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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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OPEN SESSION

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MONDAY,

SEPTEMBER 11, 2017

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The meeting was convened in room T2-B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:35 a.m., Philip Alderson, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

PHILIP O. ALDERSON, M.D., Chairman

PAT B. ZANZONICO, Ph.D, Vice Chairman

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

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

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

DARLENE METTER, M.D., Diagnostic Radiologist

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

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

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

LAURA M. WEIL, Patients' Rights Advocate

NON-VOTING: RICHARD GREEN

NRC STAFF PRESENT:

DANIEL COLLINS, Director, Division of Material Safety, State, Tribal and Rulemaking Programs

KEVIN WILLIAMS, Deputy Director, Division of Material Safety, State, Tribal and Rulemaking Programs

DOUGLAS BOLLOCK, Chief, Medical Safety and Events Assessment Branch and ACMUI Designated Federal Officer

LISA DIMMICK, Medical Radiation Safety Team Leader and ACMUI Alternate Designated Official

SOPHIE HOLIDAY, ACMUI Coordinator and ACMUI Alternate Designated Official

MARYANN AYOADE, NMSS/MSTR/MSEB/MRST

JACKIE COOK, R-IV/DNMS/MLIB

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

ASHLEY FERGUSON, NRO/DCIP/QVIB3

LATISCHA HANSON, R-IV/DNMS/MLIB

ESTHER HOUSEMAN, OGC/GCLR/RMR

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

KEVIN NULL, R-III/DNMS/MIB

DENNIS O'DOWD, R-III/DNMS/MIB

GRETCHEN RIVERA-CAPELLA, NMSS/MSTR/MSEB

ZAHID SULAIMAN, R-III/DNMS/MIB

KATHERINE TAPP, Ph.D., NMSS/MSTR/MSEB

TORRE TAYLOR, NMSS/MSTR/RPMB

IRENE WU, NMSS/MSTR/SMPB

MEMBERS OF THE PUBLIC PRESENT:

BETTE BLANKENSHIP, American Association of Physicists in Medicine

ASHLEY COCKERHAM, SirTex Medical

WANDA COSTELLO, *Unaffiliated*

PETER CRANE, *Unaffiliated*

MICHAEL FULLER, *Unaffiliated*

PAUL GUNTER, Beyond Nuclear

DESIREE KENNEDY, Elekta, Inc.

CAITLIN KUBLER, Society of Nuclear Medicine and Molecular Imaging

RICHARD MARTIN, American Association of Physicists in Medicine

STEVE MATTMULLER, Kettering Health

MICHAEL PETERS, American College of Radiology

JOSEPHINE PICCONE, Ph.D., *Unaffiliated*

CRAIG PIERCY, American Nuclear Society; Bose Public Affairs Group

MICHAEL SHEETZ, University of Pittsburgh

ROBERT THOMAS, Elekta, Inc.

CINDY TOMLINSON, American Society for Radiation Oncology

*Present via teleconference

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P R O C E E D I N G S

8:35 a.m.

MR. BOLLOCK: Good morning, everyone. As the designated federal officer of this meeting, I am pleased to welcome you to the public meeting of the Advisory Committee on Medical Use of Isotopes.

My name is Doug Bollock. I am the Branch Chief of the Medical Safety Events Assessment Branch and I have been designated as a federal officer for this advisory committee in accordance with 10 CFR Part 7.11.

Present today as the alternate designated federal officers are Lisa Dimmick, our Medical Radiation Safety Team leader, and Sophie Holiday, our ACMUI Coordinator.

This is an announced meeting of the Committee. It's being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission.

This meeting is being transcribed by the NRC. It may also be transcribed or recorded by others.

The meeting was announced in the July 12, 2017 edition of the Federal Register, Volume 82, Pages 32207 through 32208.

The function of the Committee is to advise the staff on issues and questions that arise in 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 view of the Committee and values their opinions.

I request that, whenever possible, we try to reach a consensus on the various issues 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'd like to perform a roll call of the ACMUI members participating today.

Dr. Phil Alderson.

CHAIRMAN ALDERSON: Here.

MR. BOLLOCK: Thank you.

Dr. Pat Zanzonico.

VICE CHAIRMAN ZANZONICO: Yes.

MR. BOLLOCK: Thank you.

Dr. Vasken Dilsizian.

MEMBER DILSIZIAN: Here.

MR. BOLLOCK: Thank you.

Dr. Ron Ennis.

MEMBER ENNIS: Here.

MR. BOLLOCK: Thank you.

Dr. Sue Langhorst.

MEMBER LANGHORST: Here.

MR. BOLLOCK: Thank you.

Dr. Darlene Metter.

MEMBER METTER: Here.

MR. BOLLOCK: Thank you.

Dr. Michael O'Hara.

MEMBER O'HARA: Here.

MR. BOLLOCK: Thank you.

Dr. Chris Palestro.

MEMBER PALESTRO: Here.

MR. BOLLOCK: Thank you.

Dr. John Suh.

MEMBER SUH: Here.

MR. BOLLOCK: Thank you.

And Ms. Laura Weil.

MEMBER WEIL: Here.

MR. BOLLOCK: Thank you.

I affirm that we do have a quorum of at least six members. At the table, we also have Mr. Richard Green. Mr. Richard Green has been selected as the ACMUI Nuclear Pharmacist.

And do we have Mr. Zoubir Ouhib on the

phone? Zoubir, are you able to -- yes, unfortunately, Mr. Ouhib cannot join us in person due to the effects of Hurricane Irma. And hopefully he and his family are safe. Once he's safe, if he has time, he'll call into the meeting.

Both Mr. Ouhib and Mr. Green are pending security clearance but may participate in the meeting; however, at this time, they do not have voting rights.

In the audience we also have Mr. Michael Sheetz. Mr. Sheetz has been selected as the next ACMUI Radiation Safety Officer and will begin his term after Dr. Langhorst completes her term later this month.

I would like to add that this meeting is being webcast, so other individuals may be watching online. We have a bridge line available and that phone number is 888-790-6447. The passcode to access the bridge line is 93045 followed by the pound sign.

Individuals who would like to ask a question or make a comment regarding a specific issue the committee has discussed should request permission to be recognized by the ACMUI chairperson, Dr. Philip Alderson. Dr. Alderson, at his option, may entertain comments or questions from members of the public who

are participating with us today. Comments and questions are usually addressed by the committee near the end of the presentation, after the committee has fully discussed the topic. We ask that one person speak at a time as this meeting is also closed captioned.

I would like also like to add that handouts and the agenda for this meeting are available on the NRC's public website.

At this time, I would ask everyone on the call who is not speaking to place their phones on mute. If you do not have the capability to mute your phone, please press *6 to utilize the conference line mute and unmute functions.

At this point, I would like to turn the meeting over to Mr. Kevin Williams, Deputy Director of Division of Material Safety, States, Tribal and Rulemaking Programs for some opening remarks.

MR. WILLIAMS: Good morning. As you see, I am not Dan Collins. My name is Kevin Williams and I've been in this position since right after Memorial Day. Pam Henderson did retire. Those are going to be tough shoes for me to fill and I welcome the opportunity to work with you. And Dan will be here; he just had a previous appointment, but he is coming

and he will join us later.

But I'd like to welcome you to the fall 2017 meeting of the Advisory Committee on the Medical Use of Isotopes. I look forward to a healthy exchange of information. I want to thank you for all the hard work that you do, how you give us information that is going to make our processes and procedures and the way we do things better.

Before we begin and I get into my formal comments, I did want to take an opportunity for a brief moment of silence in recognition of September 11th. So, if we could just kind of pause for probably about 30 seconds. It seems to get a little bit long but I do want to take the time to honor those who have been impacted.

(Moment of silence.)

MR. WILLIAMS: All right. I'm not very good at counting, so I apologize if I interrupted anyone.

So there is a couple of things that have been going on within the Agency itself and let me give you guys some information about what's going on with our Commission. Chairman Svinicki has been extended to another five-year term. Commissioner Baran has been re-nominated for another additional

five-year term. We are still -- there are two individuals who have been selected or at least nominated to fill the other two Commissioner positions and they're going through the process. That's going to take some time as we navigate through this. But we look forward to them getting back there and getting us back to our full complement of a five commission.

Lisa Dimmick, as Doug had mentioned, is now the team leader. Mike Fuller did retire in May. I have come on as well. So that's some changes that we have there.

And as already mentioned, Dr. Langhorst will be leaving at the end of the year -- I mean September. Sorry. The end of our calendar year -- our fiscal year.

Michael Sheetz has been selected to replace her, once Dr. Langhorst's term ends. So we appreciate all the things that you've done to assist and make us a better organization.

Some things that we have going on in the rulemaking area - Part 35 rulemaking that be put before the Commission, they -- on August 17th, the Commission held an affirmation vote to approve revisions for the expanding of Part 35 ruling. And

as we go through the process, we send something up to the Commission. The Commission gives us direction in the form of a Staff Requirements Memorandum.

So there are several activities that are coming out of that that we need to do. And the staff is currently making the necessary visions as directed by the Commission and will provide to the Office of the Chief Information Officer and the Office of Administration for their review and publication.

We anticipate that the rule will probably be published the later part of this winter.

This rule amends the medical definition for reporting and notification requirements for permanent implant brachytherapy. This rule also amends the training and experience requirements to remove the requirement to obtain a written attestation for an individual who is certified by a board with certification processes that has been recognized by the NRC or the Agreement States and addresses the request filed in a petition for rulemaking to exempt certain board certified individuals from certain T&E requirements.

Additionally, this rule amends the requirements for measuring molybdenum contamination as a new requirement for the reporting of failed

technetium and rubidium generators, and allows licensees to name Associate Radiation Safety Officers for a medical license.

The NRC has two objectives in revising its medical use and commercial nuclear pharmacy guidance. One objective is to publish the guidance for new parts 30, 32, and 35 final rule. The second is to update all the associated guidance, like the NUREG-1556 series guidance.

And as we move through this, we want to be thankful of your efforts to provide us guidance, provide us direction, good information so that we can make -- do the things that we do better, whether that's regulating guidance, development, things of that nature.

Another thing is the abnormal occurrence criteria statement. On August 24th, the Commission approved the revisions to the AO criteria policy statement in Staff Requirements Memorandum 17-0019. One of the revisions impacts AOs from medical events. The provision requires that a medical event resulting in dose that exceeds 10Gy from the administration defined in a written directive to all organs, other than the bone, and to the eye, or gonads before that event can be considered an AO. The revision did not

include an exclusion for reporting AOs of an overdose to an embryo or a fetus, which is reported under 10 CFR 35.3047.

The staff within the Office of Research will publish the new AO criteria in a Federal Register notice soon. Staff will also incorporate these revisions into Management Directive 8.1. The NRC will begin implementing this updated criteria for capturing AOs beginning October 1. The report that we submit to the Congress will still use the old criteria.

We are developing a patient release paper for the Commission to review and it will evaluate the options and recommendations on updates to the NRC's patient release program required by 10 CFR 35.75 and we'll hear about this later today from Dr. Howe and Dr. Zanzonico.

I would like to thank the ACMUI for reviewing and providing comments on the draft version of this paper and associated background information. The staff plans to deliver this paper to the Commission in December of this year.

The things that I'd like to highlight: the ACMUI subcommittees have been working hard and there are a number of subcommittee reports that will

be discussed and brought forward during today and tomorrow.

Dr. Langhorst will discuss the subcommittee's report on Medical Event Reporting and Impact on Safety Culture this morning.

Dr. Dilsizian will give a presentation this morning on ACMUI subcommittee's recommendations on the definition of patient intervention.

Dr. Zanzonico will give a presentation this afternoon on subcommittee's comments on the staff's draft commission paper on patient release.

Dr. Suh will discuss the Physical Presence Subcommittee's recommendations for -- I'm sorry -- the Leksell Gamma Knife Icon tomorrow morning.

We also have a Category 3 source security and accountability initiatives regarding the April 2017 ACMUI meeting. Ms. Irene Wu gave a presentation to the committee on the staff's reevaluation of Category 3 source accountability. Staff provided this paper to the Commission on August 18th and she will provide an update to us later. So the paper is before the Commission. The Commission will make recommendations on what they will want the staff to do.

Tomorrow we will be honoring Frank Costello, who passed away, as well as Dr. Langhorst.

Marc Dapas will be coming in, who is our Office Director, and giving the tribute, as well as providing the thank you to Dr. Langhorst.

So we have some upcoming ACMUI vacancies. We would like you to know that we posted a call for nominations to the Agreement State representative, a nuclear medicine physicist and healthcare administrator positions. The nomination period ended on August 21st; however, we extended the nomination period for the Health Care Administrator position until October 5th.

We anticipate making selections for the Agreement State representative and nuclear medicine physicist positions in the late fall time frame and the Health Care Administrator position in the later winter time frame, after consultation with the Commission.

While we are making revisions to the Part 35.1000 on the Germanium/Gallium-68 generator licensing guidance and this focused on the areas of the financial assurance and the development of the DFP.

And part of that was the revision. We

provided a clarification that granting exemption from the DFP requirement in 10 CFR Part 30 does not exempt the licensee from other financial assurance requirements. And we have a list of specific elements that should be in a legally binding agreement to return the generators to the manufacturers or the distributor.

And three, in my revision to the license condition that specifies that the licensee must return the generators to the manufacturer or distributor when they are no longer in use.

Said did a nice paper there that he published and I know he has been our point of contact there and we want to take the opportunity to recognize his contributions.

I did go a little off script there but I just wanted to thank him for his contribution because that was a long effort and it was a lot of comments that had been received and that was one thing that we were able to push over the goal lines. I did want take time to recognize that.

The Elektra -- Elekta high dose rate of remote afterload Part 21 issue - the NRC was made aware of the medical event reported August 18th that two patients were found to have an underdose of

greater than 20 percent, while being treated with a high dose rate remote afterloader with ring and tandem applications.

The medical event was caused by a discrepancy between the source step size use for the ring application for planning, calculating, and evaluator dose in the treatment planning software and the step size after they were utilized. The step size for calculations was 2.5 millimeters, while the utilized step size was 5.5 millimeters.

The difference in the step size caused the source to dwell at incorrect positions, as the source step through the ring applicator, compiling the difference in each step. As a result, the latter dwell position shifted into the shaft of the ring applicator into the vaginal canal and it's an unintended treatment site.

So the manufacturer of this software has been notified of this issue by three users who discovered it during their quality assurance testing. Elekta was in the process of writing a user notification when they were alerted to the medical event on August 8th. On August 11th, they issued a field safety notice on the software issues to all of its users, as well as internal documentation to

temporarily stop delivery of the applicator modeling software.

On August 23rd, Elekta made a 10 CFR 21 report regarding the software issue and notified the FDA.

At this time, I would like to return the meeting to Dr. Alderson. Thank you. And thank you for having this opportunity for me to be able to speak before you.

CHAIRMAN ALDERSON: Thank you for those comments. I think that will take us to Sophie.

MS. HOLIDAY: Thank you. Good morning.

As you all know, and I always like to say, this is your most favorite part of the meeting, where we get to go over all of the ACUMI's past recommendations and actions and discuss if there have been any status changes.

Before I start, I already know that for a lot of our items, I always say, are related to the Part 35 rulemaking. Nothing has changed. However, what I will note is that I'm not going to close any of these items yet for the Part 35 rulemaking. While the Commission has voted and issued the SRM, there was a request at the last meeting in April for staff to go over a detailed explanation about what happened

with the rules. So I'm not going to make a motion to close any of these items until we've done that, per requested by the Committee.

Okay so, as always, the whole 2007 chart is related to the Part 35 expanded rulemaking. We go pretty fast.

Yes, ma'am?

MEMBER LANGHORST: Sorry. I wanted to ask a question. The elective part for the gamma knife is delayed, right? So those will -- like 30.

MS. HOLIDAY: Yes.

MEMBER LANGHORST: 2007, so those will stay on.

MS. HOLIDAY: Yes, correct. So for Item 30, all of the items that they delayed, open delayed means they were not included in the current Part 35 expanded rulemaking.

MEMBER LANGHORST: Thank you.

MS. HOLIDAY: Thank you for that clarification.

So again, the same thing for Item 35. That's delayed as well.

So if we move on to the 2008 chart, all of these items are included in the Part 35 rulemaking with the exception of Items 22, and 26, and 27.

So from Item 22, this is where the ACMUI encouraged staff to begin the rulemaking process for the Y-90 microspheres. As we said many times, this resides in 35.1000 licensing guidance space. And the reason for that is is, as you will note, we're already on Revision 9. If we had put this into rulemaking, this would take us a very, very long time and we would not be able to make those nimble changes. However, this is something that is still on the staff's radar.

Again, Item 26 and Item 27 are delayed, meaning they are not included in this current Part 35 rulemaking.

Okay. So, the 2009 chart only has two items, again, related to the Part 35 expanded rulemaking. And then that brings us to the 2011 chart.

So Item 1, this has to do with the patient release criteria. This is not included in the current Part 35 rulemaking; however, you will hear a presentation later on today regarding patient release.

Item 6 is an indefinite open item where the committee will review their reporting structure on an annual basis which will take place during the spring meeting.

Items 11 through 15 are all related to the Part 35 rulemaking.

Item 16, again, has to do with patient release. As I said, you will hear about that later on today from Dr. Howe and Dr. Zanzonico.

The 2012 chart was closed. I'm sorry. I failed to mention the 2010 chart was closed as well.

So for all of 2013, all of those items are related to the Part 35 rulemaking. That's when the committee provided their comments on the draft Part 35 rule language.

To move on, 2014 we did close all of those items.

And that brings us to 2015. So the first item is Item 7, which has to do with the AO criteria. It's actually Item 7 and Item 22 have to do with the AO criteria. As you heard Mr. Williams say earlier today, the Commission voted on the AO criteria policy statement revisions and it was not accepted, Item 7, to remove the criteria where harm to the embryo fetus does not result in an AO report to the criteria.

And then Item 22 is where the Committee endorses that committee report.

So at this time, I would like to make motion to close Item 7 and 22.

CHAIRMAN ALDERSON: Any comments?

MEMBER LANGHORST: I'll just say to the committee, don't give up. Medical use is different and, in particular, the fetal dose reported under 35.3047 should not be a member of the public consideration.

So, thank you. Keep up the good work.

CHAIRMAN ALDERSON: Other comments or questions?

MS. HOLIDAY: Does anyone second my motion to close the item? Dr. Dilsizian's second.

MEMBER ENNIS: Just not related to the agenda, per se, but to this topic, did the Commission write something that we can understand their thinking about not adopting our recommendation?

MS. HOLIDAY: Well unfortunately, Katie's not in here.

My understanding is that the reason the Commission did not accept this is because currently medical events or events that involve underage minors, which is what an embryo/fetus falls under, is all captured under Section 1A of the AO criteria.

So instead of having to separate out the criteria, they kept it all under one section so that if a pregnant worker were to get exposure, things of

that nature, then that would all be captured under that particular section. So the Commission decided not to adopt the ACMUI's recommendation in that respect.

Does that help?

MR. BOLLOCK: Yes. I don't know that it was addressed in writing but I know that we did, a number of years ago, Dr. Tapp and I briefed the Commission on it and they, just in their feedback, they just felt that because the embryo/fetus could get a high dose, it could cause harm to the embryo/fetus that they wanted to continue reporting. That was just their position.

There is a -- one of the Commissioners actually agreed with our recommendation and the ACMUI's recommendation and noted that in their vote. But it was a two-to-one vote against that commissioner.

VICE CHAIRMAN ZANZONICO: Question. So what are the implications for future revision or revisiting of this issue of the ACMUI vote in favor of this motion?

MS. HOLIDAY: So currently, because the Commission has already issued their SRM, which is essentially the Commission's final decision regarding

the AO criteria, that means it's not open at the current moment because now what staff will do is they will start implementing this new AO criteria, come October 1.

However, just like all of our other pending ACMUI recommendations and actions, should the ACMUI reform a subcommittee and put forth the recommendations that would be captured. What I cannot promise is that that is something that staff will be tackling anytime soon, since the Commission has just voted out the new criteria.

VICE CHAIRMAN ZANZONICO: So let me ask it in a different way. What's the implications of not endorsing it?

MS. HOLIDAY: Of not endorsing the ACMUI's recommendation?

VICE CHAIRMAN ZANZONICO: No, no, no. I mean what I'm understanding is that we're being asked to endorse the fact that the Commission did not follow the ACMUI recommendation on this issue.

MS. HOLIDAY: So it's not necessarily a matter of the ACMUI endorsing what the Commission has done because it is kind of when the Commission has made a decision, it's the final end-all, be-all just like with the Part 35 rulemaking.

So the ACMUI can go on record and say that you do or do not agree with it but it, unfortunately, won't change anything at this current moment.

VICE CHAIRMAN ZANZONICO: Right but I think my point is I think there's value in not endorsing a Commission decision that the ACMUI disagrees with.

MS. HOLIDAY: Sure.

VICE CHAIRMAN ZANZONICO: Is that an option?

MS. HOLIDAY: That is an option. I will say that in the past Dr. Thomadsen, when he was ACMUI Chairman, wrote in a letter of dissent to the Commission, conveying the Committee's dissension with one of the Commission's decisions. I can't remember for what particular topic but the ACMUI always has the option. NRC also has an open door policy. So anytime the Committee has an issue with anything, you're welcome to speak to any of our management chain, including all the way up to the Commission.

Our members of the public are always writing to the Commission as well. So, it's not different for the Committee. So if that's something that the Committee wishes to do, you are more than

welcome to do so.

CHAIRMAN ALDERSON: So if that sort of action is going to be taken, then you're going to have to make a motion. We're going to have to discuss this and have to bring back to our forefront, forebrain, the ideas that led to this disagreement so that we can all know when we vote exactly the things upon which we are voting. So does someone want to pursue that particular path?

VICE CHAIRMAN ZANZONICO: Well, so the motion you made so what we would be voting on is that we're closing the item.

MS. HOLIDAY: It's just to close the items off of our charts.

VICE CHAIRMAN ZANZONICO: Okay. And at some point in the future, maybe after I'm off the Committee, it can be revisited.

I just wanted to understand the implications of what the vote meant. And it sounds like it is just administratively we're just closing it at the moment per the consideration.

MS. HOLIDAY: Correct. The motion that I put forward is just to close it off of my staff tracking chart.

CHAIRMAN ALDERSON: So are there any --

yes, Dr. Langhorst.

MEMBER LANGHORST: Just to clarify, since Sophie is not part of the Committee, I will make that motion to close these items so that you have a person on the Committee making that motion. I believe Dr. Dilsizian seconded it.

MEMBER DILSIZIAN: Yes, second to that.

CHAIRMAN ALDERSON: Second. Any further discussion?

All in favor?

It's unanimous.

MS. HOLIDAY: Thank you.

Okay, so then Items 12, 13, and 15 have to deal with patient intervention and that's been an ongoing topic. Dr. Dilsizian will give a talk about that later on today.

So then that brings us to the 2016 chart. So, Items 1 through 15 are related to, of course, the Part 35 rulemaking. This is the year that the ACMUI provided their comments on the Part 35 rulemaking that went out for public comment.

And then we go to Item 16, which has to deal with the training and experience requirements for all modalities in 10 CFR 35.

