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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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OPEN MEETING

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THURSDAY, SEPTEMBER 22, 2011

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

MEMBERS PRESENT:

LEON MALMUD, M.D., Chairman

BRUCE THOMADSEN, Ph.D, Vice Chair

MILTON GUIBERTEAU, M.D., Diagnostic Radiologist

SUSAN LANGHORST, Ph.D., Radiation Safety Officer

STEVEN MATTMULLER, Nuclear Pharmacist

CHRISTOPHER PALESTRO, M.D., Nuclear Medicine Physician

JOHN SUH, M.D., Radiation Oncologist

ORHAN SULEIMAN, M.D., FDA Representative

WILLIAM VAN DECKER, M.D., Nuclear Cardiologist

LAURA WEIL, Patients' Rights Advocate

MEMBERS PRESENT (CONT'D):

JAMES WELSH, M.D., Radiation Oncologist

PAT ZANZONICO, Ph.D., Nuclear Medicine Physicist

NRC STAFF PRESENT:

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

CHRIS EINBERG, Designated Federal Officer

ASHLEY COCKERHAM, Alternate Designated Federal Officer

MICHAEL FULLER, Alternate Designated Federal Officer

NEELAM BHALLA, FSME/DILR/RB-B

SUSAN CHIDAKEL, OGC/GCLR/RMR

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

JONATHAN EVANS, FSME/DILR/RB-B

SOPHIE HOLIDAY, FSME/DMSSA/LISD/RMSB

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

VARUGHESE KURIAN, FSME/DWMEP/DURLD

ED LOHR, FSME/DILR/RB-B

ANGELA McINTOSH, FSME/DMSSA/LISD/RMSB

PATRICIA PELKE, R-III/DNMS/MLB

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

DUANE WHITE, FSME/DMSSA/RMSB

SHIRLEY XU, FSME/DMSSA/LISD/LB

ALSO PRESENT:

ARMIN ANSARI, Ph.D., CDC

ART CHANG, CDC

WILLIAM DAVIDSON, UNIVERSITY OF PENNSYLVANIA

LYNN EVANS, Ph.D., CDC

LYNNE FAIROBENT, AAPM

ALBERT HYACINTH, CDC

FRANCES JENSEN, M.D. CMS/HHS

ROBERT JONES, Ph.D., CDC

JANETTE MERILL, SNM

THALIA MILLS, Ph.D., FDA

MICHAEL PETERS, ACR

SATISH PILLAI, Ph.D. CDC

MICHELLE PODGONIK, CDC

DAVID SAUNDERS, CDC

JOSEPH SHONKA, Ph.D., CDC

CINDY TOMLINSON, ASTRO

ANN WARBICK CERONE, MDS NORDION

ROBERT WHITCOMB, Ph.D., CDC

JENNA WILKES, ASNC

GARY E. WILLIAMS, VA NHPP

TABLE OF CONTENTS

P R O C E E D I N G S

1:29PM

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

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

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

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

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

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

12th, 2011 edition of the Federal Register, Volume 76, page 17362.

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

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

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

CHAIR MALMUD: Here.

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

VICE CHAIR THOMADSEN: Here.

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

MEMBER GUIBERTEAU: Here.

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

MEMBER LANGHORST: Here.

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

MR. MATTMULLER: Here.

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

MEMBER PALESTRO: Here.

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

MEMBER SUH: Here.

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

DR. SULEIMAN: Here.

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

MEMBER VAN DECKER: Here.

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

MS. WEIL: Here.

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

MEMBER WELSH: Here.

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

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

MEMBER ZANZONICO: Yes.

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

MS. HOLIDAY: Sophie Holiday.

MR. FULLER: Mike Fuller.

MR. DAIBES: Said Daibes.

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

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

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

http://video.nrc.gov.

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

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

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

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

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

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

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

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

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

comment.

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

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

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

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

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

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

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

voice to the Committee.

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

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

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

MS. HOLIDAY: Thank you, Dr. Malmud.

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

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

that better? All right.

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

Are there any questions for number 5?

(No response.)

CHAIR MALMUD: No questions.

