germany) and  
23 no more than 12 to 15 millicuries elsewhere. By contrast,  
24 Sloan-Kettering, according to Dr. Tuttle, as quoted in the  
25 ASCO Post article, administers up to 200 millicuries to  
26 outpatients.  
27

28 If you are an outpatient who has just been given 200  
29 millicuries of I-131, and you go to JFK airport to board  
30 an airplane, you will set off the radiation alarms that  
31 are ubiquitous since 9/11. At that point, you will  
32 produce a card, given you by the hospital's nuclear  
33 medicine department, explaining that you are a patient,  
34 not a terrorist. But as Dr. Tuttle explained, "in some  
35 other countries, nobody cares if you've got a card saying  
36 that you were treated at Memorial Sloan-Kettering."  
37

38 In other words, the thyroid cancer patients whom doctors  
39 in the U.S. now "whisk out the doors as soon as possible,"  
40 in the unforgettable words of ACMUI Chairman Leon Malmud,  
41 are considered a public health menace if they return to

---

<sup>5</sup> What New York City said was this: "To avoid sending iodine therapy patients home, do **NOT** advise patients to go to a hotel. A hotel presents substantial probability of close contact with infants, young children, pregnant women, and of course the general public. In a serious, and not at all implausible case, a patient could have their room or dining area cleaned by a pregnant woman who could come into very close contact with radioiodine-containing-bodily fluids." [Emphasis in the original.] I view this as binding, but I am informed by OIG that it merely constitutes "strong advice." If ever I am stopped for passing in a "Do Not Pass" zone, or for driving where a sign says "Do Not Enter," I doubt I would get far with the argument that these signs merely conveyed "strong advice."

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1 their home countries too soon. (Some of them may have  
2 come here specifically to take advantage of the NRC's lax  
3 regulations - "nuclear tourism," in the words of a 2004  
4 report from the International Commission on Radiation  
5 Protection, ICRP 94, at p. 53.) And so these foreign  
6 patients while away a few days in a New York hotel room,  
7 which is entirely understandable, for once they have been  
8 treated as outpatients and discharged, it is probably a  
9 choice between that and a park bench.

10  
11 The corollary is that if you are a patient from out of  
12 town in the U.S., from Memphis or Omaha or wherever, there  
13 is nothing to keep you from boarding a plane in New York  
14 and spending the next several hours elbow to elbow with  
15 the next passenger, who may be a small child or a pregnant  
16 woman.<sup>6</sup> And that is the essence of the problem: the  
17 protection of the public is only as good as the conscience  
18 of the individual patient.

19  
20 The ACMUI subcommittee report says that "well-informed  
21 patients are self-motivated and sensitive to the fact that  
22 they are radioactive for a period of time," and they will  
23 "typically do as much as possible to reduce potential  
24 exposure to others." This is wishful thinking, and as the  
25 saying goes, "wishing doesn't make it so." What basis is  
26 there for this statement, other than the subcommittee's  
27 desire to make a thorny problem disappear?

28  
29 I would answer the subcommittee's assurances about the  
30 character and behavior of I-131 patients in two ways.  
31 First, we thyroid cancer patients are no better or worse  
32 than other people: some of us are altruistic, some  
33 aren't. Generalizations about how considerate we are of  
34 others are purely fanciful. Secondly, when patients face  
35 a choice between exposing their own families and exposing  
36 strangers, they often decide to put their families' well-  
37 being first, even if that means contaminating the hotel

---

<sup>6</sup> Some patients do this, regrettably, notwithstanding that they will be delivering a substantial radiation dose to those near them on a long flight. Those other passengers will, of course, have no clue that they are being irradiated. Nearly 20 years ago, NIH warned the NRC about this, when the deregulation of I-131 treatments was being proposed, but it was ignored, as was everyone who raised concerns about the plan. The difference between then and now is that then, the most any patient could have in his or her system was 30 millicuries. Today patients are boarding planes with many times that much I-131 in their bodies. I am confident that no Commissioners would want a child or grandchild of theirs to be sitting elbow to elbow with such a patient on a long flight, any more than they would want a child or grandchild to be working in a hotel, cleaning a room and bathroom just contaminated by an I-131 patient. If it is not fit work for your child, it is not fit work for anyone else's child either, given that there is no informed consent involved.

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1 room that a stranger will clean and other strangers will  
2 sleep in.