So for everyone in the audience and for

participants on the webcast, you will notice that we do not have training and experience on the agenda for this meeting and the reason for that is that the subcommittee for training and experience has been redirected to focus on 35.300. So we anticipate hearing a discussion from that subcommittee in the spring meeting, which is slated for the March or April 2018 time frame.

Okay, Item 24 has to deal with the Committee's reach out to other professional societies or organizations to better the communications and interactions between the NRC, the ACMUI, and the medical community. This is an ongoing effort and we will hear presentation from Dr. Palestro, Dr. Metter, and Dr. Alderson later on during this meeting regarding those efforts.

Item 38 has to deal with the nursing mother guidelines. We will also hear a presentation from Dr. Metter later on today regarding her subcommittee's efforts on developing these recommendations.

Items 39 and 42, 43 have to deal with the Y-90 microspheres licensing guidance. Item 39, in particular, has to deal with the tubing issues related to the administration of Y-90 microspheres. The

staff was tasked with considering issuing a generic communication. Staff is still working on that. So we'll be waiting on future development for that particular topic.

CHAIRMAN ALDERSON: If it's okay, I have a point of clarification.

MS. HOLIDAY: Yes, sir.

CHAIRMAN ALDERSON: And it's just my misunderstanding, I believe. You just described Dr. Metter's upcoming report on nursing mothers; yet, on the page it says status closed.

MS. HOLIDAY: Yes, I have it closed because we're going to hear about it today. So that is a pending closed.

CHAIRMAN ALDERSON: I see.

MS. HOLIDAY: Yes, it's just in red -- it's red on the screen and in your handout because I anticipate closing it after her recommendations.

CHAIRMAN ALDERSON: I see.

MS. HOLIDAY: Sorry for any confusion.

Okay, so Item 41 has to deal with, again, the Patient Intervention Subcommittee. Again, we'll hear about that later on today.

Items 44 through 52 have to deal with the NorthStar Licensing Guidance. The Committee provided

comments on the draft licensing guidance. Dr. Howe and Ms. Ayoade's working group has been working to incorporate any comments that they've received from both the committee and the regions. So they anticipate issuing some guidance in the near future.

Okay. Well then that brings us to the 2017 chart.

So again the first item on the 2017 chart is where the Committee requested that the recommendations and actions regarding the Part 35 expanded rulemaking be reviewed during the fall meeting. As I stated when we started, we will discuss that during the spring meeting because I didn't want to rush through it. I wanted to give the ACMUI the respect and the time, given the amount of effort that the Committee has provided towards the rulemaking over many, many years. So we will discuss that in length, in detail during the spring meeting.

So I have left that item in pending so to note that we will talk about it in the spring meeting.

Okay, Item 2 has to deal with the subcommittee that was formed to review the physical presence requirements recommendations that Elekta put forward. We will hear from Dr. Suh's subcommittee tomorrow regarding their recommendations.

Item 3 has to deal with Dr. Alderson requesting that staff provide an update on the Category 3 source security initiative during the fall meeting. I have put closed because Ms. Wu will give a presentation on that tomorrow. So I can mark that item as closed.

Okay, Item 4 has to deal with the subcommittee that was formed to review the draft SECY paper or Commission paper related to patient relief. Again, we'll hear from Dr. Zanzonico about that later on today.

Number 5, again, has to deal with the nursing mother guidelines. We will, of course, hear from Dr. Metter later on today as well.

So I have marked those items as tentatively closed. Also because we made a decision in the past that once subcommittees were formed we would close the action that the subcommittees were formed. So I have marked this closed because the subcommittees have been formed. I'd like to close those items as well.

Okay, Item 8, again, has to do with Patient Intervention Subcommittee. So we'll hear about that again.

And then of course Item 10, this is where

the Committee has scheduled the fall meeting, I of course would like to make a motion to close that because here we are today during the fall 2017 meeting.

CHAIRMAN ALDERSON: Right, it's automatic. So does someone want to move? I need a motion.

MEMBER METTER: I'll move to close that.

CHAIRMAN ALDERSON: And a second.

And all in favor?

MS. HOLIDAY: Thank you.

Okay and then the last item is that the Committee requested staff provide them with information related to the escalating enforcement actions to medical licensees over a five-year span. I provided that information to the Committee over the weekend; however, I won't have us close this item until tomorrow during my closing session so as to give the Committee additional time to read information that I provided.

Okay, are there any questions or comments related to anything that I've presented?

CHAIRMAN ALDERSON: There seems to be none. Thank you, Sophie, for that report.

MS. HOLIDAY: Perfect. Thank you.

CHAIRMAN ALDERSON: Yes?

MEMBER WEIL: I received an email from a member of the public stating that there is no information about the bridge line posted online.

MS. HOLIDAY: That's right. I don't normally post the bridge line information online because we have a limited number of lines. So members of the public will contact me if they want it. However, Doug did provide the bridge line information during his opening comments. So, if you would like for him to repeat it again, I'm sure he can do that.

CHAIRMAN ALDERSON: That would be good.

MR. BOLLOCK: And then I can give it to you if you want to email back.

MEMBER WEIL: I've responded to the email but for others.

MR. BOLLOCK: Yes, for others. So the bridge line for this meeting is -- the phone number is 888-790-6447 and the pass code is 93045 followed by the pound sign.

CHAIRMAN ALDERSON: All right, thank you.

Are there any other comments from members of the Committee?

Thank you, Sophie.

MS. HOLIDAY: Thank you.

CHAIRMAN ALDERSON: So that takes us into the open forum portion of the agenda, identifying medical topics of interest for further discussion. Are there members of the Committee who would like to raise a topic for open discussion, at this point?

Yes, Dr. Langhorst.

MEMBER LANGHORST: Thank you, Dr. Alderson. I wanted to point out that there was a petition for rulemaking that was published in the Federal Register on August 23rd and this is regarding the table -- excuse me -- the Appendix B in Part 30 and to update those values in Part 30.

Now, I wanted to remind the Committee and I wanted to make note of those out there who may be wanting to respond on this, we extensively went through what was happening with that Appendix B during our Germanium-68/Gallium-68 Decommissioning Funding Plan Subcommittee. And for those people interested in responding to this petition for rulemaking, I'll point them to our ACMUI report August 12, 2015 and to the addendum where we reviewed where Part 30, Appendix B came from and what could be done to update those values.

So I just wanted to make mention that our reports are not only important for medical use but

they could be important for other types of rulemaking.

CHAIRMAN ALDERSON: Okay, thank you very much. Are there comments on that from the Committee? Other comments on that from the public? Is there someone who would like to comment on that issue online?

Hearing none, thank you.

Are there other comments the Committee would like to raise or new items?

Hearing none, do we now invite the public to do the same? Are they allowed to now comment?

MR. BOLLOCK: They are, yes, at your discretion.

CHAIRMAN ALDERSON: Yes, right. So do any members of the public have items they would like to raise at this particular point?

MR. GUNTER: Yes.

CHAIRMAN ALDERSON: There is here in the room. Please, step to the microphone.

MR. GUNTER: Thank you very much. My name is Paul Gunter and I'm with a public interest group called Beyond Nuclear.

And I think the comment, if the Committee would please consider, has to do with the use of medical isotopes and the exposure of service workers;

for example, the Mayo Clinic and the hotel system around Mayo Clinic.

And I think one of the concerns that has been discussed already by Peter Crane has to do with the exposure rates of potentially for custodial workers in those hotel systems and if there has been substantial consideration of patients who are avoiding exposures to family members and other public going to those hotel systems and, thus, increasing the exposure rates of custodial workers in those hotel systems.

And this had been raised in a Commission public briefing session a couple of years ago and I'm not sure that it has been fully deliberated is what I'm posing the question to the Committee.

And I'll close just by saying it might be worth considering some pilot program work or further research into perhaps using TLDs to observe the issue of these exposure rate to custodial workers in these hotel systems. Or if that has already been a consideration of the Committee and of the NRC, we'd welcome any kind of information that would illuminate what has been done to look at exposure rates to custodial workers who are cleaning up after patients in these hotel systems. Thank you.

CHAIRMAN ALDERSON: Yes, thank you, Mr. Gunter. This is a topic that has, I think, come up from time to time. I can understand why it is a topic of public interest.

Are there people here at the table on the Committee who would like to make a comment about this issue?

Yes, Dr. Zanzonico.

VICE CHAIRMAN ZANZONICO: Well, not to address the issue in detail at this point but there will, as was outlined, there will be two sessions later today, one from the NRC staff and one by myself on the patient release issue with an emphasis actually on possible exposures to hotel workers from released patients.

So I think not to defer your question, but that's what I'll do, defer the question for those two presentations because I think it was addressed in-depth both by NRC staff and on multiple occasions by the ACMUI.

CHAIRMAN ALDERSON: Good. All right, excellent comment.

Other comments from the Committee?

I will say that in my own experience something that is analogous but not exactly the same

is on several different occasions while I was back east at Columbia University and the Presbyterian Hospital, hospital workers, nurses and other staff who worked in non-radiation areas in the hospital would raise this very question about how they were being exposed to people who had radioactivity onboard who were coming up out of the hospital from the therapy area or otherwise. And in every one of those situations, and I can remember at least three, a full-blown study was then performed on those floors and they always resulted with everything being well, well below permitted dose amounts. So those studies were negative. That doesn't necessarily mean that that would be the same as hotel workers but it infers that it might.

In any case, I thought I would just add that comment to the record.

Okay, any other comments at this time? And I think if there are none, we'll wait until this afternoon's patient release.

MR. BOLLOCK: And just from the NRC's side, we have, I mean as Dr. Zanzonico stated, that is one of our considerations.

So we are aware of that. There have been studies. There's been reports from the ACMUI I think

back in 2010 or 2011 time frame. So yes, staff is aware of it. Staff has been considering that for years and we do have a lot of information on that. So you'll be hearing a little bit of that later this afternoon.

CHAIRMAN ALDERSON: Good. All right. So hearing no other comments, and we'll defer the remainder of this discussion until this afternoon's sessions.

Thank you. Thank you, Mr. Gunter.

Other comments from the public, either online or here in the room?

Hearing none and seeing none, I think that we've completed this particular section of the agenda.

And that will take us to the Medical Events Subcommittee report. Dr. Ennis is moving to the microphone.

MEMBER ENNIS: Good morning, everyone, and good morning NRC staff. Good to see everyone.

In case you don't remember my name.

So now it's time for the annual report on Medical Events. We will report now on the events that have been forwarded to NRC and Agreement States from October '15 through the end of September '16.

And thank you very much to my subcommittee members, who have helped me put this together, Doctors Langhorst, O'Hara, Palestro, Suh, and Zanzonico.

So we'll start off with 35.200 and there were eight events during that fiscal year, seven involved technetium and one involved F18-FDG. Fairly typical types of events, as we will see, from what we've seen in years past.

The first event was an error in dose, caused by a staff member not confirming activity to be administered. And they decided they will no longer prepare the kits at that site.

There was a situation of a link, causing excessive skin exposure in a second case. A third case was a mistake in the type of isotope and what it was being used for. It was supposed to be a gastric emptying study but was, instead, given for lymphoscintigraphy.

And the results of the skin dose, no comment about if there was a skin reaction or anything like. And they implemented a change in policy that they would verbally confirm activity and procedure with the physician before administration.

The fourth event was an issue of dose,

giving significantly more, and again, not confirming patient identity so giving the wrong dose.

The fifth case was a wrong patient administration. This report, unfortunately, was really incomplete, really not any good information about what the cause was, what the corrective action was, which speaks a little bit to some of the things we had talked about in the past about perhaps structuring this reporting in a way that could be more useful.

The sixth event, again, has to do with a gastric emptying procedure but may have actually not been, technically. It seems as though in the end they decided it was not really a medical event.

The seventh involved, again, a gastric emptying study where the wrong dose was given by an order of magnitude. No comment about whether there was any clinical implications, or complications, or side effects. And they changed their way the physician orders and retrained their technologists.

And the final one was the FDG one. And again, an error of two patients with the same last name. So they reviewed with the supervisor and changed a workflow sheet so they would not make the same mistake again.

Moving on to 35.300, so there were five events, three with radium-223, one with samarium, and one with iodine-131.

The first radium event was an error in dose. Again, an issue about patient identity and weight. It's not clear from it if it was the identity that was the problem and, therefore, the weight or they had the right patient. Presumably, they just mistook two patients and the two patients did not have the same weight. It was off by a bit.

So again, corrective action, administrative -- you know additional administrative actions. And again, just as sort of a comment, some of these corrective actions are a little vague. It's hard to really know what that means and if it means anything of substance.

The next radium event was an order of magnitude event, where the delivered and the prescribed were off by an order of magnitude. The licensee giving it believed AU intended to give the 98 microcurie does, which is the dose that was actually given, but not to those prescribed but, to be honest, it seems pretty clear the licensee was correct and what was written by the AU was not correct, presumably just leaving out a decimal point

in the correct.

But technically, the prescription wrote for 980 microcuries. So it made an event, even though actually the patient probably got the right -- what was really intended.

The third radium event was a bit of an interesting one in that it was given in a clinic that was not an authorized location to give radioactive materials and they authorized the user. The prescriber was not an authorized user. It's pretty significant.

The explanation was that prior to a merger, this may have been an authorized location and the authorized user may have been an authorized user strikes me the latter is a little strange. The first, I could potentially understand.

So for future on, they are not giving it in that location or with that authorized user but in another use within their healthcare system.

I guess these things can come up as the healthcare system continues to consolidate and perhaps the administrative staff are not aware that one of their new small centers is not an authorized user. So I don't know how that gets dealt with but I could see this happening again.

And the samarium, a slight difference in dose -- not slight. Excuse me. An error in dose and it was basically a miscalculation in the pharmacy, based on the patient weight. And the I131, we've seen this before, two capsules are supposed to be given but only one was given.

So they revised the procedures to make sure everyone involved knows how many capsules are being transferred and given.

Now we have some brachytherapy. One of these may be the case we just heard about, although that was in more detail than what I had or what we had available. What was reported was an interesting and troubling error that was just discussed.

So this may potentially have been -- no, this was not. This was a different troubling error.

So a patient with cervix cancer was being treated and a catheter was placed into the tandem and ovoids to deliver the radiation. This is not HDR. And they had trouble fitting the sources into the tandem. It just wouldn't go all the way. So they just cut off the plastic tube that was holding the sources. It didn't affect the sources itself except that the source, therefore, wasn't in the tandem as deeply as it needed to be, closed it off and left it

there. And everything fit except that the source is now not all the way at the end of the applicator but it is somewhere in the middle of the applicator.

So the tumor was not treated properly and other tissues were exposed inappropriately. So, that's a pretty significant error and it led to an underdose of tumor by 1,500, which can really be a life and death issue, frankly; an overdose to the lower rectum and vagina because the source was lower down where it should not have been.

And they attributed it to inadequate training of the people who were putting in the sources and written procedures and did some repeat training to make sure this wouldn't happen again.

That's the only non-prostate low-dose rate incident.

In terms of prostate, there are several, although some, as you will see, would not really be medical events with the new definition coming down.

So our first one, a hospital had two events where the D90 was around 70 percent. So technically, a medical event. And they did not provide enough information about activity step so that we could weigh in whether or not it would be in the new definition.

And they don't really tell you much about root cause analysis or anything. But this did lead to a retrospective investigation and 13 additional events were found by the inspector. And presumably, along the same lines. But again, no details were provided.

In another institution, there was an I-125 implant, again, about 70 percent of the D90; although in this one, there was enough information in the report to determine that 92 percent of the activity had been implanted in the target, in the prostate.

So, it actually would not be a medical event by the new definition.

Curiously, despite that, AU decided to actually make up for the low dose by giving some external radiation treatment. That's more of a medical decision than an NRC decision but it was interesting to me.

And they just caused attributed to human error.

The next event was a low D90 and, indeed, the percent of activity implanted was also low. So this is a real medical event by all definitions.

And this actually was not reported,

though. This was found on inspection by an inspector reviewing past cases. And they made some modifications in their training to try and prevent this from happening again.

Another event where the D90 was lowish, 67 percent. Again, no comment on activity. They say it had to do with seed migration. So, indeed, perhaps a fair number of the seeds were outside. So, it would be a medical event, based on activity as well.

And the corrective action is listed as new training and a new technique but, again, not specifying enough information for me to really interpret what that might mean.

And then we've had this occasionally before. I-125 was implanted into a mass mistakenly thought to be the prostate due to abnormal anatomy. So from a medical point of view I'm quite curious to understand this better but not enough information.

We have had a couple of cases in years past of implantation into the penile bulb, which can look a little bit like a prostate if you're not careful. This may have been that, too, but again, not enough information to say that. There is some comment about rectal abnormalities in the report. So that it may have been a rectal mass but, again, just

not enough information to really know.

That is the low-dose rate events for the year. In terms of HDR, two prostate, two GYN, and one skin. And the HDR -- I'm not sure if this was the one that we got more detail about. It sounds similar but not exactly the same. So I'm not sure. And this was where the catheter position was wrong. It should have been entering in the vagina but it, instead, was on the patients thigh. So, obviously, it moved or something.

And the patient actually got a skin reaction so they modified their procedures going forward, I guess, to be sure the catheter is in the right place.

And one was an error in giving the wrong patient's plan to the patient.

And then there were three equipment failures. So, again, maybe these are -- what these are, I'm not sure. There was not as much information as what we heard before in NMED. And basically what I could ascertain or what Dr. Suh could ascertain was that they work with the manufacturers and in two cases they found the problem, it was fixed; and one actually no problem was found.

It's also not completely clear. In two

cases they eventually were able to complete the treatment but in the third, it's not completely clear what they did to make up for the partial treatment.

In terms of gamma knife events for the year, there were three. One was a right/left problem treatment of trigeminal neuralgia. So that is a very high dose. One was treatment was stopped to sedate the patient. And then they restarted the treatment and the patient moved. But it wasn't really clear exactly when exactly the patient had moved. But by the end, it was pretty clear the fame was not in the right position. So that was a significant medical event.

And then the third one, a frame adapter was in the wrong position, which displaced distance by two centimeters.

So this was a new adapter so they did some additional training to make sure that wouldn't happen again. And for treatment site they put in procedure modifications to make sure they wouldn't get left/right wrong again.

In terms of microspheres, so more events of this type, as usual. Just here breaking it down more for the purposes of -- there'll be a summary slide of all the events coming up but here just to

give the two different types of spheres, looking for trends. And again, you know they flip-flop. Some years one looks like it is the more problematic one than the other. So I don't see any trend one over the other, just the general challenge of the therapy itself.

There were 19 events of wrong dose; 16 were low -- I'm sorry -- 16 were wrong dose; 14 were low; two were high. The kinds of things we've seen in the past, obstruction of the tubing, some residual activity left, errors of liver calculations, activity calculations, residual activity, isotope left in the vile, or in the meter, or a leak.

Thought sometimes not really well explained, there was one case of a wrong patient, wrong dose, wrong site type.

There do not seem to be any clinical impact of any of these. Unfortunately, the lower dose one is generally the patients were then able to be retreated to get to the proper dose and the overdoses did not seem to impact the patients clinically.

In terms of radioactive seeds localization, so there were two events, potentially. That is, two things happened. In each case the

radioactive seed was placed and surgery was scheduled appropriately but then because of a medical complication related to the patient, unrelated to the RSL itself or the procedure to place it, patients were not able to have surgery. So technically their breasts and surrounding tissues got a higher dose.

In one, the patient had a stroke and she was essentially never able to undergo. The other one, the patient got pneumonia, was very sick for a while but was eventually able to undergo breast surgery and removal of the seed, along with the tumor.

Interestingly, they assessed the dose issues slightly differently in the two reports. One goes to the length of trying to calculate dose to a point a centimeter away as a radiation oncologist would. In fact, they involved the radiation oncologist to do that. And the other one just does total breast dose a little bit more like a more general exposure kind of perspective.

I remember when we talked about RSL, we had this conversation about what's appropriate and what's important to measure and how doses close to the source can be quite high and those can have some consequences separate from whether the whole overall breast dose is high or not. So just kind of seeing

that play out in practice.

But it is, I guess, an issue whether these really are medical events. It depends on how we define patient intervention whether they should even be something that is required to be reported. And I guess we could maybe pick up on that later.

So just to give a kind of overview of the last four years, a little perspective on trends. We really don't see any, I don't think. Things go up and down slightly. Obviously, as we always say but unfortunately is always true, there is a huge number of procedures of all these types of procedures being performed and the number of events continues to be very low. Microspheres continue to be the most common, as we have seen before.

I would point out that just kind in the overview, to me, looking through all of them, there are a significant percentage, minority, where some type of time out thing seems to be what's lacking and that could address them.

And the other thing is microspheres. So if we were to think about well how can we try and drive this lower, those might be two areas for us to give some thought is there anything to be done in those two ways. But otherwise, I must say, given the

number of procedures being done both therapeutically and diagnostically across the entire country in so many different settings, the number of events and their medical implications are remarkably low.

And with that, I will close.

CHAIRMAN ALDERSON: Thank you, Dr. Ennis.

Yes, Ms. Weil.

MEMBER WEIL: I have to say thank you for that report. I continue to be uncomfortable with the fact that these reports of medical events are so often incomplete in terms of event details, or the cause of the event, and the corrective actions that are taken. And yet there appears to be no sequelae for these incomplete reports. There's no request for more information frequently. They seem to be accepted at face value, which really diminishes the value of reporting events to NRC in terms of the educational value to the medical community of what might go wrong at your place. And I don't think it should be tolerated. I think we need to take a stand and make sure that these reports are useful in the way that they are intended to be.

CHAIRMAN ALDERSON: Do you want to comment? A comment from Dr. Dilsizian or Dr. Ennis?

MEMBER ENNIS: Frankly, I agree. I'm

not sure -- I don't know if it's -- I guess maybe I would like to hear from NRC staff whether this is an execution of rule problem or a change in regulation rule would be needed to effect that.

CHAIRMAN ALDERSON: So that's thrown to the NRC staff. Does anyone wish to respond to that?

MR. BOLLOCK: Yes --

CHAIRMAN ALDERSON: Mr. Collins.

MR. COLLINS: Yes, this is Dan Collins from the NRC.

So you're right Ms. Weil, that reports often lack the information that we would need. So what happens is when the NRC inspector or if it's in an Agreement State, when their inspectors do the follow-up, through that follow-up process the Agency, whether it's the NRC or the Agreement State program will obtain the missing information.

So that doesn't get to I think your point about the quality of the actual reports themselves but the regulatory bodies do get the additional information needed to do the appropriate regulatory reviews.

MEMBER WEIL: But that doesn't address the second issue, which is the public value, the value of reporting these things publicly so that they are

useful to other institutions.

MR. COLLINS: Keep in mind, though, that the inspection reports are public documents.

CHAIRMAN ALDERSON: Yes, Dr. Ennis.

MEMBER ENNIS: So if I am understanding correctly, so NMED will only have the first pass in additional information that is garnered. When the inspectors go back and ask for more information, it does not make it into NMED, so you're saying. Is that what I understand?

MR. COLLINS: It does make it into NMED or it should make it into NMED in the closeout process. And Doug can expound on that.