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

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

Are there any questions for Item 9?

(No response.)

CHAIR MALMUD: There appear to be no questions.

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

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

Are there any questions on Item 13?

MEMBER ZANZONICO: I have a question.

MS. HOLIDAY: Yes?

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

MS. COCKERHAM: The letter was, this is

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

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

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

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

CHAIR MALMUD: I see a question. Sue?

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

that one.

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

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

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

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

Are there any questions for Item 1?

CHAIR MALMUD: I see no questions.

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

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

Are there any questions about Item 3?

CHAIR MALMUD: I see no questions.

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

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

Are there any questions for Item 5?

CHAIR MALMUD: I see no questions.

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

Are there any questions?

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

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

Are there any questions for Item 8?

CHAIR MALMUD: I see no questions.

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

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

Are there any questions on Item 9?

CHAIR MALMUD: Dr. Van Decker has a

question.

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

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

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

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

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

Are there any questions for Item 10?

CHAIR MALMUD: I see no questions.

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

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

Are there any questions to Item 11?

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

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

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

MEMBER WELSH: Thank you.

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

MS. COCKERHAM: Yes.

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

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

CHAIR MALMUD: Thank you.

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

Are there any questions to Item 12?

CHAIR MALMUD: I see none.

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

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

regulatory basis will be developed, if needed.

Are there any questions to Item 13?

CHAIR MALMUD: I see no questions.

MS. HOLIDAY: Okay. Moving on to Item 14. "ACMUI recommends the attestation to be revised to say has received the requisite training and experience in order to fulfill the radiation safety duties required by the licensee."

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

Are there any questions to Item 14?

CHAIR MALMUD: I see no questions.

MS. HOLIDAY: Okay. Moving on to Item 15, "ACMUI supports the statement that residency program directors can sign attestation letters representing consensus of residency program faculties if at least one member of the faculty is an AU in the same category designated by the applicant seeking authorized status, and that AU did not disagree with the approval."

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

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

Are there any questions?

CHAIR MALMUD: I see no questions.

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

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

Are there any questions?

CHAIR MALMUD: I see no questions.

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

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

(No response.)

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

MS. HOLIDAY: All right.

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

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

CHAIR MALMUD: We will.

MS. HOLIDAY: Thank you.

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

MS. HOLIDAY: Thank you.

CHAIR MALMUD: Thank you.

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

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

MS. HOLIDAY: Thank you, Dr. Malmud.

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

Reactor Safeguards.

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

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

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

So, as part of the SRM, on June 30th, myself, Ashley Cockerham, Michael Fuller, and Chris Einberg met with the ACRS Branch Chief, Cayetano Santos, or Tanny, to discuss the ACRS procedures and

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

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

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

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

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

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

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

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

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

Okay. The ACRS meets with the Commission

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Okay. Do we have any questions for me?

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

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

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

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

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

report is generated by the entire Committee?

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

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

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

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

MS. WEIL: Laura

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

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

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

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

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

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

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

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

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

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

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

CHAIR MALMUD: Thank you. Dr. Van Decker.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

the Commission.

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

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

MR. EINBERG: That's correct.

CHAIR MALMUD: Thank you. Susan.

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

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

CHAIR MALMUD: Could that accommodation be made?

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

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

CHAIR MALMUD: Is there another question? Sue?

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

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

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

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

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

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

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

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

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

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

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

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

MS. HOLIDAY: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. DAIBES: Yes, sir.

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

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

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

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

MR. FULLER: Dr. Zanzonico, this is Mike

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

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

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

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

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

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

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

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

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

CHAIR MALMUD: Does that address your question?

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

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

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

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

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

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

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

(No response.)

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

(No response.)

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

(No response.)

CHAIR MALMUD: I hear no response.

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

people? Okay, thank you.

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

(No response.)

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

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

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

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

Are there any other items to discuss with

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

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

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

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

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

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

CHAIR MALMUD: Sue Langhorst?

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

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

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

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

MR. EINBERG: That's a fair summary.

CHAIR MALMUD: Thank you.

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

(Laughter.)

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

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

MS. COCKERHAM: Yes.

