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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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TUESDAY,

SEPTEMBER 12, 2017

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The meeting was convened in room T2-B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:30 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 F. 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: ZOUBIR OUHIB*

NON-VOTING: RICHARD GREEN

NRC STAFF PRESENT:

MARC DAPAS, Director, Office of Nuclear Material Safety and Safeguards

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

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

Officer

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

SOPHIE HOLIDAY, ACMUI Coordinator, ACMUI Alternate Designated Official

MARYANN AYOADE, NMSS/MSTR/MSEB

JACKIE COOK, R-IV/DNMS/MLIB

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

ASHLEY FERGUSON, NRO/DCIP/QVIB3

LATISCHA HANSON, R-IV/DNMS/MLIB

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 (AAPM)

ASHLEY COCKERHAM, SirTex Medical

WANDA COSTELLO, *Unaffiliated*

MICHAEL FULLER, *Unaffiliated*

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

(8:30 a.m.)

MR. BOLLOCK: Good morning, everyone. Start of the second day of the ACMUI meeting. And I will turn it over to Dr. Alderson.

CHAIRMAN ALDERSON: Well, so this morning we are going to start with Sophie Holiday who is going to tell us about some of the NRC online resources. I do want to mention that the status update on source security given by Ms. Wu will follow Sophie's presentation directly. That presentation by Ms. Wu was originally scheduled yesterday, but it was changed to this morning. So that will be from 8:45 to 9:15. Sophie?

MS. HOLIDAY: All right. So I am going to do my presentation over hear from the computer so you guys can't see my face in the front and center of the room. So for those of you who do not know, NRC has a public website. You can access it through www.nrc.gov. The purpose of my presentation today is that there was a lot of discussion at various professional society organizational meetings about wondering how to access NRC's tools, for lack of a better word -- online resources, what information is available to members of the public and how easy is it

to navigate the public website.

I can tell you, I have worked for the NRC for almost 10 years and it is not always the easiest to navigate. There has been a time where I have actually had to call Dr. Langhorst to ask how she got certain documents.

(Laughter.)

MS. HOLIDAY: When you go to www.nrc.gov this is the page that will pull up. There are various tabs here, and for those of you who are interested in medical, for obvious reasons, there is a section here called nuclear materials. Under this tab you will see special nuclear material; source material; byproduct material; medical, industrial and academic uses; radium; uranium recovery; fuel cycle facilities; materials transportation and research activities. The most relevant to this group will be the medical, industrial and academic uses.

So when you click that link this website pulls up. Can you all see this?

CHAIRMAN ALDERSON: Yes.

MS. HOLIDAY: Okay. So under here it gives you all of the basic information about what we regulate. On the right side, the key topics and the related information are probably going to be your most

used website links. There is enforcement actions. This is of course like the information I have provided to the Committee over the weekend.

Information about patients administered of radioactive iodine -- so for patient release information. The medical use licensing Part 35 Toolkit -- this is the website that I use the most. Response to the 2016 GAO Audit -- this is a presentation that we gave to the ACMUI a year ago. And then if you scroll down under related information, there is the ACMUI link. There is also an MOU or Memorandum of Understanding between the NRC and the FDA.

And then public availability of material licensee applications and of course a NUREG. So if -- uh-oh. If we click the Toolkit, this is going to be your best friend -- for members of the public, for public stakeholders, for licensees. Under here we have a section called announcements. All of our most relevant information we post on this link. So when we were doing the Part 35 rule making, this was something that was included under announcements. When we were doing the data collection for patient release, that is also under this section. So that part is updated periodically.

As Doug mentioned yesterday we do have -- we created a website for patient release as a result of Dr. Howe's project -- ongoing project -- that is another link that we created. So I will just open that very quickly. Uh-oh. Sorry, give me just a second. So this is the website. So information for patients administered radioactive iodine -- there is a lot of background information. This is pretty much telling you why we created this website.

And as Doug indicated, there are a lot of links to other professional society documentation. So this is all definitions and then here is links to ThyCa information. There's information from SNMMI. There are links to NRC's regulatory issue summaries, or RISs. There is a radiation dose assessment resource, so this is a particular area where anybody who is needing broad information about patient release can go to our website and find information about it.

Okay, so if we go back to the medical toolkit, there are other major topics that we have identified. So of course, the ongoing shortages of molybdenum-99 and technetium-99m. Regulations and medical policies statement -- the purpose of medical event reporting. Medical event presentations -- if you will recall Doug made a mention of how after this

meeting ends -- shortly after we will post the ACMUI's medical event presentation from this year. That gets posted on there along with Donna-Beth's standard presentation that she does in the spring as well.

The Medical List Server -- this is a very important link. NRC will send information out to a List Server, which is -- anybody can subscribe to it. Any time medical related information is published in a federal register -- so that could be the ACMUI meetings. That could be the patient release data collection information, the issuance of 10 CFR 35.1000 licensing guidance -- we dispatch that through the Medical List Server.

Another link is the Emerging Technologies and 10 CFR 35.1000 table. So I am going to scroll down after I go through these links. And that lists all of the -- it houses all of the links to our 35.1000 licensing guidance documents, along with other emerging technologies that staff may have determined not to be 35.1000 such as Radium-223 Dichloride.

There's other links for guidances, or other guidance, inspection procedures, license types, fees and forms. So just to scroll very quickly -- again, this is the announcements section. And this is the little blurb about the moly-99 and technetium-99m.

Under regulations the medical policy statement there is a link to the 2014 proposed rule, the current Part-35.

And then if you scroll down, your other various links -- the Medical Policy Statement, other 10 CFR parts that are relevant to byproduct material or source materials. And then of course I mentioned regulatory issue summary earlier so you can get a link to all of the regulatory issue summaries that are related to medical use licensees from 1999 going forward, as well as information notices that we have published as well.

So here is a section about why we do medical event reporting. Of course that was one of the hot topics yesterday. Dr. Langhorst gave a presentation about medical event reporting and its impacts on safety culture at medical-use licensees. So staff developed -- Dr. Daibes developed this little blurb about why we actually require medical event reporting. So you can read this information if you are interested.

And here are the links from 2014 going forward for the Medical Event presentations. This is obviously a relatively new thing that we put onto our website. So it can show you the differences between

staff's report of medical events for the fiscal year as well as the ACMUI's medical event reporting.

So here is a list for if your -- Medical List Server. All it is is you click it and it tells you how to request subscription to the Medical List Server. Emerging technologies and 35.1000 -- this explains to you why we have 35.1000, or 10 CFR part 35 subpart K. And here are all of the emerging technologies that staff has handled since approximately 2002. So here it will tell you if it was licensed under 35.1000, if the request was retracted, if it was licensed under a different section.

And if there were older guidances, such as for the Y-90 microspheres, we have also kept that as a hyperlink. So you can see the differences between the older versions and the current version. So we will hear later from Dr. Suh's subcommittee about the Perfexion/Icon. So prior to that it was just the Perfexion license. After May 2016 it was superseded, combining the Perfexion and Icon into a new licensing guidance document.

So if you scroll down you will see other guidance documents. These are really what we call our NUREGs. So NUREG-1556 Volume 9 -- this is probably

the most relevant to everybody in this room. This has to deal with guidance about how to apply for a materials license. Dr. Langhorst is very, very familiar with this along with the other volumes here.

But once these documents are updated -- included the Part 35 language slated for early next year, this website will be updated as well. And these are other guidance documents that staff finds of use for the medical community. There is also a link for specialty board certification. There is another document -- this will be updated soon -- High Dose-Rate Remote Afterloader Brachytherapy Devices Approved for Patient Treatment Using Sources Exceeding 10 Curies.

Here are a link to some of the most relevant inspection procedures for medical use licensees. So if you ever want to know how NRC will inspect your program, these are the inspection procedures that we are looking for -- or that we are using. And these of course are the program codes for the various different license types. And then of course fees and then additional forms that you would have to use as a medical use licensee.

And then the only other website I want to show you is one that everybody in this room should be

very, very, very familiar with. This is the ACMUI's website. So all information related to ACMUI I will post on this website. So this is the general information about the committee. This is a link to the membership -- the history of ACMUI, the ACMUI's charter -- which is renewed every two years. It will be up for renewal next year. The ACMUI bylaws, which the ACMUI voted on and approved a few years ago.

And then this link -- ACMUI meetings and subcommittee reports. This is where you will find information related to all of our public meetings. So for example, 2017 -- currently we only have the April 26th and 27th and then the September 11th and 12th meetings for this year. You will find the agenda, the transcripts, the meeting handouts and the meeting summaries. Obviously, we don't have a transcript for this meeting yet because it is still ongoing, but once that is available we post this -- approximately 30 to 60 days after the meeting.

A meeting summary will be posted as well for this meeting. So for anyone that would like to get a transcript of everything that has happened in this meeting, you are able to get this on our website. And then this information goes all the way back until 1993.

So that's just the gist of our public website. I wanted to give this overview presentation so that the committee and the audience members -- both here in the room and on the website -- are able to know how you can navigate our website to get information. I guess one final link that I will mention -- because I am thinking of Dr. Langhorst -- is public meetings.

And so when you are trying to watch our meeting on webcast you can click here under public meetings. If there are commission meetings that are current, you can also click under here. And so this will give you the commission meeting webcast information, public meeting schedule -- the public meetings schedule lists all public meetings that are happening at the NRC, not just medical or materials. This includes reactor information as well.

And so for each commission meeting there are always transcripts available shortly after the meeting. If there are meeting handouts those are posted on that website as well. Are there any questions from the committee?

(No audible response.)

CHAIRMAN ALDERSON: Any questions for Ms. Holiday? Shall we ask people on the phone? Because I

wonder if anyone is listening in or watching. Anyone on the phone or watching who would like to ask a question about the website?

(No audible response.)

CHAIRMAN ALDERSON: Hearing none, any final questions from the audience? Yes, Dr. Howe.

DR. HOWE: Can you pull up SECY papers.

MS. HOLIDAY: Sure I can. That's going to be a trick for me because I always do that from our internal -

(Off-microphone comments)

MS. HOLIDAY: Here I am, still getting schooled on our website.

(Laughter.)

MS. HOLIDAY: So under document collections you will scroll down -- oh, here you can also see the other links to the ACMUI, ACRS, ACNW&M. And then our -- our major collection for all documents as well -- reg. guides, the regulations, NUREGs, management directives, MOUs. Right.

So under Commission documents this will house all of our SECY papers, or commission papers, SRMs, Staff Requirements Memorandum -- which is when the commission directs staff to do something, or it is their response to a paper or a meeting -- Commission

voting records -- if you want to see individual Commissioners' votes for any documents that have come across their desks.

COMs or COMSECYs, Commission Action Memorandums -- so a couple members asked me yesterday when there was a reference to COMWDM instead of a regular SRM or regular SECY, that's -- that can be found here. And this is a link that Dr. Langhorst directed me to a couple weeks ago for commission meeting agendas, slides, transcripts, meeting SRMs, and full-written explanations for closed meetings.

So for the Part 35 affirmation vote, this is how she was able to obtain that information -- by clicking this link. Thank you, Donna-Beth.

CHAIRMAN ALDERSON: Good. Any other questions? Yes?

MEMBER WEIL: Well on the previous page, what is the difference between --

CHAIRMAN ALDERSON: Your microphone?

MS. HOLIDAY: What previous page?

MEMBER WEIL: If it's under --

MS. HOLIDAY: Under the Medical Toolkit?

MEMBER WEIL: No, no. It was under the -- in the document collections, go down to ACMUI.

MS. HOLIDAY: It's only red because I

clicked it.

MEMBER WEIL: Oh.

MS. HOLIDAY: I'm sorry.

CHAIRMAN ALDERSON: Any other questions?

(No audible response.)

CHAIRMAN ALDERSON: Well, thank you very much for this walk through the website.

MS. HOLIDAY: Thank you.

CHAIRMAN ALDERSON: Now the next item on the agenda as previously announced is Irene Wu, who will give us a status update on the source security and accountability.

MS. WU: Okay. Good morning, everybody. So I was here last April -- end of April giving you an update. And at that point we had just finished -- we had finished all of our public outreach related to the Category 3 Source Security and Accountability Reevaluation. So this presentation today is going to kind of do a short recap of some of the slides that you saw the last go-round, but we are not going to recap some of the -- oh, thank you -- the -- the outreach because we went through that the last time. And we will go forward and talk more about what the conclusions and the recommendations that came out of this paper.

So if you recall this -- this slide is part of the last presentation with a few changes. Overview -- basic overview, you know, there is a lot of history for source security and accountability initiatives going on at the NRC. A lot of them stem from past GAO licensing audits and investigations.

Then back in 2009 we looked at Category 3 for the first time -- whether or not we wanted to track those type sources in the national source tracking system. If you recall then in 2016 -- at the end of 2016 we finished our internal -- or, program review of the Part 37 -- 10 CFR Part 37 Physical Security Requirements for Category 1 and 2 material.

There was also another GAO investigation that began a few years prior. That report was also in 2016. And then there was this staff requirements memorandum that directed us to look at whether we needed to do more for Category 3 sources. So that was the last bullet under 2016.

So 2016, 2017 -- very busy. We -- in the early part of 2017 -- and I have a slide coming up on this -- in February we issued an information SECY paper that had some information on kind of everything that we were doing and how we were going to -- some work on this Category 3 reevaluation. And then just

in August, the SECY paper on the reevaluation went up to the commission. And so it's -- it's on their desks and they are looking at it -- and that's SECY-17-0083. And that is available on the public website that Sophie showed you just a second ago.

And then what we see coming is we know that GAO is indicated to us in the past that they plan to do another audit on Part 37. And then -- this will make more sense in a little bit -- but we do plan to do an integrated rule making plan covering a lot of the rule making recommendations that came out of some of these -- these items that I just talked about.

So this is just a highlight of the nine tasks -- it is split on two slides -- the nine tasks that were specifically delineated in the Staff Requirements Memorandum. And what I just wanted to mention is that, you know, as you can see it's a -- a lot of things recovered in the ten months that this working group reviewed everything and the main things that -- that took a lot of time and effort were the collaboration with all affected stakeholders.

We did a lot of public outreach in the beginning. There was also on the previous slide the vulnerability assessment piece -- looking at whether the threat changed at all. And then also the cost-

benefit analysis on task number 5. So those were sort of three things that, hadn't been done in the past, in the initial evaluation, and really fed into how we came about these recommendations in this -- in this analysis.

So as I mentioned before, SECY-17-0025 -- this is that information paper that went up in February. I don't think I mentioned this last time, so I did want to have a slide on it this time. But again, this just highlighted sort of the activities that came about following that last GAO audit. The working groups -- the pre-licensing working group -- or, enhancements to pre-licensing guidance working group and the -- which is PLWG -- and the LVWG, which is the License Verification and Transfer of Category 3 Sources working group.

Main thing to point out was the paper told the commission that we were going to be taking the recommendations that came out of the LDWG and merging those into the Category 3 initiatives that I worked on. And then we also mentioned to the commission hey, we are starting up this working group and these are the activities that they will be working on. And then also mention to them that there is this plan to integrate all of these rule making activities -- the

ones that have already been finished -- like those related to the Part 37 Program Review -- and then anything that would come out of the Category 3 analysis.

And then sort of prior to all of this there was a SECY paper that went up to the commission -- SECY-16-00115 -- related to financial assurance of Category 1 and 2 sources. And so the plan is to integrate all of that. And I have a diagram on the next slide that shows this in a graphical format.

So again the yellow box in the middle is all the Category 3 activities. And it gives you an idea of the timelines and -- and if you look right now we -- we just finished that purple circle -- oval in the middle of the commission paper. The red box is essentially the -- everything that came out of the GAO audit. And then the Part 37 program review is in the orange.

And again, the plan is to integrate all of the rule making activities mainly because it is a lot of the same constituents that would be affected. And so we don't want to be opening up the rules multiple times. So we want to be efficient and effective in that.