MR. BOLLOCK: Yes, they both, NRC and Agreement States go back and update the information in NMED. And there is a number of reasons for different levels of information. You know we like to have as much information as we can with the cause of the event and corrective actions. And just on an event by event basis, if the event really was -- if it was fairly simplistic human error, a lot of times they just say well, we corrected this initial thing. So, it depends on the level of the event and how much was involved a lot of times for what we'll get back for the information.

And on I guess some cases these events actually turn out when they do the investment of the licensee investigation and look into it, they go away. Sometimes they'll update that in an event notification, sometimes they won't. But this kind of a significant -- the more significant the event, the more follow-up we'll have, the more information we'll have. And you know there's always the minimum requirements and then some licensees are better than others -- they're not better but provide more information than others.

But we do, whether it's an immediate inspection or a follow on the periodic inspections, all of our inspectors and the Agreement States, they look at the events. They'll follow-up what the licensee has done and if they get new information, they feed back into the NMED.

CHAIRMAN ALDERSON: Dr. Howe had the next comment and then we'll go to Chris Palestro.

DR. HOWE: And just because this is what is currently required in the written report, which is after the initial 24-hour notification, and that is the licensee's name, the name of the prescribing physician, a brief description of the event, why the event occurred, the effect, if any, on the individuals

who received administration, and what actions, if any, have been taken or are planned to prevent recurrence, and certification that they've notified the patient or responsible rep of the party.

Now the other point is when I had the short forms of the medical events developed, at the bottom of each medical event we'll see references. And the references are for the inspection reports and for the subsequent reports being made by either NRC or the Agreement States. I will say that sometimes those references do not provide a lot of additional information but NMED looks at those references and puts that additional information that comes in into the NMED paragraph. And in some cases you'll see they've requested additional information but they haven't gotten it.

So I don't know if that helps any but that's the information they are required to give. We do provide you with the references at the bottom so if you want to look at those references, you can ask us and we can get those references for you.

CHAIRMAN ALDERSON: Dr. Palestro had a comment. Thank you, Doctor.

MEMBER PALESTRO: Yes, my question is if the information in NMED is updated periodically,

would it be more advantageous or more useful, instead of looking in this case say at the fiscal year 2016, that we had gone back and reviewed say fiscal year 2015 or 2014, where that information might already have been updated and so many of the questions we're asking now might have been answered.

CHAIRMAN ALDERSON: Dr. Howe seems to want to answer that question.

DR. HOWE: What we did for a number of years is I presented the information in the fall meeting for the fiscal year that just ended. Now, I present the information in the spring meeting so that you have an additional six months after the event has occurred for additional information given to NMED. And then when you look at things for the fall meeting, there's additional months.

So, I don't think you're really going to get much more information on these events by going back a fiscal year before this because there is plenty of opportunity for licensees and Agreement States to get that information in to NMED and then to get it into the database, but you'll find sometimes the information is quite lacking.

CHAIRMAN ALDERSON: Are there any -- yes, Dr. Ennis has one.

MEMBER ENNIS: My other question for NRC staff is when and how does NRC involve a physician expert to help them sort through a medical event.

MR. BOLLOCK: So we appoint a medical consultant. So we have a few medical consultants. Actually if we can't get a medical consultant, we can use ACMUI staff members, as needed, to review certain MEs. But, again, it's the more significant events that there was -- we believe there may be some permanent patient harm or some deterministic effects from the event. That's when we'll get a medical consultant involved. So that is a few times a year. It's not as common. Again, a lot of these events, as it turns out the patient -- there is no permanent patient harm. In a lot of cases, there is not even -- no reddening of the skin.

It's, again, typically the more severe the event, the more significant the event, the more information we'll have. And the less significant the event, the more likely after the inspectors or whoever from the state that goes out but they just go with the licensee gives the minimum information and that's enough in that case.

So again, typically the more significant the event, the more information we have.

CHAIRMAN ALDERSON: Yes, Dr. Langhorst.

MEMBER LANGHORST: I know that NRC is very good in posting licensee responses in the 15-day report for medical event reporting but how do you get to state reports? I mean do the States post this? Do the Agreement States post this? I mean I've never been able to find that.

MR. BOLLOCK: States report. So licensees in the States report to their State and the State reports to us. They share their information.

MEMBER LANGHORST: Correct. But is that posted on NRC's website?

MR. BOLLOCK: Yes.

MEMBER LANGHORST: And so how do you get to that?

MR. BOLLOCK: It's the same, the event notification page.

MEMBER LANGHORST: Right, the event notification is there.

MR. BOLLOCK: Right.

MEMBER LANGHORST: But all the subsequent reports, how do you get to those?

MR. BOLLOCK: So those would be like --

MEMBER LANGHORST: For Agreement States.

MR. BOLLOCK: -- you've heard about like

an Agreement State inspection, things like that. That would be dependent on State to State. I believe most, if not all, are publicly available. We can --

MEMBER LANGHORST: How do you find those?

MR. BOLLOCK: Yes, so those, because it is a State regulator, it's their document. You'd have to reach out to the States to get those reports but they do --

MEMBER LANGHORST: But they don't necessarily post them like the NRC posts.

MR. BOLLOCK: Yes, I don't think so. I don't know that they have.

MEMBER LANGHORST: So it is very difficult for most of these medical event reports because most are coming from Agreement States. It's inconsistent and it's hard to get that information.

And so that's what's frustrating.

MR. BOLLOCK: Yes, the most consistent information is this report and Donna-Beth's report. So we actually share those on our public website. So after this meeting, in the next couple weeks, you'll see Dr. Ennis' report on our website. And then next spring you'll see Dr. Howe's presentation for the next years.

MEMBER LANGHORST: I will point out,

again, very few -- very few errors in regard to how many procedures are done across this country.

MR. BOLLOCK: Yes, absolutely.

CHAIRMAN ALDERSON: All right. Yes, Dr. Dilsizian.

MEMBER DILSIZIAN: I wanted to kind of expand on that. You know every time I listen to these presentations, I'm kind of blown away with the low number of events, compared to the number of procedures. And we say oh, that's fantastic, we have great physicians out there.

But then the minute you kind of poked the hole a bit more, you always say that if the inspector reviewed previous records, there were six or seven more events that were not detected.

And that kind of seems to be the theme, which comes back to what is the best way to really turn on this. Now, we don't want to make it punitive and we also understand that the NRC inspectors are not physicians and they may not really get to understand this. It seems to come back to the whole peer review, QC/QA. For example, diagnostic imaging, 300 studies of our peers determined if they were correct or not. I was wondering whether this really belongs not back to the peer physicians to review and

just make sure that additional events were not there unrecognized.

CHAIRMAN ALDERSON: Comments on that?

MEMBER ENNIS: Well, I mean medical events are an NRC-regulated thing because it's radiation. So it just gets to that where is the line between medicine and whatever.

So I don't think we're going to really argue that point but we want to work I think to make this more effective and efficient.

CHAIRMAN ALDERSON: Yes, Mr. Green -- oh, I'm sorry.

MR. COLLINS: So this is Dan Collins from NRC NMSS again.

So it seems to me that one of the things that is still hanging from this conversation is how do we get at public availability of the event reports or information, particularly from the Agreement States.

So what I would suggest is, as an action item coming out of this meeting, the NRC staff will have a dialogue with the Organization of Agreement States to see if we can find a way to centralize the information coming out of Agreement State follow-up.

So, I can't promise on what the outcome

would be but we are certainly happy to have that dialogue with OAS.

CHAIRMAN ALDERSON: That's good. Very good action. Yes.

Is that satisfactory with us moving forward? Good.

All right, one more comment and then we'll wrap this up.

MEMBER ENNIS: Just one more comment for NRC. In the decision-making that went into bringing on an expert, certainly where it looks like it's a significantly clinical event that seems quite appropriate. But I must say my sense is sometimes I can tell that like that should really not have happened. And fortunately, no big harm happened to the patient but I don't know how you would pick up on those but I guess just be aware that you may want to involve physicians sometimes where it doesn't make sense to you or it is not something that you've seen before. And even though there was no big harm, it may be a real problem or they just got lucky that there was no harm and getting a physician expert involved to weigh in to say oh, no, all right. I get how that happens; we've had that happen versus oh, my gosh, this shows a real lack of understanding of

something -- just as another type of criteria when you want to bring in an expert.

MR. BOLLOCK: Yes, we do take that into consideration. We just had an event where we got actually two medical consultants involved, a physician and medical physicist because the inspectors, right away, were thinking that I mean it was -- so the NRC is mindful of that. We know we have those resources to use. We're not afraid and don't hesitate to use them. And even during the course of inspection you can add the medical consultant. You don't have to -- you know we can always add the resource as needed.

And our inspectors, I believe, are aware of that. In the case of three and a half years, let them -- our regional inspectors have not hesitated to do that.

And under the States, in some cases they actually have physicians on staff. You know they have their resources. And at one point, we've assisted. So I believe there is the awareness that that's a possibility is there. But again, you know it is really the more significant or even potentially. So when I say it is a significant event, it is actually a potentially significant event will have -

- we've had or utilized our medical consultants on those as well.

CHAIRMAN ALDERSON: Yes, Dr. Langhorst.

MEMBER LANGHORST: Dr. Alderson, I know that was the last comment but I just want to make one more and this I was made aware of recently.

The NRC published in June a NUREG-2170, which is entitled A Risk-Informed Approach to Understanding Human Error in Radiation Therapy. And a lot of discussion goes into what medical events have happened and have resulted from human error.

It is unfortunate that in that report they don't go into the total numbers - that the numbers are very low, but I think it's worth reading. And so I just want to make mention of that.

CHAIRMAN ALDERSON: So we'll add that reference into this discussion.

And it's been a good discussion, actually. And you know the really critical question about whether there is a systematic difference in the quality of these reports from the Agreement States versus the NRC states is a significant one. And Mr. Collins, you said that you're going to be following that up. So I think that's an excellent thing to do and the committee will look forward to that report.

Thank you very much.

Okay, I believe that brings the Medical Event Committee report to a close. And the next thing on the agenda, you'll happy to know, is a break.

So we'll go into break for the next 30 minutes and we'll reconvene for 10:30.

(Whereupon, the above-entitled matter went off the record at 9:57 a.m. and resumed at 10:32 a.m.)

CHAIRMAN ALDERSON: All right, let's take our seats so we can reconvene the session, please.

All right, the next section will be Medical Event Reporting and its Impacts on Safety Culture. This is the report by Dr. Langhorst of that subcommittee. Dr. Langhorst.

MEMBER LANGHORST: Thank you very much. First off, I'd like to thank my subcommittee. You guys are awesome to work with.

I also want to recognize the work that Frank Costello did and the help that Mr. Zoubir Ouhib gave our subcommittee on our interim report.

And a big thanks goes to Dr. Katie Tapp for her support of this work, too.

So as a reminder, our subcommittee's charge was to explore the impact of medical event

reporting and its impact on self-reporting or licensees-patient safety culture; identify potential ways to improve effectiveness of self-reporting in support of a culture of safety; and suggest ways to share medical event reports and lessons learned with the medical community to promote safety. Pretty much what we have just been discussing.

At our April 2017 meeting, we presented an interim report giving a common perspective on: the fundamental principles of radiological protection; the NRC's regulatory history regarding patient safety; development of safety culture programs in the healthcare industry; and current patient safety groups influencing medical use of byproduct materials.

Our subcommittee was asked to provide this final report with specific options that the NRC may take to encourage a licensee's patient safety culture, while maintaining its regulatory authority to protect patients during medical use of byproduct materials.

From the ACMUI's discussion of our interim report last spring, there were these major topics: First, the NRC medical event reporting criteria are set at conservative levels, which NRC

describes as rarely causing patient harm. Other types of patient safety events, such as sentinel events reported to the Joint Commission typically require that a patient is harmed or is at identified risk of harm to reach the criteria before reporting that to the organization.

Reporting medical events to a federal agency like the NRC can trigger other reporting requirements, such as, in my case, we have to report to the Joint Commission and to our State agencies.

On insignificant events or events on par with patient safety events that normally would be evaluated in-house.

The next topic. Given that the medical events rarely cause patient harm, why is NRC notification required by the next calendar day and why is NRC quick to inspect looking for violations?

A licensee is not given time to review what has happened before notification and the quick inspection focuses initial attention on the narrow aspect of the NRC regulatory compliance, rather than on the overall process improvement to identify what were the precursors and how we prevent recurrence.

Another topic. In discussing alternative ways to look at improvements, patient

safety requirements under professional organization accreditation programs was brought up, such as the American College of Radiology or the ASTRO Accreditation programs. And those should be considered along with the patient safety organizations, and accrediting organizations discussed in our interim report.

Another point was raised by the NRC staff and suggested that the subcommittee explore the Reactor Oversight Process Program and the way in which the NRC and reactor community developed and tested this change in regulatory oversight for a possible way of implementing NRC medical event oversight improvements using our current regulations.

And finally, in developing our final report, the subcommittee was reminded of past ACMUI discussions in which the requirement to report medical events to the referring physician and the patient for most medical events serve no productive purpose and may be harmful. The reporting requirement can cause unnecessary patient worry.

With these topics in mind, the subcommittee worked to develop its recommendations and that is what we bring you today.

We know that changing Part 35 regulations

does not happen quickly and the NRC would not start another Part 35 rulemaking until the recently approved rulemaking is fully implemented. That's a few years from now.

So for the short-term, the subcommittee developed the following recommendation: establish and test a program to allow medical licensees to evaluate their own medical events, as described in 35.3045, or described in 35.1000 licensing guidance, or also included is the 35.3047, which is the embryo/fetus dose with what we're calling an NRC-approved patient safety program.

An approved patient safety program can be any one or a combination of the following: a licensee patient safety program which commits to reporting to a patient safety organization approved under the health and human services regulation 42 CFR 3 and which has Part 35 expertise -- we have had ASTRO representatives speak to us about their PSO called RO-ILS and we've had Dr. Bruce Thomadsen speak about the Center for Advancement of Radiological Sciences or CARS PSO -- a licensee patient safety program evaluated by an accrediting organization approved by the Centers for Medicare and Medicaid Services, such as the Joint Commission or others mentioned in our

subcommittee interim report; or a licensee patient safety program which is established as part of accreditation by a professional organization for medical uses defined under Part 35.

An NRC-approved patient safety program would continue to report medical events required by the regulations, current regulations, with the following condition: the NRC would not include this event notification in the event notification report posted on its website. If this is not possible, then we suggest the medical event notification posted on the website would leave the licensee information and location anonymous.

The NRC will not conduct a reactive inspection of the medical event, unless the event results in or will likely result in death, unintended permanent harm, or unintended significant temporary harm for which medical intervention was or will be required to alleviate that harm or reduce the radiation effects.

The medical use licensee will write a report available for the next NRC inspection, describing the event cause and corrective actions taken.

The NRC will develop, with ACMUI advice,

new temporary inspection procedures for the NRC review of licensee patient safety event report and will evaluate with the ACMUI advice needed to change enforcement, manual procedures regarding medical events to support a test of this program.

The NRC should test out this program, and we suggest, with two large medical centers, two community hospitals, two rural hospitals, and two patient clinics for a year and evaluate the medical event reports with the ACMUI. Now, this is to get a widespread sampling of licensees but we know with the low amount of medical events there are, it may not be a big sampling but at least it could test the program and the evaluation of them.

During this test period, the NRC, with advice from the ACMUI, should do the following: develop the minimum criteria for patient safety program reviews; that is, that the patient safety event and related issues are well-defined; the relevant facts and circumstances are identified and collected; and the findings and conclusions are identified and substantiated by the information and evidence associated with the medical event or incident. And I put in incident here because it may not be a medical event but it could be one of those

precursors that you would like to see your organization review.

Causes and program weaknesses or shortcomings are identified for that patient safety incident and corrective actions taken and evaluation of past patient procedures to determine the extent of condition for similar patient safety incidents. And this is done by the patient safety -- the licensee's patient safety program.

Also during this test period, assess how this change in medical event reporting impacts the NRC's ability to protect the patient health and to minimize danger to the patient's life and that includes having access to that medical care; evaluate the different types of patient safety programs and how lessons learned from their patient safety incident reviews are shared with the medical community, just as we were talking earlier.

After the test period is completed, and we hopefully would assume successfully completed, the NRC should consider opening the program to all NRC medical use licensees who request approval of their patient safety program and to Agreement States who request to implement the program with their medical licensees. This program could continue until the

long-term changes, including rulemaking on medical event reporting are completed.

The subcommittee next developed the following recommendations for long-term changes: medical use is different in that physicians expose patients purposely to radiation or radioactive materials to diagnose or treat injury or disease. The focus of NRC regulatory oversight and expertise on the medical use of byproduct material does not include the oversight of the practice of medicine. Regulator in the medical community continue to debate where that demarcation of NRC oversight of medical use ends and the practice of medicine begins.

At the heart of this debate is the intent by both the regulators and the medical community to support patient safety and deliver effective patient care.

Given the increased complexities associated with medical use of byproduct materials, especially in regard to therapeutic procedures and the development and sophistication of patient safety programs, we recommend the NRC take the following actions to modify the NRC medical use policy and medical use regulations and guidance. We suggest that they redefine NRC's perspective of patient

safety to be different from occupational safety and from public safety.

The NRC has departed from fundamental principles of radiation protection by setting patient dose limits; those in Part 35.3045 and 3047. The NRC has applied values of dose limits to patients, which are the same as occupational dose limits.

The NRC has explicitly stated that the Commission considers a patient to be a member of the public to be protected by the NRC. We believe the Commission should reevaluate its perspective on patient safety to be more in line with the fundamental principles of radiation protection and the ICRP exposure to category of occupational exposure, public exposures, and medical exposures of patients.

Due to its strong regulatory authority, the NRC has been a leader in shaping a licensee's positive safety culture. The NRC has considered its patient safety model as part of its public health and safety charge. The recent developments and sophistication of patient safety laws, regulations, and programs can be utilized by the NRC in reviewing patient safety events in sharing lessons learned in support of improved overall patient safety and medical outcomes.

We recommend that the NRC partner with the Department of Health and Human Services, especially their agency for Healthcare Research and Quality and with the ACMUI to develop a national database taxonomy specific for reporting patient events involving medical use of byproduct material.

The Health and Human Services is working through its agency for Healthcare Research and Quality to develop sets of common definitions and reporting formats, common formats they call them, for reporting on healthcare quality and patient safety, as directed by the Patient Safety Act. This is in order to facilitate the creation of and maintain a network of patient safety databases that provides an interactive evidence-based management resource for providers, patient safety organizations and other entities.

The NRC should explore partnering with the Health and Human Services and agency of Healthcare Research and Quality in developing a segment of that network of patient safety databases to which NRC medical use licensee patient safety programs would be required to report medical event information. The event taxonomy should include the criteria for which a licensee is required to report the event, both to

the NRC and to the national database; that criteria for which the licensee is required to report to the national database; and the criteria for which the licensee is encouraged to report to the national database.

In addition, the taxonomy should define the minimum specific information required to be reported by the licensee to ensure the reports are interpretable and meaningful. The information shared with national database would be anonymous and used for the purpose of reducing errors by identifying causes of preventable errors, developing, demonstrating, and evaluating strategies for reducing errors and improving patient safety, and determining effective strategies for all medical licensees.

The NRC medical use regulations should continue to support patient safety by establishing the training and experience requirement for authorized personnel, equipment requirements, radiopharmaceutical and sealed source requirements, and medical radiation safety program requirements.

The NRC policy and regulations should update the requirements for the patient safety program to verify the active involvement of the licensee's patient safety program review of medical

errors and reporting of these reviews to the national patient safety database.

This is the end of my talk but we would like to have Dr. Dilsizian give his portion of the catch to our report.

MEMBER DILSIZIAN: Thank you very much. Just to kind of follow-up because following our Part 2, Patient Intervention Subcommittee report in the spring, we were charged for specifying how unintentional treatment outcome events would be reported to the NRC and how we can modify to be less punitive and more informative and educational, which is consistent with the current presentation.

So our subcommittee members involved Dr. Ennis, Dr. Suh, and Laura Weil. I just want to thank them. And we had a brief discussion and conversation of how to address this. The next slide, please.

Again, the topic that we were addressing previously was that the treatment outcome discussion was specified to Y-90 microsphere treatment and we expanded that to all treatments. And our discussion went to the unintentional treatment outcome, due to anatomic or physiologic anomalies and/or imaging uncertainties that fall into the category of either medicine or practice. And such reporting, since it

was unpredictable and unavoidable, and for three patient-specific events, it would not help to have, therefore, a regulation related to these topics and we recommended that this cannot be regulated.

However, the issue came down to -- next slide -- how do we report these events. And so what's new in our presentation now is to have definition of what is a high-impact event and what is a low-impact event and that only high-impact events should really require timely notification to the NRC to reactive inspection, and timely written reports. And the low impact events, perhaps, would not or should not require notification to NRC. Next slide.

So the low-impact events which, again, you have to define, would undergo self-evaluation and corrective action and reporting to the NRC-approved patient safety organizations that Sue outlined and accrediting organizations or institutional robust patient safety program -- next slide please -- while, ideally, only high-impact events should be reported and made public and so we can learn something from those events.

The low-impact events should be anonymous. Again, this was the issue about being punitive. If it's low-impact events, once it

triggers to the NRC, it appears that you've done something major. If it's really a low-impact event, we feel that that should be anonymous to the licensee information and the location.

And that's all. Thank you very much.

CHAIRMAN ALDERSON: Thanks to both of you. These were very tightly related, so we decided we would just present them this particular way so that this can all be discussed together.

So at this particular point, these two reports now are open for discussion here in the room to the committee.

Yes, Dr. Zanzonico.

VICE CHAIRMAN ZANZONICO: Well, I wanted to thank the subcommittees for their work and really -- I wasn't part of that effort -- but really endorse what's being recommended, in particular, transitioning the issue of medical events and medical event reporting from a regulatory to a professional practice context where I think it actually belongs. And obviously, there is precedent for that within the NRC regulatory framework, with respect to training and education requirements. In that area the NRC essentially defers to certifying organizations, the professional organizations to establish training and

experience requirements for practice in different subspecialties. And this seems to be consistent with that paragon in which the professional organizations, primarily, will define a significant or reportable medical event, rather than leaving it in a regulatory context. So I think that's an important kind of paradigm shift. And I just want to endorse that thought process.

CHAIRMAN ALDERSON: Thank you. Other comments?

I think that inherent to what Dr. Zanzonico just said and Dr. Dilsizian as well, there is this big issue of defining the difference between -- the thresholds for high and low. So inferred by these comments, then, you're suggesting that that definition would be ideally referred back to professional organizations. Is that what you're suggesting, that those professional organizations would then come back to this, to the ACMUI and to the NRC with a group of suggestions, of this is what we suggest and then those decisions then could be made here?

Is that --

VICE CHAIRMAN ZANZONICO: Yes, I mean to base the criteria for reportable event on what amounts

to some arbitrary percent deviation from the administered activity of dose without consideration of the clinical impact, there is lack of logic in that. And doing what professional organizations and patient safety organizations offer or are interested in is how do these events, whatever you call them, impact clinical care, actually impact patient safety and so forth.

And so those seem to be the most relevant criteria, rather than what amount to arbitrary criteria for reportability.

CHAIRMAN ALDERSON: Okay. Yes, Dr. Langhorst.