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

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

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

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

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

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

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

sorts of things.

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

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

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

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

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

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

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

Okay. So, the NRC solicited for public comments in a Federal Register Notice on October 20th.

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

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

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

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

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

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

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

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

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

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

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

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

and access for inspection.

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

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

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

that falls under non-authentication.

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

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

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

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

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

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

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

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

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

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

MEMBER ZANZONICO: So, just to follow-up.

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

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

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

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

CHAIR MALMUD: Slide 15.

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

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

MS. COCKERHAM: For a long time, yes.

CHAIR MALMUD: Thank you for clarifying that.

MS. COCKERHAM: Yes.

CHAIR MALMUD: Questions? Comments? Steve Mattmuller.

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

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

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

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

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

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

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

CHAIR MALMUD: Did that answer your question, Steve?

MEMBER MATTMULLER: Yes.

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

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

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

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

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

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

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

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

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

CHAIR MALMUD: Dr. Van Decker.

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

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

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

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

options for purchasers to look at.

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

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

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

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

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

CHAIR MALMUD: Thank you. Dr. Guiberteau.

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

standard for documents that need to be signed electronically.

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

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

We actually got a request from one of our

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIR MALMUD: Exactly. Dr. Van Decker.

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

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

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

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

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

We have a system in place at our

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

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

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

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

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

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

(No response.)

CHAIR MALMUD: I think that the systems

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

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

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

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

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

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

However, I think all of us who are

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

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

(Laughter.)

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

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

CHAIR MALMUD: Absolutely.

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

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

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

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

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

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

Are there any other questions or issues to be –- yes, Dr. Palestro.

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

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

CHAIR MALMUD: Sue?

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

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

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

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

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

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

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

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

Other questions? Ashley?

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

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

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

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

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

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

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

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

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

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

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

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

CHAIR MALMUD: Ashley?

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

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

CHAIR MALMUD: Dr. Guiberteau?

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

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

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

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

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

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

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

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

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

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

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

CHAIR MALMUD: Okay.

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

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

CHAIR MALMUD: Now, I understand. You're

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

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

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

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

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

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

MS. COCKERHAM: Dr. Malmud?

CHAIR MALMUD: Yes, please, Ashley?

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

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

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

Yes, Laura Weil?

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

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

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

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

(Off mic comment.)

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

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

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

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

CHAIR MALMUD: Thank you.

MS. FAIROBENT: You're welcome.

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

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

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

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

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

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

CHAIR MALMUD: Thank you. Sue?

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

good enough?

CHAIR MALMUD: Bruce?

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

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

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

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

CHAIR MALMUD: Okay.

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

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

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

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

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

VICE CHAIR THOMADSEN: Certainly.

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

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

CHAIR MALMUD: Was your positive statement a volunteering to…

MEMBER SUH: Yes, I will help the effort.

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

MEMBER PALESTRO: Yes.

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

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

CHAIR MALMUD: Small or large?

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

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

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

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

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

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

(Laughter.)

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

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

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

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

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

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

CHAIR MALMUD: He seconded the motion.

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

MS. HOLIDAY: Okay.

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

(Laughter.)

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

MS. HOLIDAY: I do. Thank you.

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

MS. COCKERHAM: Please take your name tags off.

CHAIR MALMUD: I beg your pardon?

MS. COCKERHAM: Please take your name tags off.

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

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

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

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

CHAIR MALMUD: Thank you all.

(Whereupon, the proceedings went off the record at 4:52:57 p.m.)

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.

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

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

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

II. Misinformation about the release of radioactive patients

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

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

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

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

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

10 CFR 35.75 is short and crystal clear.[1] (See Appendix B, where it is reproduced in full.) It would have been completely impossible for the subcommittee members to have misunderstood it – *if they had read it.* Plainly, during their five months of effort, handsomely compensated from NRC funds, none had thought to do so.[1] In an ideal world, Dr. Langhorst and her subcommittee would have apologized to the Commission for the inadequacy of their work and returned the money NRC paid them for it.[2]

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[1] 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.

[2] 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.

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

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

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

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

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

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

In March 2011, the Commissioners received a report from

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

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

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

Charlie had it right on the money.