Okay, so now moving into what the working

group for the Category 3 reevaluation really looked at. Again, we had four main activities. So from those nine tasks we bundled them into four activities. The first activity was really taking the previous working group -- the License Verification working group -- what they did and the recommendations they had and building upon them. And then from there we developed options and pros and cons for each of those options.

Activity two was the vulnerability assessment, the threat piece. And we looked, like I said, the current threat environment, evaluation of vulnerabilities associated with the use of materials and then looked at the potential consequences that could occur as a result of malicious acts. Third activity I mentioned was the cost-benefit analysis. So what we did for each of the options that we developed -- we looked at what the one-time implementation costs would be and the annual operating costs -- not only to the NRC but also to agreement states as well as licensees. And then we also looked at the benefits for those options.

And then the last activity was the stakeholder outreach. So this was a big part of the last presentation I gave here. We did a federal register notice to solicit comments. We also did

public meetings, webinars, various presentations to industry groups. We also set up a website and did a blog posting.

And from all of that we got about a thousand comments from various different entities which we used to inform our evaluation. Okay. So when we were trying to write the SECY paper and trying to figure out what to present to the commission, we -- we thought about it in the sense of four main concerns. And so here are the first two, and the second two are on the next slide.

The first one -- and this all comes from, you know, the -- the last GAO sting, the SRMN and all of these -- these past evaluations, we came up with these four main issues. One is the ability for someone to obtain a valid license using a fictitious company or by providing false information.

And the options that we came up for that -- which I will show you -- mainly -- or the -- what we talked about for this concern was mainly related to pre-licensing and pre-licensing guidance. The second concern is the ability to alter a valid license to obtain more material than they are authorized to. Or to just counterfeit a license. To, you know, pull one off the web, make some changes to it and then obtain

radioactive materials illicitly. So the options we came up to address this concern relate to license verification and that license verification system.

Concern three has to do with the ability to accumulate or aggregate Category 3 sources to then a Category 2 quantity of material, which would then require enhanced security. So the options we came up with this have to do with the National Source Tracking System, or Part 37. And then the last one, which I don't necessarily think applies to this group as much, but I will mention it here anyways.

Concern four is the -- is general licenses. So the limited accountability and lack of pre-licensing and lack of inspections and oversight of these Category 3 sources that are contained within generally licensed devices. Okay, so concern one -- mainly this working group pulled forward the recommendations by the previous working group -- the Pre-Licensing working group -- that was stood up post the last GAO audit. So there were both non-rule making and rule making recommendations that came out of that.

The non-rule making recommendations related to enhancing pre-licensing guidance, doing additional training, making some updates to the NUREG-

15-56 and then also doing -- developing procedures, a self-assessment or like an audit tool. So we all -- we have all that documented in an action plan.

And then we also had a rule making recommendation, which was included as part of the info paper to the commission in February. But that was to require safety and security equipment to be in place for all new, unknown applicants prior to issuing a license. So that would likely be a change to Parts 30, 40 and 70.

Okay, so that -- is pretty much -- most of that was all included in that commission paper. Concern two, we actually came up with six options. They are split between two slides to address -- and again, if you remember, concern two was license alteration and falsification. So the options here were one, don't do anything. Two was to do -- require license verification through the License Verification System or the regulatory authority for Cat. 3 -- Cat. -- we are already doing it for Cat. 1 and 2, but to do it also for 3. And then also to introduce the concept of reduced frequency. So if they are sending sources to -- or sending material to an established entity, they wouldn't have to do it as often.

Number three would be Category 3 license

verification through LDS and the regulatory authority only by MNDs. So if they are sending it back to an MND you wouldn't -- manufacturer and distributor -- you wouldn't have to do those verifications. But only manufacturers and distributors would have to do those verifications.

Number four for concern two would be Category 3 through 5 license verification through LVS and the regulatory authority with the reduced frequency as I mentioned before. And number five would be Category 3 license verification through LVS and the regulatory authority and then doing something also for Category 4 and 5 like -- the right radioactive material, but at a lower scale. So it would be license authentication, just a more simplified license verification.

And then -- and number six for this was to do authentication for down to Cat. 5. So I know that was a lot to swallow but the point is is we looked a lot of different iterations and we also -- and we -- we looked at what to do for Cat. 3, but since in the past the GAO has stung us before below Cat. 3, we also looked at some options of what to do below Cat. 3.

Okay, so concern three, again this was -- these are options to address aggregation. And the

options were going to include NSTS and Part 37. So there were five options here. There is no action, there is tracking of Cat. 3 sources and NSTS -- the same as the way we do for Category 1 and 2. There is tracking of Category 3 sources, NSTS and then also making some system changes to NSTS so that you would do pre-reporting for transfers. Trying to make things a little bit more real-time and trying to address aggregation better.

Number four would be instead of tracking it -- Category 3 sources on a transaction basis it would be done on an annual inventory basis. And then option 5 was looking at those folks -- those Category 3 licensees who have the ability to aggregate Category 3 sources to a Category 2 quantity to implement subpart B. So that's the trustworthy and reliability determination aspect of Part 37. So that was option five for concern three.

Okay. And then lastly concern four, again this was Category 3 general licenses. We had four options here. Mainly it was no action, having -- number two be having the MNDs notify their regulator to -- prior to transferring those devices so that we would be able to perform a pre-licensing evaluation.

Number three builds upon that where it

would be that plus inspection. And then the last one would be to convert Category 3 general licenses to specific licenses. So if you counted all that up, I can't -- I think it is about 15 or so options that this group evaluated across -- across the board. And so to do the -- to do the cost/benefit analysis and the pros and cons for all that was a lot. But I think it was a very -- it gave us a lot of options. It gave the steering committee a lot of options. And then finally NRC staff to make a decision on -- on which way to proceed.

Okay, so as I mentioned before we wrote the SECY paper. That's with the Commission right now -- 17-0083. And I just wanted to give you a little flavor of what that paper looks like if you haven't had a chance to read it yet.

But the main paper is set up pretty straightforward. The background goes through, again, those nine SRN tasks, mentions the working group formation. In the discussion that's -- that's the meat of the paper. It talks through -- like I just went through -- the concerns -- those four concerns, each of the options to address each concern. For each concern we talk through what the stakeholder feedback was that we received. And then it goes through the

thought process -- how we came about the recommendations. And it also mentions any -- the coordination we did with Agreement States.

And then I will focus more on the conclusion, commitments and recommendations coming up. Oh -- so these are the -- so our SECY paper has seven enclosures. We -- we didn't have nine per the nine tasks, but we -- we came pretty close. So we have seven.

And I will -- I will point out three of them are non-public mainly because some of them are, you know, sensitive, internal or security-related information. The non-public pieces are the threat, consequences and vulnerability assessment. Then there's the -- enclosure six which talks through the working recommendations and then how that proceeded to the steering committee direction. And then -- and then you -- you will see the staff recommendations in the paper. And then the last one is resources. That's typically kept non-public.

Okay. I am doing okay on time. All right, so conclusion. And again, this was -- the way this was framed in the paper was by each concern. So for concern one -- that was pre-licensing -- this -- this is exactly like the slide before where we have

those enhancements to guidance for an action plan -- those are the non-rule making enhancements. And then there's the rule making where we are proposing safety and security equipment for all new, unknown applicants prior to issuing a license.

For concern two, again, this is to do with any changes to license verification, the recommendation -- the conclusion was to not make any changes to the current requirements. However, we do have -- we did propose an update to Part 30 which would require some rule making. And that would mainly be to remove an obsolete method of using a reporting service -- a record service.

And then the other one would be to require follow-up -- so -- require follow-up with one of the other methods in the part. In an emergency situation you can use an oral verification and so that -- that's -- those are the two updates that we propose. I think it is later on another slide. And then the last piece for concern two is that we wanted to continue to encourage Agreement States to adopt WBL. All right.

Okay, concern three, again this was changes to NSTS, applying Part 37 to Category 3 and for this we concluded no change to the current requirements. And then concern four, this was

Category 3 general licenses. We concluded no change in the current requirements due to security accountability. However, we do want to conduct a reevaluation to ensure continued protection of health and safety in the current environment.

So, some commitments that we made in the paper were to update the integrated rulemaking plan that we mentioned in that February information paper to include any Commission recommendations. So once they give us direction on this paper, then we would -- if any of those required rule making, we would then include that in the rule making plan. And then -- which is planned I think for five months following the receipt of the SRN.

And then the -- also as I mentioned on the last slide was to conduct additional technical evaluation to verify that the existing general license program continues to provide protection of public health and safety in the current environment. So again, if rule making recommendations come out of that, we would integrate that as part of that integrated rule making plan.

Okay, recommendations. So this is for the commission to consider and act upon and vote on. So the first thing I mentioned was to approve potential

rule making to amend Parts 30, 40 and 70 for the unknown entities and having their safety and security equipment to be in place. I know this seems a bit redundant, but we have it set -- we have it stated multiple places in the paper. The second recommendation is to not direct the NRC staff to amend regulations related to, you know, requiring license verification through LVS for Cat. 3 quantities of radioactive material. Not directing the staff to require inclusion of Cat. resources in NSTS. Not direct the staff to impose security requirements, prevent aggregation of Category 3 sources to a Cat. 2 quantity. And then not direct the staff to limit the quantity of byproduct material on a generally licensed device.

Okay, yes. And then this is what I mentioned earlier which was that we do have a rulemaking recommendation in there to clarify some of the license -- existing license verification methods for transfers involving essentially Category 3 through 5 quantities of material. And that's the oral certification method. And then the -- I am removing the obsolete method.

So we do have a website which we have a link to the SECY paper from. And then I put my

contact information on the slide in case you have any follow-up questions.

CHAIRMAN ALDERSON: Okay, thank you. Thank you, Ms. Wu. Are there comments from -- or questions maybe from the ACMUI? Dr. Zanzonico?

VICE CHAIRMAN ZANZONICO: Thank you very much. Frankly, I am not familiar with -- with -- as well as I should be with all of this. But what I am inferring is that for nuclear medicine installations -- existing nuclear medicine installations there is essentially no action -- no -- no change. Is that correct?

MS. WU: Yes, that is correct.

VICE CHAIRMAN ZANZONICO: Okay. And -- and for -- for brachytherapy installations with high dose rate sources there's existing -- existing installations, is there an impact on those?

MS. WU: And that's mostly Category 2? Is that correct?

(Simultaneous speaking.)

VICE CHAIRMAN ZANZONICO: I think -- so most of them would be Cat. 2? Is that correct?

MS. WU: Or Cat. 3?

MEMBER LANGHORST: For the HDRs, those are Cat. 3. So those --

(Simultaneous speaking.)

VICE CHAIRMAN ZANZONICO: Those are Cat. 3? Okay.

MS. WU: Okay.

MEMBER LANGHORST: Right. So you have to be concerned about if you are combining them. But -- but there should be no action on that.

VICE CHAIRMAN ZANZONICO: Okay.

MS. WU: Again, we have to wait for, you know, Commission direction. But with the recommendations that went up --

(Simultaneous speaking.)

VICE CHAIRMAN ZANZONICO: So I am inferring that overall there is little practical impact on existing medical installations. Is that a fair summary statement?

MS. WU: I think that's fair.

(Simultaneous speaking.)

MR. COLLINS: Yes, so Dr. Zanzonico, I think the practical impact would really be for any new applicants.

VICE CHAIRMAN ZANZONICO: Right.

MR. COLLINS: Where the -- the changes in the pre-licensing guidance that Irene discussed would -- would -- you know, help ensure a more robust

licensing review prior to issuing a --

(Simultaneous speaking.)

VICE CHAIRMAN ZANZONICO: So that -- that would lead to my second question. So the requirement for safety security information, is that for lack of a better term an indirect way of verifying the veracity of a -- of a -- a new license application?

MR. COLLINS: Right. So the idea behind that is if -- if there is a requirement for the safety and security equipment to be actually in place prior to issuing the -- issuing to the license, exactly as you said, the -- the thought is that that's how you kind of verify that -- or it lends credence to -- to the applicant's claim that they -

VICE CHAIRMAN ZANZONICO: And how prescriptive is that? I mean, are you detailing what kind of safety and security information if there were an intent to do that in rulemaking?

MS. WU: Yes, that would be something we would deal with in rulemaking space.

MR. COLLINS: So the actual details, though, of what that equipment has to be -- that's in guidance. We wouldn't actually put that too prescriptively into the rule itself.

VICE CHAIRMAN ZANZONICO: And so just a

follow-up question to that, so let's say you have a large medical center that's taking over some satellite facility and wants to do nuclear or brachytherapy procedures in that facility. So -- so the main -- the main campus, so to speak, would be an existing licensee. So a known user. Would the satellite facility at a new location be considered a known user? Or an unknown user? Or has that been thought through?

MR. COLLINS: Well, so it hasn't been completely thought through yes. But my sense of it is that if -- if you are talking about an existing licensee essentially expanding its program, we would probably view it as it's an existing licensee.

VICE CHAIRMAN ZANZONICO: Even if it's a -- it's a geographically separate installation?

MR. COLLINS: Yes, because it would still be on the same license.

VICE CHAIRMAN ZANZONICO: Okay. All right.

MS. WU: Right.

MR. COLLINS: And if that facility already exists, right, then we wouldn't necessarily get into the pre-licensing portion of the guidance. Right? It would be treated as an amendment. Yes, Ron?

MEMBER ENNIS: Just following up on the new licensee issue -- so are we -- are you saying that whatever would have been required a little bit down the road for such licensees now is just going to be required to be in place before granting them the license? Or are these enhanced security features that existing licensees are not required to have but we will now require new licensees to have some level of enhanced security?

MS. WU: Yes, it is just moving the time frame up a little bit. So it would just be -- safety and security equipment that they would obtain down the line now has to be -- now -- with this proposed recommendation would be done prior to the -- receiving that license.

MEMBER ENNIS: And the way NRC will verify that -- is that through? Or that's --

MS. WU: Oh, it would be done through a pre-licensing site visit.

MEMBER ENNIS: Site visit, got it.

CHAIRMAN ALDERSON: So one of the types of sources that I think got discussed some when these things were being considered was with the -- was the blood irradiators. I mean, they are in medical centers, but they aren't in nuclear medicine or

radiation oncology. Where do they fall under this?

MS. WU: Right. So those are already being -- my understanding is those are Cat. 2 and they are already being -- you know, for -- Part 37 already applies to them. Their sources are already tracked in the National Source Tracking System.

CHAIRMAN ALDERSON: So it has already been taken care of?

MS. WU: Correct.

CHAIRMAN ALDERSON: Okay, thank you.

MS. WU: This is more focused on Category 3.

CHAIRMAN ALDERSON: Okay. Other questions in the room? Questions about this?

(No audible response.)

CHAIRMAN ALDERSON: Anyone on the phone who would like to ask comment -- make a comment about source security for Category 3?

(No audible response.)

CHAIRMAN ALDERSON: Hearing none and seeing no one in the room, I think that we are finished with this report. Thank you.

MS. WU: Thank you.

CHAIRMAN ALDERSON: All right, we are now ready for Dr. Suh who will talk to us about the

physical presence requirements for the Leksell Gamma Knife Icon. This is a follow-up to a previous discussion.

MEMBER SUH: Good morning. So I am here to discuss physical presence requirements for the Leksell Gamma Knife Icon. I would like to thank the subcommittee members, Dr. Ron Ennis, Ms. Laura Weil. And especially thank Sophie Holiday for putting some data as needed as an NRC staff resource.

So subcommittee charge was to propose the appropriate physical presence requirement for the Leksell Gamma Knife Icon radiosurgery unit. Just some background about the Gamma Knife for those of you not as familiar -- it is one of the major stereotactic radiosurgery systems treating various vascular malformations, benign brain tumors, malignant brain tumors, and functional disorders.

Since 1968 worldwide over 1 million patients have been treated with the Gamma Knife. In the United States, to give you an idea of breakdown of the units, this is data from Elekta, the maker of the Gamma Knife. There are 77 Perfexion units and 22 Icon units in operation currently. To get some background about the Leksell Gamma Knife, there are -- the original model was the Model U model, which was placed

at the University of Pittsburgh back in 1987.