MEMBER LANGHORST: I think that the NRC was almost the only game in town, at one point, as far as medical event reporting goes, and gave -- I mean we can tell by our medical event reports that Dr. Ennis gave earlier that there are not many of these errors that happen and that's because of the strong regulatory oversight by the NRC in regard to that.

But things have changed and it's obvious that the NRC does not -- they rely on us for this medical use advice and probably should rely more on the medical community and the professional

organizations in regard to this.

There is the Reactor Oversight process, the NEI, Nuclear Energy Institute, was crucial in helping define what were the categories and what was the structure kind of of that program, along with the NRC. And so I encourage the professional organizations to be involved not only with ACMUI but with the NRC on what could be put together for this type of program in the medical event reporting area.

I think it's important to come back to having a defined this is what you need to have in this report and have it be in a meaningful way, not only to other licensees but to members of the public as far as what you learn from this. And you can learn a lot from what they call near misses to help prevent some of these events from happening.

And when you're in a regulatory space, you report what you have to report and you work your program to make sure that you don't have to report that.

But to be able to report near misses and learn from other people's situations and have this data evaluated like by these PSOs or by your accrediting agencies, this can be really helpful to licensees across the country.

CHAIRMAN ALDERSON: Dr. Zanzonico.

VICE CHAIRMAN ZANZONICO: I just wanted to qualify my earlier comment. And it wasn't meant as a criticism of the NRC. I mean they filled and they fill a lot of the time a vacuum and we understand that, as regulators, they need inspectable criteria. And certainly the most straightforward and unambiguous inspectable criteria are quantitative based on metrics like activity and absorbed dose. But as Dr. Langhorst pointed out, there has been a cultural change in medical practice with the advent of PSOs and so forth, where there is a lot of introspection on patient safety and medical events and so forth. So that may be the vacuum that the NRC regulations once filled can now be better filled by things like PSOs and other professional organizations.

CHAIRMAN ALDERSON: Dr. Metter.

MEMBER METTER: I like the paradigm shift towards shifting the responsibility to more of the medical community but I would be concerned that some of these patient safety organizations, some of the accreditation organizations, that they should also have a person, a physician, or someone with expertise in the area that they're looking at because if, let's

say, you have a patient safety maybe administrators or those individuals, that having someone on the committee who can actually look at the medical use and see the appropriateness of the medical use and what effect it would have on the patient.

So just with that caveat that you have actually the expertise to review what's being left out.

CHAIRMAN ALDERSON: Ms. Weil.

MEMBER WEIL: And I'd like to reiterate my often-stated position that we can't look at Centers of Excellence as the paradigm that exists everywhere and need to consider that whatever shift happens takes into account the smaller facilities and perhaps the ones without -- who don't make use of patient safety organizations so that those kinds of practice issues are captures a well.

CHAIRMAN ALDERSON: Okay. Other comments from the ACMUI? Other comments -- yes, Dr. Suh.

MEMBER SUH: So I like the direction that we're heading. I think that there has been a perception at the NRC that the report can be sometimes viewed punitively. So by having professional societies have a bigger role in terms of what

constitutes a medical event, you move in the right direction.

And I think for many, for a physician, for instance, that if a professional society said well this was considered a low incident, this was considered a higher incident that would constitute a medical event, I think it would also provide psychological safety, which is a big word that we're using today in terms of making sure that you do the right thing for the right patient.

So I think moving from this punitive to more of a psychological safety, it would be actually a very good move for everyone involved and also would also -- I think it is also important studies have clearly shown it is important that you can keep a recording of these events, near misses. Doing a lot of near misses.

I can tell you at our institution we look at it very diligently and by looking at near misses, you prevent the big incident or medical event from occurring.

So I think you can point at if you have a culture where you feel safe to report these events but, again, I like the way that your report has been structured moving forward from perhaps a punitively

viewed perception to more of a proactive psychological safety approach.

CHAIRMAN ALDERSON: Thank you.

Other comments from the ACMUI? And are there other comments in the room, other than the ACMUI?

Yes, come to the microphone. Please identify yourself.

MS. TOMLINSON: Sure. Cindy Tomlinson from ASTRO. Dr. Alderson, I'm going to read a statement on behalf of ASTRO, if you don't mind.

CHAIRMAN ALDERSON: Please.

MS. TOMLINSON: Chairman Alderson, members of the ACMUI, and NRC staff, thank you for allowing me to provide this statement on medical event reporting and its impact on medical licensee, patient safety culture, on behalf of ASTRO, the American Society for Radiation Oncology.

ASTRO is the largest radiation oncology society in the world, with more than 10,000 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology, and physics, the society is dedicated to improving patient care through education, clinical practice, advancement of science,

and advocacy. ASTRO's highest priority has always been ensuring patients receive the safe most effective treatments.

ASTRO is pleased to support the recommendations offered by the subcommittee to promote a culture of safety for medical licensees. The progressive recommendations align with ASTRO's commitment to improving quality and safety in radiation oncology while, at the same time, maintaining NRC's regulatory authority to protect patients during medical use of byproduct materials.

We believe that both ASTRO's Accreditation Program for Excellence, also known as APEx and RO-ILS, the Radiation Oncology Incident Learning System, fulfill the spirit and the requirements set forth by the subcommittee.

The mission of APEx is to recognize facilities by objectively assessing the radiation oncology care team, policies and procedures, and the facility. APEx supports quality improvement and patient safety in radiation therapy practices. The APEx program establishes standards of performance derived from evidence-based guidelines and consensus statements for radiation oncology. Facilities that obtain APEx practice accreditation will have the

systems, personnel, policies, and procedures that are needed to deliver safe, high-quality patient care. Obtaining APEx accreditation is a multi-step process, beginning with an application and contract, followed by a thorough self-assessment, including a robust medical record review and document upload of relevant processes, procedures, and other documents; a facility visit by radiation oncology professionals who are trained as APEx surveyors; and finally, a determination made by ASTRO's APEx Committee.

APEx was launched in February 2015 and, to date, has accredited 57 facilities with 192 currently in the program. The APEx standards represent the cornerstone of the program. To develop the APEx program, ASTRO convened a task force made up of representatives from all disciplines within radiation oncology. The resulting standards were derived for an interdisciplinary, inclusive, and transparent process. Using the Safety is No Accident: A Framework for Quality Radiation Oncology and Care Consensus Report as a foundation, a comprehensive set of standards and evidence indicators was drafted and refined with a final set of standards approved by the ASTRO Board of Directors in January 2014.

The APEx standards identify systemic -- systematic -- sorry -- systematic quality and safety approaches that build on and reinforce regulatory requirements to add value for practitioners and healthcare consumers. They are organized around five pillars: the process of care, the radiation oncology team, safety, quality management and assurance, and patient-centered care. The ASTRO standards translate the goals outlined by Safety is No Accident into objective, verifiable expectations for performance in radiation oncology practice.

Of the 16 APEx standards, the culture of safety standard specifically requires that the radiation oncology practice foster a culture in which all team members participate in assuring safety, capitalize on opportunities to improve safety, and does not take reprisals upon staff that report safety concerns. This standard ensures that the practice fosters a culture where learning from patient safety events and unsafe conditions is a part of the process of care and is a mandatory component of the program. We believe that the most effective way for facilities to take action on a safety event or unsafe condition is for them to take ownership of the corrective actions in a non-punitive environment. The

facilities are in the best position to make changes and improve safety, since they are most familiar with their own processes and procedures. We are pleased that the NRC is embracing this approach to safety culture, especially when it comes to medical event reporting.

As the ACMUI members may recall from our October 2016 presentation, RO-ILS embodies the same ideals, albeit in a slightly different way. RO-ILS facilitates the collection and reporting of patient safety events from all participating facilities to make suggestions for change. The mission of RO-ILS is to facilitate safer and higher quality care in radiation oncology by providing a mechanism for shared learning in a secure, non-punitive environment. RO-ILS currently has more than 360 facilities participating and close to 4,000 events submitted. To date, we have issued 11 quarterly reports and three years in review. The years in review described participation, aggregate data, and other activities accomplished in the past year.

The RO-ILS data elements collect, among other things, the type of radioisotope and equipment used, how and where the event was discovered, whether or not the event was systematic affecting local

patients, the dose deviation between the planned course of treatment and the delivered dose, and the significance of the event as it relates to patient safety.

In addition, there are multiple free text questions that ask for details about the event, including a narrative of what happened, what might prevent future events, and what changes the facility has made in response to the event.

While important legal protections prevent RO-ILS from sharing reported information by a facility, the facility has the ability and is often required to share relevant information with the NRC and other federal and state regulators.

ASTRO applauds the subcommittee for their work to improve the safety culture of radiation oncology. We are committed to working with the ACMUI and the NRC on this recommendation and are happy to provide the ACMUI and the NRC with more information about the effects of RO-ILS and I'm happy to answer any questions you might have.

So one other quick thing. Ms. Weil, you mentioned sort of making sure the smaller clinics and other folks are participating. The majority of our RO-ILS participants are freestanding centers, not

necessarily connected to an academic center.

CHAIRMAN ALDERSON: So are there comments now related to this presentation? Dr. Ennis.

MEMBER ENNIS: That was a great, Cindy. Could you just explain for us APEx, what someone who is accredited, a program that is accredited with APEx, like what specifically for error reporting, near-miss reporting, is required to report to APEx?

MS. TOMLINSON: So the APEx standards are we have Tier I standards and Tier II standards. And the Tier I standards, you have to have. The Tier II standards kind of give you like extra bonus points. That's the way it's been explained to me. And participating in a PSO, in a patient safety organization is one of those Tier II recommendations that it is recommended that you do that.

I'm not as familiar with APEx as I am with like RO-ILS but I do believe that in the document upload process, the processes with dealing with medical events and things of that nature are to be uploaded because the facilities need to comply with NRC requirements and other regulatory requirements.

Does that answer your question?

MEMBER ENNIS: Yes.

CHAIRMAN ALDERSON: I believe that Mr.

Collins has a comment that he would like to make.

MR. COLLINS: Yes. So I just -- thank you, Dr. Alderson.

I just would like to offer a couple of thoughts for consideration. So it seems to me, and this isn't the first time this has come up, but when we get into the discussions about the medical event reporting requirements that the NRC has, that sometimes folks get confused about whether or not those medical event reporting requirements are somehow based on an assessment of efficacy of the medical treatment or the impact -- the medical impact on the patient, when that's not really the case.

You know medical event reporting requirements that we have are really looking at radiological safety both for the patient, for the facility staff, and for other members of the public who might be nearby or somehow otherwise impacted. So I would just like for us to keep that in mind.

And the other thought is, and it's not clear to me whether or not the recommendations that you're thinking about are to go to something that is truly analogous to the reactor oversight process or is it something that is just kind of drawing insights from it.

And the reason why I bring this up is because if you really want to go to something truly analogous to it, you wind up with a program that is far more complex, based in probabilistic risk assessments, methodologies, and performance indicators that apply to licensees. And I will tell you from my time in the reactor world when there were issues about whether or not there was a violation or a licensee was out of compliance, we have had experience with very lengthy back and forth dialogues with some licensees trying -- just arguing over the risk numbers.

So just I'm bringing that up for everybody's awareness, just for you to think about as you are finalizing your recommendation.

CHAIRMAN ALDERSON: Dr. Langhorst, please comment.

MEMBER LANGHORST: Thank you very much for that caution. And yes, I did talk to some of my reactor connections and no, we don't want it anyway like that program. But it was an example of the NRC and the regulated community looking at how do we do something different. Can we develop a program to test it out? And how do we get to that point and what are its goals? That gave me great comfort that

the NRC had done something like that.

In the reactor world, you have loads of experts on your staff. How many physicians do you have on your staff?

MR. COLLINS: They're all in this room right now.

MEMBER LANGHORST: They're all in this room right now. And so it can't be the same.

I will also state that -- and please, my medical physics friends, please don't get mad at me but medical physicists, as with the physicians, try to treat toward the perfect, which is what you want to give your patient. That's not how it can be regulated. That's why D-90s are a physics term. In no way should they be a regulatory term because that's not appropriate.

So how do you make the regulations fit what you're trying to do? And one of the things that we want the NRC to look at is that patient safety is different from occupational safety and it's different from public safety. And we want that to be considered.

We know things can't change quickly and so we offered up a suggestion that's not easy either to work with the current regulations and be able to

have a program that can take advantage of this development of patients safety programs and these different ways that that information can get out to help patient safety programs at all levels and in all areas of the phone tree.

So thank you again for that caution but I do know we don't want to make it like the reactor oversight process.

CHAIRMAN ALDERSON: Dr. Metter.

MEMBER METTER: I liked your test program for the NRC patient safety that you proposed. And the two large hospital, medical centers, and the different categories you have I was just wondering would you consider maybe one of the large hospitals and community hospitals in each category maybe one being from an NRC system and one being from an Agreement.

MEMBER LANGHORST: We stuck with NRC because the NRC has control over the NRC. Sometimes you may not feel that way but that's why we focused on NRC right now.

MEMBER METTER: But I was wondering if you would open it up. I mean there might be some Agreement States who may want to be one of the centers that you have mentioned. I'm just putting that out.

CHAIRMAN ALDERSON: Yes, Dr. Ennis.

MEMBER ENNIS: Well, like we said, we have issues we'll have issues we have to sort through but one that gets to a bit of Laura's comment from slightly different angles. Somehow making sure through this process that the data gets aggregated is important. I think if we are going to make a big change like this, there is a lot to be gained by that and without that component, there's a lot to be lost, particularly at the smaller facilities who, in some situations, may actually have the most to gain from the educational process, not having as much oversight and other people to critique you on an ongoing basis if you have. But if it evolved to a situation where every site was just having his own or her own quality improvement program and it ends there, that would be a step backwards. So some way of making sure the data gets aggregated.

CHAIRMAN ALDERSON: So I've got a couple of comments that I would like to make using the chair's prerogative but before I do that, I'm going to ask once more are there any other comments here in the room. We haven't heard anyone else want to speak. No one is coming forward.

Is there anyone on the open phone line

that wants to speak to this particular issue?

So hearing none and having no one come forward, then I would like to make a couple of comments.

There are a number of things that we probably should decide at this meeting. The very first one is at a conceptual basis. Forget all of the details. At a conceptual basis, does the ACMUI support this idea? That's the first thing. Because if that's not true, well then, the rest doesn't really matter.

So I'm going to follow that up with some other questions of that type but let's dwell on that one for a minute. So at a conceptual basis, I would like the ACMUI to comment or make a motion about the fact that we support or do not support this concept of developing -- attempting to develop a new kind of safety culture.

Comments? Yes, Dr. Metter.

MEMBER METTER: I move that the ACMUI support the concept of a patient safety culture.

CHAIRMAN ALDERSON: Is there a second? There is.

Is there discussion? Hearing none, we'll call the question. All those in favor, raise your

hand.

VICE CHAIRMAN ZANZONICO: Just can I ask a clarification?

CHAIRMAN ALDERSON: Yes.

VICE CHAIRMAN ZANZONICO: I understand the motion, as it was verbalized, but does that essentially mean we're endorsing the subcommittee report?

CHAIRMAN ALDERSON: No, we didn't say we were endorsing the subcommittee report.

VICE CHAIRMAN ZANZONICO: No, okay. That's what I wanted to understand.

CHAIRMAN ALDERSON: We're just endorsing the concept of this.

VICE CHAIRMAN ZANZONICO: Okay.

CHAIRMAN ALDERSON: So, again, people raise their hand. I think everyone's hand was up. Yes, everyone's hand. So, that's unanimous.

So that's expected. I expected a thank you for that motion.

And now you get into some of the more interesting problems. So, a question that would be, in part, relevant to what you asked, I want to ask the NRC, I mean given the short-term we'll call it pilot program that's been suggested as part of this

report, is that feasible? I mean could that be done? Could the NRC work with the ACMUI to do that?

I don't know the answer to that question. Is that possible?

MR. BOLLOCK: It's possible. Timeliness and -- just the timeliness would be a challenge just because of our resources. I mean this would -- to even help come up with this program and monitor, and then I know part of the recommendation is to come after they pilot it for a year, a certain amount of time, and then setting up our goals for success and seeing if we need those, and that evaluation. That all takes, I mean that's my staff and there is six of them right here. That's all we've got right now.

CHAIRMAN ALDERSON: Right.

MR. BOLLOCK: So that really is our biggest challenge for this.

CHAIRMAN ALDERSON: Right.

MR. BOLLOCK: Again, not saying that we couldn't do this, or shouldn't do this, or at least consider it and looking at your report and what you want, we would have to go through and consider feasibility and how much resource-wise to get back to you all to give our estimates. Again, it's just really the resources is the limiting factor for us.

CHAIRMAN ALDERSON: Right. So the essence of the answer, which is the answer that we all expected, it's possible but it's complex and it would be difficult. It could be done but it will be complex to do it.

MR. BOLLOCK: Right and I was just kind of taking notes going through as Dr. Langhorst was presenting. I have seen the draft report and Katie's been involved so we're aware of some of the thoughts from the subcommittee. And just what would each one of the recommendations or subsets of the recommendations, what are the take resource-wise, time-wise. Some of the things we're talking you know changes to our management directives, which is challenging enough but that's fairly -- some of them there are changes to our regulations. Some of them are just coordinating with HHS and kind of figuring that out. There is varying levels of resources needed and time to evaluate and getting back to you.

Whatever we do, we would have to -- I think there may be continued dialogue between us and the ACMUI to see what -- where we kind of get the most bang for the buck in each one of the recommendations.

CHAIRMAN ALDERSON: Now, can this sort

of program -- I'm just still trying to clarify in my own mind how this would go forward. Can this sort of program be done without a Federal Register notice? Is this some kind of like a research that you can just do between the NRC and the ACMUI or does this result in a notice in the Federal Register and then that gets into another whole area?

MR. BOLLOCK: For the pilot program?

CHAIRMAN ALDERSON: Right.

MR. BOLLOCK: Not necessarily.

CHAIRMAN ALDERSON: Okay, not necessarily.

MR. BOLLOCK: We could do that internally. However, to get to fully implement all of the recommendations --

CHAIRMAN ALDERSON: Oh, yes.

MR. BOLLOCK: -- it would, absolutely.

CHAIRMAN ALDERSON: It would absolutely.

MR. BOLLOCK: And again, there are some rule changes that would be needed. I mean right now we require to have the licensee's name of the physician. So we would have to make --

CHAIRMAN ALDERSON: I'm simply asking if we did this pilot program, as it is proposed, can you do that outside of the full you know disclosure,

Federal Register rut.

MR. COLLINS: So at the very least we would have to put together what the pilot program looks like and we would probably have to write a paper to the Commission and seek their approval to be able to move forward with that.

CHAIRMAN ALDERSON: Okay.

MR. COLLINS: Whether or not there would be a Federal Register notice, we would have to work that out in the process of development.

CHAIRMAN ALDERSON: And the reason I'm asking is not because -- I mean ultimately, you want to let everyone know what you're doing but the Federal Register would bring us in a whole other series of thoughts like well, who wants to be involved. Well, ASTRO wants to be involved. I don't know where the lady from ASTRO went but she's over there. But you know and what about the Society of Nuclear Medicine, and the American College of Radiology, and so on, and so on, and so on? Because everybody would sort of think that well, for their constituents they want their safety program to be considered and so on. So it gets very big and very complex in a hurry.

MR. BOLLOCK: Yes, there's a lot of outreach needed to -- you know just looking at this

to be successful in any way, it would take a lot of outreach.

CHAIRMAN ALDERSON: Right. Now if the Commission were to say this looks interesting and it's research and we think that in a very pilot small program like this we could do this, then it still is complex as the difficulties of the workload and what have you but it can move. If it has to go the other route, then you really have to consider a whole larger type of administrative public consideration.

Dr. Howe would like to comment.

DR. HOWE: I think Sue hit on one of the major points here and that is that we have very few medical events. We have very few medical events in NRC States because there is less than them than Agreement States. And so you could set up your pilot and set up your structure but you may not be able to test it because you may not have any medical events to run through to see if the pilot works. And I think that's something you have to keep in mind.

CHAIRMAN ALDERSON: Very good comment. That was a very good comment. It would be a very small sample of very rare events. You wind up with nothing.

MEMBER LANGHORST: I would argue that.

The PSOs currently -- I'm going to just use the PSOs right now -- all of that reporting is voluntary. And I know that gives the NRC pause but maybe in combination with NRC, this is a different route to go that reporting has to be done, if you choose the PSO route. And that could help develop that program and get more information out, in particular, on the non-medical event reviews.

Now, obviously, the NRC can't require a licensee to report everything. It has to be what they have currently in their regulations. But that could encourage that and if NRC could help support that effort because medical use is different, that's what we're asking. And if it was easy, we would already be doing it.

CHAIRMAN ALDERSON: Yes.

MEMBER LANGHORST: So please don't say because it involves Federal Register, that's on down the road. But I would hope what we're doing now is not the greatest because NRC's reporting criteria is so very low. Other patient event criteria is not as low and there is an inconsistency. Inconsistencies in safety culture don't work very well. And so we're trying to see is there a way to utilize patient safety programs, as they have been developing, and maybe

even strengthen that as we go forward in regard to what NRC regulates for the medical use of byproduct material.

CHAIRMAN ALDERSON: Now there's another -- I understand that and there is another way that one could go about this. And this was kind of what I was moving through in my own mind as I was going through these questions.

Rather than doing a short-term pilot, which has some of the issues that we've all discussed, another thing that you could do would be to -- given that the concept of moving the medical event program to a safety culture space does seem to be broadly supported. You could go immediately -- I'll probably get fouled up in my Federal Register now, which is pretty minimal here, but immediately to an announcement in the register, which would be something like what we would call in academia an RFP, a request for proposal, and say that it has been determined that it would be positive for medical event reporting to move to a safety culture. We know that there are many organizations, ASTRO among them, but you wouldn't say that, but there are many organizations that have such programs in existence today. And so we invite interested organizations to

submit to the NRC and to the ACMUI a proposal for such a program. And one or more of such programs may in fact be approved at some time in the future if these programs are deemed acceptable. Something like that.

And so you just jump into the second part and then you outsource the whole thing to these other organizations.

Yes, make a comment.

MS. TOMLINSON: Cindy Tomlinson from ASTRO.

Dr. Langhorst, I just wanted to mention you were talking about near-misses and things of that nature. In RO-ILS, and I don't have the numbers in front of me and I apologize for that, but the majority of our events that are reported are considered to be near-misses. So things that could potentially reach the patient but they are caught in time that cause no patient harm and that would not rise to the level of reporting to the NRC.

And that's what you want to see. You want to see a lot more near-misses, a lot fewer what you guys would determine to be medical events, and that things are being caught early on in the QA process. So just showing that QA processes are

working and that things are being caught long before they even reach the patient.

And what I'll do is, Dr. Alderson, I will get to Sophie some -- most of the more recent data, our year in review, and a copy of my statement so that it can be disseminated to the committee.

CHAIRMAN ALDERSON: That's very good.

MS. TOMLINSON: And I apologize for not doing that anyway.

CHAIRMAN ALDERSON: So to summarize what we just went through the last couple of minutes, I hope no one misunderstood my comments. They were very positive about the concept. I was trying to figure out how to get through the tangles we usually get into and get to a solution. So to really make it -- to reduce it to some very short words, it's sort of one approach is pilot it and the other approach, the one I just suggested, was outsource it. And there is a lot of details that go into getting to both of those two places.