3  
4 The same article quoted Dr. Richard Kloos, CEO of the  
5 American Thyroid Association, as agreeing that staying in  
6 a hotel "can be done safely and reasonably." He  
7 suggested, however, that patients pre-register, so as to  
8 minimize their time in the lobby. For Dr. Kloos, it  
9 seems, the only people in the hotel whose radiation  
10 exposure matters are the other hotel guests. As for the  
11 housekeepers who scrub the contaminated sinks and toilets  
12 and handle the contaminated linens, and are at far greater  
13 radiation risk than anyone standing in the registration  
14 line in the lobby, they don't even enter the equation.  
15

16 Compounding the problem is the fact that in a hotel near a  
17 major cancer center, one housekeeper may clean numerous  
18 contaminated rooms in the course of a year, accumulating  
19 an ever greater radiation dose each time. Jim Luehman  
20 made that point in the Commission meeting of October 20,  
21 2011, but the ACMUI members paid no attention. In the  
22 October 21, 2010, ACMUI meeting, at p. 54 of the  
23 transcript, we see Dr. Zanzonico saying: "The largest  
24 doses we found, which were, predictably, to the  
25 housekeeping staff, were less than 100 millirems, so below  
26 even the dose limit for 'sensitive' populations."  
27

28 But what about the pregnant housekeeper who cleans five or  
29 ten such rooms, and accumulates a dose from each one?  
30 What is happening to her baby's thyroid? Moreover, the  
31 subcommittee's analysis was based on someone holding  
32 sheets on which an I-131 patient had sweated. Saliva and  
33 urine are far hotter than sweat. Did the subcommittee  
34 calculate the dose to a housekeeper who, wearing only  
35 rubber gloves, cleans a sink in which a radioactive  
36 patient has just brushed his or her teeth, and the toilet  
37 in which a patient has recently urinated? Were all those  
38 added together? The subcommittee seems to have assumed,  
39 with no basis whatsoever for that assumption, that  
40 housekeepers would clean at most one such room per year.  
41 This is fantasy, not reality, and public health standards  
42 need to be grounded in the real world, not in make-  
43 believe.  
44

45 Perhaps, however, I am doing the subcommittee an  
46 injustice, and it did take in this point. If so, that  
47 might explain the ACMUI's fervent insistence that release  
48 criteria must be based on a per-release, rather than per  
49 year, basis, contrary to what the ICRP and NCRP prescribe.  
50 For if you look at doses to affected members of the public  
51 on a per-release basis, then a housekeeper could clean a  
52 hundred contaminated rooms in a year and NRC's regulatory

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1 standards would not be exceeded, since her exposures would  
2 not be summed.

3  
4 If the Commission is really interested in obtaining data  
5 pertinent to the hazards posed by released patients,  
6 perhaps it should ask permission of the hotels in the  
7 vicinity of Sloan-Kettering, the Mayo Clinic,  
8 Massachusetts General Hospital, and a few others, to  
9 install radiation detectors. In that way, when the  
10 monitors signal the arrival of a radioactive patient,  
11 inspectors could track the person and measure the actual  
12 radioactivity left in the room.

13  
14 I do not imagine that the NRC or the ACMUI would be eager  
15 to set off down that path, which would alert hotels to the  
16 contamination that radioactive patients are bringing into  
17 their hotels, and their potential liability to those  
18 contaminated by them. But if you want meaningful data,  
19 you are not going to get it from listening to the ACMUI's  
20 assurances of how selfless and thoughtful we I-131  
21 patients are. Are we so selfless and thoughtful that we  
22 will bring along our own cleaning equipment and clean our  
23 own sinks and toilets? Even if we do, what are we  
24 supposed to do with our linens? Patients who are sent  
25 home are told to wash their bed linens separately from  
26 those of other family members. How is that supposed to  
27 happen in a hotel? We can hardly strip the beds and take  
28 the linens with us, explaining to the hotel staff that we  
29 intend to launder them at home and then return them.

30  
31 We saw in the Braidwood Motel incident, in 2007, that the  
32 only situation in which a hotel guest is likely to know  
33 about contamination from an I-131 patient is if he or she  
34 works in a nuclear power plant, in which case he will set  
35 off the radiation alarms at work. One patient, checking  
36 into that motel to protect her family from radiation,  
37 managed to cause alarms to sound in two nuclear plants,  
38 Braidwood and La Salle. A Braidwood worker was the next  
39 person to occupy her room, and he was found to be  
40 contaminated on his skin and clothing. A day later, the  
41 LaSalle worker set off the alarms. He had stayed in the  
42 same motel, but in a different room. His only contact  
43 with contamination came from his sheets, which had been  
44 laundered together with those of the patient. The I-131  
45 had been transferred in the washer and dryer.