The Model B was developed in the mid-1990s. The Model C was later on and then the Model 4C. And the common theme between Model B, C and 4C is that there's 201 Cobalt-60 sources that are stationary. There are external helmets that measure 4, 8 -- 14 and 18 helmets as showing by the picture to your right. And these units would require -- for the Model B manual trunnions where the authorized user and the authorized medical physicist would actually set the trunnions manually for the X, Y and Z coordinates.

Whereas with the Model C and the Model 4C that is an automatic positioning system which allowed for less manual setting of the X, Y, Z coordinates. In 2006 the Gamma Perfexion was developed -- which was different than the Model B, C and 4C in that rather than having 201 Cobalt-60 sources, this had 192 Cobalt-60 sources which moved within eight permanently installed, independent movable sectors. So rather than having four different sized beams, these now have three different sized beams of 4, 8 and 16 millimeters.

There is one collimator body and as you can see from this picture the helmet is no longer externalized outside the machine, it is now

internalized inside the machine. And each of these collimator bodies correspond to the openings at each of the sectors. There is also a robotic automated table that moves up and down to set to the various X, Y, Z coordinates for that patient.

Very recently the -- the most current version of the Gamma Knife -- it is called the Gamma Knife Icon. And this is -- has the body of a Perfexion unit, but some of the key differences between the Perfexion and the Icon -- so the Icon system there is an integrated stereotactic Cone-beam CT image. Stereotactic Cone-beam imaging is actually very common now in many modern linear accelerators and recently -- the Gamma Knife now has this feature.

Also it allows for Online Adaptive Dose Control, meaning that there's actually some fiducials that are actually tracked during the treatment. And if it migrates outside the specified distance that the authorized user is not comfortable with, the machine will shut down and actually have the patient come out of the machine.

And also allows for a frameless mask-based systems. With the previous units, with the Model B, C, 4C and the Perfexion, there is not the option of doing frameless mask-based treatment. The only

potential advantage of mask-based treatment is that unlike using the invasive head frame, that's number one and number two, is actual fraction of treatments have made to prove value for some patients with certain tumors and other diagnoses.

In terms of background about current regulation, the Model B, C and 4C are under 10 CFR Part 35, Subpart 10; Subset 10 CFR 35.600. The Gamma Knife Perfexion and the Gamma Knife Icon are under 10 CFR 35, Subpart K which is 10 CFR 35.1000. All Gamma Knifes regardless of the model type must adhere to the provisions under 10 CFR 35.615(f)(3).

In terms of the physical presence requirements via the 10 CFR 35.615(f)(3) is that, quote, an authorized user, AU, and an authorized medical physicist, AMP, are physically present throughout all treatments involving the unit. So that is the present definition. The NRC further defined physical presence as a distance, quote, such that each can communicate with the other within hearing distance of the normal voice. So this is the current definition of physical presence.

In terms of rationale for having the authorized user present for the entire treatment for the Gamma Knife, here are some of the -- the

rationale. The authorized user has knowledge and appropriate training to ensure the safe and effective delivery of stereotactic radiosurgery. The current physical presence definition is not ambiguous. It ensures the AU is present for all portions -- critical portions of the procedure, able to address any medical issues that may arise during the treatment and verify the correct dose will be delivered to the target or targets.

To continue, the authorized user also has the competency to recognize and respond to any aberration of treatment and ensure response times are within seconds if needed. Also, the medical issues that may occur during the Gamma Knife such -- which may include pain from the frame, which we have heard about at one of the medical event reporting yesterday. Nausea, vomiting, and in rare cases seizures.

An incorrect dose of radiation may result secondary to system failure, it could be a combination of software, hardware, combination of both software and hardware. Having the authorized user present at the console area also allows for immediate availability for critical decision making, which sometimes is necessary. Also allows for the authorized user to help assist to remove the patient

from the machine in case of malfunction -- provide greater confidence to the patient and family during treatment of being present near the console area.

So in terms of the rationale for looking at perhaps modifying the physical presence requirement was given to many advance the Icon unit, which I just summarized. The subcommittee examined the current physical presence requirements to see if any modification could be considered. If one evaluates the number of medical events -- and this is from calendar year 2006 -- 20 -- 2017, there's twelve reportable events from Gamma Knife Perfexion and only a minority were identified during treatment.

If one categorizes these event numbers of -- they can be categorized into four areas. Number one is event positioning -- you can see that there were four of such incorrect positions. Number two is training deviation, machine malfunction, computer issue, and image process error. You can see there are four event numbers for that. Patient issues, which were three issues. And then failure to correct service procedures for maintenance, which was one event number. So you can see these are the total -- these are the 12 medical events that we are reporting from calendar year 2006 to 2017.

So in terms of the subcommittee recommendations, given the very low number of medical events and advances with the Icon unit, the subcommittee recommends that the authorized user and the authorized medical physicist be physically present during the initiation of all treatments involving the unit. And one of the reasons that we felt strongly the authorized user should be present at the beginning of treatment is that this gives the authorized user the opportunity to not proceed with treatment if the incorrect side is being treated. That has occurred on four occasions over the past 11 years.

Number two is the authorized medical physicist be physical present throughout all patient treatments involving the unit. As you can see from the previous medical events, there have been some issues with software, hardware, authorized medical physicists could address those if needed. The third recommendation was that the current physical presence requirement for the authorized user be modified by allowing the authorized user to be present in the department during treatment -- which is defined for the Icon as within a two-minute walk to the console area and immediately available to come to the treatment room.

The reason we did not use the definition of a department -- departments can vary in meaning. There are some Gamma Knives which are not housed in specific department. Some Gamma Knives are housed in a neurosurgery department rather than an oncology department, so that can be a very vague definition. The other is that -- just to give an example of -- before we recently moved to our new cancer center, our Gamma Knife was physically ten minutes away, although you could technically call part of our department, which I feel is not safe.

It's too far of a distance. And also it is very important that the authorized user be able to immediately come to the treatment room if necessary. So they can't -- he or she cannot be involved in a procedure or another task that would not allow them to go -- come to the Gamma center to address the need issues.

In addition to the authorized user and authorized medical physicist, we recommend as a matter of good medical practice that appropriate trained nursing or auxiliary staff be present at the end of treatment to respond to any immediate medical needs. You can see over the past 11 years there has been several episodes of medical events that have occurred.

And just having the authorized medical physicist present at the console area may not be sufficient.

At the conclusion of treatment the authorized user must be present at the Icon console to discuss any treatment or patient issues with the patient, physicist and nurse. The reason for having the authorized user present when the patient comes out of the Gamma Knife is that they can address any issues immediately rather than trying to figure out what may have happened -- if there was any aberration from the actual treatment delivered. Here are the acronyms that are used. Thank you.

CHAIRMAN ALDERSON: Okay. Thank you very much. So I just want to clarify that these recommendations as stated here -- that we now have to discuss and which would really change the way -- some of the physical ways that this is practiced. These apply only to the Icon, not to the Perfexion.

MEMBER SUH: Yes.

CHAIRMAN ALDERSON: Just to the 22 units that are Icon. All right. Given that clarification, majority of the people probably understand it already. I would like to ask for questions or comments. There are two. We will start with Dr. Zanzonico.

VICE CHAIRMAN ZANZONICO: So couple

questions. You indicated that of the reportable medical events over the last decade, four were related to patient positioning. Were any of those specifically for the Icon system?

MEMBER SUH: No, those are all for Perfexion.

VICE CHAIRMAN ZANZONICO: All for predecessor system?

DR. SUH: Yes.

VICE CHAIRMAN ZANZONICO: And typically how long is the overall duration of the treatment? I am just trying to get a sense of --

DR. SUH: Sure.

VICE CHAIRMAN ZANZONICO: Said within a two-minute walk, is that like 90 percent of a treatment? Or 10 percent of a treatment?

DR. SUH: No. Sure, sure. That is an excellent question. So a number of factors weigh in to how long a treatment will last. So number one will be the -- how strong your source is. So given half-life, you know, approximately five years. Should be time that we double after five years. So that's one of the reasons why Gamma Knife sources are -- Cobalt-60 sources are replaced about every five to six years.

So just to give you an idea, we currently

have a relatively new source. And our treatments right now are averaging between about -- you know, if it's a single lesion, give a -- and it also depends on the dose that we can give. Just -- probably between 15 minutes to about an hour as a source ages it will probably be closer to about an hour to two hours overall.

There are some cases where the treatments can be very long. So probably the longest treatment I have actually had personally is about seven hours. Now when you've had those type of treatments, what we invariably have to do is give a patient a break. A restroom break. The authorized user may need a restroom break. And there's -- so just to break the treatment.

So -- and just to get back to, you know, so may question why -- is there a fundamental difference between a Perfexion and the Icon system? So having a stereotactic home beam actually on the unit -- so for us we use it as a practice, use it as -- first session we were treating a functional site. We were treating fibromyalgia. We were giving very high doses to the nerve. We actually will take an image with the CT stand and verify the position is correct. So it just gives an extra double check that

through the incorrect side will not be treated.

And one of the things that -- being part of the committee I have noticed is that it is every-other year or so there's invariably a medical center that treats the wrong side -- which in my opinion should not happen.

CHAIRMAN ALDERSON: Yes.

MEMBER DILSIZIAN: Great presentation. So I understand the -- all the authorized medical physicists on site and then you propose that, given that there's some medical events, perhaps a nurse or some healthcare provider should also be present. I guess my question is, would there be any pre-defined prescription for those nurses? For example, the patient is having seizures or hypertension -- by the time the physician is walking for two minutes, what kind of things can a nurse do without a -- you know, prescribed kind of guideline.

MEMBER SUH: So I -- I think there are medicines that actually can be prescribed -- pre-orders that can be sent. Fortunately, the number of medical events that occur during treatment is actually very few. And I think it is incumbent on the authorized user -- the neurosurgeon who is involved in the case to select the correct patient.

So I think that will actually help mitigate the number of potential medical events is that -- or, medical issues that may occur during the actual treatment delivery. You know, one of the things that some of you may be thinking is well why do we put some type of time period between the console area and the authorized user?

So there are some departments where the Gamma Knife may be in the lower level and the offices may be physically on the sixth floor. All right? So again, it is -- we felt that time was a much better measurement rather than using distance because distance could be either horizontal, it could be vertical. And one could imagine that if the elevator didn't work or someone had -- you know, it could be delayed. So we -- that's why we wanted to have it a certain time distance. So one could argue, could it be a one-minute versus three minute?

Now one of the things that we made explicit is that the authorized user has to be present. So just getting back here to the question, Dr. Zanzonico, if it was a ten-minute treatment, the authorized user needs to be present during the initiation of treatment and then they have to be present at the end when the patient delivered -- is

coming out of the machine. So in my mind it doesn't really make a lot of sense for the authorized user to leave the console area. So if it is a shorter treatment, he or she can -- would have to make that decision, would be physically present that entire time.

So for some of these cases there's really not going to be any modification in the physical presence requirements. It would be for these longer treatments that last two or three hours. It just gives more flexibility to the authorized user with the understanding that the authorized user has to be immediately available. And in terms of how that messaging system comes on -- if it's a cell phone, paging system, et cetera -- that's something that each medical center would need to work out. And it's -- we feel it's not within the purview of our subcommittee to make that recommendation of how they would communicate.

MEMBER DILSIZIAN: Let me just follow up. So, the only reason I bring it up is that you were concerned enough, the Committee, to say that you wanted a medical staff beyond the physicist to be present. So even though the medical events are less, you were concerned enough to say I would like to also

have a nurse to be there.

I just wanted to make sure that that individual will last -- the two-minute period thing anticipating the physician to be there, has the right to intervene with serious events. I am just not sure -

(Simultaneous speaking.)

MEMBER SUH: Yes, just -- yes -- so just in case if there are -- And again, part of it also is, I think, as an authorized user you also have a good sense of who is going to be a sick and someone who is going to be well. So there are some patients who I know will -- will not be an issue if it's a one-hour treatment. There are other patients who have multiple brain metastases where I may not feel as comfortable being away from that console area and I may decide to stay during that entire time just in case the rare seizure does occur during the -- the actual treatment delivery.

The NRC initiative does not regulate nursing or ancillary staff so it is a -- it is a best practice, doesn't mean that it's -- each center will need to decide how to utilize that and what they are comfortable with.

CHAIRMAN ALDERSON: Yes, Mr. O'Hara.

MEMBER O'HARA: The -- is it -- is it common medical practice for CyberKnife to have a physician and a medical physicist present during treatment?

MEMBER SUH: So right now it is not as a common practice. In terms of best practice, I can share with you what we do in Cleveland. We do not have the CyberKnife, we have a Linac-based system that we use for radiosurgery that require the physician, the authorized user to actually be present during the actual initiation of treatment to check the stereotactic imaging.

And just because of my Gamma training I am actually physically present through the entire treatment and actually see the patient leave the room. Is that a practice that occurs in all cases? No, it does not. Although I think it is a best practice in terms of having the radiation oncologist in this case present during that -- that treatment time period. But again, that's really more medical practice in terms of how each center dictates things. But again, we try to follow -- I try to follow more of a Gamma-type of presence during treatment delivery.

CHAIRMAN ALDERSON: Dr. Ennis?

MEMBER ENNIS: Just to help on the -- Dr.

O'Hara's comment also. So we also -- similar to what Dr. Suh indicated work for stereotactic -- Linac-based stereotactic procedures require the physician, essentially the authorized user, to be present -- until now, the entire time. Although we actually are considering -- were considering, I just left, but -- were considering a change to the -- requiring presence for the beginning and then immediately available within a -- essentially the same kind of standard within the two-minute walk kind of thing just in case an event were to come up.

I think the fact that that's not required is because there's not a regulatory body like the NRC. It's not because it ought to be that way. I think the fact that we have a regulatory body like the NRC is actually a positive when it comes to this. And in my opinion it would be preferred if that was the standard for all stereotactic procedures. But there's just not a regulatory mechanism to put that in place.

MEMBER SUH: And one of the things I also comment is that if you look at the number of medical events that have been reported over the past decade, there are very few. And then the -- I think part of it is -- there aren't hundreds and hundreds of Gamma Knife centers around. In addition, the training

that's required. There's required training so that each user -- medical physicist, the neurosurgeon, the radiation oncologist -- actually has very strict training that's required before the hospitals sign off on actual treatment.

So it is actual a very strong model in terms of really trying to enhance safety and quality. And that's one of the reasons why the Gamma Knife is the device that is used for many different indications within the brain.

CHAIRMAN ALDERSON: Yes, Dr. Langhorst.

MEMBER LANGHORST: Thank you for this report. This is really good. One thing that I want to clarify for both the medical -- authorized medical physicist and authorized user, if you are asking for regulatory and the guidance document changes, it makes a difference if you say the authorized user or an authorized user. So is your intent to have only one authorized user be able to do this? Like, if that authorized user can't come, can another authorized user do -- come in?

MEMBER SUH: No, the -- no, the --

MEMBER LANGHORST: Or you're -- you're saying the authorized user?

MEMBER SUH: No, so -- so an authorized

user can actually be physically present at the console areas.

MEMBER LANGHOST: Okay, I think you need to carefully go through the report to see where you say the authorized user because that -- that has --

MEMBER SUH: Okay, no that's --

MEMBER LANGHOST: That has tripped us up on the radiation safety officer in the regulations.

(Laughter.)

MEMBER LANGHOST: The same thing, be careful in looking at the authorized medical physicist. I think in here you -- you guys talk about an authorized medical physicist, so there can be kind of a tag-team work where somebody could come in and relieve somebody else. So --

MEMBER SUH: No, thank you for that comment. So just to share with you a practice that we have is we have a very busy Gamma Knife center. And what we do is we actually have four authorized users. So if I can't physically be present at the console area, one of my colleagues -- I will call them and say can you come over at 2:00 to relieve me so I can go and do other tasks that are needed. And he or she will be physically there at the console area.