I don't know if anyone wants to suggest -- but if you don't make some sort of a decision like that, what I think will happen to a very well-intentioned program is it will eventually sort of fritter away and they'll say Dr. Langhorst had a great

idea back there in 2017.

MR. BOLLOCK: Dr. Alderson, just to that point, I think even if we did pilot it with a number of these organizations, if they're using some other PSO, outside organization other than their own patient safety program, they're not -- I guess like a large institution has a staff and the knowledge and wherewithal, they can do -- I believe what the suggestion is they could do their own reviews of these but those that can't send them to another organization.

Because I know one of the slides was talking about substantiating incident, defining it, relevant facts and circumstances, looking at the finding and conclusions, identify that it's substantiated, and looking at the cause program weaknesses or shortcomings. That to me sounds all internal. So that is a -- I mean that is resources for each licensee would have to be doing that. Even if they do use a RO-ILS, right, that's an information sharing platform as far as I know, is there some feedback from that? Is there a part of RO-ILS that reviews that and would send it back?

And if there are, even if we do pilot it and they decide to use one of those, we would have to

still look at that and do our evaluation and say does this meet that.

So it's not necessarily a ''we pilot it for you.'' We would need to look at whatever the pilot is using to evaluate does this meet the intent, does it meet the purpose of our regulations, and what Dr. Langhorst's subcommittee is saying.

CHAIRMAN ALDERSON: So another and third -- I'm sorry. Did you have another comment?

MS. TOMLINSON: Oh, I was going to answer Mr. Bollock's question.

So Cindy Tomlinson with ASTRO. So because it is a PSO, RO-ILS itself cannot share information pertinent to a licensee with NRC. The licensee, however, can show you whatever they would like to. There might be some slight legal anomalies in there but yes, the licensee can show the NRC inspector, hey, this is the stuff that we've reported in the last year. They can do analysis on their own data. They do not have access to other licensees' data, so other participants' data.

What happens is quarterly we have an advisory council that is representative of basically the entire practice team -- we're missing a nurse so we know we need nurses who might be interested. That

would be awesome -- that reviews the data quarterly and then produces quarterly reports back to the community. So it's not a quarterly report on say Dr. Suh's clinic. It's a report on all of the aggregate data that goes back out to the community.

So that's how our participants get their feedback but, again, they are able to take a look at their own data, do analysis on their own data, and make changes based on their own data.

So it is sort of a multi-step kind of process, multi-tier process but it wouldn't be -- but we wouldn't report back to -- like if Dr. Suh's clinic submits to RO-ILS, we wouldn't then tell NRC like hey, Dr. Suh submitted to RO-ILS. It would be the clinic saying we are participating in RO-ILS, and this is my interpretation, at least, of this recommendation, is that the clinic is participating in these patient safety programs, whether it's an accreditation program, or RO-ILS, or another PSO and we are using that data and the data and the information they are getting back from the program to make their clinic safer.

MR. BOLLOCK: Okay, I think I understand that, that it's not necessarily that it would be shared with us it's more does RO-ILS receive their

information and who is doing -- I mean part of what is presented in this patient safety program is looking at the event, kind of that analysis of the event, and so then there can be a cause --

MS. TOMLINSON: And there is feedback.

MR. BOLLOCK: Well, okay, so there is. Yes, I thought there was some feedback.

MS. TOMLINSON: There is the quarterly report feedback to the whole community. But the clinics, there is no -- RO-ILS doesn't have any power to look at every clinic's specific stuff and then send it back to them.

MR. BOLLOCK: Right, okay.

MS. TOMLINSON: The clinic, however, can do it themselves. They can look at their own data. We look at the aggregate data and find trends and things of that nature and submit it back to you.

MR. BOLLOCK: Yes, I was going to say --

MS. TOMLINSON: Now, the thing is I will say that the trends that we might be finding might not be relevant to NRC because remember we are also collecting data from the x-ray side. It's not just on the materials side. So there might not be and I haven't looked at the data recently enough to tell you any numbers on the material side and I can

certainly get that to Sophie and give it to you all later.

But so that's how that works. I can't speak for other agencies or organizations but the radiation oncology realm we are using and it's both sides of the coin. So most of our stuff is linear accelerator related because that's the majority of what we do.

CHAIRMAN ALDERSON: Thank you. So given the complexity of this, I mean if you imagine that the complexity of it as we have now discussed it out, it seems that we might be back to Pat's comment, that perhaps it is time to formally say that we do or do not approve this report, which is a more formal action than just conceptually agreeing with the idea.

And if we agree with the report, if we support the report, then either this Committee or some other Committee -- this is going to be a longer term issue. This is going to have to continue to go forward and we're going to have subsequent work and reports back to try to develop a really practical way that something can be done with this.

Well anyway, so I'm suggesting and Dr. Langhorst will comment, I'm suggesting perhaps that we go now to the step of formally approving the

Committee report.

Dr. Langhorst.

MEMBER LANGHORST: No, go ahead.

CHAIRMAN ALDERSON: All right. Well, would someone like to make that motion?

EMBER DILSIZIAN: I have a question.

CHAIRMAN ALDERSON: Yes.

MEMBER DILSIZIAN: I guess before we vote on it, you know I am part of the Committee and I just didn't think about it that the data over a one-year period, as Donna brought up, may not be sufficient.

I think that's important because it's not the concept alone. Is it is practical enough to use several, a few centers who may not have enough data to actually conclude. So I think it's worth discussing that before voting.

CHAIRMAN ALDERSON: Okay. So, let's discuss that question, then. I mean that's Dr. Dilsizian wants us to discuss because he's concerned about the report, which concludes that pilot project, that that may not really be feasible.

Yes.

MR. GREEN: I like the suggestion you made of doing an RFP. Ask the community to step forward. Now whether the professional societies of

SNMMI or ASTRO, you know I'm aware of four accreditation bodies, AOA, DNV, the Joint Commission, and one more I can't remember the acronym for, they don't really have expertise in radiology in this field. But if we submit a request for RFPs, I think they'll develop it. And then that rising tide will improve patient care across the spectrum, no matter whether a hospital is accredited by this provider or that provider, or whether a clinic that doesn't have accreditation might have participants who belong to a professional society.

I think there's a great deal of value in doing the RFP, rather than the trial process because you might just come out with zero. You know millions of diagnostic doses, 15 million per annum and you have under ten. So, I think the RFP has merit.

CHAIRMAN ALDERSON: Dr. Ennis will be next.

MEMBER ENNIS: I feel like I need some feedback and maybe some time but from NRC staff on this. I think our thinking about proposing this was a baby step to get everyone comfortable with the concept. And the other route is more of an all or nothing kind of approach. So I think we need to hear from NRC is a baby step really where you want to go

first, if you're going to need a bigger baby step. Maybe we need to do ten facilities of each type and two years. We don't have to get locked in to two facilities for one year. But I think conceptually like we heard Pat talked before, let's talk a little bit about we need to do a baby step trial project and then we can tweak how many years and how many facilities or do we just want to develop the program.

MR. COLLINS: So yes, this is Dan Collins from the NRC. I would suggest it would be best if we were to take whatever the concept is and provide that to the Commission with the recommendation and get their approval to move forward on it before we start down the road of getting an RFP or something similar because not only are the resources much more intense for doing that but then we're going to go to any outside organization. And you're starting off with the full public comment thing.

And that's not necessarily a bad thing but in terms of just being able to manage the program and expectations I think the first place to start is with concept and getting the Commission's approval first to start.

CHAIRMAN ALDERSON: So the idea of

concepts and Commission approval is on the side of approving the report because the report includes this pilot project. And then the next step after that, if that happens would be the yes, all right, that this is put together and then presented internally to the Commission to say well, can we or could we do this. And the answer may come back no.

There's a hand over here somewhere. Yes, Katie Tapp.

DR. TAPP: This is Katie Tapp. I think Sophie will correct me if I'm wrong but you can vote with an amendment to the report to say not two facilities but the number of facilities and the number of years will be evaluated and looked at, whatever the motion would be. But you can amend that in the report and vote on the report, as Dr. Ennis said, with this different value than just two.

CHAIRMAN ALDERSON: Okay, yes, Dr. Ennis again.

MEMBER ENNIS: Along those lines, one of the things that we think we can get that maybe will be in this direction is the near-miss issue. So then there'll be a lot more events, we all think, than what's being reported. Even if all the medical events out there are actually being reported, if we

call near-misses into this, I don't know how we go about that but, again, that would strengthen the case why this is a good way to go, number one, and also give us more evidence that this approach is working, if we are including near-misses in this pilot program.

CHAIRMAN ALDERSON: Dr. Langhorst.

MEMBER LANGHORST: I think also the fact, though, the medical team has very limited resources is a big indicator of why we need to go this route because NRC is not into the medical community. I mean they just don't have the expertise. They don't have the desire to do it because they don't have a big program.

And I think the important thing is to have the information out there of what people are learning, have it be in like what they're calling for this national database so that people with these incidents, and I say incidents rather than events, where it might be a near-miss, or even nothing to do with medical use but has a strong application in medical use of byproduct material, that is shared publicly, and that people learn from it, and that it supports overall patient safety, and the patient's ability to get that medical treatment.

CHAIRMAN ALDERSON: Yes, Ms. Weil.

MEMBER WEIL: I think it's really important that we present to the Commission that the intention here is a gigantic paradigm shift away from what did you do wrong to what are you doing to promote patient safety, which would be the capture of the near-misses, and the voluntary reporting, and comprehensive reporting which the patient safety organizations require of group cause analysis and corrective action, which you're not capturing, necessarily, in the current NRC methods.

CHAIRMAN ALDERSON: Dr. Metter. Yes, we'll go down the list.

MEMBER METTER: One last comment in that the medical community, over the last several years, has been changing their paradigm to more value. What value do you give to patient care? So I think we can kind of frame it as these incidents can add best practices to assist in the value that we give to our patients to prevent such events.

So I think if you frame it that way, that ought to fall in very nicely to how health care is actually looking at how to handle patient care.

CHAIRMAN ALDERSON: Sophie would like to comment. Thank you.

MS. HOLIDAY: Okay, so I just want to

make two quick comments. So I just want to confirm what Katie said. If what the Committee wishes to do is to amend the report to reflect a different number of institutions that are participating in this pilot, expanding the number of years that you're looking at, that will need to come forth as a recommendation during this meeting to amend that report so that it can be reflected in the final report.

Secondly, as Mr. Collins said, this is looking like it's something that has to go forth to the Commission, which means it would have to move forward in a Commission paper or a SECY paper, which is something that staff would write. And if that's the case, then of course the subcommittee's report, with these amendments, would be attached as an enclosure. This is similar to how we pursue Part 35 rulemaking, or NUREG-1556, AO criteria, things of that nature. If the Committee has a formal position, we include your committee report as part of -- be enclosed into the SECY paper so that the Commission has the ACMUI's position on record as well.

CHAIRMAN ALDERSON: Okay. Did everyone understand that? Those were all comments relevant to the issue of should we -- the motion that was originally put out there. Are we going to support

the report as it is now? And so that motion is still on the table.

VICE CHAIRMAN ZANZONICO: So if I understood correctly, Sophie, you're saying that details like the number of centers or the duration of the study would have to be specified in our approved motion. Is that correct?

So could we leave it open-ended and amend the motion to say with numbers of centers and duration to be determined?

CHAIRMAN ALDERSON: To be determined, that's the way to do it. That's the way to do it.

MEMBER LANGHORST: Or we could say here are suggested numbers and duration but that is to be determined. I mean we were asked to give specifics and so we did.

CHAIRMAN ALDERSON: Okay.

MEMBER LANGHORST: And so I think that we make it more suggestions instead of hard and fast recommendations.

VICE CHAIRMAN ZANZONICO: I'm just actually at a point where in terms of the rules of order we can pass the motion without being locked into something that we later regret.

CHAIRMAN ALDERSON: Yes, Mr. Collins.

MR. COLLINS: So just real quick. To Dr. Zanzonico's point, you could conceivably leave it open-ended with the thought that any Commission paper would be coming through the ACMUI for your review and comment before it goes to the Commission anyway.

So that might be part of your recommendation for the staff to consider that.

CHAIRMAN ALDERSON: Okay. That's an easy way to do it, just make that part open-ended.

Dr. Metter.

MEMBER METTER: Well perhaps we can even go further in that we can add that we support the concept of a pilot program with the numbers to be determined at a future date.

CHAIRMAN ALDERSON: That's good. I like that. I like that.

All right, that seems like a -- are we ready to perhaps now, considering these options, consider approving the committee report, as amended?

Yes.

MEMBER LANGHORST: One thing I wanted to add was with Dr. Dilsizian's presentation also for the patient intervention, we discussed how we might include that into our report and suggest that that be an addendum to our report from that subcommittee and

essentially goes through that and ask that those points be considered as the overall recommendations for our subcommittee report.

CHAIRMAN ALDERSON: Right. So we're suggesting that when we talk about this, we're considering Dr. Dilsizian's report and yours together as the report that would be approved, as amended, in terms of the specifics and that would go forward then to the NRC to be put together as a SECY paper or whatever to go to the Commission for their views.

All right, well that's, again, the motion. And I think that's been seconded when we were back there. I don't know if we got to a second. Does someone want to second there?

MEMBER WEIL: No.

CHAIRMAN ALDERSON: No.

MEMBER WEIL: Just a comment. Perhaps we need some discussion on the Patient Intervention report before we approve it.

CHAIRMAN ALDERSON: All right. All right. Fine, the Patient Intervention is -- that specific segment is open for discussion, since it's now been concluded.

Comments? Comments from the audience, from the ACMUI? From Dr. Langhorst.

MEMBER LANGHORST: From my perspective, and in discussing with other members of our subcommittee and your subcommittee, Dr. Dilsizian, it seemed like we were on the same page and this was just another perspective of trying to define these high and low events.

CHAIRMAN ALDERSON: Good. All right, any further comments? All right, so -- yes, Dr. Palestro.

MEMBER. PALESTRO: Yes, before we vote, could I ask for a restatement of the amendment?

CHAIRMAN ALDERSON: All right. Yes, Darlene did a very good job of that.

MEMBER METTER: Well, I would like to amend that the concept of the pilot program be approved with the number of sites and the duration of evaluation to be determined at a later point in time.

CHAIRMAN ALDERSON: That is the amendment.

MEMBER LANGHORST: I would like to ask what was the motion because I don't remember a motion being made on accepting the report.

CHAIRMAN ALDERSON: I think we were headed in that direction.

MEMBER LANGHORST: Okay, so we haven't

had that motion yet.

CHAIRMAN ALDERSON: Would someone like to make that motion to accept the report, as amended? That is a second.

All right, so we have a motion and it's seconded to accept the report, as amended.

Further discussion? Seeing none, all in favor?

It's unanimous. So, the report is accepted, as amended.

MR. BOLLOCK: Okay do you, for Dr. Dilsizian's recommendations and his slides because that's not in the report. I know the discussion was kind of going that way.

MEMBER LANGHORST: I would like to move that we add an addendum to the report which has Dr. Dilsizian's subcommittee's recommendations that you saw on the slide and that those with the statement on there that say this also should be included in the discussions of the programs developed on our report.

CHAIRMAN ALDERSON: Is there a second for that? Yes, good.

Is there further discussion?

All in favor?

That's also unanimous.

MS. HOLIDAY: Dr. Alderson, just to reiterate for the record, the recommendation that I have is that the ACMUI unanimously endorsed the Medical Event Reporting Impact on Medical Licensee Patient Safety Culture draft report, as amended, to support the concept of the pilot program with the number of sites and durations to be determined at a later date and to include the Patient Intervention Subcommittee recommendations as an addendum.

CHAIRMAN ALDERSON: Exactly as we said.

MS. HOLIDAY: Thank you.

CHAIRMAN ALDERSON: Thank you very much, Sue, for a wonderful report. Thank you and thanks to all of you for your input. That was a very useful session.

All right. Well, it's five minutes to twelve and let's see. Well, it's time to go to lunch. That's what the agenda says.

So, all in favor?

VICE CHAIRMAN ZANZONICO: But we'll still meet at one.

CHAIRMAN ALDERSON: Yes, we're reconvening at one. Yes, reconvening at one.

(Whereupon, the above-entitled matter went off the record at 11:54 a.m. and resumed at 1:06

p.m.)

CHAIRMAN ALDERSON: All right, we'll call the session to order, the afternoon session. We're a few minutes late but that's okay.

Dr. Metter is going to present her subcommittee report on the Nursing Mother Guidelines.

MEMBER METTER: Thank you, Dr. Alderson, and good afternoon. I will be presenting the subcommittee report on the Nursing Mother Guidelines for the Medical Administration of Radioactive Materials.

But before I start, I'd like to thank the rest of my Subcommittee Members, Dr. Vasken Dilsizian, Dr. Christopher Palestro, and Dr. Pat Zanzonico.

Now, the subcommittee charge was to review the radiation exposure of diagnostic and therapeutic radiopharmaceuticals, including brachytherapy, to the nursing mother and child.

Now, at times, a nursing mother may need a diagnostic or therapeutic nuclear medicine procedure. However, radiopharmaceuticals often appear in breast milk.

Therefore, the use of radiopharmaceuticals during nursing raises a

radiation exposure concern to both the nursing mother and nursing child.

According to 10 CFR 35.75, in-licensees can release a patient who has received radioactive materials, and in this case, the nursing mother, if the Total Effective Dose Equivalent to any individual member of the public, and in this case, the nursing child, will not exceed 5 millisieverts or 0.5 rem.

Now, if a nursing mother receives a radiopharmaceutical and continues to breast-feed, and if the nursing child's dose could exceed an Effective Dose Equivalent of 1 millisievert or 0.1 rem, the mother must be given written instructions as to any potential adverse consequences if breastfeeding is not interrupted or ceased.

She must also be given written instruction and guidance on the discontinuation of nursing. Nursing or breastfeeding, as you all know, is infant feeding from the female breast. Now, breast milk is an excellent source of nutrition for the infant or nursing child, and the process of milk production is termed lactation.

Now, lactation begins shortly after delivery and becomes quickly relatively constant shortly after delivery, and is driven by the hormone

called prolactin.

Now, milk production can occur without prolactin and prolactin is most abundant when the child is suckling and milk is being removed from the breast.

Involution, or the cessation of lactation, occurs about six weeks after the last breastfeeding. Now, if milk is radioactive, there's often a certain period of time that interruption time is going to be required for nursing.

And breast milk during this interruption time can be handled in one of two ways.

If breast milk is pumped before the mother receives the radiopharmaceutical, it's not radioactive. So, the mother can use this milk during the interruption period to feed her infant.

If breast milk is pumped after the mother receives the radiopharmaceutical, most often this will be radioactive, and the milk can then be expressed and discarded, or held for decay in storage until it's no longer radioactive, and used to feed the child.

We know many drugs, and therefore, radiopharmaceuticals, entered the maternal circulation, and this can be either through the oral

or perennial routes.

And therefore, allows for secretion of these drugs and radiopharmaceuticals into the breast milk. Radiopharmaceutical drugs uptake these at about three to four hours after administration.

So, now let's look at the radiation dose to the nursing mother, and a majority of it will come from her lactating breast.

We know that radiopharmaceutical uptakes in a lactating breast, and therefore, the absorbed dose to the maternal breast is great than in the non-lactating breast.

The main source of exposure to the maternal breast will be the radioactive milk in her lactating breast.

Mostly radiopharmaceuticals have less than ten percent excretion into milk of the initial administered activity, with the majority falling in the range of 0.3 percent to 5 percent of the initial activity.

Two major exceptions, however, are 67 Gallium Citrate and I-131 Sodium Iodide. These tend to give ten percent or greater excretion into breast milk of the initial administered activity, and therefore, has a higher absorbed dose for the maternal

breast.

A major concern is I-131 Sodium Iodide in the lactating breast. As mentioned, the lactating breast has a higher I-131 uptake than the non-lactating breast.

For example, 150 millisievert dose of Sodium Iodide I-131 gives approximately 200 rads, or 2 gray, to the maternal breast.

Therefore, before I-131 therapy or any does of I-131 is considered to the nursing mother, it is recommended that you stop nursing six weeks after her last breastfeeding, so that involution or the cessation of lactation can occur.

So, at the time of the I-131 administration, this will minimize her breast dose.

Now, let's look at radiation exposure to the nursing child. This comes from two sources, the external source, which is the mother, and the internal source, which is ingestion of radioactive milk, external source but internal to child.

Now, our tenets for ALARA, which is our radiation protection Bible, I guess, is going to be time, distance, and shielding.

So, if the mother is the radiation source, the distance stemming from the close

proximity that she has with her child for childcare and feeding is significant. And then the time interval can be TEDE significant.

And therefore, the dose that the mother gives to the child where these two parameters can be quite significant, the dose to the child will be from her breast exposure and then her whole-body exposure as external sources.

Interim milk ingestion is going to be the internal source. Again, less than ten percent of radiopharmaceuticals administered get into the milk, usually, again, within a range of 0.3 to 5 percent.

And the dose to the child from an internal source would be the amount of the milk ingested, and that's about 800 CCs per day.

So, if you look at the total dose to the nursing child, it'll be from the external, maternal exposure, and the internally-ingested milk.

Now, if breastfeeding is not interrupted and the mother receives radioactive material, most radiopharmaceutical doses will slightly exceed the 1 millisievert or 0.1 rem dose to the nursing child.

So, often, there's going to be a need for temporary nursing interruption period.

Now, let's look at other procedures,

radiotherapy and other radioactive sources, that could be a potential exposure to the nursing child. And there'll be three predominant procedures.

One is brachytherapy, Radioembolic therapy, which is yttrium-90 microspheres, and Radioactive Seed Localization, that the nursing mother could undergo.

So, let's look at Brachytherapy. This is boost radiation dose for certain early-stage breast cancers at the lumpectomy site.

This is done after surgery and whole-body radiation, that extra boost dose to the lumpectomy site. And this is a multi-catheter, traditionally, approach, which is a complex procedure and has a steep learning curve.

Recently, however, there's been notice to be a decline in brachytherapy, and the rationale being a wider access of external electron radiotherapy which can actually give this boost dose.

And a concept coming up that perhaps Brachytherapy isn't needed for all early-stage breast cancers. Despite this, brachytherapy remains an important mode of treatment for certain breast cancer patients.

Now, mammosite has a new brachytherapy

technique that appears to be simpler. It uses a single balloon catheter that delivers two treatment doses to the lumpectomy sites per day for a total of five days.

The second type of therapy or radioactive source could be radioembolic therapy, with yttrium-90 microsphere.

As we know, Y-90 is a pure beta agent, and this is given by the Interventional Radiologist as the intra-arterial embolization of these microspheres for certain liver tumors.

Radioactive Seed Localization, this is a pre-operative localization of non-palpable breast lesions for surgical incision.

And usually, an I-125 seed is implanted into the breast approximately two to seven days prior to the surgical procedure, or it can actually even involve the same-day procedure.

Generally, the source is located by gamma probe during the inter-operative procedure, and the seed and targeted breast tissue is removed at the time of surgery.

Our subcommittee recommendation for nursing mothers for the medical use of radioactive materials is based on multiple recommendations.