46  
47 In the ACMUI meeting of April 12, 2011, at p. 148 of the  
48 transcript, we see Chairman Malmud indulging in a bit of  
49 sarcasm about the newspaper reports that had contrasted  
50 the NRC's regulations on radioactive animals and  
51 radioactive people. (A cat given three millicuries of I-  
52 131 for feline hyperthyroidism must be hospitalized for a

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1 minimum of 72 hours, whereas the cat's owner, given 300  
2 millicuries, can be treated as an outpatient and  
3 released.) Dr. Malmud said:

4  
5 And we are not cats or dogs. We don't  
6 generally urinate in the street. So the  
7 concern about the effluent of the radiation for  
8 animals is different from that for humans.  
9 Humans generally use toilet facilities, and the  
10 effluent is diluted immediately, so that these  
11 are very different issues from the ones that  
12 have been highlighted in the newspaper.

13  
14 The effluent is diluted immediately, of course, only if it  
15 lands in the toilet bowl and is flushed away, and as Dr.  
16 Malmud surely knows, in his more serious moments, men are  
17 frequently careless when they urinate: according to ICRP  
18 94, at p. 27, men leave 75 times as much radioactivity on  
19 the toilet rim as women during the first 48 hours after  
20 treatment. In a hotel, it is a housekeeper who cleans up  
21 the rim of the toilet bowl and any urine that has missed  
22 the toilet altogether.

23  
24 I make no apologies for feeling sympathy for people who  
25 are mistreated - and to put someone in danger is to  
26 mistreat them, even if they are unaware of it - because  
27 they belong to a class that is viewed as somehow  
28 expendable, unworthy of the concern and protection that  
29 would go without saying for those us who occupy more  
30 privileged positions in life. In this case, my concern is  
31 for the hotel housekeepers. They have a hard enough lot  
32 in life without being irradiated, and possibly also having  
33 their unborn babies permanently harmed by thyroid cancer,  
34 retardation, or both, through the tightfistedness of  
35 insurance companies and the indifference and/or ignorance  
36 of doctors and regulators. (I will explain that statement  
37 more fully below, at p. 10-11, in quoting from the  
38 transcript of an ACMUI meeting in October 2007.)

39  
40 I do not mean by this to downplay the risk to thyroid  
41 cancer patients' own families. That continues to be a  
42 serious issue: patients sent home to households where  
43 there are small children, and where keeping a safe  
44 distance, and having one's own bathroom to oneself, is not  
45 an option. I suggest that the NRC staff should subscribe  
46 to the listserv of the Thyroid Cancer Survivors'  
47 Association - I am sure that Gary Bloom, the Executive  
48 Director, would give his approval - to get a feel, day by  
49 day, for the experiences of the hundreds and thousands of  
50 patients who submit their comments and questions. You  
51 would read, for example, of the woman in New Jersey who  
52 writes that she has been told that there is no point in

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1 even asking for inpatient treatment, because even if the  
2 insurance company gives its preapproval, it sometimes  
3 withdraws that approval after the fact, so that the  
4 hospital will not take the financial risk of treating  
5 anyone as an inpatient. There are many, many such  
6 stories, and though some would dismiss them as  
7 "anecdotal," or suggest that only a doctor's word on such  
8 matters can be relied upon, these reports are submitted by  
9 people with no motivation to be anything but candid.

10  
11 Two years ago, Jim Luehman of the NRC staff and I shared a  
12 podium at the annual conference of the Thyroid Cancer  
13 Survivors' Association, in Danvers, Massachusetts. (His  
14 presence there was greatly appreciated by all.) I am sure  
15 Jim remembers as well as I the questions and comments from  
16 the floor: the young woman who was sent home to her  
17 toddlers radioactive, and who commented that it not easy  
18 to keep your distance from a one-year-old and a three-  
19 year-old, and another woman who was told by the hospital  
20 to stay in a hotel for the first night and have her  
21 husband pick her up the following day. These people had  
22 no reason to fabricate anything, and though they didn't  
23 have medical degrees, I am sure that Jim would agree with  
24 me that they were unquestionably telling the truth.