MEMBER LANGHORST: Okay.

MEMBER SUH: So fortunately we have that -- - that flexibility. Not all centers do, and I think that -- and one of the -- by actually allowing this two-minute proposal from the console area, it just gives some flexibility for the authorized user to do things like bathroom breaks, which -- you know, all of us need. So it does provide flexibility, which I think is important.

MEMBER LANGHORST: And then I had one other question. In the longer treatments where a patient needs to have a break, is there any recommendation -- does the authorized user need to be there at those times? Or --

MEMBER SUH: Yes. So if there is a break -- and then that's actually another good point is that if the patient needs a break and they are unhooked from the unit, then yes. You actually have to place the patient back on unit and the authorized user should be present to make sure that they are going in the correct direction -- right versus left.

MEMBER LANGHORST: You might want to address that in the report, too.

MEMBER SUH: No, I think that's an excellent point. That's an excellent point because --

MEMBER LANGHORST: Thank you.

CHAIRMAN ALDERSON: Very good. Very good. Other comments from the committee? Yes, Dr. Zanzonico.

VICE CHAIRMAN ZANZONICO: So given how few of these Icon systems are available, is it fair to say that -- that a -- the requirement for the -- for the AU to be present the duration of the procedure impacts the availability of the procedure generally?

MEMBER SUH: I don't believe so because these units -- if the medical center makes the investment for a Gamma Knife -- which are -- they would actually make sure they have the resources available. And right now the numbers I showed were 77 Perfexion units and 23 Icon units. The numbers are rapidly changing because this is a newer model. It allows for fraction treatment with a mask-based system.

And there are some patients who frankly don't want to have an invasive head frame that's on their head for four, six, eight hours. They'd rather have the mask-based system. And with the coupling of the stereotactic cone-beam CT, I have much greater confidence that we're treating that area if it's right versus left versus upper versus lower areas of the brain.

CHAIRMAN ALDERSON: Good. Other questions from the committee?

(No audible response.)

CHAIRMAN ALDERSON: Are there comments from the audience here in the room? So we do have -- Mr. Sheetz is coming to the microphone.

MR. SHEETZ: Hello, Mike Sheetz, University of Pittsburgh. As pointed out in the presentation we were the first Gamma Knife licensee in the United States in 1987. We have had every model of the Gamma Knife and we have treated over 15,000 patients. We currently have both the Perfexion model and the Icon model.

As pointed out by the subcommittee, there have been very few medical events and the minority of these that could have been detected during the treatment process were due to patient movement. Our experience has been that the majority of emergent events are medical issues with the patients -- with just nausea or hypertension. They have to be addressed medically.

I fully support the subcommittee's recommendation to allow the AU to be present in the department and not physically present at the treatment consoles. This will allow for more efficient use of

the AU's time in patient care and other duties. I would also suggest that this level of physical presence also apply to frame-based treatments as there's not much inherently different between the mask-based and the frame-based with respect to what can go wrong.

There's actually more moving parts on the mask-base with the cone-beam CT co-registration and the motion management detection system. So I think we should consider that frame-based also follow this same criteria for physical presence -- it will also allow for a lot more relief for frame-based treatments with Icon and then also allow those treatments with the Perfexion unit.

It -- is there interest to note that the physical presence requirement was a result of corrective action from an HDR incident that occurred in 1992 where the source broke off inside the patient while the radiation monitors were alarming, the people there thought it was malfunctioning and so the patient returned to a nursing home with the source in place. Patient subsequently died. The source detected the medical waste.

A couple weeks later, same model of HDR device, another source broke off and a patient for the

medical physicist recognized this and secured the source and removed it from a patient. Following that there was an order for all HDR licensees to have the AU and AMP physically present for any HDR treatments. And so the original intent of the physical presence requirement was to be able to address medical emergencies from a radiation standpoint.

With respect to this, if an emergency occurs, it is easy to remove the patient from the body and focused beam of radiation. Thank you.

CHAIRMAN ALDERSON: All right, and I think that that comment -- particularly since the recommendation is there to expand this beyond Icon to Perfexion -- that requires -- I would like to have Dr. Suh comment on that. Why -- why the proposal was made only for the Icon, not for the Icon and Perfexion. And then other people may wish to comment.

MEMBER SUH: Sure. So initially the subcommittee charge was to look at the Icon. We actually did look at -- went on to incorporate the Perfexion. The -- and getting back to your point, the -- in terms of the -- the Icon system in the document -- we're not saying it has to be a mask-based system or a frame-based system. So with the Icon you have the luxury of choosing one or the other.

But I find, I don't know if anyone else on the subcommittee feels that there are some fundamental differences with the Icon system versus Perfexion system. There's onboard imaging, which the Perfexion does not have. That is a clear difference. Number two is it allows for mask-based treatment, which the Perfexion system clearly does not have. And number three it has a motion-management detection system which the Perfexion unit does not have.

And for those reasons I feel there is enough fundamental difference between the Perfexion versus the Icon that I would favor that any physical presence requirement changes that we propose -- that it be for the -- for the Icon system. But again that's something up -- now actually up for discussion for the committee here as well.

CHAIRMAN ALDERSON: Okay, good.

MS. HOLIDAY: Dr. Alderson, if I may -- this is Sophie. Can you hear me?

CHAIRMAN ALDERSON: You have a comment?

MS. HOLIDAY: Yes, Sophie.

(Laughter.)

MS. HOLIDAY: So if I am not mistaken, Dr. Suh -- and correct me if I am wrong. I thought that during the subcommittee's discussions we said that the

recommendations you were putting forward were for the Icon in the frameless mode because only the frameless mode is where the HDMM system and the cone-beam CT is used. Because once you use the stereotactic head frame, you don't use the cone-beam CT or the -- or the motion management system.

MEMBER SUH: No, you still can use the cone-beam CT. So for any functional case that we use -- at least at our center -- we actually will get an image based. We get an image.

MS. HOLIDAY: Is that the standard practice for all of the other institutions that are using the Icon?

MEMBER SUH: So that's -- I think it varies. I couldn't tell you what the standard practice is -- that means what we consider best practice.

MS. HOLIDAY: Okay.

MEMBER SUH: Do you want to comment if you use -- do you use -- do you have a cone-beam that you actually will use with the frame?

MR. SHEETZ: We do not use the cone-beam for frame-based -- for releasing the imaging off the MRI, frequent plan. That is the same with Perfexion. So the -- the Icon for mask we will do the cone-beam CT and the motion management features of the Icon.

But otherwise, if we do a frame-based on Icon, it is exactly the same as a Perfexion-based treatment.

CHAIRMAN ALDERSON: Yes, Dr. Langhorst.

MEMBER LANGHORST: Just looking at your report on page 5 of 7 in the summary, it does say for the Icon when used with the frameless mask.

MEMBER SUH: Okay.

MEMBER LANGHORST: So your report does specifically say only in that case.

MEMBER SUH: Okay.

CHAIRMAN ALDERSON: And is that correct? Is Dr. Langhorst correct in that -- so this -- the recommendation is only for the frameless mask approach. Is that correct?

MEMBER SUH: If that's what the report says, then in that case it is an oversight on my part that's -- for saying mask. I mean the mask -- there is -- there is clearly a fundamental -- different than mask versus a frame-based system. So -- and if you have the Icon system. But --

CHAIRMAN ALDERSON: So until further notice, we will have to go with the report. Unless you suggest to change the --

MEMBER LANGHORST: I also question why it needed to be limited to that. So --

VICE CHAIRMAN ZANZONICO: I mean, I don't quite know the sequence of the coding CT, but wouldn't the presence of the frame create artifacts on the cone-beam image that would interfere with the proper positioning?

MEMBER SUH: No, it just gives you a sense of right versus left. So -

VICE CHAIRMAN ZANZONICO: Oh, okay.

MEMBER SUH: It's what we do when we do stereotactic treatments. We -- we get an image just to make sure that -- that we have the correct position.

CHAIRMAN ALDERSON: Are there further comments from the Committee? Yes.

MR. COLLINS: Question for clarification, thank you Dr. Alderson. So Dr. Suh, thank you for the report and then the presentation. That is very helpful. I was wondering if you could talk a little bit more about subcommittee's recommendation number four. And particularly what I am wondering about is -- so for the first three recommendations the nexus to patient safety for me is pretty clear. For the fourth I am not sure what it is that would be discussed with the patient at the termination or at the conclusion of a treatment that would be patient-safety focused

versus practice of medicine. So that is where I am confused. If you could talk about that, that would be helpful.

MEMBER SUH: So one of -- so one of the things that we have seen in the medical event report is that sometimes when the patient is taken off the machine they've noticed that the frame has moved. And that's something that the authorized user would be physically present to actually see if that frame has moved or not. That -- that would be number one.

Number two is, my personal feeling is that if you -- the Gamma Knife, as a procedure -- and actually at the end of the procedure, patients and families actually would like to speak -- the opportunity to speak to a doctor. And if we have a -- one of the proposals from last meeting was to just have the authorized user present the very beginning of treatment and not be present at the end is -- I think is -- again it's -- it's more of a practice of medicine, but I do feel that being able to see the patient come out completely is actually -- is helpful from a quality and also from a medical practice standpoint.

MR. COLLINS: Thank you.

CHAIRMAN ALDERSON: But the issue -- the

issue, though, is an important one. I am glad you raised the point. Because we debate in this forum on a regular basis the -- the boundaries between regulation and medical practice. And we talk frequently about the NRC not overstepping the bound into medical practice.

So if this recommendation, which clearly is very sound medically, is only medical one might suggest it really ought -- it should not be a part of the official recommendations that we approve because it's across the border.

MS. HOLIDAY: Dr. Alderson, this is Sophie. I think -- just to provide a little bit of clarification, currently per the regulations the AU has to be physically present at the initiation, during the duration, during the termination. So this is just to -- I think this is what the intent of the subcommittee was -- was just to capture that fact holistically but only with the departure where they say the AU can be two minutes away from the console.

So this wasn't necessarily Dr. Suh's, subcommittee's attempt to raise a non-regulatory -- or non-radiation safety aspect, this is just them completing the whole circle in terms of the AU being present at the beginning, at the end -- but not

necessarily during the duration.

CHAIRMAN ALDERSON: Yes. No, I understand. Are there any comments from anyone else in the room?

(No audible response.)

CHAIRMAN ALDERSON: How about people on the phone? Is anyone on the phone listening in to the session wish to make a comment on this issue?

MR. OUHIB: Yes.

CHAIRMAN ALDERSON: Just identify -

MR. OUHIB: Hello?

CHAIRMAN ALDERSON: Yes -

MR. OUHIB: Yes, hello. This is Zoubir.

CHAIRMAN ALDERSON: Oh, hello.

(Simultaneous speaking.)

(Laughter.)

MR. OUHIB: Hello, everyone.

(Laughter.)

MR. OUHIB: Yes, yes. Great -- great report there. I was just curious, while it is probably obvious, should we have a clear definition for the authorized user and the authorized medical physicist specific to the device itself in terms of training, education, and so on and so forth? For that -- for that device? And emergency response and so on?

Should that be clarified at the very beginning?

MS. HOLIDAY: Zoubir, this is Sophie. In our 35.1000 licensing guidance document we do clearly identify what the training and experience requirements are for the AU and the AMP for the Icon device as well as the Perfexion.

CHAIRMAN ALDERSON: Good.

(Simultaneous speaking.)

MR. OUHIB: Okay --

MEMBER LANGHORST: And also for the RSO.

MR. OUHIB: Yes, perfect. Thank you.

DR. HOWE: And we also list them -- and we also list them on the license for those authorizations. So it's not just they get the training, but they have to list it on the license or the permit for a broad-scope license.

CHAIRMAN ALDERSON: Good, good. So that's been covered then, good. Thank you. Anything else, Zoubir?

MR. OUHIB: Yes. So should that be added to the -- at the end of the -- that last slide, authorized users as defined per -- and then put in that information in there? Or not?

MS. HOLIDAY: I don't think that's necessary because the focus of this presentation was

just to address the physical presence requirements.

MR. OUHIB: Okay.

MS. HOLIDAY: It wasn't necessarily to amend the training and experience requirements for those authorized individuals.

CHAIRMAN ALDERSON: Good.

MR. OUHIB: Great, thank you.

CHAIRMAN ALDERSON: Okay, thank you. Anyone else on the phone who would like to comment?

(No audible response.)

CHAIRMAN ALDERSON: All right, so we had all the comments now. And at this point I think we are ready to look at the actual proposal and for this committee to determine whether it supports this -- this report -- it approves this report. So would anyone like to -- we have had discussion, would anyone like to make a motion to that effect?

PARTICIPANT: Motion to approve.

MEMBER ENNIS: Motion to approve with modifications. Sue pointed out something that was an important modification --

MEMBER SUH: Yes, if there's interruption of treatment with the authorized user.

(Simultaneous speaking.)

MEMBER ENNIS: And interruption --

interruption of treatment that AU be required to -

VICE CHAIRMAN ZANZONICO: And frameless versus -

MEMBER LANGHORST: Yes, and the authorized user versus an authorized user.

MEMBER ENNIS: Right. And that's -- should be an authorized user, or an authorized medical physicist. But also stipulating that if there is an interruption of treatment the patient is taken out of the unit -- I guess is how we would define it?

MEMBER SUH: If you unhook the patient from the unit, that you'd have to -

MEMBER ENNIS: Right, that the AU must be present to resume treatment. So with that -- with those amendments.

(Simultaneous speaking.)

CHAIRMAN ALDERSON: With those -- approval and -

MEMBER SUH: Well, the -

CHAIRMAN ALDERSON: All right, do we have a second?

(Simultaneous speaking.)

VICE CHAIRMAN ZANZONICO: Well the -- I guess the issue is the mask versus frame. I mean, some of you said explicitly for mask -- for the mask-

based system.

MEMBER LANGHORST: But before we move off of Dr. Ennis's comment, I wanted to say you need to be able to take the patient out quickly. So you can't wait for the AU for interruption.

MEMBER ENNIS: Right. No, just to put them back in --

MEMBER LANGHORST: But to put them back in is what -- and so I want to make that clear that you can't -- you don't wait for the AU to take the patient out.

MEMBER SUH: And that's one of the reasons why the -- the training is very rigorous with the authorized medical physicist and others who are involved.

MEMBER LANGHORST: There are a lot of people involved in these procedures. It's not just one authorized medical physicist there left to his or her own devices.

CHAIRMAN ALDERSON: Are there further comments from the Committee?

(No audible response.)

CHAIRMAN ALDERSON: So we have now a motion and a second to approve the report as amended. Is there further discussion?

MEMBER SUH: I think the other thing is -

(Simultaneous speaking.)

MS. HOLIDAY: May I ask a question? I thought I heard discussions about if you guys wanted to amend the report to also include the Perfexion? So is that something that is still on the table? Or are we only doing this solely for the frameless mask use of the Icon?

CHAIRMAN ALDERSON: Comment, please.

MEMBER LANGHORST: My opinion is -- is I -- I think that the subcommittee should look at that more closely to -- whether -- because it is difficult to -- it is easy to say for the Icon unit you can do this. It is not as easy to say only if you are using the mask versus the frame. And I would like to hear from the subcommittee whether the frame -- using the frame on the Icon would be just as safe, too.

CHAIRMAN ALDERSON: So I -- I would like to just point out as a matter of procedure -- oh, I'm -- I'll -- I will make a comment and then I will go to the microphone. That you could -- since apparently the report -- the report is written in the limited format, you could in fact approve the report as amended -- because that didn't relate to that -- and that would allow in that situation for the AU to be

two-minutes away.

You then could come back at a subsequent time -- the next meeting, for example, with additional information about getting to that bigger question. Now there is somebody at the microphone and Sophie has got her hand up again. I am going to go to the microphone.

MR. SHEETZ: I just want to point out that the medical events -- the 12 that occurred since 2006 -- were from the Perfexion with the frame-based treatments. So we really don't have a track record yet for the mask-based treatments.