We looked at a wide set of recommendations, and the subcommittee chose to use the most conservative, and sometimes very conservative, recommended timeframes, which is generally going to be the longest-time interruption period.

Now, we used the maximum dose to the nursing child of 1 millisievert and incorporated the current NRC and ICRP recommendations.

The subcommittee generally used one time interval for each radioisotope, and this looked into the different factors, particularly the following three clearance scenarios, and applies to all three of them.

The first is the interrupted time period for breastfeeding. The second is the physical proximity interruption time period of mother to child. And the third is the radioactive decay needed for radioactive milk for decay and storage.

So, for technetium-labeled agents, there are many labeled radiopharmaceuticals. I know the 24 hour recommended period is going to be excessive for some, but it's still maintained within the 1 millisievert exposure to the nursing child.

And really, if you just use one time

interval, it simplified the guidelines, avoids confusion, and limits the potential error.

For Fluorine-18 or Gallium-68 labeled radiopharmaceuticals, 12 hours. For the PET agents, C-11, N-13, O-15, and Rubidium-82, since the PET agents have very short half-lives, the mother is no longer radioactive when she leaves the clinic so no breastfeeding cessation is needed for these agents.

I-123 sodium iodide, seven days. For indium-labeled white cells, seven days. 201 thallous chloride, 14 days. 89 zirconium, 28 days. And 177 lutetium, diagnostic purposes, 35 days.

Breastfeeding cessation is recommended for the following. I-131 Sodium Iodide, recommended for the current child to breastfeeding stop six weeks prior to the I-131 scheduled dose.

Breastfeeding cessation is also recommended for 67 Gallium-Citrate, 177 Lutetium therapeutic doses, these are higher doses, and any alpha emitter.

Brachytherapy and radioactive source/ seeds, Y-90 microspheres do not enter the system of the breast tissue or breast milk. So, really, no nursing interruption period is needed for Y-90 microspheres.

As long as there's no radioactive source or seed within the maternal breast, there is not radioactivity, so the mother can nurse during the timeframe when there are no radioactive materials within her breast.

And lastly and importantly is patient information. Nuclear medicine and nuclear cardiology clinics should post signs to alert the nursing mothers to inform the nuclear medicine staff as to a nursing condition so that radiation safety precautions can be implemented with respect to a nursing mother either before, during, or after, their scheduled nuclear medicine procedure.

These are the recommendations that I've used for this presentation. Thank you.

CHAIRMAN ALDERSON: Oh, good, thank you. Very nice and clear. So, questions, comments? Yes, just one?

MEMBER WEIL: Did you come up with any recommendation for how far in advance of treatment this information should be given to the nursing mother so perhaps she has time to pump and store breast milk?

MEMBER METTER: This is predominantly known to be for I believe the I-131 therapy because of the high dose, you should stop. But --

VICE CHAIRMAN ZANZONICO: The simple answer is no. There will be, as you know, as part of the patient release program, a recommendation to provide radiation safety precautions in advance of the treatment.

And so the assumption is that advice related to breastfeeding would be part of that briefing, so to speak. But we didn't specifically address it as part of this report.

MEMBER WEIL: Can I follow up on that?

CHAIRMAN ALDERSON: Please.

MEMBER WEIL: So, in the patient release subcommittee report, we did not recommend a particular timeline?

VICE CHAIRMAN ZANZONICO: Correct.

MEMBER WEIL: So, the six-week breastfeeding cessation is a significant -- it's significant, let's leave it at that.

The other interesting thing that I noted is that the exposure to the child from an irradiated mom is 1 millisievert.

But I believe the NRC regulation for position patient release is 5 millisievert for a family member, including children?

MR. BOLLOCK: The regulation also address

this, but the regulation is that for expected dose over the 0.1 rem or 100 millirem, that they're just given instructions.

So, it is written instructions so it is in alignment with the patient release.

MEMBER WEIL: But patients can be released if no member of the caregiver's family will receive more than 5 millisievert, correct?

MR. BOLLOCK: Yes.

MEMBER WEIL: So, you're recommending 1 millisievert?

MR. BOLLOCK: No, that's not -- do you want to speak?

MEMBER METTER: It's the dose that we're giving the maximum dose to the child.

MEMBER WEIL: To the child, maximum dose to the child, but patient, mom, after I-131 can be released home if no member of her family will receive more than 5 millisievert. And that includes children. And your report is recommending that any child in that family should receive no more than 1 millisievert.

MEMBER METTER: Right, well, what happens is, after that, you'd have to give guidance regarding that. And I think Dr. Tapp has something to say.

DR. TAPP: If I may, or Dr. Metter can also answer this, 35.75 does require that instructions be given if the child is likely to receive 1 millisievert based on no interruption of breastfeeding.

And there's specific guidelines, then, of instructions that need to be provided. They still are allowed to be released but they have to have instructions to keep the child's dose as low as possible.

DR. HOWE: But, Laura, you're correct. The release does cite it as 500 millirem to any individual, including a nursing child.

VICE CHAIRMAN ZANZONICO: Right. If I may, also, the recommendations from this subcommittee are specifically in relation to breastfeeding.

So, there'll be other roots of exposure, so to speak, just not on breastfeeding-related exposure, which could bring the dose to about 100 millirem but still below the 500 millirem.

So, these are expressly the precautions, with respect to breastfeeding, for the applicable regulations.

CHAIRMAN ALDERSON: Are there other questions or comments? I understand your problem

with what is apparent inconsistency.

MEMBER WEIL: So, I have a suggestion that maybe we either take it as an action item to look more into it and see -- I understand we should at least look at it a little bit more just to make sure that we can provide a better answer.

MEMBER LANGHORST: I'm confused at this also. So, Dr. Zanzonico, is this on slide -- well, they're not numbered.

Where it says the recommendations for nursing mothers, the dose to the child, you're saying, should only be internal dose? Or...

VICE CHAIRMAN ZANZONICO: The algorithm that was used was the internal dose plus the external dose associated with breastfeeding.

So, we followed that recommendation, which is basically from the reg requiring guidance for breastfeeding.

So, that dose includes an internal breastfeeding dose and an external dose associated with breastfeeding, but not other external exposure in the course of their life.

MEMBER LANGHORST: So, this is a recommendation to limit the dose of the child? Or a recommendation when written directions need to be

given to her?

VICE CHAIRMAN ZANZONICO: Yes, it's the latter.

MEMBER LANGHORST: Okay, that's not clear from this.

DR. ZANZONICO: Okay, so we need to clarify that in our report.

MR. BOLLOCK: Yes, I think it was clear to at least myself and some of our staff from your draft report that that's what your intent was. That's why it is -- we didn't take it as a recommendation to lower the release limits.

It's just re-emphasizing that if expected to expose any member over 100 -- well, specifically for a nursing child, over 100, you get that the doctor gives the instructions, actually additional instructions, for the breastfeeding mother, which includes, I think it was almost verbatim from the regulation guidance, interruption or discontinuation, and information of potential consequences, if any, of failure to follow the guidance.

So, we didn't read this report as a recommendation to make a regulatory change. I think it's recognizing that if you're going to expose the child to greater than 0.1 rem, that you give

instructions.

And these were kind of guidance in helping with those instructions, is how we took it.

CHAIRMAN ALDERSON: It isn't as inconsistent, now that I've listened to your discussion, it's not as inconsistent as I think --

MR. BOLLOCK: Yes, so we just want to make that clear.

CHAIRMAN ALDERSON: You're just calling out a subset here and saying if it's going to be this much, then you've got to do more for that subset, even though it's within the reg.

MR. BOLLOCK: Right, so if anyone thinks it's inconsistent, we can -- we just want to make sure it's clear here.

VICE CHAIRMAN ZANZONICO: Well, clearly, we have some very well-informed individuals who've highlighted a lack of clarity. So, we should at least amend the report, which is a draft report, to clarify that point.

MEMBER LANGHORST: I think you do state in the report that the ICRP has that recommendation, but I guess, what you need to say is what the subcommittee's recommending.

And so my understanding is the

subcommittee's recommending that these are the precautions to take if it's greater than 100 millirem to ensure that you're meeting the criteria of 35.75.

VICE CHAIRMAN ZANZONICO: That's exactly it.

MEMBER LANGHORST: Okay, thank you.

CHAIRMAN ALDERSON: Yes, Laura?

MEMBER WEIL: I would be more comfortable if the subcommittee recommended a specific timeframe for instructions being given to nursing mothers who are receiving, I guess, specifically, I-131.

Because it's necessary for a nursing mom to have time to stop breastfeeding so that she hasn't got an active lactating breast, which will increase her risk, as well as put her child at risk.

And just saying instructions will be provided or posting signs in the office doesn't strike me as proactive enough.

MEMBER METTER: Well, if the mother's going to undergo I-131, usually it's going to be for therapy, and usually, that instruction is given ahead of time, as far as discussion with the mother by the doctor.

And usually, that's actually considered -- and usually, it's going to be nuclear medicine

physicians that are doing that.

MEMBER WEIL: Given anecdotal evidence from patients who receive I-131, which this committee has heard before and which we certainly discussed in the patient release subcommittee, you really can't count on that being -- we need to say that needs to happen because you can't count on that happening.

Sometimes patients are not given instructions until the day of therapy.

VICE CHAIRMAN ZANZONICO: So, if we had language in the latest patient release subcommittee report on the subcommittee -- on the second paper, rather, we can use that language in terms of giving precautions in advance, and incorporate that into the breastfeeding report.

And it avoided, as you know, a prescribing of a specific period of time, but it did give a strong advisement to inform the patient of all the necessary precautions, which in this case would be breastfeeding, as far in advance as possible.

CHAIRMAN ALDERSON: Dr. Howe is next.

DR. HOWE: I'm just a little bit confused. You're talking about I-131 therapy.

NRC's experience in that in 1990 was that we had a patient that was getting a whole-body scan,

not a therapy dose, but a whole-body scan, because they no longer had a thyroid.

And the licensee did not ask if the person was nursing, and they received the dose, they waited 24 hours, they nursed their child.

The child ended up with an estimated dose, which was proven in about three different ways, of 30,000 rads to the thyroid.

So, it's not enough to just say therapy. The whole-body dose can also be a thing. And in that case, they hadn't asked whether she was nursing, so there was no time to cease.

So, just keep those things in mind. And that's a real incident.

CHAIRMAN ALDERSON: Dr. Palestro is next.

MEMBER PALESTRO: Yes, my only comment was going to be, and now Donna just kind of shot that down, would be that if authorized user -- I was going to say that it would be incredulous to me that the authorized user would administer a dose of I-131 to a woman without first addressing those issues, whether it's therapy or diagnostic.

And neither of those have to be done immediately; they're not that urgent, particularly nowadays. With Virugen, it can be maintained on

Synthroid for those six weeks.

So, I guess, even if you're going to have the defined time in advance, if they don't answer the question, it doesn't solve the problem, you're right.

MEMBER WEIL: So, just one final comment on this, and then I'll cease.

We were comfortable without providing a specific timeframe in the patient release subcommittee report but that's because there isn't a defined interval that needs to be addresses, as in the case of a lactating mother. We need six weeks.

So, there's a rationale there for a defined interval between instructions and receiving the radiopharmaceutical.

So, I, for one, am not comfortable with that being an amorphous in-advance-of-treatment statement. I think it needs to be much more specific in the case of lactating breasts.

CHAIRMAN ALDERSON: So, I'll make a follow up on that statement. As I've listened to the discussion, I think it's a very good report and I think that the guidelines that are presented are potentially extremely useful.

The question along the same lines is so, how do we now be sure that patients and practitioners

are getting this advice?

We'll put it in the Committee book and we'll hope that people learn about it, and it'll keep happening. So, what's the plan?

I mean, there needs to be a plan to take this kind of information, even on these last few slides, it's got to be out there so that people know.

I don't know, do you put it in the Federal Register? This is a communication problem.

But how do you get this out there where people now know that a learned group has looked at this and this is the right advice and this is what we should do? What's the answer to that?

VICE CHAIRMAN ZANZONICO: Well, I think as with any other measures, it would be in regulatory guidance, and I think authorized users and licensees pay attention to that. And that would be the root of disseminating this information.

CHAIRMAN ALDERSON: You mean the NRC would disseminate this through Regulatory Guidance?

VICE CHAIRMAN ZANZONICO: That would be my presumption.

MR. BOLLOCK: Yes, we are planning on updating Reg 8.39, which is the patient release, and this report would -- we're going to take all

authorization we have to help update that.

So, we would take this report, the information on the report, and likely use that, along with others, other information to update the Reg Guide.

Some immediate things we could do, just that we have the capability to do and we could, once the report's official, once the report's final and going to be made public, it'll be on the NRC public website.

We can put it on Medical List Server. There's a number of things we could do to advertise your subcommittee's report. So, the immediate thing --

CHAIRMAN ALDERSON: This is the kind of thing that would seem to me that anything you could do to further publicize it is a good thing.

And it makes me think about our communication agenda and whether our people, like Darlene and Chris who are involved in that communication, should actually make sure once the document is written and it goes out in an official way, could then take that same document, be given that, and send it to the ACR or the Society of Nuclear Medicine, whatever organizations are out there, with

the idea that we'll hope you'll get this out to all of your members.

Because this has come from the NRC, and so on and so forth.

MR. BOLLOCK: Yes, we also have a recreated -- as part of our Patient Release Project over the years, we have a website that we primarily use to reference other guidance for patient release.

And we typically use guidance from the Society of Nuclear Medicine and ThyCa and things like that on our website.

So, we can add this to it as well. I'm sure my staff before they put anything on our website will take a look at it.

Not that we don't trust the subcommittee report; as far as we know, it's one of the more thorough reports we've seen. We're actually very impressed and thankful for the thoroughness and all the effort that went into it.

But, yes, we can put it on that website. There's a number of things we can do immediately in near term to get it out to public domain to be useful. Katie has some things like that.

CHAIRMAN ALDERSON: Dr. Tapp?

DR. TAPP: This is Katie Tapp. I

actually had a question for the subcommittee, just so I'm clear.

The six weeks' cessation of breastfeeding before radioactive iodine procedures is not too protect the child, but it's actually to protect the patient's breast?

MEMBER METTER: Correct.

DR. TAPP: That's correct, so it would still be up to the practitioner and the patient to make sure they balance the treatment of the disease and that dose?

I don't think that would be the practitioner, or practice of medicine to balance those risk-benefits. Is that correct?

MEMBER METTER: You mean the final dose that is administered to the mother?

DR. TAPP: Knowing that she's still lactating?

MEMBER METTER: Right, so usually six weeks is really the timeframe that the mother will stop lactation. And so I'm not quite understanding what your question is.

DR. TAPP: It's solely a risk to the patient, not to a member of the public or the nursing child? I just want to make sure that was correct.

MEMBER METTER: Correct in the sense of -- you mean as far as -- oh, I see, when the mother receives the radiopharmaceutical.

It's mainly to the mother, but then the nursing child also, because she's not receiving -- right. It's really actually to both of them.

CHAIRMAN ALDERSON: I agree with that. It's to both.

The mother also, because there would be a great -- I think there will be a tendency if the mother hasn't stopped lactating and still her breasts are still full, and the child is still crying for milk, there's going to be this tendency to capitulate.

So, I think it does affect both.

MEMBER DILSIZIAN: So, I guess we need to inform the endocrinologist, right, six weeks before -- the nuclear medicine physician is not really involved six weeks before.

So, the advice as to -- we can circulate all we want to --

CHAIRMAN ALDERSON: But it has to get to the endocrinologist.

MEMBER DILSIZIAN: Yes, we can circulate to ACR but I don't think we'll be able to get to the treating physician.

CHAIRMAN ALDERSON: But our people have to get it to those consultants, that's right. Any other questions or comments on this report?

Well, great guidelines and very important, and hopefully, we can do everything we can to get the word out.

VICE CHAIRMAN ZANZONICO: Well, Laura's made us aware of a very inconvenient truth, and so I would just like to come up with some concrete action plan as to how to address that.

Namely, should we include in our report some prescriptive interval of time, like six weeks, prior to the planned therapy for cessation of breastfeeding to address this point?

MEMBER WEIL: I have some suggested language.

VICE CHAIRMAN ZANZONICO: Okay.

MEMBER WEIL: So, somewhere in your report you say that instructions need to be provided in advance, correct?

MEMBER METTER: I believe so.

MEMBER WEIL: Probably just in advance, in advance of treatment or whatever.

And after that, a qualifying statement saying except in the case of the breastfeeding

patient, when instructions must be provided at least six weeks in advance to allow for cessation of breastfeeding.

VICE CHAIRMAN ZANZONICO: I would just say again the issue of must is a red flag, because there may be medical issues. And there's many different treatments --

MEMBER WEIL: You're right.

VICE CHAIRMAN ZANZONICO: -- where the welfare of the mother trumps that --

MEMBER WEIL: Well, probably not in the situation of thyroid cancer?

VICE CHAIRMAN ZANZONICO: But they should, I think, rather than they must.

MEMBER WEIL: It should be. Yes, okay.

MR. SHEETZ: Mike Sheetz, University of Pittsburgh. I've heard the subcommittee report. I think the recommendations would be really useful for the medical community by grouping the recommendations by category of isotope, as opposed to each radiopharmaceutical being listed with a different recommendation, as is in the literature.

I do want to point out that it has been reported that Y-90 has been detected in patients treated with Y-90 microspheres, while it's a very

small percent.

And I don't know of any literature that states whether it's located in breast milk or not, so we may want to put some precaution there until information's available.

CHAIRMAN ALDERSON: Well, that sort of thing, I certainly don't know the answer to that question.

MEMBER METTER: I don't know the answer to that.

CHAIRMAN ALDERSON: If any of you are going to do any Y-90s in the right circumstances.

VICE CHAIRMAN ZANZONICO: The only reason I hesitate to address that point is I actually reviewed the paper for Health Physics. I reported that but it's not in the literature yet.

So, it's kind of a dilemma.

MEMBER WEIL: There's I think someone on the phone who would like to make a comment.

VICE CHAIRMAN ZANZONICO: We've got someone on the phone who would like to make a comment.

CHAIRMAN ALDERSON: Very good, is there someone on the phone would like to make a comment?

MR. CRANE: Yes, there is.

CHAIRMAN ALDERSON: Please, speak up so

we can hear you.

MR. CRANE: Can you hear me?

CHAIRMAN ALDERSON: Yes, that's better.

MR. CRANE: Okay, should I just bellow?

CHAIRMAN ALDERSON: Yes, you're doing fine.

MEMBER WEIL: Please identify yourself.

CHAIRMAN ALDERSON: Identify yourself, please?

MR. CRANE: Sure, my name is Peter Crane. I'm an NRC retiree and my experience with the NRC.

And medical regulation goes back literally to 1975, and I have a good deal of institutional history, which I would have liked to contribute to the previous session, except there wasn't a call to the phones unfortunately.

I want to commend the speaker for the seriousness with which the issue of the nursing mothers has been taken. I think that's admirable.

And I want to second what Dr. Alderson just said about there needing to be a plan so people know. Because there is inevitably a great gap in the dissemination of knowledge within the profession, to licensees.

I had an example of this a couple of years

ago when Dr. Mike Tuttle, who's -- no, this was Bryan McIver, was making a presentation on new thinking in the use of I-131 and thyroid cancer.

And I asked, well, this is fine for the Sloan Kettering's and the MD Anderson's and the Moffitt's, but how do you get this out to the hospitals where the real care is going on?

And he said realistically, we know it takes ten years. So, the profession realizes that getting the word out is a formidable issue.

I was troubled at the beginning of this presentation because I thought I heard the briefers saying that the standard of 35.75 was allowed no more than 0.1 or 100 millirems to a child or a nursing child, when that is not the case.

It is, of course, and this was clarified by Laura Weil and Donna-Beth Howe, that in fact, it is 500 millirems to anyone.

This is contrary to what the International Commission on Radiation Protection and the National Council on Radiation Protection recommend. They think it ought to be a maximum of 100 millirems, and the NRC has so far been unwilling to do that.

I think it's troubling that under the

NRC's rule, you could have a dose of 95 millirems to a nursing child, to any child, and it would require not only no -- it would require no information of any kind to that patient.

And I think that's certainly troubling. I wanted to pick up on Donna-Beth Howe's point about the diagnostic dose of the whole-body scan that delivered 30,000 rads to the child, the baby's, thyroid.

It was a myth that was being propagated very widely in the '90s by the opponents of NRC Regulation that diagnostic doses were inherently safe and opposed no risk to the public at all. And this certainly contradicts that.

I think that this, the issue of the nursing mother, ties into the issue of patient release in one serious way, which is with regard to hotel workers.

Because, as you probably know, in I think 2009, the City of New York Health Department warned people against releasing patients to hotels, saying that there was a quite plausible possibility that a hotel worker who is nursing or pregnant and cleans up a contaminated hotel room, could absorb a dose and pass it onto the nursing child and deliver a

significant dose.

And you may recall that at the ACMUI meeting of October 2010, Jim Luehman of the NRC staff made the point that this undercuts the proposition that a person is likely to receive a dose from a released patient only once in a lifetime.

This could happen repeatedly in a hotel near a major cancer center, and the patient could be picking up a dose each time.

I guess I would like to stress that if you think that children should not be getting more than 1 millirem, more than 100 millirems, it's going to take a rule change to accomplish that.

And I personally think it's high time that the NRC did bring itself into sync with international standards. And if that's your position, I think that ought to be clear.

And I also wanted to pick up, finally, on something that Susan Langhorst said in the previous meeting, in which she pointed out that the NRC had inadequate or, sort of, minimal resources for the medical area.

And I think that is a critical point, I think she's utterly right, that the material section has always been a stepchild and if the NRC is going

to do this job at all, it ought to be doing it well.

And it's fish or cut bait. They should do it right and give the area the resources it needs and the attention it needs, or it should say Food and Drug Administration, take over, we don't have the interest, we don't have the resources.

So, that's my comment.

CHAIRMAN ALDERSON: So, Dr. Crane, I'd like to ask you one more thing, since we will review a very good transcription of these events, Crane could be spelled in two different ways. How do you spell your last name?

MR. CRANE: I spelt it C-R-A-N-E, and I am no doctor. I am a retired lawyer.

CHAIRMAN ALDERSON: Very good, all right. Thank you, sir. C-R-A-N-E.

MR. CRANE: Thank you, Doctor. Thank you, goodbye.

CHAIRMAN ALDERSON: Goodbye. Are there any other comments on the phone before -- Mr. Green has a comment here.

MR. GREEN: I appreciate the amount of work that went into this subcommittee report, and I do like its brevity in that it does not get into all 29 FDA-approved drugs, but groups them by nuclide.

But I see that that has been -- we've jumped tracks. The I-123 Sodium Iodide is nuclide chemical specific. It doesn't talk about DAT scan or MIBG.

Could that be broadened to all I-23-labeled compounds? The same with the Indium-111 leukocytes, it doesn't encompass the other two radiopharmaceuticals that are currently approved that are Indium-labeled.

One is lutetium-only prostate cancer where they're not going to lactate, but the Octreoscan is still on the market. Could that be broadened to Indium-labeled drugs and still be safe?

And not be deleterious to clinical practice? And thallous chloride, again, is where we are drug-specific. Can we make them all nuclides for simplicity?