#### 25 26 **IV. Conclusion**

27  
28 I do not doubt that the Commission desires to do the right  
29 thing by the American public, including thyroid cancer  
30 patients, their families, and the ordinary citizens who go  
31 to hotels and ride public transportation also used by  
32 radioactive patients. I applaud Commissioner  
33 Apostolakis's decision to attend the upcoming conference  
34 of the Thyroid Cancer Survivors' Association, to be held  
35 in Los Angeles in October. I also commend the Commission  
36 for choosing a Patients' Rights Advocate, Laura Weil, who  
37 seems splendidly qualified to make that position once  
38 again what it was intended to be, a voice for patients'  
39 rights and interests.

40  
41 What I do question, however, is the quality of some of the  
42 information the Commission gets. I wonder whether the  
43 Commission has been made fully aware that the decisions on  
44 who will be hospitalized for I-131 treatments have largely  
45 been taken out of the hands of doctors by the insurance  
46 companies, which have in the main stopped paying for  
47 inpatient treatment, regardless of the patient's home  
48 situation. This has made a mockery of the Commission's  
49 intent, in 1997, to allow patient care to be tailored to  
50 the individual home situation.

51  
52 The Commission need not take my word for it; it can take

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1 Dr. Malmud's. The present reality was described vividly  
2 in an ACMUI meeting in October 2007. No one has suggested  
3 that the description given in that meeting was inaccurate:  
4

5 Dr. Eggli: ... We can't get a preceptor to  
6 admit most patients to the hospital anymore  
7 from the insurance companies since the release  
8 rule went into effect. ... If I am admitting  
9 somebody [with] less than 200 millicuries, the  
10 chances that I can get an insurance  
11 authorization for a hospitalization to isolate  
12 them, **even when I have family situations that**  
13 **require it**, it's fighting tooth and nail with  
14 the insurance companies....

15 Dr. Malmud: It is not now possible to treat a  
16 patient at our hospital and many hospitals in  
17 the Philadelphia area with I-131 in high doses  
18 for thyroid cancer because in order to do that  
19 a patient has to be isolated in a room which  
20 itself is isolated from the rooms next door.

21 Therefore, **all patients are discharged upon**  
22 **treatment. We whisk them out the doors as fast**  
23 **as possible.** They are given outpatient doses  
24 between 100 and 200 millicuries of I-131,  
25 depending upon the extent of their thyroid  
26 cancer and occasionally, even higher doses. ...

27 **There's also an impossibility of keeping the**  
28 **patient in the hospital since the insurer will**  
29 **not cover it.** The insurer will not cover it,  
30 will not cover the inpatient stay. It will  
31 cover the treatment, but not the inpatient  
32 stay. ...

33 Being in the hospital today in most situations  
34 is an absolute impossibility. The nursing staff  
35 won't care for the patient. The other personnel  
36 in the hospital don't want to be near the  
37 patient. The hospital doesn't want the patient  
38 in the hospital. More than one room has to be  
39 reserved for the patient. It's an  
40 impossibility.

41 ... Within the hospital, this patient is an  
42 unwelcome guest currently. Uninsured, **their**  
43 **wonderful insurance stops because it's no**  
44 **longer necessary for them to be an inpatient.**  
45 [Emphasis added.]<sup>8</sup>  
46

47 This, unfortunately, is the real world of 21<sup>st</sup> Century

---

<sup>8</sup><http://pbadupws.nrc.gov/docs/ML0808/ML080850674.pdf> See pp.  
187-188.

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1 medicine, in which all too often, the insurance companies  
2 have the whip hand, and doctors trail along behind,  
3 powerless to do what the best interests of their patients  
4 demand.