CHAIRMAN ALDERSON: Sophie.

MS. HOLIDAY: Okay, so procedurally, as you understand, these are the Committee's recommendations for the actions that you wish staff to pursue. That does not necessarily mean between now and the spring meeting that the guidance will have been revised. So following the ACMUI's final report -- if this is the final report as amended -- this is a recommendation that I will have to take back to my NRC Agreements State Working Group. And they will have to work through management to make the decision as to whether or not to actually amend the guidance. So I just want to clarify that.

CHAIRMAN ALDERSON: Okay. So now we know that if we approve the report as amended and written, then we still will need an action from the NRC to make that the official guidance out for practice. But the question now is that -- I think the question that is still on the table is this issue of the Perfexion. Should that be included now? Or does that have to be a follow-up later? My opinion is it has to be later. Let's get some other.

MEMBER LANGHORST: Well, I wonder if the subcommittee could convene, talk about it, and then have a teleconference with the -- with the ACMUI before the spring meeting to clarify that point. And if they decide no to, then you could still get together and approve the report as it stands with the amendments we talked about.

CHAIRMAN ALDERSON: All right, so -- so the recommendation from Dr. Langhorst is that we -- I think this is implicit in your recommendation, that we not approve anything right now, that we go back to the committee -- that they discuss the issue, that they have a teleconference and they get back to us. And by the time we get to the spring meeting that decision has been fully resolved. Is that what you are recommending?

MEMBER LANGHORST: That is what I am suggesting and -- and whether the subcommittee wants to do that or -- or go in the different pieces, as you have suggested.

CHAIRMAN ALDERSON: Yes, okay. Well we need some comments on that form members of the committee.

VICE CHAIRMAN ZANZONICO: But it wouldn't have to wait until the spring meeting. I mean, there could be an intervening subcommittee meeting to amend the report and then shortly thereafter a full ACMUI teleconference to approve it, so there wouldn't be an undue delay in terms of what Sophie has to do.

CHAIRMAN ALDERSON: That's correct. Okay, everyone is nodding that that's procedurally correct, yes, as stated. So we have a recommendation from Dr. Langhorst. That is essentially a proposal. Is someone going to second that? Several people. Do we want to discuss it further?

(No audible response.)

CHAIRMAN ALDERSON: No one seems to wish to do that, so in all -- do you want to comment, John, as the head of the committee?

MEMBER SUH: No. I am happy to take that. It's very useful feedback about things. So, I -- no.

We can -- we can convene as a subcommittee and make the recommendations in terms of -

(Simultaneous speaking.)

CHAIRMAN ALDERSON: All right, so the subcommittee chair is willing to accept this approach. So all those in favor?

(Show of hands.)

CHAIRMAN ALDERSON: That's unanimous. So are there any other comments?

(No audible response.)

CHAIRMAN ALDERSON: Okay. Hearing none, then that is what will happen. This will go back to committee right now. And then potentially there will be a teleconference set up -- Sophie will work with you on that -- can be coming back to the ACMUI for a teleconference if that is necessary if you reach an endpoint. And hopefully this will all be smoothly taken care of by the spring. Thanks very much.

MEMBER SUH: Thank you.

CHAIRMAN ALDERSON: All right, well it now is -- according to that clock on the wall, which is a little bit fast -- it is about two minute to ten, which is when we are scheduled to have a break. So I think that -- unless there are items that need to come to the floor right now related to something we've done

this morning, we will go on break and we will reconvene at 10:30 for a report on Y-90 Microsphere Licensing Guides. Thank you. We stand adjourned.

(Whereupon, the above-entitled matter went off the record at 9:56 a.m. and resumed at 10:30 a.m.)

CHAIRMAN ALDERSON: We'll reconvene the session. We're now going to hear from Dr. Katie Tapp. She'll provide an update on the Y-90 Microspheres Brachytherapy Licensing Guidance.

DR. TAPP: Thank you, Dr. Alderson. Like you said, I'm here to provide an update on the Y-90 Microspheres Brachytherapy Licensing Guidance. First I wanted to go through the working group members working on the licensing guidance.

First it's myself, then Bob Dansereau from New York State is the co-chair in the working group. Then we have Victor Diaz from New Mexico, Sara Forster from Region III, and Penny Lanzisera from Region I.

History on the licensing guidance, the Yttrium-90 Microspheres Licensing Guidance was issued in 2002 originally, and you can remember in February of 2016 we issued a Revision 9. We immediately opened up a working group to start working on recommendations from both staff and ACMUI to start Revision 10. A draft of that revision was reviewed by a sub-committee

and discussed at the October 7, 2017 ACMUI meeting.

That draft revision that the ACMUI sub-committee reviewed had significant changes to three sections. Those sections included the training and experience section, some addition information on the waste and disposal section, and then a new section that provided a reference for autopsy and creation information because we received lots of questions regarding radiation safety for past patients specifically related to cremation so we wanted to provide a reference to data that licensees could look at.

Those were the three changes that were in the draft when the ACMUI reviewed this in the fall. The new draft is also adding one additional change, significant change, where we're adding the definition for the term shunting, just to clarify what is the meaning of shunting in the terms of licensing guidance space.

To give some history again, on the training and experience section of the Y-90 licensing guidance, it includes two components. The first component is the radiation training and experience, radiation safety training experience part. This is relatively standard.

The training we expect an individual to have to become an authorized user, which would include either being a 300 or 400 authorized user or if they're an intervention radiologist the number of years of experience we expect them to have in training, or board certifications. This would also include specific classroom and laboratory training for by-product materials, as some intervention radiologists would deal more with linear accelerators or x-rays, and not with by-product materials as well as specific work experience for Yttrium-90 microspheres.

Then there is a second part that all individuals must have for Yttrium-90 authorized user status, which is specific clinical experience using the devices to deliver the Yttrium-90 microspheres. That training includes operations of the delivery systems, safety procedures, clinical use and three supervised in vivo cases under the supervision of somebody previously trained or a manufacturer. The supervision of the three in vivo cases must be under either an authorized user or a manufacturer representative, which is known an alternative pathway.

This alternative pathway was introduced in 2008, due to the limited number of authorized users to

provide supervision, and it's unique to HM-90 microsphere radiation therapy, not found in other modalities in 10 CFR 35.

The Draft Revision 10, the working group recommended the removal of the alternative pathway. The working group believed that after ten years of licensing authorized users for HM-90 microspheres there should be adequate numbers of authorized users available to provide the supervision necessary for new physicians to get that work experience to become authorized users. The working group understood that some individuals may be under the process of getting their training experience this way, so we wanted to provide a two-year grace period.

The ACMUI reviewed this, as I said, last fall, and new recommendations were that the alternative pathway should remain because there is still uncertainty if a sufficient number of training experience opportunities for new AUs and that manufacturer training provides a uniform standard of didactic and in vitro clinical training. They also recommended that the working group should consider additional requirements for these proctors, because manufacture representatives, the licensing guide does not state that they have to be physicians.

As the working group has reviewed the ACMUIs recommendations and has gone through the document again, the consideration is for the draft revision of Licensing Guidance 10 is to still recommend alternative pathway be removed with a grace period, and then recommend A), supervision from the last recommendation the ACMUI received to make sure that individual provides work experienced in AU for the work experience in evaluation of treatment and administrative controls to prevent medical events.

We believe that this should be an AU's position, because these two items are more medically related and a representative who is not medically trained may not be able to provide a detailed work experience for these two items.

The working group is still recommending that there is a grace period of two years prior to the removal of that alternative pathway, and during this grace period there is a recommendation that there is a six-month limit for completing three supervised in vivo cases after the AU is put on the license, so these three supervised cases would occur, the manufacturer representative would come in and we want to make sure that the training and experience they have received to be put on the license has not been

forgotten so we suggested a three-year limit for that, for them to complete those three cases. This would avoid significant time frames between the training and the actual clinical experience.

We do recognize that on a case by case basis there must be an allowance for longer time periods as maybe patients aren't available to receive this training. There might be some other condition where in a case by case basis alone should be necessary.

I said there was one addition that the working group is suggesting adding to Revision 10, and that's regarding lung shunting. In Revision 9 we excluded reporting of lung shunting as a medical event if lung shunt was evaluated prior to treatment. We wanted to make sure it was clear for the purpose of this guidance what the definition of lung shunting is, so the definition we added is, shunting is defined as the unexpected blood flow causing Yttrium-90 microspheres to flow to an unwanted location. This is the working group's recommendation for Draft Revision 10. This is the first time we're doing this, but based on the ACMUI recommendation back to us was, we don't have enough information available at this time to remove that pathway, with still uncertainties around

is there enough authorized users out there to provide this training.

So the NRC wanted to reach out for public comments to find out what the public has to say and medical stakeholders have to say, if there are enough authorized users. So we are going to issue the Draft Revision for public comment, planning on relative soon. The public comment period will be 60 days, as we're going to send this out.

When it does go out, we will alert the major professional societies and the two manufacturers involved to make sure they have time to review and provide us comments. In the public comments solicitation we're going to ask several questions for consideration. The first will be mostly on training and experience and that is questions regarding the minimum clinical experience necessary for Yttrium-90, whether the training experience is adequate if someone goes from one manufacturer to another or should there be lenience if someone's already trained with one, moving to the next.

If there's a reason why Yttrium-90 does not need written attestation such as other modalities found in 10 CFR 35. Currently the licensing guidance is not required for written attestation, so we're

asking is there a reason why it should not, why it should be different.

Then there's a specific question on the removal of the alternate pathway. This is the question on, should we be removing the manufacturer representative, is there enough AUs out there to provide this training, and then the timing of the in vivo case completion during the grace period, or if we decide to keep the alternative pathway, is that timeliness for the in vivo case completion, a good time, is that six months a good time to complete that.

And then we're asking for public comments specific to the medical event definition, is there anybody out there who has some guidance back to us to clarify medical events in cases of Yttrium-90. And there is the acronyms I have. Any questions?

CHAIRMAN ALDERSON: Thank you. Good. So it seems, if I'm hearing this correctly, that it's one of these situations where we have a disagreement or a different position between the ACMUI and the NRC. The ACMUI said keep the alternate pathway, the NRC is not happy with that so they want to put out a draft document with the pathway being sunset, and ask for comments. Is that correct?

DR. TAPP: I wouldn't really call it a

disagreement. I believe from the ACUMI recommendation, you stated that you wanted to keep it the way it is because it wasn't clear if it was enough authorized users out there. So we wanted to find out that information. That's why we decided to go out for public comment.

CHAIRMAN ALDERSON: So I'd like to get comments from the ACUMI on this so Michael O'Hara raised his hand.

MEMBER O'HARA: How many authorized users are there? Do you know?

DR. TAPP: No, we don't know. It's difficult to quantify because that Agreement States permit holders and broad scopes and permit holders for our master materials licenses.

CHAIRMAN ALDERSON: Thank you. Mr. Green?

MR. GREEN: I was wondering, when we saw the advent of interstitial radial therapy with Iodine 125, prostate radioactive therapy seeds, when did that happen, how long was that permissible under a alternate pathway training model before that training model was removed, if it was removed? Because it's a similar process, ten years so far with radial therapy with Yttrium. How long was the interstitial brachytherapy therapy before that alternate pathway

was removed?

CHAIRMAN ALDERSON: Who knows the answer to that question? Anyone from the NRC know that? Anyone on the committee? I certainly don't know the answer to that.

DR. HOWE: Can you repeat what you believe happened?

MR. GREEN: At one point, I-125 prostate brachytherapy therapy interstitial seeds were new. There must have been manufacturers who provided training modalities for that brand-new application of radioactive materials in humans. Then over time, that alternate pathway of developer, manufacturer-provided training, built up a body of authorized users sufficient that authorized users could train each other. I presume that alternate pathway of manufacturer-provided training was removed. That's what we're looking at here. Who knows the history of I-125 seeds?

DR. HOWE: I've been at the NRC since 1988, and this is the first time I'm hearing that new market. We did have a number of years where we had approved manual brachytherapy on certain types of procedures, and one was whether interstitial was equivalent to another term.

We finally made a decision that interstitial was equivalent to another term and therefore it was authorized under 400, but the training and experience for 35.400 has not changed since '87 and was updated with board certifications in 2006. So there's always been an alternative pathway, but I do not believe there was a real alternative pathway that recognized something as different as the Yttrium-90 alternative.

CHAIRMAN ALDERSON: So we can't clarify the point now, because no one seems to know the, Dr. Ennis?

MEMBER ENNIS: Well, no. Brachytherapy has been around for probably longer than the NRC has been around, and is not a special PV for each application of brachytherapy. It's not like you need special lung brachytherapy training, experience, special prostate, it's just manual brachytherapy. The only thing that's now new is medical event definition has been part of that specific for prostate therapy. That's the only specific thing applying to prostate radiotherapy. The rest is just regular therapy.

CHAIRMAN ALDERSON: Yes, Dr. Langhorst.

MEMBER LANGHORST: Dr. Tapp, I wanted to come back to shunting and the definition for that. You

talked at one point about a new definition for shunting, and then you talked only specifically about lung shunting. In our ACMUI report that led to Version 9 of the guidance document, was about going to the gut. So I'm confused as to what the working group is working on as far as definition of shunting, lung shunting, and how that impacts the medical event reporting items.

DR. TAPP: I apologize if this line is misleading, but it is shunting. I'm used to specifically looking at lung shunting, which is the manufacturers, which you can see, but the definition is still applicable to both lung shunting and gut shunting, which is shunting going by blood flow.

MEMBER LANGHORST: Okay, so the definition isn't going to be for lung shunting, it's going to be for shunting.

DR. TAPP: Shunting, yes.

MEMBER LANGHORST: Okay. Thank you for that clarification. And just one minor item, the date on your meeting should be 2016 where we reviewed it, because you have us in the future. I do that all the time, and I'm always thankful that people point that out to me.

CHAIRMAN ALDERSON: Other comments from,

yes, Dr. Zanzonico?

VICE CHAIRMAN ZANZONICO: I just have a general question. What's the rationale, other than sort of uniformity, for eliminating the alternate pathway? Implicit in that is that it's somehow less satisfactory than peer to peer training.

DR. TAPP: The rationale from the working group is that it was initially provided because of a problem. 35.1000 guidance is supposed to be for unique aspects, different from regulations. It wasn't unique about it, you provide conditions and 35.1000 guidance. This a unique aspect that was occurring in 2008. We didn't have enough authorized users, and now we believe, we're reaching out to find out if that is still a unique aspect for Yttrium-90. If it's not a unique aspect that needs a specific condition under licensing guidance, we want to bring it back towards the tendency of R-35 regulations.

That is the main reason the working group is looking at it, because it's unique and we have an alternative pathway specific to one modality, is time consuming for our regions and for agreement states for licensing purposes to follow up on these and to make sure the individuals who are in our licenses still have training that's required to follow up and make

sure that they have a manufacturer representative present for the first three cases instead of just doing one and then starting to treat patients on their own. So there is time components because it's unique for one modality.

CHAIRMAN ALDERSON: Yes, Dr. Dilsizian.

MEMBER DILSIZIAN: I thought that the better explanation was your slide number 9, which said that if we are really trying to evaluate treatments or prevention of ME, you need a physician by you. I like that. I thought that was best explanation rather than all the other things you mentioned.

DR. TAPP: And that's specific for the work experience part.

MEMBER DILSIZIAN: So I think that would be the case you're making, why you like AU, rather than industry representative. It's nice if some initially, you know, and you use the trainer, but once you have enough experience I like this. Those are the two important points to be able to eliminate that alternative pathway.

CHAIRMAN ALDERSON: Yes, Dr. Langhorst.

MEMBER LANGHORST: Dr. Tapp, you mentioned about this alternative pathway that our recommendations had suggested that maybe you want to

put more requirements in the manufacturers' training. Is that no longer being considered?

DR. TAPP: The work experience section can be provided by a manufacturer representative. We were not suggesting getting rid of the work experience parts that aren't included here, which is the operation of the device and other components associated with the work experience. Those will still be provided by the training that the manufacturer representatives give. But from the recommendation, these two specifically, we thought physicians would be important.