VICE CHAIRMAN ZANZONICO: Can I suggest something or would you like to respond? Okay, so as we said, this is a draft report and there's a number of very good points raised.

If these comments could be sent to Darlene, who's Chairman of the Subcommittee, then after, we could have a subsequent open meeting, a teleconference to finalize the report after

incorporating these comments.

Because it just seems there's enough substantive points raised that we're not in a position to approve the report at this point.

CHAIRMAN ALDERSON: I think that's a great suggestion, actually. Darlene, do you have a comment on that?

MEMBER METTER: I agree, and the other thing regarding the first bullet in this recommendation of a maximum dose of 1 millisievert, that is actually under the doses that you'd have to go for additional action.

So that's why we chose the 1 millisievert on this, because additionally, you have to take additional actions as was mentioned.

CHAIRMAN ALDERSON: Well, I think, in summary, that this has been a terrific report. It obviously is of great interest to a number of different constituent communities. It's very important to get it out there.

And the Committee now has suggested that the way they'll incorporate all the good comments is to have a follow-up conference call to this meeting, and then use that to help finalize their report, which I guess will have to come back in front of this

Committee at the next meeting or in a subsequent meeting.

All right, are there any further comments on this subject before we move onto the next issue? I see none. Dr. Metter, thank you very much.

MEMBER METTER: I'd like to thank the rest of my Subcommittee Members for this, and thank you.

CHAIRMAN ALDERSON: All right, that brings us to Dr. Howe, Patient Release Project Update.

DR. HOWE: Okay, I'll be talking about the Patient Release Project Update, and I don't have a lot of time. I only have 15 minutes, so it's kind of interesting trying to figure out what to say in those 15 minutes.

Why are we here? Well, we had a Commission document and it's the COMAMM-14-001 that came from both our Former Chairmen, and one of our Former Commissioners.

And the title of it was Background and Proposed Direction to NRC Staff to Verify Assumptions Made Concerning Patient Release Guidance. And that was issued in April 2014.

And there were a number of elements of this. What they wanted us to do was to go out and

get input from a wide spectrum of stakeholders, the public, patients, patient groups, physicians, professional societies, licensees, the ACMUI, and Agreement States.

And we approached them by going out with the Federal Register Notice, in fact we went out with multiple Federal Register Notices, and having public meetings.

The SRM asked us to do two things. We split them into two parts. Part One, we went out in 2016; from November to February we had information collection, and we asked what patients -- were able to help them understand the I-131 treatment process.

We asked physicians and licensees their best practices when making informed decisions on when to release I-131 patients.

And we asked for instructions provided to patients on how to reduce radiation doses to others. We also asked if there were brochures out there.

We were specific about I-131 because that is the treatment that, for most therapy treatments, is the one that's most prevalent and can create both an external and an internal radiation hazard.

Part Two was to explore with the public, licensees, State Partners, whether the agency should

make changes to 10 CFR Part 35.75 for specific reasons.

We went out with the Federal Register Notice and we asked six questions. We asked open questions. We asked you do you think we should do this? Do you think we should do that?

If so, tell us why you think we should, tell us what the safety basis is for releasing the patient for the public, for the licensee, for other individuals.

And the results of this information collection on Part Two is going to form the basis for a second paper on whether to pursue changes in 10 CFR 35.75.

So, we got 132 responders. That's a pretty big number. For Part 35, we got 45 responders. Now, out of 132 responders, we had 41 that were repeat responses.

One person writes a response and other people write in and say we agree with so-and-so's response, and they send a form letter that says we agree with this.

They copy over their response and put their name on the bond, so we really only had about 90 individual responses to look at.

How were these broken down? We got 47 responses from Sodium Iodide I-131 patients. That's a quite large number of responses from the patient community.

We got three responses from patient relatives, two parents and a spouse. We got six professional and medically-related organizations.

We got five medical facilities, and in that case, it came from the Radiation Safety Committee, or if it came from the Department, then we considered it part of the medical facility.

We got 65 medical personnel that responded, that includes nurses. We had nine repeat responses from the nurse community.

We had technologists; we had six repeat responses from technologists. We had medical physicists and consultants. We had 24 repeat responses from that category.

We had two additional repeats from medical physicists and we had one additional repeat that was technical, probably from a medical or health physicist. And we also got responses from individual doctors.

We had two responders that I couldn't tell whether they were in the medical personnel field

or they were sodium iodide patients. And we had responses from four Agreement States.

Not everybody answered the six questions. Some of the professionals and the patients -- most of the patients provided life experiences. One thing I'd like to say about this data is we have 132 responders. This is not enough to be statistically significant. The breakdown of responses within each category is not enough to be statistically significant or to make recommendations based on this is what this community feels.

So, and the other part is that most of our medical personnel did respond to all six questions and gave us a basis. In some cases, the responses were very technical. They referenced ICRP's, NCRP's, NRC's original documents, NRC's Regulatory Guides.

But our responses from the patients were not. So, you can't really compare the responses from the patients with the responses from the medical personnel.

And you have to figure out, in some cases, what the patients were really trying to tell you. So, there has to be some interpretation in there.

So, it's not a simple question of so many responded this way, so many percent responded a

different way.

So, what I'd like to do is go through, and I've been really wrestling with how to do this. Because with 132 responses, it's pretty much all over the place on how to present this in a manner that makes sense or gives you a flavor for the depth of the responses I had.

So, what I'd like to do is I'll probably cover about two questions at a time, and the first one was the activity-based patient release threshold. So, we go back to that.

And actually, this is not just an activity base that we had back before the 1997 change, but it was an activity and radiation measurement-based patient release threshold. And we also had one about the timeframe.

So, the medical community, I think it's not a surprise to anyone, was pretty much unanimous. We don't want to go back to activity-based, we want to stay with dose-based. We believe there's more flexibility.

They gave additional reasons. We think the patients like it better, we think it is less stressful for our patients, we believe it gives us flexibility.

And what did I hear from the patient side? What I heard from the patient side is it is not less stressful to go home. It is very stressful to be a cancer patient and have to rearrange your whole life when kids are there, to be home and isolated.

We would prefer to be in hospitals or we would like to have the choice.

And most of them felt that -- you have to infer they're talking about an activity base because they see the dose-based criteria as essentially closing the option for being hospitalized, and making it very difficult.

And I had some patients that had bad hospital experiences, so they wanted to go home. They think they could have done better at home.

I have many that went home and felt that they had medical conditions that would have been better treated, should have been treated, in the hospital, but they were sent home too early.

So, I had a wide spectrum there, but I think most of the patients would like to have a choice on hospitalization. Most of the patients were very vocal in they didn't believe patients should go to hotels.

Now, to move onto the timeframe for the

current dose limit. NRC is on record in a risk document that we believe it is a per year basis. There have been other interpretations from NRC Staff after that point that says no, we really think what we wrote was per year -- I mean, per event.

So, we asked what should you have? I think the medical community came out very clearly they went per event. I think there is confusion in the medical community. We had one person at a public meeting that thought it was per lifetime.

We've had Agreement States that believe that it should be per year because per year is how we do other radiation doses to the public and members of the occupational workers. So, we had a spectrum on that.

And with regard to the Agreement States, I had one Agreement State that, essentially, for all six questions, didn't bother to respond to the six, just said flat-out no. We don't want any changes, we like things the way they are.

The other three Agreement States gave me different opinions, and once again, I've got 4 Agreement States out of 37.

There's no way that you can draw any conclusion that this is what the Agreement States

feel, other than this is what individual Agreement States believe and gave us as comments.

Questions 3 and 4 kind of go together. Should we have the same dose criteria, 500 millirem, to all members of the general public, including all family members, young children, pregnant women, caregivers, hotel workers, and other members of the public, when considering the release of the patients?

And 4 is if we have a new requirement for the release of a patient who's likely to expose a young child, should we have a new requirement for the release of a patient who's likely to expose young children or pregnant women to doses above the Part 20 limit, which is 100 millirem?

And the medical community, for the most part, believed they should stay with the 500 millirem.

There were some members of the medical community that believed we already had two different release criteria, 500 millirem for the maximally-exposed person, the caregiver, and 100 millirem for the nursing child, the child, and the pregnant women.

That's not the correct interpretation of what our Regulation says, but we had a number of people that believed that was already the case.

We had members of the medical community

that thought there should be 100 millirem criteria for children and pregnant women, because they're the most sensitive members of the public.

The patients very rarely spoke about this particular question, but those that did wanted 100 millirem for all members of the public except the caregiver.

I did have two commenters that believed that there should be a higher limit for certain caregivers that give their consent. And that there should be the same limit for caregivers that give their consent whether the patient is hospitalized or released.

And that's based on an exemption that we are giving for patients that are hospitalized. And if the AU agrees and the caregiver agrees, they can get an excess of the 500 millirem.

Okay, so I had members of the medical community who thought it was 100. I had members, many members, of the patients that believed it should be 100 millirem.

And the Agreement States, I had a few that I think agree and thought that 100 millirem would be a reasonable limit for children.

And new requirements for release of a

patient. This is an interesting one because it's not exactly the same question as 3.

This would be, should there be a requirement if somebody has to do something if they're going to expose young children or pregnant women? I had a number of different approaches.

One medical consultant RSO indicated that what he does is he knows the limits are 500 millirem and so for the maximally-exposed person, he does calculations on what he should provide for instruction at the 500 millirem level.

But if he knows there's a child or pregnant woman in the family, then he makes calculations based on 100 millirem and adjust those instructions for the children and the pregnant women to the 100 millirem level.

So, that could be a consideration in the rulemaking, is that you might give instructions at different levels, depending on the situation.

And then I had some patients and some medical community that believe that if you're going to expose a child or a pregnant woman to 100 millirem, that should be a reason for hospitalizing.

So, I had a wide spectrum from a number of people. I think the Agreement States also, my

four Agreement States, thought that there could be some considerations for the child.

And my next two questions go together also.

One is a specific requirement for licensees to have patient isolation discussion with the patients in sufficient time prior to administration, to provide the patient time to make isolation arrangements, for the licensee to make plans to hold the patient if the patient cannot be immediately released.

And the other would be for NRC to explicitly include a timeframe for providing instructions in the regulations that the instructions should be given prior to the procedure.

In the medical community, almost everyone just across the board believed that the only way to really ensure that doses to members of the public are low and below the release levels is if the patient will comply with the instructions. And if the patient is given adequate instructions.

So, there was a uniform agreement that instructions need to be given. They looked at this question and they said, yes, instructions need to be given early enough for people to make the right

decisions to make the arrangements as they need at home, or to be hospitalized if they can't be released.

I had some counterpoints. One counterpoint was they thought this might be a burden for the standalone therapy treatment facilities. And that's an interesting comment because that would make the assumption that every patient that was treated would automatically be released.

And there would be no one from the standalone facility that would require hospitalization. And it's hard to imagine that all patients could be released.

What was in disagreement was how to do this. The medical community does not like to be regulated. They do not like to have specific regulations.

So, most of the medical community said no, we don't need a requirement, we need a new guidance. There's also an understanding that if it's in guidance it doesn't have to be followed, it can't be enforced. So, I think there's a preference from the patient side and from others that this be a requirement. I had Agreement States that believe this needed to be a requirement.

There was a lot of concern about how do

you quantify the sufficient time prior to administration to allow for these decisions to be made and the arrangements to be made. That could be handled in rule space.

We could come up with a performance method that would fluctuate, depending on whether you got a lot of time between when you needed the treatment. And the time between diagnosis and treatment was very quick.

So, that could be done in rule-making space, but I think there was a uniform agreement that this absolutely had to happen. And instructions have to be, the discussion has to be, given early enough.

And another point for giving the discussions early is how are you going to make the instructions fit the patient if you haven't talked to the patient to find out what the limitations are?

And that has to be done early on so that you get the right instructions and you get the right release time. Question 6 was should you give these prior to the procedure? Most of the negative comments on this were that they did not see how NRC could come up with a specific time, a day, hours, weeks, that would fit all cases.

And there needed to be flexibility in

case someone needed treatment very quickly. And that's another thing where we could probably come up with a performance criteria that would be sliding, that could meet this requirement.

So, all the patients say, yes, we need time to make arrangements. The physicians agreed that you need to give instructions.

And since right now in the rule from 1997, you have delegated the ultimate responsibility of keeping patient radiation doses to members of the public as low as possible to the patient.

And the best way to do that is to have an informed patient that understands what their responsibilities are.

You can make calculations as a licensee, you can have expectations, but if the patient doesn't understand what they're supposed to be doing and isn't capable of following that instruction, then you won't achieve what you need to achieve to release them.

So, that's pretty much a quick overview of the data that I got. And what are the next steps? Well, we have the ACMUI Subcommittee Report.

We are going to be sending out the draft second paper to the Agreement States for review. And we're going to have a regional review of the draft's

second paper, and we expect to have the second paper up to the EDL commission in December of 2017.

Any questions?

CHAIRMAN ALDERSON: All right, excellent report. This is open for questions now. This is touching on a number of the issues that we've touched on in some other reports this afternoon.

Some difficult and controversial issues. So, comments? Dr. Zanzonico?

VICE CHAIRMAN ZANZONICO: Thank you very much. As you said, many of these responses were based on very limited numbers with respect to each category.

In particular, the number of responses from patients who said they wanted to be administered to the hospital at the time of their treatment.

Do you recollect the number of responses that corresponded to?

DR. HOWE: The vast majority of the patients which I had 47 of, and I may have had like 48 of them because one could have been a patient, wanted the option for hospitalization.

I had probably two or three that said I had a really good experience going home, I'm fine with that.

I had a number of those 44 that said I had a bad experience, I was still sick when I went home, I got sicker when I got home and I felt I should have been hospitalized.

VICE CHAIRMAN ZANZONICO: And the responses, again, were not parsed enough to determine among those patients who either wanted the option or preferred to stay in the hospital, that that response was based on how they felt physically as opposed to concerned about radiation exposure to their family and friends?

DR. HOWE: Many of them cited concern about radiation exposure to members of the public and their family. A number of them that expressed concerns were also based on things that happened to them when they went home.

And then a number of them got sick after they went home. They got nauseous, they threw up, they had heart afibrillization type of things, so a number of them -- and colds, where they're sneezing and blowing their nose all over the place.

So, a number of them had situations that they believed could have been handled better. I would not expect the patient community as a whole to give me really in-depth scientific things. They are

telling their life story.

CHAIRMAN ALDERSON: Yes, Chris Palestro?

MEMBER PALESTRO: My one concern about that, and I don't think there's any way around that, is that the patients had what they viewed as an unhappy experience at home and if they had the option, they would have much preferred to have been in the hospital.

The problem is they weren't also in the hospital to able to have a comparison. And so it wasn't really that much better than being at home. You know, the grass always looks greener on the other side of the street.

DR. HOWE: I think I had maybe one or two patients, they were hospitalized, and their experience at the hospital was really bad. So, they felt they would have been better off at home.

So, in both directions, I have a very limited sample size. But I have a very large sample size compared to patient responses from other things when we've gone out and asked them for information.

But is it statistical? Is it scientific?

CHAIRMAN ALDERSON: Dr. Langhorst?

MEMBER LANGHORST: I just wanted to make one perspective comment, and that is if a pregnant

woman is pregnant in Denver, they would be getting 100 millirem more in a year over that pregnancy than we do here in Washington D.C. or we do in St. Louis.

These levels are extremely conservative and of the order of background radiation. Thank you.

CHAIRMAN ALDERSON: Yes, good comment to put it in that context. Other comments?

Part of what I was talking to Katie Tapp about this issue a little earlier before this session started, part of the issue here is what the insurance companies will do.

Because no one is going to want to stay in the hospital if their option is to pay for it. They're only going to want to be there if their insurance will pay for it.

And the insurers will only pay for it if the guidelines or the regulations are quite clear that they must pay if this is the case. And I don't think that exists today.

So, that's part of this whole equation.

DR. HOWE: And I got comments with respect to that also, I've got comments from the Society of Nuclear Medicine, I think it's the Society of Nuclear Medicine, that they've had physicians that have written the letters to the insurers to get the

patients hospitalized, and they've been denied.

So, they're frustrated that when they believe the patient needs to be hospitalized for radiation safety concerns, they're not able to get insurers to pay.

I think I also had comments from patients and from the Agreement States that getting the insurance is absolutely important for being able to hospitalize.

CHAIRMAN ALDERSON: Yes, Ms. Weil?

MEMBER WEIL: Thank you, Dr. Howe, for this presentation and for presenting patients' voices, which is not something we often hear here.

I think that we need to accept responsibility for the fact that this insurance situation exists, because it exists specifically because of the 1997 Patient Release Rule.

And if that insurance situation is going to change, then the rule needs to change.

DR. HOWE: Laura, I think I'm hearing you say if the rule is somehow written, it might help the insurance situation?

CHAIRMAN ALDERSON: Comments on that? That's a very important comment and it suggests to me, at least just listening to it, that it would

suggest that perhaps we need to dive more definitively into the 1997 Rule and see where that applies.

And then perhaps make a recommendation as a committee for that change in a specific way. I don't know the Rule well enough to make a comment on that at all.

It just seems to me that's part of what we're dealing with here. Anyone want to comment on that? Does anyone know the '97 Rule all that well?

DR. HOWE: Well, the '97 Rule essentially would not release patients unless they were below 30 millicuries, or had a radiation dose measurement at a meter that was 5 millirem per hour or less.

And that meant all I-131 thyroid carcinoma patients could not meet that criteria when they were given their dose, so they were not releasable.

And because they were not releasable, hospitals had rooms that were specifically shielded for I-131 patients.

And if you are a free-standing practice, at licensing time, you had to provide information that showed where your patients could go if you treated them in excess of 30 millicuries.

Now, there has been a change in treatment

of thyroid carcinoma patients or recommendations for treating thyroid carcinoma patients, where there are more thyroid carcinoma patients. It's an increase for a year now, at about 64,000.

I think I read in the Thyroid Association that they're starting to recommend not as much I-131 treatment and that for thyroid carcinoma, if there's a good surgical result, not to immediately to go to I-131, to wait and see if there's a reason for it and, in some cases, to cut the dose down.

Now, one of the other things that happened back as a result of the '97 Rule was that patients had their treatment fractionalized.

So, if you needed to be treated with 100 millicuries, you got 30 millicuries, and then you came back not the next day, but you came back probably in a about a week or two and you got another 30 millicuries, until you got up to the dose they thought you needed.

Now, it appears from the American Thyroid Association that they're talking about going back down to a 30 millicurie treatment to then give you, as being adequate if they need it. And that also saves some of its side effects for later.

VICE CHAIRMAN ZANZONICO: I think we

should be careful.

I mean, that may be for oblation of a thyroid remnant, but I don't think the ATA or any other professional organization is recommending for metastatic thyroid cancer, where you have the largest doses, that you get anywhere near 30 millicuries.

I mean, I know there was a tendency to reduce the rate of Y-90 dosage for metastatic thyroid cancer from what used to be.

But we're still talking about of the order of hundred of millicuries, 100 to 200, perhaps even more.

So, there's an important distinction between radio Y-90 ablation of remnants post-thyroidectomy versus treatment of metastatic thyroid cancer.

CHAIRMAN ALDERSON: Yes, Dr. Palestro?

MEMBER PALESTRO: You know, in listening to the discussion, I get the sense that we're looking for ways to have patients potentially admitted to the hospital by perhaps going back to these '97 Rules and so forth.

But I think the real issue is not how to get patients admitted to the hospital for I-131 therapy. The question is do these patients really

need to be admitted to the hospital?

And I think that's the issue that needs to be addressed, and I think in some ways, the subcommittee report addresses that. I think that's really the issue.

DR. HOWE: I also got comments where, especially from the American Thyroid Association, that if there was some intermediate, not full medical care but some intermediate place that the patients could go that was still under medical care, but not for really ill patients.

They think that would be a help with this. And I got that also from some of the patients.

CHAIRMAN ALDERSON: These items seem to relate, again, in some ways to some of the things we were discussing earlier.

And the next report coming up is about patient release and so, again, I think that fits very closely with this.

So, if there are further comments, we can take them now or we can move on to Dr. Zanzonico and his report. And then we can try to pull all that together in the half hour that remains in the open session today.

Yes, Mr. Green?

MR. GREEN: Dr. Howe, you've talked a lot about the mathematics and the dosing, but you also collected literature, guidance documents, brochures.

Is there a way that the NRC can collect, category, or provide guidance to the industry and the patients where we can get the best of that?

DR. HOWE: The Part One of the process which was asking for guidance, et cetera, we did a number of things that you've heard about today.

We put up a website that we referenced a lot of this material so the patients could go and find it. We just provided an information notice on best practices for our things to talk about for releasing patients.

So, we've tried to make that information available.

We can probably go back and update things more, but we are trying to make the information available on Phase One, and then we're working on the second paper for Phase Two.

CHAIRMAN ALDERSON: Okay, so we'll move on to Dr. Zanzonico and his subcommittee's report.

And if there are members of the public who are out there and would like to make a phone comment, a comment over the phone to us, we will try

to do that as part of this next and final report, which will in some ways sort of wrap together some of these things we've been talking about.

So, Dr. Zanzonico is on.

VICE CHAIRMAN ZANZONICO: Okay, thank you very much, Dr. Alderson. So, I'm presenting the draft report on our subcommittee report on the patient release commission paper.

And as always, I want to thank my Subcommittee Members. We really had a very engaged, hardworking committee, all of whom contributed importantly to what I'll present, Susan Langhorst, Chris Palestro, Laura Weil, and myself.

And the charge of our subcommittee was to review and provide recommendations on the draft second paper entitled Staff Recommendations for Revisions to the Patient Release Program.

Just in terms of background, by now, I think we're all familiar, the current Dose-Based Patient Release Rule replaced the long-standing Activity-based Rule, what many of us refer to as the 30 millicurie Rule, in 1997.

And as we've heard multiple times now, the current dose-based rule allows the licensee to release a patient if the projected Total Effective

Dose Equivalent, TEDE, to any other individual from exposure to patient is not likely to exceed 5 millisieverts or 0.5 rem.

So, there was an informational document for the commission, which asked for evaluation of whether there were gaps in the available data regarding doses received by doses to the public from released radiotherapy patients.

And if gaps were found, to provide recommendations on whether and how such data to address such gaps could be approved.

And then there was a subsequent SECY paper, which identified gaps and primarily related to internal doses to members of the public because, as you know, the model guidance ignores the internal dose contribution, Reg Guide 8.39, for example.

And two, whether it addressed the question of doses, both internal and external, to members of the public from patients released to locations other than their primary residence, most notably hotels and nursing homes.

And so the document our subcommittee reviewed was the draft SECY paper, Staff Recommendations for Revisions to the Patient Release Program, and two support documents to that SECY paper.

One was the results of a licensee survey on assessment of where patients reside immediately following their release report. And a rather extensive report, which incorporated literature reviewed plus model calculations.

That was entitled Patient Release Following Radio-Iodine Therapy, a review of the technical literature dose calculations and recommendations.

So, these were the three documents that we reviewed in preparing our report.

And so the next series of slides presents our comments and recommendations. And I think our entire subcommittee was impressed with the rigor of the literature review and the model calculations.

It was really very thorough, very balanced, and the model calculations were really state of the art. They were based on MCNP6 Monte Carlo simulations, which really is state of the art in dosimetry.