5  
6 As the ACMUI subcommittee and the ATA journal have  
7 demonstrated, you can have impressive credentials and  
8 still get your facts wrong. The NRC's 1997 deregulation  
9 is testimony to that. It took the NRC staff until 2008 -  
10 four years after the issuance of ICRP 94 removed all doubt  
11 on the subject - to acknowledge publicly that the 1997  
12 rule had erred in dismissing the risk posed by  
13 contamination from I-131 patients. The staff was relying  
14 on erroneous advice from Dr. Myron Pollycove, then a  
15 Visiting Medical Fellow, whose decidedly non-mainstream  
16 views on radiation risk were singled out for criticism by  
17 the National Academy of Sciences in BEIR VII, its  
18 authoritative report on the biological effects of ionizing  
19 radiation. (More recently, in a 2008 article, Dr.  
20 Pollycove wrote that if a nuclear accident occurred, "the  
21 radiation exposure would not be harmful and might even be  
22 beneficial.") Unfortunately, we find ourselves struggling  
23 today with the consequences of that grave mistake.<sup>9</sup>

24  
25 In short, rather than telling the staff to proceed on the  
26 assumption that the guidance on patients is being  
27 followed, the Commission should take a step back, and ask  
28 **whether** the guidance is being followed. On that point, it  
29 is not good enough to rely on the self-serving statements  
30 of doctors' professional associations. It means outreach  
31 to the patients, to find out their experiences. If the  
32 Commission wants to know whether its regulations are doing  
33 an adequate job of protecting the public, it has to go  
34 beyond the nominal experts and find out what is happening  
35 on the ground: in patients' homes, in hospitals, and in

---

<sup>9</sup> At the time that the deregulation of I-131 was first proposed, in 1992, Dr. Malmud submitted comments to the NRC in his capacity as President of the Society of Nuclear Medicine. As I wrote to him on November 21, 2010, a review of those comments indicate that what the NRC did in that rule change went radically beyond what Dr. Malmud himself recommended, which was that the NRC should follow NCRP 37. Under NCRP 37, the maximum outpatient dose of I-131 was 80 millicuries, and patients were to wear tags or wristbands identifying them as radiation hazards. NCRP 37 prescribes the precautions appropriate for a person receiving 50 millicuries of I-131 as an outpatient: in the first week, if there is anyone under 45 in the household, no one under 45 is allowed in the same room, or within 9 feet, for more than a few minutes a day. Only after eight weeks is unrestricted contact with others permitted. Where patients lived in multi-family buildings, the proximity of neighbors was to be considered in evaluating the risk to others, and under some circumstances, release of patients required notification of local health departments. We have come a long, long way since then.

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the hotels where too many radioactive patients still go,  
either because doctors recommend it, or because they have  
no place else to go, or because they have decided on their  
own to protect their families from exposure to radiation.

Respectfully submitted,

/s/

Peter Crane  
Counsel for Special Projects, USNRC (retired)  
September 19, 2011

cc: the Commissioners  
Rep. Ed Markey  
Rep. Fred Upton  
Rep. Jim McDermott  
Sen. Barbara Boxer  
Sen. Charles Grassley

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4 **How Can Patients Who Receive Radioactive Iodine Treatment for**  
5 **Thyroid Cancer Reduce the Chance of Radiation Risks to Others?**  
6

7 By Charlotte Bath

8 March 1, 2011, Volume 2, Issue 4  
9

10 Although patients treated with radioactive iodine (I-131) for  
11 thyroid cancer may theoretically expose those in their  
12 immediate environment to low levels of radiation for a few  
13 days, reports about radioactive patients released from the  
14 hospital and endangering those they meet seem to have taken on  
15 a half-life of their own. The issue continues to come up in  
16 Congress and the media, as it did recently when the Nuclear  
17 Regulatory Commission (NRC) met to review its recommendations  
18 on the medical use of radioactive materials. The NRC statement  
19 issued after the meeting on December 13, 2010,<sup>1</sup> affirmed its  
20 previous analysis that patients treated with radioactive iodine  
21 can be safely discharged if their radiation dose to others is  
22 under 500 millirems (5 millisieverts [mSv]) and that radiation  
23 exposure can be effectively managed by following instructions  
24 based on NRC recommendations and provided by the treating  
25 facility to patients likely to expose others to radiation doses  
26 of 100 millirems (1 mSv) or more.  
27

28 **Specific Guidelines**  
29

30 Richard T. Kloos, MD "The framework of this is that the lowest  
31 known levels of radiation that cause harm are somewhere between  
32 10,000 to 100,000 millirems (100 to 1,000 mSv) and there is no  
33 evidence below 10,000 millirems of any harm," stated Richard T.  
34 Kloos, MD, Professor, The Ohio State University, Divisions of  
35 Endocrinology and Nuclear Medicine, Co-Director of The Ohio  
36 State University Thyroid Cancer Unit, and Secretary/Chief  
37 Operating Officer of The American Thyroid Association. "People  
38 can go home if they are expected to not give anybody else in  
39 the public more than 5 mSv....Verbal and written instructions are  
40 required for patients who might expose others to more than 1  
41 mSv," he added.  
42