And it can still be a manufacturer representative, it just needs to be a physician who has a status. Our understanding is the manufacturers do have physicians who sometimes provide this training.

MEMBER LANGHORST: As we reviewed the draft licensing guidance, I know we were concerned about new licensees and where would authorized users come from, and if an authorized user is allowed through the manufacturer, I mean I know they already do that, I think that would be very helpful so that it does not negate a new licensee coming on board to be able to get this training and try to find out who's going to

be an authorized user to come train me on this. So that was one of the reasons why we didn't feel it was wise to totally get rid of that pathway.

CHAIRMAN ALDERSON: Chris, did you have your hand up?

MEMBER PALESTRO: Yes. I remember when this discussion came up last year and I had reservations about it then and I still have reservations. I think to an outsider looking at the situation when you have the manufacturer participating in the training, it's a conflict of interest. Real or perceived, it's a conflict of interest.

My own personal opinion is I find it hard to believe that in ten years there aren't enough AUs throughout the country that can train other individuals to do it, and if there aren't many AUs, or a lack of them, then maybe the procedure's not performed all that often. So that's a possibility.

I certainly don't disagree with trying to determine how many AUs are out there and whether there is a sufficient number, although we've been through that experience with our delving into training and experience and haven't gotten very far with it so again, I will reiterate my opposition to this on the basis of a conflict of interest.

CHAIRMAN ALDERSON: Yes.

MEMBER WEIL: I think there are two conflicts of interest, the one that Dr. Palestro explains eloquently but there's also the conflict that hospital A is not necessarily going to be interested in training physicians at hospital B to provide a service that they would rather have a monopoly on. So in terms of patient access and the ethics of that, it's a very complicated equation.

CHAIRMAN ALDERSON: I'd also point out in just an analogy, and this is an intermediate question, not falling really hard on either side, but we have spent a number of hours at this table arguing the availability to patients, access availability of things like Bexxar, and the big issue that comes up there is not what's happening in the big cities, it's what's happening in the rural community.

And so here, it's a situation whereby eliminating an alternate pathway, it would be wonderful to know the geographic location of all of these things. You might be exactly moving right into another repeat of something like Bexxar where we'll later have complaints that people who live in rural don't have an AU there and they have to travel into the city to get these microspheres.

DR. TAPP: And I will state that we are seeing smaller and smaller clinical-based settings now starting to use Yttrium-90 microspheres. It's starting to be seen more often. It is becoming a more prevalent procedure for intervention radiologists now, with all the new forms of oncology. And it is being trained in a lot of residency programs. But we may not be there yet. That's why we want to reach out to the public, to make sure there is not a hole.

CHAIRMAN ALDERSON: Yes. Good. Yes, Dr. Langhorst.

MEMBER LANGHORST: I do want to say I think it's a wonderful idea that this licensing guidance is going out for public comments, so thank you very much.

CHAIRMAN ALDERSON: Further comments from the committee? Further comments from the audience? Does anyone like to speak who is here today? Is there anyone on the phone who would like to speak to this issue?

MR. OUHIB: Yes, hi, this is Zoubir.

CHAIRMAN ALDERSON: Yes, Zoubir, please.

MR. OUHIB: Just a comment. I think, maybe I can only speak for one manufacturer, is that there is a training for authorized users. There is a training course that people have to attend and acquire

adequate training. So I think, and the other thing is I recall at one of the meetings, at the most, maybe the last meeting, but there was a medical event where a manufacturer representative was actually present during the first case where a medical event had occurred.

So that's another concern that I actually have. So maybe going to a training course where they have done many, many cases and they can talk about possible events and all that, would be better than having a manufacturer representative come in and train the staff. So that's just my two cents.

CHAIRMAN ALDERSON: Thank you, Zoubir. Any other comments from people who are on the phone today? Hearing none, then we're at a point where we should decide whether in fact this proposal to move ahead with an alternate pathway as this report, is approved.

DR. TAPP: You could make a motion. I don't think one is necessary --

(Simultaneous talking.)

CHAIRMAN ALDERSON: That's already been decided?

MR. OUHIB: Yes, right here.

DR. TAPP: Yes, and once we're done with the public comments we will evaluate them, update the

licensing guidance as necessary, and then send it back, probably, to ACMUI for peer review and that's where I would expect --

CHAIRMAN ALDERSON: All right.

DR. TAPP: When you actually have the data from the public comments.

CHAIRMAN ALDERSON: So you're simply informing us of what's going to go forward, and if it, after you've got the data, we'll hear about it again.

MR. BOLLOCK: Yes, we still owe the ACMUI a report.

CHAIRMAN ALDERSON: All right. Any other comments from anyone? Hearing none, thank you very much.

DR. TAPP: Thank you.

CHAIRMAN ALDERSON: That brings us to Dr. Palestro and Dr. Metter, who will bring us up to date on the communications with the medical community. Some of you may know, on some of the older revisions here my name was on that but I discussed it with Drs. Palestro and Metter and we decided that really, it's been their work after we brought it forward here, so that they should make this report.

MEMBER PALESTRO: Thank you, Dr. Alderson. Our inaugural sessions were held in May 2017 in

Washington D.C., the annual meeting of the American College of Radiology, and then again at the Society of Nuclear Medicine and Molecular Imaging annual meeting in June in Denver, Colorado.

At the inaugural sessions, really, we ran essentially the same session consisting in overview and an explanation of the ACMUI by Darlene. I touched on some of the current topics and we also had an NRC staff member to discuss regulators. And for the American College of Radiology meeting it was Mr. Bollock, and for the Society of Nuclear Medicine meeting is was Dr. Daibes Figueroa, and then we concluded with a question and answer session.

These inaugural sessions, they were really our first go-round. We had modest turnouts in terms of attendance but we did have good dialog, good interaction between the panelists and the attendees. I think part of the issue in terms of attendance, or ways to improve attendance, were that they weren't CME or SAM sessions, and I think nowadays at meeting such as this you really need to try to organize the courses and the sessions that CME and if we can, preferably, is SAM, so-called Self-Assessment Module sessions. I think that will improve the attendance.

I think another potential issue with

attendance, particularly with the American College of Radiology, was the timing of the session. We held it later on in the week, and apparently many of the individuals who ordinarily would be interested in matters the ACMUI focuses on, those sessions were held primarily towards the beginning of the week. So we would look to go back and try to revise the timing.

And again, as I had just said, I think we need to organize these as, at the very least, CME and preferably SAM sessions. Dr. Metter has said she'd be gracious enough to write all the questions for the SAM session, and for that I thank her.

We also conceivably could come up with interactive scenarios, create issues, create situations, and identify resolutions with some sort of audience participation. We've also talked about maybe expanding to additional venues such as program director meetings at these larger meetings. I think I'd like to hold back on that until we get these initial sessions up and running and debugged a little bit more.

And now that we have a little bit more time this year, I know that the solicitations for sessions from the Society of Nuclear Medicine will be going out some time this month, but certainly in

advance you're welcome to send either Dr. Metter of me or I guess even Sophie, topics that you might consider of interest or concern that we could conceivably work into the meetings. So certainly any of your suggestions are welcome.

I just made some notes over the course of this meeting and I think some of the topics could be potentially very useful and I think would be of interest to attendees. Certainly accessing the NRC website would be very helpful. I found Sophie's presentation this morning very useful. Darlene's presentation of breast feeding yesterday. That has a lot of practical implications, as does patient release for I-131.

And for myself, I always take a lot of interest in the summary of the medical events, even though oftentimes there's a lot of detail missing, but I think if you look at them there are certain trends that most of these events tend to occur as a result of procedural failures of one sort or another, and it's the type of thing that you can go through that with the attendees and point out, are you doing identifications early, or you need to go back and look just to make sure, that sort of thing. The Y-90 I think also is another topic that would be useful for

discussion and presentation.

Then finally, I think these are all very good, but I really think it's very important that an NRC staff member be there, because we did have some questions that certainly neither Darlene or I could answer and it was very helpful to have the staff member there to clarify certain things.

CHAIRMAN ALDERSON: Good. Excellent report. I'm delighted that the two of you got together and really got this started and that you had a decent initial experience. Has anyone else actually reached out? We discussed at this meeting other ways that other people might reach out. Darlene, you have a comment?

MEMBER METTER: I just also want to comment that actually doing these sessions, going over the medical events was actually a very important time that we can say look, we're not, we're regulators but we're not penalizing you, this is for best patient care. I think that can help change the culture or the attitude that programs may have regarding regulators, and that we're here to help you do best practices, to help you to do value medicine, value-based medicine, good patient care. I think that would be a good focus on that rather than being penalized, being like okay, how

can you suggest that we change things? Maybe, like you said, make it an audience participation and let them come up with some of the ideas that maybe they could use at their place.

CHAIRMAN ALDERSON: Good. Would anyone else like to comment? John?

MEMBER SUH: Yes. On Saturday, September 23, I'll be speaking to the ARRO, which stands for the Association of Residents in Radiation Oncology. There's a panel meeting in San Diego, which is our ASTRO meeting, so they wanted an overview about what the ACMUI is, what we do, and the tact I was going to take was just to go through some of the medical events that have been reported, just to let them know that these are quality, safety issues you should think about in your practices.

These are, most of the individuals who attend the ARRO meeting are graduate residents, so it's a session, I believe it's going from 9 to 5pm, just like job search and what to look for, etc.

CHAIRMAN ALDERSON: It's a full day session?

DR. SUH: Full day session, Saturday.

CHAIRMAN ALDERSON: All right. So you'll have like one session, or one --

MEMBER SUH: They're giving me, I think, 20 minutes to go through things. I'll speak fast.

CHAIRMAN ALDERSON: And the acronym for ARRO, is it two As? A-A-R-R --

MEMBER SUH: A-R-R-O.

CHAIRMAN ALDERSON: Just one A.

MEMBER SUH: Yes. One A. One A, R-R-O.

CHAIRMAN ALDERSON: Very good, well, that's excellent. That's an excellent additional example.

MR. BOLLOCK: And Lisa Dimmick, our new medical team leader, will actually be going to ASTRO so she can --

CHAIRMAN ALDERSON: Oh, Lisa will be there for that session?

MS. DIMMICK: I don't know if I'll be there. I can support that session.

CHAIRMAN ALDERSON: Good. Excellent. I see someone at the microphone.

MS. KUBLER: Hi, yes, Caitlin Kubler with the Society of Nuclear Medicine and Molecular Imaging. I'd be happy to work with Dr. Palestro. We've been in email contact about setting up a SAM session at this year's annual meeting. It'll be in Philadelphia, so I think we'll have more policy-oriented people there. We can also survey some of our membership in those topics

that you mentioned, I think would be very helpful to talk about.

I would say on the medical event reporting topic, that you just kind of put it in perspective because sometimes we have some people that attend the meeting that they kind of blow things out of proportion and the hotel workers, radiation trash, that issue kind of quickly got blown out of perspective so I would just say in that area you might want to keep it in perspective.

But I'm happy to work with you and I think we can do more advertising, we can put something in our newsletter and on the website. I think that would also help increase attendance. Some of our people didn't know until later about the event. I think that would definitely help.

CHAIRMAN ALDERSON: Excellent. That's great.

MEMBER PALESTRO: Question for you. Do you know whether requests for proposals is going to be issued? I haven't seen anything yet.

MS. KUBLER: No, I mean, because they're doing a new structure this year as you saw, so it might be a little later. It might not be until towards the middle of October, actually. But I can reach out

to you if we have anything further.

MEMBER PALESTRO: Okay.

CHAIRMAN ALDERSON: Dr. Metter?

MEMBER METTER: I'd be happy to share the slides. It would be the general overview, I'd be happy to share the slides for that so you don't have to redo it.

MEMBER SUH: That would be great. From my hotel room I took a picture of the NRC building.

(Laughter.)

MEMBER METTER: Perhaps there could be a repository where we can maybe pull some of these together so we can share, something like that might be helpful.

CHAIRMAN ALDERSON: Excellent. Very good. Yes, Mr. Green.

MR. GREEN: I can just say, as an attendee of the SMMI session that Dr. Palestro and Dr. Metter presented, it was very well received and there was good dialog, and interactions that occurred after the presentations were done. There was still lingering and discussing and it was great to have representatives from the NRC there, so I think that the community was very receptive and would like to see it again.

CHAIRMAN ALDERSON: Excellent. Good. I'm

glad to get that positive feedback from this program, and I know when we discussed this the other time, several members of the ACMUI sitting around the table pointed out that they already had, not specific representatives coming to a specific session, but they already had aspects of their programs which they thought were fulfilling this need. But again, I would ask you all to consider whether in fact your organizations, whether this might be an interesting thing to consider doing on a periodic basis.

Yes, Dr. Ennis?

MEMBER ENNIS: So I think making it into a SAM is a great one because we too have had challenges sometimes when we've done these types of things at ASTRO, getting all our attendance. So if you are able to develop that I would love to be able to share that.

CHAIRMAN ALDERSON: The kind of very things that radiation oncologists would need in SAM will be --

MEMBER ENNIS: Yeah. And it would really help me kind of figure out how to do that.

MEMBER METTER: I think the first SAM would be really interesting, because do they know what it stands for? Some basic things, you know, and every year you just make it a little more.

CHAIRMAN ALDERSON: Okay, well, that's excellent. Any further comments on this particular initiative? From the ACMUI? Any other comments from the audience here? Anybody on the phone who wishes to comment. Hearing none, I --

MR. OUHIB: Hello?

CHAIRMAN ALDERSON: Yes, someone on the phone?

MR. OUHIB: Yes, this is Zoubir.

CHAIRMAN ALDERSON: Zoubir.

MR. OUHIB: Yes, can you hear me? Just to give an update, I actually had done a presentation at the ACR for the ACRO committee on Category III and intend to give an update at the upcoming ASTRO meeting. We also did, with the help of Duncan White and Katherine Tapp, thank you, both of you, an article on the BrachyBlast which is a newsletter from the American Brachytherapy Society, to sort of inform people where things are at on Category III. We certainly intend to keep people informed on that.

I think the purpose of that is there are people who unfortunately cannot make it to the meetings to hear the presentation, but they certainly can access the newsletter. And we did a SAM session on medical event at the AAPM, and that went very well.

CHAIRMAN ALDERSON: Well, good. So that's another example of things that are happening. That's excellent. Thank you, Zoubir. Any other comments from anyone on the phone? Hearing none, and looking at the agenda, I believe that we have completed the activities from the morning. The afternoon activities, which begin at 1pm, we'll look at those in that specific order because people are coming specifically for this honorary presentation to Frank and then special presentation to Dr. Langhorst. So we will reconvene at 1pm. Yes?

MS. HOLIDAY: Dr. Alderson, if you don't mind, since we're running a little bit early, my proposal if the Committee will accept it, is for us to go ahead and discuss the spring meeting date so we can get that out of the way?

CHAIRMAN ALDERSON: That would be great. Very good. Sophie would like to discuss a spring meeting date, the item called Administrative Closing, which is now listed at 3pm.

MS. HOLIDAY: Okay, for this portion of the meeting I just want to go ahead and propose some tentative dates for the spring 2018 meeting. As many of you are aware, our vice-chairman, Dr. Pat Zanzonico, will be rotating off of the Committee after

serving his two terms, eight years, and so that is something that we would like to give some consideration to. Dr. Zanzonico's last date of his term is actually March 8. According to the lovely document you see on your screen, the only day that would work for Dr. Zanzonico to be present at the meeting would be March 1st and March 2nd.

Staff provided a meeting doodle to the Committee previously, a couple months ago, to poll the Committee for their availability and as it turns out, the 1st and the 2nd there were no conflicts so I would like to confirm with the committee there are any other members that have conflicts with Thursday, March 1, and Friday, March 2.

MEMBER ENNIS: I could accommodate, but I do have a conflict that would require - so if I'm the only one I'll make it work, although I may not be able to be present for the entire day.