And as I think we all acknowledged, I don't think there's very much debate on this point, and that is that the current dose-based approach to assessing patient releasability was validated as more protective of public safety than the activity-based

approach.

And the reports we reviewed, and as has been cited multiple times, we know, for example, that a patient treated for hyper-thyroidism or Graves disease with as little as 10 to 15 millicuries of I-131 iodide can certainly deliver a higher radiation dose to members of their household than a thyroid cancer patient treated with several hundred millicuries, just because of the marked difference in kinetics in those two patient populations.

We also concluded that the current 5 millisievert and 1 millisievert projected dose limits for family members and the general public respectively should remain a per-event limit, and are appropriate for all potentially exposed cohorts, including pregnant women and children, and importantly, for all radiotherapy administrations.

Understandably, the NRC guidance has dealt primarily with I-131 Iodide treatments, and that of course, remains the most widely-used type of treatment.

But even now, and certainly in the foreseeable future, there will be many different types of radionuclide therapies. Lutetium-177, peptides to treat neuroendocrine cancer.

We know that there are remarkably specific radiopharmaceuticals targeting prostate-specific membrane androgen in prostate cancer. And those look like they can easily be translated to a therapeutic application.

So, now we're talking about a very big population with a new application and a new isotope.

And even though radionuclidetherapy, as long as it's been studied, has been disappointing, there are new strategies such as multi-step targeting, which at least have the potential for more effective applications of antibodies in treating a variety of cancers and a variety of isotopes.

So, it's important that whatever the NRC and the ACMUI recommend, that it not be short-sighted and overly dedicated to I-131 Iodide.

We certainly also believe that the 100 millirem dose limit for requirement patient safety instructions should remain in place.

And just a personal note, I think it's important to make a distinction between a dose limit and, for lack of a better term, what might be considered design criteria.

For example, when a facility is installing a new CT scanner or any other radiation-

generating device or installation, there has to be some criteria applied for things like shielding and citing of the device and so forth.

And often those design criteria are more conservative than the regulations just for purposes of practicality and just prudent conservatism.

But a design criteria should not be interpreted as a dose limit, and it absolutely should not be interpreted as a benchmark above which something becomes hazardous, and below which it's not hazardous.

And I think in the context of the discussion of, for example, the precautions for breastfeeding patients, that, yes, a 100 millirem limit is sort of a design criteria as to when precautions should be discussed and recommended, but should not be interpreted as a regulatory or safe limit.

Third comment, the assumption in regulatory guidance that the internal dose contribution is negligible has certainly been validated.

There's actually very extensive literature which was reviewed which included, among other things, measurements of the thyroid burden of

household members of thyroid cancer patients. And the doses were surprisingly low.

There's a rule of thumb that many of you may know that it is assumed that one-millionth, 10 to the -6, of the activity from a radioactive patient gets incorporated into members of the household or the environment where that patient lives or works or resides.

And in the analysis in the documents we've reviewed, they went tenfold higher than that, and assumed it was 10 to the -5.

And even that benchmark for internalization didn't result in a dose limit, an internal dose limit that significantly contributed to the overall TEDE.

And as was noted, other assumptions and methods in the regulatory guidance are excessively conservative, and I would like to make a personal plug that for NCRP Report No. 155. I've invested interest, I was the co-author of that report.

But I think it incorporates a great deal of the practical flexibility in generating recommendations objectively, systematically, and so forth. And it also includes a template document for the duration of precautions and so forth.

So, I think, frankly, it addressed a lot of, for lack of a better term, the shortcomings of existing guidance on this point.

And I think surprisingly, in the survey, the licensee survey, it demonstrated that patients staying at hotels following radionuclide therapy is not a widespread practice.

I think if you tally up the results presented, it was well in the ten percent of all treated patients actually chose to go to a hotel immediately post-treatment.

And importantly, it was very unlikely to result in doses to workers and others at greater than 1 millisievert.

In fact, the estimates that were generated, again using conservative assumptions, is that a hotel worker or a custodian worker taking care of a room occupied by a radionuclide therapy patient would get about 5 millisieverts per patient staying at that hotel.

So, that would take 20 such patients staying at that hotel, and that custodial worker caring for all of them, to reach the 100 millirem limit.

So, again, I think this was another point

where this survey does it completely independently and by very different methodology arrived at the same conclusions our ACMUI subcommittee on this point several years ago.

Certainly, instructions must be provided to the patient well in advance of a planned therapy, that is not on the day of administration, but without compromising patient care.

And again, there was a great deal of lively debate within our subcommittee as to whether there should be a prescriptive time interval introduced.

And we stopped short of recommending that again in the interest of clinical considerations, where there may be instances where there may not be an option in the interest of the wellbeing of the patient to postpone therapy strictly for the purpose of making sure there was some prescribed period of time in advance of which they were given these instructions.

The NRC should consider, we think, updating Appendix U in NUREG 1556 to reference Regulatory Guide 8.39.

I think in the user community, Reg Guide 8.39, whatever its deficiencies may be, is the go-to

document for determining patient releasability, rather than NUREG 1556.

And since it's a regulatory, since it's a guidance, document rather than a rule, it has a little bit more flexibility and so forth.

So, we would recommend keeping 8.39 in place, and if anything, simply referencing Appendix U, 8.39.

Again, we felt that all of the documents and information and the documents we reviewed really validated the ACMUI's Patient Release Report from 2010.

And I really want to emphasize that we think the Patient Release Program should be applicable to all radionuclides. It should be flexible and not overly conservative so as to not encumber the development of new medical procedures.

As I said, I think we're -- I know you won't be into this sort of thing, but I think we are at the precipice of an expansion in radionuclide therapy given the development of really molecularly-targeted agents in some of the big cancers that would expand the use of radiation therapy.

And certainly, no one wants that encumbered by excessive regulation. And there are

our abbreviations. So, I'm happy to take any questions.

CHAIRMAN ALDERSON: Thank you, very nice report. It seems to draw together many of the issues we've discussed over the last several hours, in a way that assures us that with good study by this committee that what's out there is pretty solid.

So, we'll take comments now. That may not be the case but that's how it seems.

MEMBER WEIL: Just a question. Pat, I think on Slide 9 when you were talking about exposure of hotel workers, either you misstated the values or I misheard them. Could you just find it?

VICE CHAIRMAN ZANZONICO: We read the document just before and my reading was that the model calculations based on the Monte Carlo Analysis to radiation work is on the basis of kinetics of iodide in the patients. They estimated 5 millirem per hospital worker -- I mean, per hotel worker per patient stay. Did I misstate that?

CHAIRMAN ALDERSON: Dr. Tapp?

DR. TAPP: Yes, this is Katie Tapp. The document we provided for you guys to review, we did specify that research was double-checking those numbers.

And they have identified it's at least ten percent lower in 5 millirem. We want to double-check it using --

VICE CHAIRMAN ZANZONICO: In our ACMUI report, the 2010 report, we estimated that as well completely independently and we came up with 30 millirem, which I think is reasonable agreement, given all the variable and confounding factors.

So, I really consider those corroborative kinds of results.

CHAIRMAN ALDERSON: Good. Yes, Dr. Ennis?

MEMBER ENNIS: I had a couple of questions. On this topic, do we want to then incorporate that fact into some kind of guidance or something that if there is such a place, like at a big center that does a lot of these, that hotel workers should be measured or they should not care for more than X number of patients per year?

VICE CHAIRMAN ZANZONICO: I guess that's debatable. If you ask me, it would be no because, again, we're trying frankly to parse radiation doses to certain cohorts of individuals like hospital workers, which are in the weeds frankly. That is within the range of variability of background doses.

And I think from a regulatory point of view, a dangerous precedent, and from a scientific point of view, an unsavant precedent.

So, I think all of the analyses that have been done to date demonstrate there's no realistic, there's really no credible scenario, which is how the document we review phrased it, that hotel workers would get an excess of 100 millirem.

Now, does that mean there might be some instance where one hotel worker got 103 millirem? Does that really warrant the implications of monitoring hotel workers, non-radiation workers?

I don't think there's any scientifically plausible argument for that.

MR. BOLLOCK: Dr. Zanzonico, just when you're saying that plausible cases, because what we've seen -- are you talking cumulative, multiple patients in that?

VICE CHAIRMAN ZANZONICO: Well, I'm basing it on what the report had said, that they estimated 5 millirem per hospital stay, so 20 hospital stays -- no, the hotel stay. Per stay, not per day.

MR. BOLLOCK: Right, so it was per patient.

VICE CHAIRMAN ZANZONICO: Per patient,

right.

CHAIRMAN ALDERSON: So this relates directly to a comment that was made by a member of the public right here at the microphone this morning. Now, I don't know if that gentleman is still here, probably not.

VICE CHAIRMAN ZANZONICO: I think we would have known.

CHAIRMAN ALDERSON: Yes, he'd be up there at the microphone. Whereas, he was dealing with a hotel and I guess a hotel across the street from the Mayo Clinic, where a lot of patients go over, many, many patients go over, and whether this was an issue.

And so I think the question you're asking isn't -- you're both saying the right thing. It isn't anything about the scientific credibility of what's come forward, that's very solid.

But the question is are there still instances of extreme situations where further consideration might be given? That's what the question is.

And I'll make a further -- so, a contextual reason why that kind of statement might be more important in this day and age is because we are now beginning to live in the era of individualized

therapy, precision medicine.

It's all over, it's everywhere. All the medicine that we've done has been based on the concept that science gives you standard doses for standard conditions and you treat standard patients with those. But each individual isn't standard anymore, according to the people who are pushing precision medicine.

And so a lot of people in high places in the government and NIH and other places. So, this is that same reasoning. Yes, there's no question the science is solid on average, there's no question it's correct.

Are there circumstances where it could, you know, be reconsidered? And so I guess what Ron is saying is are there situations where there just should be some sort of statement that under extreme conditions, further consideration might be given individually?

And I think that's what he's getting at.

MEMBER DILSIZIAN: So, we can take that step one further, but just take the Mayo patients and at the end of the day, let's say 5 to 20 patients are treated, and the same hotel service person is changing the sheets.

Well, that's an unusual case, that's an extreme case, and monitoring in that patient, in that individual, will probably show it. But that's an extreme case.

VICE CHAIRMAN ZANZONICO: I can't imagine we want to recommend doing radiation monitoring of random individuals in society.

I guess you could come up with a compromise of a recommendation to the effect that patients treated at a particular center, if they chose to stay at a hotel, should not uniformly stay at the same hotel.

Something to that -- it really gets unwieldy though. And I think the other point to recognize is that both in our analysis and the ACMUI analysis and in this analysis, the assumptions were conservative.

So, these are probably significant overestimates. Again, sort of analogous to the point Dr. Langhorst made earlier, you get about 5 to 6 millirem in flying from the East Coast to the West Coast.

So, should airline passengers be alerted if they're transcontinental commuters that they approach or exceed the 100 millirem limit? That's

probably a more realistic scenario than would be a hospital worker scenario.

CHAIRMAN ALDERSON: Right, and the hospital --

VICE CHAIRMAN ZANZONICO: The hotel workers.

CHAIRMAN ALDERSON: Mr. Green?

MR. GREEN: I'd like to just make a comment in support of specifically Recommendation 4 not requiring a specific regulatory time limit to required instructions being given to the patient.

We see in the community that a large proportion of radioiodine-123 uptake in scans morph same day into a hyper-thyroid or Graves Disease therapeutic I-131 dose, because the kit is a kit for the preparation of capsules.

So, the pharmaceutical can dispense the diagnostic I-123 in the morning and have the uptake and scan performed at the hospital or the clinic.

And that patient who came in from out of town or from rural areas can be dosed the same day, given an hour, hour and a half, delay, if the pharmacy can prepare a capsule.

So, I would support the need for advice and direction and guidance and written brochures, but

I would not want to impose a time requirement.

VICE CHAIRMAN ZANZONICO: And I think that's why it's important to include verbiage like without compromising patient care, because as desirable as it may be to provide instructions as far in advance as possible, there may just be some real-world considerations for the well-being of the patient that supersede that.

CHAIRMAN ALDERSON: Dr. Ennis wants to comment further?

MEMBER ENNIS: Yes, so on this topic, two aspects. So, one, it may be possible to say something like some encouraging language that would be given in advance while then allowing an escape, if you will, when medical decisions are needed.

But I'm still a bit uncomfortable with this requirement of giving patient information in that I don't see how that really is going to happen in any way that's going to change anything.

If we're talking about the patients, I mean, particularly what we were talking about before, where it seems like what we were basically saying is we're going to have to out and educate the endocrinologists about six weeks in advance.

In my opinion, this is Authorized User

territory. It's my responsibility as an Authorized User to take care of that.

In fact, that's one of the crucial and core elements of my responsibility, is authorizing to take care of the patient protection issues, not the endocrinologist.

So, I think what we really need is patients need to be referred in earlier. We need to change practice.

Pat, I know this is potentially a big deal, but I don't see that punting it to an endocrinologist or another physician is an effective way of protecting the public.

And if that means educating our referring physicians that a patient needs to come for a consult first and treatment six weeks later, then I think that's what it means.

Otherwise, I don't think we're really carrying out our responsibility as an Authorized User in these settings.

CHAIRMAN ALDERSON: And ultimately to consider the Mayo Clinic scenario again.

You recall this morning that when the gentleman was speaking, I made an example of hospital workers at New York Presbyterian, and I said in those

cases when those things came up, we studied it.

You know, we put monitors out, we checked it out. In every case, there was no problem. So, the same thing obviously can be done with the Mayo Clinic and the hotel.

So, this is not difficult to do. I don't think it's the responsibility of the NRC to educate them to all do that, but I think it's in fact easy to do. If that's really a concern, they can study it.

Further comments or questions on this issue? Yes, Mr. Daibes?

DR. DAIBES: Is there a ratio on how many patients are in a location in the United States?

VICE CHAIRMAN ZANZONICO: Well, I can't speak for other institutions.

We've done very, very few in-patient, although just alluding to the earlier very legitimate point that was made about insurance companies, we do have patients that stay in the hospital that are either incontinent or suffer from some sort of dementia where they can't possibly be expected to follow various precautions, and they do stay in the hospital.

This is not the only medical instance where they want us to fight with insurance companies

and where they deny coverage.

As unfortunate as it is, that just strikes me as beyond the scope of our committee. But to answer your question, very few patients nowadays are treated as in-patients, at least at Memorial, practically none.

CHAIRMAN ALDERSON: Other questions or comments on this report? Thank you very much, Dr. Zanzonico. I think your Committee did an excellent job with that. It's just a couple of minutes until 3:00 P.M.

MR. CRANE: Do you just want to go to the phones?

CHAIRMAN ALDERSON: Yes, absolutely, you're correct. Yes, you're correct.

VICE CHAIRMAN ZANZONICO: I'm sorry for the SECY report, do we want to endorse the report? Do we want to make a motion to endorse the report?

CHAIRMAN ALDERSON: First thing we want to do, and I promise to do it about 15 minutes ago and was about not to do it, is to make sure that there's no one on the phone who would like to comment on this issue or any of these issues in the last hours?

MR. CRANE: Yes, please.

CHAIRMAN ALDERSON: We have a comment from the phone?

MR. CRANE: Yes.

CHAIRMAN ALDERSON: Hello, yes, please identify yourself, and speak up a bit.

MR. CRANE: Yes, this is Peter Crane.

CHAIRMAN ALDERSON: Oh, it's Peter Crane.

MR. CRANE: Former NRC lawyer, also 44-year survivor of thyroid cancer.

I was treated as an outpatient with I-131 twice with 29.9 millicuries in order to oblate the remnant, and then 5 doses as an in-patient with 100, 150, 150, 150, 150, for what was supposed to be a recurrence later on at NIH.

So, I have some experience of this.

I can tell you a lot of about the genesis of the 1997 rule but I can't do it in two minutes. I'd be happy, Dr. Alderson, to send you a memo that I sent to the NRC a few years ago that will illuminate this. It is not a pretty story.

You will perhaps know that the idea of going to a dose-based rule was raised originally in 1980 by Dr. Eugene Saenger at the University of Cincinnati, best known for the human radiation experiments he conducted.

The NRC in 1986 codified its rules, put what had been license conditions into Part 35.

And they said there was this proposal for going to a dose-based standard and that this was unacceptable because, although it's easy to do the calculations, the mathematics is not that difficult, it's the underlying assumptions of knowing how close the patient is to whom.

The original proposal in 1997 that came in was to relax the Rule for everything except I-131 because it was known that I-131 was a special case.

However, then a proposal came in from the American College of Nuclear Medicine that said we should have up to 400 millicuries of I-131, and the original petitioner changed the petition to remove that exception for I-131.

There were comments, highly critical comments, from six states all saying I-131 is a special case, it presents dangers that none of the others do.

But none of this got to the Commission. Instead, it was represented as this very popular thing that was going to be good for the patient because it was going to increase flexibility.

There was going to be greater choice

between in-patient or out-patient and there was going to be a psychological benefit, and so forth.

Now, what people did not realize at the time, and I think Dr. Laura Weil made this point, that the NRC has got to own the facts of the insurance situation.

The thought was that in appropriate cases, patients could go home if they lived by themselves, if they could take care of themselves, and this would be a plus. But the patient who needed it would stay in the hospital.

The problem was that was soon as the rule was passed, a lot of insurance companies decided as a blanket matter that they weren't going to pay for any in-patient treatment.

So, the doctor who prescribed in-patient treatment was in danger of not being reimbursed.

And the effect of this, the best evidence of this, is an ACMUI Meeting from 2007, where Dr. Leon Malmud, who has been the Chairman of the committee, says that in his hospital, we whisk them all out the doors as quickly as possible.

Nobody is an in-patient anymore, there is no question of that. A Dr. Eggli says it's impossible to get an authorization for in-patient treatment even

when I have family situations that require it.

So, the point is do you want to make doctors spend time on the phone that could be used to be treating patients, instead fighting with insurance companies who are adamantly refusing?

The answer is it's much easier to send everybody home and that's become the new norm. Now, Dr. Zanzonico said that -- I should put in a note. There was some question of the gentleman this morning and why he isn't there.

I think that is Paul Gunter, and Paul Gunter is with an organization called Beyond Nuclear, and he is tied up this afternoon and regrets not being able to be there.

He is tied up making sure the nuclear plants in Texas that have been affected by the hurricane are in the process of safe shutdown. So, it's not lack of interest on his part that he's not there.

Dr. Zanzonico makes the point that the dose-based rule is not less protective than the activity-based rule.

The NRC said in 1997, yes, we know that there's better protection afforded to the family members in the hospital than in the home.

But this is offset by the fact that staff members are receiving less doses, and so will people who make frequent visits to the hospitals like members of the clergy.

The other thing about the 1997 rule is that it's based, as has been acknowledged repeatedly, only on external dose. It disregards internal dose.

This was based on the advice of the NRC's consultant, Dr. Pollycove, who is a believer in hormesis, who thought that I-131 was not cancer carcinogenic.

But the 30 millicurie rule protected against both internal and external dose. The dose-based rule protects only against external dose. So, I disagree and there are studies.

There's a study by Dr. Grigsby on a handful of patients. He had his patients be at the other end of the room taking several showers a day, while there were film badges on the family members in the other part of the house. That's not good data.

And Dr. Grigsby also says he's treated 1000 patients, he told the NRC he's treated 1000 patients and never had a case of vomiting. Tell that to an audience of thyroid cancer patients and they'd burst out laughing, because we know better.

Dr. Zanzonico says that ten percent of hotels is a small number. I don't think that's a small number, and if the patient is pregnant, if the hotel worker, rather, is pregnant or nursing -- I made a presentation at an International Atomic Energy Agency Conference in Bonn in 2012 on the subject of this rule.

Incidentally, the guy who was chairing that session was a doctor at Sloan Kettering and he announced cheerfully from the platform that the NRC's Rules said 500 for caregivers, 100 for members of the public.

And I had to put up my hand and say that's a common misconception. That's not the Rule, just read the Rule.

Well, I can tell you the people in Bonn were just appalled at the idea that hotel workers were being exposed to radiation without their knowledge. Because the whole basis of radiation protection is informed consent, and there is no informed consent to these people. And I think dragging in irrelevancies about how you can get more radiation on a plane, that's fine.

If you're pregnant and you don't want to fly or you don't want to go to Denver or whatever,

that's your privilege.

But these people are being exposed without their knowledge. And the suggestion was made that perhaps we could arrange for them to go to different hospitals.

Well, Dr. Zanzonico's hospital, Sloan Kettering, gives more I-131 treatments than any other in the world.

And it is a fair bet that if you're a patient there, you're going to one of the eight hotels listed on the MSKCC website as having preferential rates for Sloan Kettering patients.

And as far as informing them, you could simply do this.

You could say it is a reasonable inference if you are a hospital giving a treatment to somebody who comes from overseas or across the country that upon release, they are either going to the airport, which is unlikely, or they're going to a hotel. Because they're not going to be sleeping in Central Park.

So, if you are releasing somebody from far away and you make a reasonable effort to ascertain where they're going, you ascertain that they're going to a hotel, you say, fine, we'll call the hotel and

tell them by the way we are sending over a patient who has 200 millicuries of radioactive iodine in their system.

They will be emitting some of this, just want you to know that. You might want to assign somebody who is not of childbearing age and definitely not pregnant to clean the room.

What's so wrong with that? What's wrong with that is that no hotel in its right mind would let you get away with that. Isn't that correct?

So, I don't want to take more of your time, but Dr. Alderson, if you don't mind, I will send you an account of the genesis of the 1997 Rule. I'll send you the paper that presented in Bonn.

CHAIRMAN ALDERSON: We thank you for that, Mr. Crane.

I think the best way to make sure the Committee gets most of it seen or that we can get it around is in fact to send it to Sophie Holiday, and she will see that I get it or the committee gets it as best is relevant.

And Sophie's address is widely available.

MR. CRANE: Okay, will do.

CHAIRMAN ALDERSON: And she's smiling now in anticipation of receiving this document. So,

thank you very much for your comments.

Those were very helpful and continue to illuminate what is, in fact, still, despite excellent science, a somewhat controversial subject. Thank you very much.

MR. CRANE: Goodbye.

CHAIRMAN ALDERSON: Goodbye. Anyone else on the phone? I'm hearing none. Are there any further comments on this issue as we get ready wrap up the open portion of today's meeting?

Hearing and seeing none. We'll call the open session to close. I'm sorry, there was a hand?

VICE CHAIRMAN ZANZONICO: We need to act on -- we need to have that motion.

CHAIRMAN ALDERSON: Yes, you're right, we didn't act on this document. All right, so we need a motion.

VICE CHAIRMAN ZANZONICO: Can I make the motion?

CHAIRMAN ALDERSON: Make the motion.

VICE CHAIRMAN ZANZONICO: I make the motion to approve the subcommittee report.

CHAIRMAN ALDERSON: Is there a second? Is there further discussion of this motion? I'm hearing none. All in favor, raise your hand. That's

unanimous.

And that should then close the business of today. Sophie, is it possible to take a brief break now?

Yes, ten-minute break and then we'll reconvene at about 3:30 p.m., and we'll go along with the training part of the session.

(Whereupon, the above-entitled matter went off the record at 3:20 p.m.)