The OGC attorney who wrote the brief told OIG in his first interview that the word "permit" should have been replaced with the word "prohibit." He too was absolutely correct. His admission was significant, given that "permit" and "prohibit" are antonyms.[3]

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

[3]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."

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

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

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

[4] 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

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

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

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

III. The Commission's July 13 Directive to the Staff

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

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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."

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

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

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

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

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

[5] 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."

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

The corollary is that if you are a patient from out of town in the U.S., from Memphis or Omaha or wherever, there is nothing to keep you from boarding a plane in New York and spending the next several hours elbow to elbow with the next passenger, who may be a small child or a pregnant woman.[6] And that is the essence of the problem: the protection of the public is only as good as the conscience of the individual patient.

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

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

[6] 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV. Conclusion

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

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

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

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

> Dr. Eggli: ... We can't get a preceptor to admit most patients to the hospital anymore from the insurance companies since the release rule went into effect. ... If I am admitting somebody [with] less than 200 millicuries, the chances that I can get an insurance authorization for a hospitalization to isolate them, **even when I have family situations that require it**, it's fighting tooth and nail with the insurance companies....
>
> Dr. Malmud: It is not now possible to treat a patient at our hospital and many hospitals in the Philadelphia area with I-131 in high doses for thyroid cancer because in order to do that a patient has to be isolated in a room which itself is isolated from the rooms next door.
>
> Therefore, **all patients are discharged upon treatment. We whisk them out the doors as fast as possible.** They are given outpatient doses between 100 and 200 millicuries of I-131, depending upon the extent of their thyroid cancer and occasionally, even higher doses. ...
>
> **There's also an impossibility of keeping the patient in the hospital since the insurer will not cover it.** The insurer will not cover it, will not cover the inpatient stay. It will cover the treatment, but not the inpatient stay. ...
>
> Being in the hospital today in most situations is an absolute impossibility. The nursing staff won't care for the patient. The other personnel in the hospital don't want to be near the patient. The hospital doesn't want the patient in the hospital. More than one room has to be reserved for the patient. It's an impossibility.
>
> ... Within the hospital, this patient is an unwelcome guest currently. Uninsured, **their wonderful insurance stops because it's no longer necessary for them to be an inpatient.** [Emphasis added.][8]

This, unfortunately, is the real world of 21st Century

[8] http://pbadupws.nrc.gov/docs/ML0808/ML080850674.pdf See pp. 187-188.

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

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

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

[9] 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.

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

APPENDIX A – ASCO POST ARTICLE

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

By Charlotte Bath
March 1, 2011, Volume 2, Issue 4

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

Specific Guidelines

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

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

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

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

Current Standard of Practice

The NRC statement is an update to 1997 modifications of a regulation acknowledging that a facility licensed to provide radiation treatment "is best qualified to assess the suitability of individual patients to release post-treatment and to provide personalized guidance to patients to assure compliance with the applicable release criteria." According to a joint statement2 from the American Thyroid Association, The Endocrine Society, the Society of Nuclear Medicine, and the American Association of Clinical Endocrinologists, "A goal of this rule change was to avoid isolation of a patient in the hospital for prolonged periods if the patient's release to home would be safe for the patient, the patient's family, and the public. This approach enhances patient satisfaction and is the current standard of medical practice."

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

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

Self-motivated Patients

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

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

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

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

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

Room at the Inn?

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

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

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

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

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

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

References

1. Nuclear Regulatory Commission Advisory Committee on the Medical Use of Isotopes Patient Release Report, December 13, 2010.

2. Joint Statement on Radioactive Precautions Following Radioactive Iodine Therapy, American Thyroid Association, Endocrine Society, Society of Nuclear Medicine, American Association of Clinical Endocrinologists, October 20, 2010.

http://www.ascopost.com/articles/march-1-2011/how-can-patients-who-receive-radioactive-iodine-treatment-for-thyroid-cancer-reduce-the-chance-of-radiation-risks-to-others/

APPENDIX B – 10 CFR 35.75

§ 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.

(a) A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).[1]

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

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

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

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

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

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