MS. HOLIDAY: Okay.

CHAIRMAN ALDERSON: Anyone else? Everyone else okay with that, looks like? Looks like that's it.

MS. HOLIDAY: Okay. So with that being said, if the Committee will have March 1 and 2 as their first choice for the spring meeting. The next thing is for us to choose a backup date, as that's

something that we always do. All of the tentative backup dates, I can tell you there was at least one member that had a conflict, so it's just going to be a pick and choose which date you're okay with.

For March 12 and March 13, I saw that Dr. Suh had a conflict and of course Dr. Zanzonico's term will be over, so the 12th and 13th poses as a conflict for Dr. Suh. Is that date okay with the rest of the committee? Okay, I'm seeing head nods. What about the 14th and 15th? Does anybody have any conflict on the 14th and 15th?

Okay, if there are no conflicts for the 14th and 15th, my suggestion would be that we put the 14th and 15th as our second-choice backup date, with our first choice being Thursday March 1 and Friday March 2.

CHAIRMAN ALDERSON: When we usually discuss this for a meeting, we usually talk about the fact that we might have an opportunity to meet with the commission, and that has an impact on our choices. You haven't mentioned that yet, so how does that --

MS. HOLIDAY: Correct. You're beating me to the punch, Dr. Alderson. And as Sue says, you're getting in my mind, which is a scary thing.

(Laughter.)

MS. HOLIDAY: As a result of this discussion with staff, we will run the request up through the management chain to poll the Commission. The Commission has the calendar agenda planning meeting every month that they perform, so staff will propose those dates with the caveat that our vice-chairman will be rotating off so the preference would be for the Commission, if they can accommodate, to have their commission meeting with the API on either March 1 or March 2. We will absolutely provide that information to the Commission.

CHAIRMAN ALDERSON: Good. All right. Thank you. Are there any other items that need to be discussed in what is currently called Administrative Closing?

MS. HOLIDAY: We could go over the recommendations and actions chart, if you want to go ahead and do that.

CHAIRMAN ALDERSON: I think it would be better for us just to clear this item so that --

MS. HOLIDAY: Sure. If you will bear with me, this is a very rough draft, these are the action items that have taken place over the past two days of this meeting.

The first one is where Mr. Dan Collins

proposed a staff action to engage discussions with the Organization of Agreement States to find a way to centralize medical event reporting from the agreement states. That's an action item. You have something to say?

MR. BOLLOCK: Yeah, just want to add to that. I said yesterday that two of the things we used to pass on, events and evaluations is not a best presentation, and Dr. Ennis' presentations, we can do a better job especially for Dr. Ennis and his subcommittee for the events. We'll try to get more information because sometimes, like I was saying, there are inspection reports and things like that that aren't necessarily just off of NMED.

And so we will strive, staff will strive, to give you more, better information at least if it's a case where a medical event was reported and after inspection and a review from the licensee it was a no, never mind, it really wasn't, this was okay, if we have that we can feed that. So we will strive to get that subcommittee the best information possible so we can try to have these presentations be as useful and have as much information as possible.

CHAIRMAN ALDERSON: Thank you.

MS. HOLIDAY: I decided to do my

presentation from the computer. For items 13 through 19, these were recommendations and Dr. Langhorst is set to make a report related to the medical event reporting impact for medical licensees patient safety culture, so I just reiterated them on the screen.

Of course for item 20 this is where the full committee unanimously endorsed that subcommittee report with the amendment to support the concept of the pilot program with number size and duration to be determined at a later date, as well as to include the patient intervention subcommittee recommendations as an addendum. Are there any questions or comments related to items 13 through 20?

CHAIRMAN ALDERSON: Anyone have a comment, question? Seeing none, I think the people are satisfied with how those were presented.

MS. HOLIDAY: Okay. Item 21 had to deal with the Nursing Mothers Guideline Subcommittee Report. The Committee decided that we will hold a public teleconference in the near future to discuss amendments to that report. Amendments will include, but are not limited to, a suggested time frame for providing written and oral instructions to patients who will stop breastfeeding altogether, and consideration to revise the radionuclides to be non-

chemical specific. Are there any questions or comments on item 21?

CHAIRMAN ALDERSON: Apparently there are none.

VICE CHAIRMAN ZANZONICO: I guess there is one, I'm sorry, just in terms of wording. I think the second suggestion was they be non-pharmaceutical specific. Rather than non-radionuclides specific.

MS. HOLIDAY: Sure. Thank you.

CHAIRMAN ALDERSON: That's a good change.

MS. HOLIDAY: Okay. So then item 22 through 27 are the recommendations that are contained in the ACMUI comments on the patient release draft paper subcommittee report. Again, just add that Dr. Langhorst's subcommittee, the recommendations are all just reiterated here on our chart. Item 28 is where the full committee unanimously approved that patient release subcommittee report. Are there any questions related to these items?

Okay, seeing none, that brings us to the last and final recommendation, which is that the ACMUI agreed to hold a future public teleconference to discuss amendments to the physical presence requirement for the Leksell Gamma Knife Icon subcommittee report. Amendments will include the

distinction between 'an' or 'the' AU or AMP, the AU presence for re-initiation of procedure following interruption, and possible incorporation of changes to the physical presence requirements for the Leksell Gamma Knife Perfexion. Are there any questions or comments related to item 30?

MEMBER ENNIS: Sophie, there's also the issue about whether the icon will be specific to the mask or it would be for all icon users.

MS. HOLIDAY: Sure. Are you okay with, whether the physical presence requirements will be limited to the frame-based or frameless-based option for the Leksell Gamma Knife icon.

CHAIRMAN ALDERSON: That's okay.

MS. HOLIDAY: Then the only other item I did not add was of course our tentative dates for the spring meeting, which will be March 1 to March 2 as the first choice, and the second choice as March 14 and 15. Does the Committee have any further questions or comments related to any of the items on this chart? Dr. Ennis.

MEMBER ENNIS: I have, going back to the one item about the --

MS. HOLIDAY: Patient oral instructions?

MEMBER ENNIS: Exactly. You didn't really

mention it today so it's more of an editorial comment that we, that special may include who is supposed to be giving that education.

MS. HOLIDAY: Sure. At this time I would just suggest leaving it as this, because I have --

MEMBER ENNIS: Yes, I just wanted to make the editorial comment, not something to change.

MS. HOLIDAY: Sure. Thank you.

CHAIRMAN ALDERSON: Any other comments on Sophie's draft? Hearing none, I think we've finished with this particular discussion, and that means we are ready and right on time to adjourn, and so there will be a 90-minute break and that is because of the special character of the events that are to follow and people that are scheduled to be here at that specific time. We will reconvene at 1pm.

VICE CHAIRMAN ZANZONICO: Just before we leave, for this afternoon, will we forgo the break scheduled from 2 to 2:30, is that correct?

CHAIRMAN ALDERSON: That is correct.

VICE CHAIRMAN ZANZONICO: And so we should end by 2:30.

MS. HOLIDAY: 2:45.

MR. BOLLOCK: Or perhaps earlier, right? I think you're suggesting that we push on the open

forum, because this is the closed session, and that will be up to the chair or vice chair, if you'd like to move up the open forum and --

CHAIRMAN ALDERSON: We'll move up the open forum and we'll see what happens. If nothing much happens we'll go even earlier. Okay. Thank you. We'll be back at 1pm for the special presentation.

(Whereupon, the above-entitled matter went off the record at 11:25 a.m. and resumed at 1:04 p.m.)

CHAIRMAN ALDERSON: We're ready to get started. Mr. Dapas, please.

MR. DAPAS: Okay. For those of you that haven't had a chance to meet yet, I'm Marc Dapas, and I'm the Office Director for the NRC's Office of Nuclear Material Safety and Safeguards.

I apologize for the forced nature of my voice here. I think I overindulged in enthusiastic cheering for the Navy football team this weekend. It was my 35th class reunion. So I apologize that my voice is not up to 100 percent. So, please bear with me.

But let me start out by saying that I am honored to have the opportunity today to say a few words commemorating the life and significant

contributions to the NRC of Frank Costello. It is so nice to have his wife Wanda join us today.

Thank you for making the trip, Wanda.

MS. COSTELLO: Thank you.

MR. DAPAS: As many of you are aware, Frank was appointed to the Advisory Committee on the Medical Uses of Isotopes, or ACMUI, as the Agreement State Representative in May of 2014. Before joining the committee, Frank served 30 years with the NRC in Region I as a materials license reviewer, inspector, supervisor, and executive.

While I had met Frank earlier in my career, it wasn't until I became the Deputy Regional Administrator in the NRC's Region I office in 2005 that I really got to know Frank. We connected right from the start.

Frank impressed me with his welcome knowledge, experience, and material regulatory perspective, as well as his no-nonsense approach to matters. I could always rely on Frank to tell me exactly what he thought, but sometimes it was not necessarily what I wanted to hear. But Frank always conveyed his views in a respectful manner.

Frank was extremely dedicated to the agency's public health and safety mission. I learned

a great deal from him; lessons that I've applied throughout my career.

After retiring from the NRC, Frank went to work in the Pennsylvania Bureau of Radiation Control with Dave Allard and others. Frank was recently recognized with the Organization of Agreement States' Hall of Fame Award for his contributions to both the NRC and the Agreement States. He strongly believed in the National Materials Program, so much so that he applied to serve on the ACMUI.

As the Agreement State Representative on the ACMUI, Frank did what he did best: he brought people together. Frank would attend the annual Organization of Agreement States meeting where he would keep the States well-informed about his role on the Committee and how he served as the liaison and advocate for his fellow Agreement State employees.

I'm told it's typical for most ACMUI members to remain a bit more reserved during their first few Committee meetings before volunteering to serve on subcommittees or giving various presentations. Frank was not your typical member, or so I've been told. He was engaged from his very first meeting.

Frank's expertise in the field of health

physics was broadly recognized. His familiarity with the NRC's policies and in-depth knowledge of regulatory issues with regard to 10 CFR Part 35 were essential in informing the ACMUI about how regulatory and policy changes could impact the Agreement States, which constitute 87 percent of the licensees in this country.

Frank also brought forth issues and concerns from the Agreement State community, including the need for alignment on the interpretation of patient intervention, as well as the compatibility categorization for various provisions of the Part 35 regulations. Frank briefed the Commission in April of 2015 on the ACMUI's comments pertaining to licensing guidance for the yttrium-90 microspheres brachytherapy.

In large part due to the presentation, the NRC staff issued a revision to the guidance in February 2016.

Frank also served on numerous ACMUI subcommittees where he shaped many subcommittee views on important matters. These included major revisions to 10 C.F.R. Parts 30, 32, and 35 pertaining to the medical use of byproduct material; material event reporting criteria for the Yttrium-90 microspheres

brachytherapy; impacts of decommissioning funding plan requirements on the use of Germanium-68 and Gallium-68 generators for medical purposes; revisions to licensing guidance for radioactive seed localization; yttrium-90 microspheres; and the NorthStar molybdenum-99/technetium-99 generator, also known as RadioGenix; patient intervention; the advance notice of proposed rulemaking on potential changes to radiation protection requirements to regulations in Part 20; the Annual Report of the Medical Events; and enhancing communications between the medical community and the regulator.

So these are just some of the important matters that Frank engaged on as a member of various ACMUI subcommittees.

I can say without a doubt that Frank provided significant input to all of the regulatory products and activities that I have just mentioned. He had lasting impacts on the Committee, the NRC, and I'm sure the Agreement State Program in Pennsylvania. We are most thankful to have known Frank and to have had the opportunity to work with him.

At this time I would like to present you, Ms. Wanda Costello, with a few tokens of our appreciation and utmost gratitude for your husband's

work and dedication to excellence.

First, let me present you with a flag. This is a flag that was flown over the U.S. Capitol in Frank's honor. And if you can come up with me, actually we'll get a picture of you in front of the flag. In front of this flag.

(Photos taken.)

MR. DAPAS: The certificate I have says, "The flag of the United States of America. This is to certify that the accompanying flag was flown over the United States Capitol on April 18th, 2017, at the request of the Honorable Benjamin L. Cardin, United States Senator. This flag was flown for Mr. Francis Costello in honor of your retirement after 30 years of federal service."

I also have a Certificate of Appreciation signed by our Chairman Kristine Svinicki.

"Certificate of Appreciation honoring Francis M. Costello in recognition of 3 years of service and leadership to the Advisory Committee on the Medical Uses of Isotopes, which resulted in significant contributions to the work of the U.S. Nuclear Regulatory Commission." Dated the 21st of March, 2017, Kristine L. Svinicki, Chairman.

And, lastly, we want to present you with a

gold lapel pin that has the United States Nuclear Regulatory Commission emblem on it. Thank you so much.

MS. COSTELLO: Thank you.

MR. DAPAS: Thank you for making the trip and thank you for being here.

MS. COSTELLO: Thank you so much. Thank you.

(Applause.)

MR. DAPAS: I'll turn it back over to you, Mr. Alderson.

CHAIRMAN ALDERSON: Thank you. Thank you, Mr. Dapas.

So, I will just make a few opening comments at this particular part of the sessions before the Committee and other people here from the NRC make their comments. So, I will turn it open to the remainder of you in just a few seconds.

I wanted to reiterate to Mrs. Costello how much we all appreciated working with Frank. He was a great colleague. And we do miss him, not only in his professional but also in a personal way.

He did contribute to the ACMUI from the very beginning. I started at that same, very same time. And I thought he was a veteran. Well, in fact

he was a veteran of 30 years in the NRC. But he really moved right in and began to contribute from the beginning.

He knew about the Agreement States. The way that Frank would communicate what they wanted, the Agreement States, to us, and the fact that he would go back to the OAS meetings and talk to them about what we were doing is a forerunner of what we're trying to do ourselves right now in reaching out to the various specialist societies with which we work. He really knew NRC policy and procedure. He was always forthright. He was accurate because he knew policy and procedure.

And he also, as you said, knew how to bring ideas and people together. So, he didn't cross the boundary where he was no longer correct, politically correct. People would be able to listen and relate to what he said.

I remember him frequently recommending how to use 35.1000 instead of going to rulemaking. You know, get it out there in guidance. He must have said that again and again and again. So he was a very practical man and a good man. And I personally enjoyed working with him very much. And I'm sorry he's not with us now.

Thank you for being here.

I would like to invite any others who would like to comment. Pat Zanzonico.

VICE CHAIRMAN ZANZONICO: I'm very glad to make a few comments.

And like many of us on the Committee, I first met Frank as a member of the Committee. And as Dr. Alderson has said, we were really impressed by the depth and breadth of his knowledge; it was really amazing.

But I think far more importantly, he was such a friendly person and had such an infectious enthusiasm about everything. You felt like you knew him your entire life. So it really was a pleasure and a tribute to know him and to work with him.

And as Dr. Alderson and others have said, we really miss him very much.

MS. COSTELLO: Thank you.

MEMBER ENNIS: Just echoing those comments.

I came on shortly after him. And really similar perspective. To me he exemplified some of the traits that essentially are exemplified but sometimes are in short supply: integrity, honesty, humility, and dedication. And he will be missed.

MS. COSTELLO: Thank you.

MEMBER PALESTRO: I didn't know Frank very well but I'm really sorry that I didn't get to know him. But over the short period of time I've been with the Committee I've learned a great deal. And I do, I do truly miss him. And I send my condolences to you and to your family.

MS. COSTELLO: Thank you.

MEMBER WEIL: I really valued Frank's presence on this Committee. I always felt that there was at least one other patient advocate in the room when he was here.

MEMBER LANGHORST: I have remarks in my talk.

CHAIRMAN ALDERSON: Oh, in your talk later. Very good.

MS. HOLIDAY: Dr. Alderson, if I may?

CHAIRMAN ALDERSON: Please.

MS. HOLIDAY: So, I think my relationship with Frank can be summed up as I knew his number by heart.

(Laughter.)