43 "Each hospital has very specific written guidelines that define  
44 which patients can be treated as an outpatient and which  
45 patients need to be admitted to the hospital for radioactive  
46 iodine therapy," explained R. Michael Tuttle, MD, Attending  
47 Physician, Endocrinology Service, Memorial Sloan-Kettering  
48 Cancer Center, and Professor of Medicine at Weill Medical  
49 College of Cornell University. "In some of my thyroid cancer  
50 patients, I give 400 or 500 millicuries to treat radioactive  
51 iodine-avid metastatic disease, and I would never do that for  
52 an outpatient. There is no reliable way to make that safe."  
53

54 He said that he would also not administer radioactive iodine  
55 outpatient treatment to patients who, because of their age,  
56 other medical conditions, or cognitive impairment, might not be  
57 able to understand or follow precautions to minimize radiation  
58 exposure to others. "Those patients are not treated as

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1 outpatients," he said. "We wouldn't treat somebody as an  
2 outpatient unless we can be comfortable that they will follow  
3 the rules" about minimizing risks to others.

#### 4 **Current Standard of Practice**

5  
6  
7 The NRC statement is an update to 1997 modifications of a  
8 regulation acknowledging that a facility licensed to provide  
9 radiation treatment "is best qualified to assess the  
10 suitability of individual patients to release post-treatment  
11 and to provide personalized guidance to patients to assure  
12 compliance with the applicable release criteria." According to  
13 a joint statement<sup>2</sup> from the American Thyroid Association, The  
14 Endocrine Society, the Society of Nuclear Medicine, and the  
15 American Association of Clinical Endocrinologists, "A goal of  
16 this rule change was to avoid isolation of a patient in the  
17 hospital for prolonged periods if the patient's release to home  
18 would be safe for the patient, the patient's family, and the  
19 public. This approach enhances patient satisfaction and is the  
20 current standard of medical practice."

21  
22 Most patients with thyroid cancer usually have surgery first.  
23 "They go home in a day or two and then usually we give  
24 radioactive iodine somewhere between 1 and 2 months after the  
25 surgery," Dr. Tuttle said. "So their surgical wound is healed."

26  
27 Although dependent on the individual, the average I-131 dose  
28 for the treatment of thyroid cancer ranges from 30 to 200 mCi.  
29 Usually a single dose is all that is needed. "I used to be in  
30 the army, so I tell patients it is my heat-seeking missile,"  
31 Dr. Tuttle said. "They swallow it and it goes everywhere  
32 through their body, identifying and destroying thyroid cancer  
33 metastases." He estimated that less than 10% of patients get a  
34 second dose 6 months or a year later.

#### 35 **Self-motivated Patients**

36  
37  
38 The NRC statement says that "well-informed patients are self-  
39 motivated and sensitive to the fact that they are radioactive  
40 for a period of time," and they will "typically do as much as  
41 possible to reduce potential exposure to others." Dr. Tuttle  
42 and Dr. Kloos agreed on this point.

43  
44 "It is definitely an issue that patients ask about because  
45 everybody is afraid that they are going to expose their family  
46 or anybody else to radiation," Dr. Tuttle stated. "Most  
47 patients are more interested in that than they are about the  
48 side effects and how the radioactive iodine might hurt them.  
49 Because they are pretty convinced that it is a safe medicine  
50 for them."

51  
52 Many patients knowing they will receive I-131 have researched  
53 the treatment and are often "reassured that actually what we  
54 ask them to do is much less imposing than what they thought it  
55 was going to be and is something they can easily follow," Dr.  
56 Kloos said. "It is quite rare that someone is just so  
57 frightened or concerned about this that they elect not to  
58 receive radioiodine out of concern or fears."

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1  
2 The general advice offered by Dr. Tuttle is "to stay at arm's  
3 length from everybody for a day or two." The written  
4 instructions patients take with them are more detailed,  
5 "because the specifics of how long-whether it is 1, 2, or 3  
6 days-depends on the dose that we give. It also depends on their  
7 age, because young people get rid of the radioactive iodine  
8 faster than older people."  
9

10 Dr. Kloos tells patients to "act like you have the flu for the  
11 next day or two. Avoid close contact. Avoid swapping bodily  
12 fluids. Avoid kissing, sex, and sharing cups or utensils. Avoid  
13 food taste testing for others, and for the next day act like  
14 you are infectious, keeping time and distance between you and  
15 another person," he tells patients. If patients can do this,  
16 their risk of exposing others to radiation is low. "If they  
17 can't, we talk about admitting them to the hospital."  
18 Dr. Kloos reminds patients that they will not actually feel  
19 like they have the flu. "Most people feel nothing," he said. "A  
20 few will feel a little nausea," which can be treated with  
21 antiemetics.  
22

### 23 **Room at the Inn?**

24  
25 Radiation detectors have become increasingly prevalent and  
26 sensitive and "can detect minute amounts of radiation, way  
27 below levels that can cause any kind of harm," Dr. Kloos said.  
28

29 "My patients will set off airport detectors for a week or 10  
30 days after treatment," Dr. Tuttle reported. "They will set off  
31 the detectors on the interstate," he said. While police and  
32 transportation workers are generally aware that medical  
33 radiation can set off detectors, it can create anxiety among  
34 patients and fellow travelers. Patients treated at Memorial  
35 Sloan-Kettering Cancer Center receive a card indicating that  
36 they were treated with radioactive iodine. Although that may be  
37 helpful at U.S. airports, "in some other countries, nobody  
38 cares if you've got a card that says you were treated at  
39 Memorial Sloan-Kettering," Dr. Tuttle noted. For that reason,  
40 staff members often caution international patients to wait a  
41 few days after radiation treatment before flying home.  
42

43 But where do they stay? Some reports have raised concerns about  
44 staying in hotels and exposing workers there to radiation  
45 risks.  
46

47 "We tend to discourage people from staying at hotels, although  
48 when we look at the data, it seems perfectly fine for them to  
49 do so," Dr. Tuttle said. "Many patients don't have a choice  
50 because they are flying in for their treatments. If we treat  
51 them, they are usually not going to be able to fly for 2 or 3  
52 days," because of precautions to keep at least an arm's  
53 distance from others and possibilities about setting off  
54 alarms. "We have carefully looked at this because we have lots  
55 of people flying in. When we set up these outpatient rules, we  
56 asked the question, 'Should we just admit people if they have  
57 to stay at a hotel?' Our physicists and nuclear medicine people  
58 very carefully went through all the data, and we are absolutely

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1 comfortable that it is safe for these patients to be in a  
2 hotel," Dr. Tuttle said.

3  
4 Staying in a hotel "can be done safely and reasonably," Dr.  
5 Kloos agreed, but physicians need to discuss with patients some  
6 additional risk-reduction strategies. These measures include  
7 checking in before treatment so they can go directly to their  
8 room afterwards and avoiding interactions in the lobby.

9  
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15  
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21  
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3 **§ 35.75 Release of individuals containing**  
4 **unsealed byproduct material or implants**  
5 **containing byproduct material.**

6 (a) A licensee may authorize the release from its control  
7 of any individual who has been administered unsealed  
8 byproduct material or implants containing byproduct  
9 material if the total effective dose equivalent to any  
10 other individual from exposure to the released individual  
11 is not likely to exceed 5 mSv (0.5 rem).<sup>1</sup>

12 (b) A licensee shall provide the released individual, or  
13 the individual's parent or guardian, with instructions,  
14 including written instructions, on actions recommended to  
15 maintain doses to other individuals as low as is  
16 reasonably achievable if the total effective dose  
17 equivalent to any other individual is likely to exceed 1  
18 mSv (0.1 rem). If the total effective dose equivalent to a  
19 nursing infant or child could exceed 1 mSv (0.1 rem)  
20 assuming there were no interruption of breast-feeding, the  
21 instructions must also include—

22 (1) Guidance on the interruption or discontinuation of  
23 breast-feeding; and

24 (2) Information on the potential consequences, if any, of  
25 failure to follow the guidance.

26 (c) A licensee shall maintain a record of the basis for  
27 authorizing the release of an individual in accordance  
28 with § 35.2075(a).

29 (d) The licensee shall maintain a record of instructions  
30 provided to a breast-feeding female in accordance with §  
31 35.2075(b).

32 [67 FR 20370, Apr. 24, 2002 as amended at 70 FR 16363,  
33 Mar. 30, 2005; 72 FR 45151, Aug. 13, 2007]

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