MS. HOLIDAY: There are only a few members on the Committee whose phone numbers I knew by heart, and Frank was one of the two. Frank was not shy about

calling me at all, or rather any of the NRC staff or management, conveying his thoughts, his comments, his perspective for the impact of NRC's regulations as they would have it on the Agreement States.

And Frank really was the people's man. Not like that.

But, you know, I really appreciated having Frank on the Committee. His knowledge was just incomparable. And when Marc said that he brought people together, he truly did bring everybody together.

I remember Frank's very first meeting, and it was Dr. Alderson's first meeting, and Dr. Ennis' first meeting, and I want to say Dr. Dilsizian's. And it really blew staff away to hear Frank just pipe up. Like Marc said, you know, it's not common for ACMUI members to really engage in the meeting because they're testing the waters out. But Frank was a person that just dove right in.

And he was not shy about offering his two cents. He was not shy about when Josie was our division director, calling Josie up and telling her if staff was doing something wrong, or if staff was doing something right, which we appreciated. But, you know, I can tell you on behalf of at least the medical team,

we were so appreciative of Frank.

You know, from his former days as an NRC staffer and manager, as well as his contributions on this Committee. I attended the OAS meeting where Frank gave the presentation, his initial presentation in Chicago where he really did advocate for his fellow Agreement State employees to reach out to him because he was their liaison for the Committee. He was another way that Agreement States could reach NRC staff without going directly to the NRC staff. He brought those perspectives together.

And I can only say thank you.

MS. COSTELLO: Thank you.

CHAIRMAN ALDERSON: Are there any others in the room who would like to comment? Dr. Howe.

DR. HOWE: I just want to say a few words.

First of all, it was fun working with Frank. You never knew what to expect. It was always a good time. And he was always looking out for those below him and he was thinking about those folks that were new to the field.

I run the NorthStar group. We have a representative from Pennsylvania's group there because Frank recommended her. Said she's really interested in this. You need to get her on your Committee. And

we did.

And so Frank was always looking out for the people coming up in addition to all of the really important things that were going on that he was working on every day.

So, I miss Frank. Thank you.

CHAIRMAN ALDERSON: Any others who would like to speak.

(No response.)

CHAIRMAN ALDERSON: Back to you, Dan.

MR. COLLINS: Thank you, Dr. Alderson.

So, Wanda, again thank you for coming today. And like everybody else, I'm sorry for your loss.

MS. COSTELLO: Thank you.

MR. COLLINS: I didn't have a chance to work as closely with Frank as some of the others here. When I transferred up to NRC Region I he had already retired. But, you know, like we heard from Sophie, he wasn't shy about calling. And it wasn't always to, you know, to talk necessarily about a particular issue, but sometimes it was in an umbrella of a particular issue that he would kind of provide mentoring from afar for me, because he knew that I came from a reactor background and I didn't have a

materials background.

And he was very helpful and very diplomatic in how he engaged me and to help steer the direction of my thought into a new regulatory framework.

One of the things that I noticed was that for me he was kind of teaching through analogies. And I didn't always understand it at first because it would be something about the Phillies game in 1968.

(Laughter.)

MR. COLLINS: And I'd have to think about it. But it would be like days or weeks later when I'd say, okay, there's a nugget in there. And he was trying to tell me something. And once I understood the nugget, you know, it was there that I understood Frank's genius.

So I miss Frank.

MS. COSTELLO: Can I say something?

CHAIRMAN ALDERSON: Please.

MS. COSTELLO: First of all, thank you all very much. Fran was -- I called him Fran -- Fran was in awe of all of you. He used to come home from the meetings and tell me there are all these doctors, all Ph.D.s. Have I gone crazy? Well, I'm not, and they are.

So, he appreciated all that you brought every day. And this is very meaningful to me. And I told Josie I was going to cry. And I just want to say thank you very much.

Thank you.

CHAIRMAN ALDERSON: Thank you.

DR. PICCONE: Can I pick up from her, please.

I knew Frank for over 30 years as a colleague, as a mentor, as my big brother when I first joined the agency, and as my friend. Frank loved this Committee. He loved the work of this Committee, which is why he was so engaged with this Committee.

And I can tell you that that big, round, smiling face is looking down right now and enjoying this recognition because he loved this work.

So thank you very much.

MS. COSTELLO: Thank you. That's true. And I've known Josie all that time.

DR. PICCONE: And we share grandchildren.

CHAIRMAN ALDERSON: Thank you very much. We all appreciate thank.

MS. COSTELLO: Thank you.

CHAIRMAN ALDERSON: Appreciate you being here.

MS. COSTELLO: Thank you so much.

CHAIRMAN ALDERSON: That brings us on to the next portion of the meeting which is a presentation to Dr. Langhorst. This will be Dr. Langhorst's last meeting with the committee.

And my schedule indicates that these comments will also be made by Mr. Dapas. But if that's not correct then we will -- Mr. Dapas is ready. Very good.

MR. DAPAS: Well, thank you. I appreciate the opportunity to share a few thoughts with you.

Dr. Langhorst has served on the ACMUI since September of 2009. And after her first term on the Committee ended she was renewed for a second term in 2013.

Dr. Langhorst briefed the Commission on several important matters during her time on the committee. These included NRC resources devoted to the regulation of medical uses of byproduct material; general views on the regulation of medical uses of byproduct material; and source tracking for Category 3 sources and its impact on medical use, a subject to which I've had the opportunity to devote a considerable amount of effort, and a very important topical area.

Dr. Langhorst's physics expertise, familiarity with the NRC's policies, and her in-depth knowledge of the regulatory issues with regard to both 10 CFR Part 20 and Part 35 have enabled her to significantly contribute to the Committee's deliberations on a variety of subjects.

Dr. Langhorst is unique in that she is one of two members on the committee who is currently working for an NRC licensee. As such, her input was particularly valuable to the committee in terms of an appreciation for the practical implications of proposed regulatory requirements on NRC licensees.

In considering a number of high priority issues, the ACMUI has benefitted significantly from Dr. Langhorst's expertise. For example, she has played an important role in the Committee's deliberations on a major revision to Part 35; changes to the medical event report requirements for permanent brachytherapy; as well as reporting criteria for events involving the yttrium-90 microspheres brachytherapy; the licensing of radium-223 dichloride; the review of petitions for rulemaking involving hormesis linear no-threshold concepts; training and experience requirements for all modalities; licensing guidance for the use of Germanium-68/Gallium-68

generators; and the annual reporting of medical events.

Dr. Langhorst also served as chair to give ACMUI subcommittees, namely, Revisions to the Abnormal Occurrence of Reporting Criteria; the release of patients administered radioactive materials; the proposed rulemaking on potential changes to the radiation protection regulations in 10 CFR Part 20; revisions to NUREG-1556, Volume 9, pertaining to consolidated guidance of our medical use licenses; and medical event reporting and impact on safety culture.

As the contributions I have mentioned reflect, Dr. Langhorst has been an invaluable member of the ACMUI. At this time I would like to present you with a few tokens of our appreciation, and gratitude for your eight years of dedicated service.

Flag of the United States of America, this is to cert -- "This certificate is to certify that the accompanying flag was flown over the United States Capitol on July 26th, 2017. At the request of the Honorable Chris Van Hollen, United States Senator, this flag was flown for Susan Langhorst, Ph.D., in honor of your retirement and end of term."

MEMBER LANGHORST: Thank you very much.

MR. DAPAS: I also have a Certificate of

Appreciation from our Chairman Kristine Svinicki "presented to Susan M. Langhorst, Ph.D., in recognition of eight years of service and leadership to the Advisory Committee on the Medical Uses of Isotopes which resulted in significant contributions to the work of the U.S. Nuclear Regulatory Commission."

In a personalized note, "Susan, thank you so much for your support to the committee's work. All the best to you, Kristine Svinicki."

(Photos taken.)

MEMBER LANGHORST: Thank you very much. I so appreciate it.

MR. DAPAS: Thank you for your service, Susan. Thank you very much.

MEMBER LANGHORST: Thank you.

(Applause.)

MEMBER LANGHORST: You want me up there or?

CHAIRMAN ALDERSON: It's your choice, wherever you'd like to be.

MEMBER LANGHORST: Oh. I'll stay here.

Now this is hard. Thank you, Dr. Alderson.

So, I know we're near the end and so I

tried to cut my remarks down to 90 minutes, so.

(Laughter.)

MEMBER LANGHORST: First-off, I want to thank Washington University for their support in allowing me to be at these meetings and working a few hours every week to do the work that I've done here.

I've had two previous ACMUI members at my university. And they said, Yes, it's two meetings a year. And maybe some telephone meetings. And, yes, they didn't tell me everything.

And I also want to thank some of my former employers because of what they taught me. I was first introduced as a medical use RSO at University of Missouri at Columbia. Aida would give me a big thumbs up on that.

And also, my work as Health Physics Manager at the University of Missouri Research Reactor where I learned the very important business of medical isotope production.

Please forgive me.

I want to thank the NRC, the medical team I had not known before, and really didn't know of too much. So, wow. I have been so impressed by you and your work and your challenges in trying to run a program with so few people. I've seen more firsthand

the challenges of changing commissioners and changing administrations, and so I know that always bring the responsibility of trying to make sure people know what the issues are.

So I applaud the medical team on keeping at that.

I will say that the security issues that we have to go through to get members on board, I hope that can be fixed. Because we can't afford -- yes, who can believe that that's not going to be me soon -- we can't afford not to have a full membership. And, as Marc mentioned, and maybe it was Dan -- I don't remember now -- when Dr. Alderson goes out of the committee there will be no NRC licensees represented at this table.

I hope that as we get new people on, that will be a consideration. I know it's helpful to have more people from east coast than it is necessarily west coast but, again, I hope those people out there who are on that half of the country will consider serving.

To the medical community and professional organizations, I encourage you to participate. Participate with this committee and, I'll put a plug in, participate on the patient safety work. Be

engaged with regulatory rulemaking because your voices make a difference. And work on those safety issues.

The balancing with patient care, we know that the medical history is very complicated. I think our president has thrown that out, too. And it is as many competing interests; we spoke of insurance earlier in this meeting. It's not easy but you have to keep working it.

ACMUI members, Darlene, don't be shy about asking questions, especially on process. And even if you know the answer, it's good to ask the question because some of the other members may not even know enough to ask the question. So that's what I became a lot more vocal at these meetings than when I started on that side of the table.

And, again, for you, too, the change in NRC commissioners, the change in NRC administration requires this group to revisit these concepts often sometimes, more often than you think. But make sure everybody's up to speed.

And even you have such a variety of perspective. And Frank was good at that. Frank was good at bringing everybody's perspective in. And I remember when he brought up on microspheres, it was he was inspecting and they were asking the question. And

he said, I didn't know how to answer it. And so he brought it here.

So we need to be familiar with the committee's past. I've already suggested to my replacement: read the past reports. Even if you're re-working that concept, re-read that, because that is a good place to see what the thoughts were previous.

And there's a list of old members. Reach out to those people who you know because they can give you some of the historical perspective too, as can several of the medical team.

On a personal note, I'm thankful for knowing all of you and calling you my friends. I've never, I would never have met you, most of you had I not been on this committee. And I'm sorry I'm a little weepy, but I will miss that very much.

And I thank you very much.

(Applause.)

MEMBER LANGHORST: I didn't do as good as Wanda.

(Laughter.)

CHAIRMAN ALDERSON: Sue, it's been a pleasure to have you on this Committee. And you brought such an enormous amount of knowledge and hard work and insight to this committee that has been

extraordinarily valuable to the committee and to the NRC. So, indeed, not only in a personal but in a very professional way you will be tremendously missed.

I don't know who that substitute is who is going to come in for you, but they have big shoes to fill, classical ones.

MEMBER LANGHORST: He's been speaking at this meeting, so.

CHAIRMAN ALDERSON: Oh, that's right, he has.

MEMBER LANGHORST: Yes. Mike Sheetz.

CHAIRMAN ALDERSON: That's right. Very good, that's right. Thank you very much.

All right. Well, thank you. Thank you very much.

MEMBER LANGHORST: Thank you.

CHAIRMAN ALDERSON: All right. I believe that that moves us into the next and final portion of this agenda. And as we said when we broke for lunch, we were moving the open forum up directly to follow Dr. Langhorst's comments.

And so now we will begin the open forum where it's on the table to discuss medical topics of interest that have previously been identified or discussed at this meeting. So the floor is open for

such discussion.

I hear the ACMUI is not raising any such issues. Is there someone in the room who wishes to raise such an issue?

No one is moving. Oh yes, here's a hand from Mr. Green.

MR. GREEN: I apologize. I don't always get up to speed on my acronyms. But there is a letter that came from one of the Commissioners when they approved Part 35 that was a working directive to staff to -- it was very interesting the wording that was used there. I think they basically challenged ACMUI to look at the training and experience requirements for, as you are the standing committee for all modalities, but I think they said, hey, you need to speed that up and let it go through 100 and 200, you know, they said it jumped 300. It was interesting the wording that was used there in the direction by the commissioners.

CHAIRMAN ALDERSON: Well, that, Dr. Palestro heads that Committee if you want to give a brief update on where that is.

MEMBER PALESTRO: Yes. The long and short answer of it is that we originally planned to present on 200 at this meeting, and progress through the 300

to try to debug our approach to the matter. But the powers to be decided that it was, it was more urgent to go right into 300.

And so we will have a preliminary report at the spring meeting. And then it's our intention to have a final report for the fall 2018 meeting.

DR. BOLLOCK: And, Dr. Alderson, I can address this. It was directed to staff, not to you. So, actually Dr. Palestro's subcommittee work is separate. What they were specifically looking at is for staff. It won't be easy.

Our plan -- and this is very new, we were just directed to do this -- but our plan is with our evaluation that they're asking for, which is an evaluation of radiopharmaceuticals, and either classes or specific radiopharmaceuticals to see by each individual, each specific class if that would change the training and experience requirements for, like, a ready unit dose and things like that.

So it's more of a change in our policy of how we evaluate, how we could possibly do that to see if that's feasible. It's another way to do things. It's just like the FDA looks at everything. They look at every single drug that comes out. We don't. We're raising participation right now to the 300 for

basically all drugs that they're talking about.

So there it's for us to evaluate if it's feasible to look at it in a different way and a more individual class. So that's the direction that we've been given.

So the goal is an evaluation to Commission at the end of August of 2018. Again, our plan is to come with our evaluation. And then likely an outcome would be to have ACMUI review our evaluation to make sure that we're speaking in -- you know, we make sense in what we're saying from your perspective. So that's, that's what that tasking was.

And I just wanted to add, if I can have a moment. With the Part 35 rule, the activation hearing, the Chairman actually took a moment to, which she normally doesn't do, at the activation hearing they take two minutes, they all agree. They say, yep, we all pass the rule as -- you know, and have the staff go off and do it. But she took a moment and spoke about the complexity of the rule and the effort by all stakeholders, including staff and the ACMUI. So, she specifically mentioned ACMUI and was thankful for all the hard work.

So I just wanted to share that with you that it was, it was recognized by the Chairman for all

the work on the Part 35. So thank you all.

CHAIRMAN ALDERSON: And we're glad to hear that. The committee will keep the good work up.

Other questions or comments? Yes?

MR. COLLINS: Dr. Alderson, if I just might take back to what Doug was just sharing with you about the staff's forthcoming evaluation of those training and experience requirements. Irene Wu, who you know from the Category 3 work, is actually going to be helping us on the project management of that.

So if she reaches out to you on that, we just want to let you know that's why is because her time is getting freed up a little bit now with the Category 3 work as it applies. And so we're going to help augment the staff resources on the Doug's team with Irene.

CHAIRMAN ALDERSON: That's good. Very good, thank you.

Other items? New issues to be brought before us at this time?

(No response.)

CHAIRMAN ALDERSON: Hearing none, seeing no hands, a motion, I believe that we are set to adjourn this meeting. I want to thank all of you for coming, being here, and providing all your support.

So we'll see you in a few months. More work to do in the meantime. Thank you very much.

(Whereupon, at 1:45 p.m., the meeting was concluded.)