Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

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

Docket Number: (n/a)

Location: Rockville, Maryland

Date: Wednesday, April 26, 2017

Work Order No.: NRC-3037 Pages 1-248

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

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

+ + + + +

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

+ + + + +

MEETING

+ + + + +

WEDNESDAY,

APRIL 26, 2017

+ + + + +

The meeting was convened in room T2-B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:00 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:

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

JOSEPH NICK, Acting Deputy Director, Division of Material Safety, State, Tribal and Rulemaking Programs (MSTR)

DOUGLAS BOLLOCK, ACMUI Designated Federal Officer

MICHELLE SMETHERS, ACMUI Alternate Designated Federal Officer and ACMUI Coordinator

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

MICHAEL FULLER, NMSS/MSTR/MSEB

VINCENT HOLAHAN, Ph.D., NMSS/MSTR

SOPHIE HOLIDAY, NMSS/MSTR/MSEB

ESTHER HOUSEMAN, OGC/GCLR/RMR

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

MANUEL JIMENEZ, NRR/DRA/ARCB

MINH-THUY NGUYEN, RES/DSA/RPB

GRETCHEN RIVERA-CAPELLA, NMSS/MSTR/MSEB

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)

MICHAEL CALLAHAN, CCMSC Corp

ALEX FLIRT, Affiliation unknown

CATHERINE GILMORE-LAWLESS, Elekta

DESIREE KENNEDY, Elekta

CAITLIN KUBLER, Society of Nuclear Medicine and Molecular Imaging (SNMMI)

SUSAN LOHMAN, Elekta

RICHARD MARTIN, American Association of Physicists in Medicine (AAPM)

AVI OLER, Spectrum Pharmaceuticals

MICHAEL PETERS, American College of Radiology

JOSEPHINE PICCONE, Independent

CRAIG PIERCY, American Nuclear Society (ANS)

GLORIA ROMANELLI, American College of Radiology (ACR)

MICHAEL STEWART, Walter Reed National Military Medical Center

CINDY TOMLINSON, American Society for Radiation Oncology

C-O-N-T-E-N-T-S

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

8:04 a.m.

CHAIRMAN ALDERSON: Before we start into the usual series of events, I certainly want to acknowledge the fact Frank Costello is no longer with us. A great colleague. I'm sure that most of you know, having read in the emails that have gone back and forth from the organization, that probably next fall at the autumn meeting there will be a more formal recognition of Frank and his work. His family is potentially planning to be here at that time. So we will not do a formal recognition of Frank today.

But suffice it for those of you who've read the information, I didn't realize that for 30 years, Frank worked for the NRC. And he was engaged with Agreement State issues in Region 1.

But then he went to Pennsylvania where he became their representative to the Agreement States group. And then he came here to this particular committee and brought that tremendous expertise of his, that willingness to always get engaged in the discussions in a Frank way, but in a very good way,

because he really knew the regulations and knew how the organization worked. So he was always valuable. Even when he was on the phone and not sitting here personally he was valuable because of all he could bring.

So I look forward to -- and I'm sure all of you do, too, to next fall when we'll be able to recognize him in a more formal way. And I might suggest that just for a moment, just for a moment we have a moment of silence out of respect for Frank, and then we'll turn it over to Doug and go on with the regular meeting.

(Moment of silence.)

CHAIRMAN ALDERSON: Thank you very much and thanks to Frank for all he did for all of us.

Doug, the meeting is yours.

MR. BOLLOCK: Okay. Thank you, Dr. Alderson.

Okay. Good morning, everyone. As the designated federal officer for this meeting I'm pleased to welcome you to the public meeting of the Advisory Committee on the Medical Uses of Isotopes. My name is Doug Bollock. I'm the Branch Chief of the Medical Safety and Events Assessment Branch and I have been designated as the federal officer for this advisory committee in accordance with 10 CFR Part 7.11.

Present today as the alternate designated federal officer is Michelle Smethers, our ACMUI Coordinator.

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

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

The meeting was announced in the February 27, 2017 edition of the *Federal Register*, Volume 82, pages 11950 through 11951.

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

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

At this point I'd like to perform a roll call of the ACMUI members participating today.

Chairman, Dr. Philip Alderson, healthcare administrator?

CHAIRMAN ALDERSON: Here.

MR. BOLLOCK: Thank you. Our vice chairman, Dr. Pat Zanzonico, nuclear medicine physicist?

VICE CHAIR ZANZONICO: Here.

MR. BOLLOCK: Thank you. Our nuclear cardiologist, Dr. Vasken Dilsizian?

MEMBER DILSIZIAN: Here.

MR. BOLLOCK: Thank you. Our radiation oncologist Dr. Ronald Ennis?

MEMBER ENNIS: Here.

MR. BOLLOCK: Thank you. Radiation safety officer, Dr. Sue Langhorst?

MEMBER LANGHORST: Here.

MR. BOLLOCK: Thank you. Our diagnostic radiologist, Dr. Darlene Metter?

MEMBER METTER: Here.

MR. BOLLOCK: Thank you. Our FDA representative, Dr. Michael O'Hara?

MEMBER O'HARA: Here.

MR. BOLLOCK: Thank you. Nuclear medicine physician, Dr. Christopher Palestro?

MEMBER PALESTRO: Here.

MR. BOLLOCK: Thank you. Radiation oncologist, Dr. John Suh?

MEMBER SUH: Here.

MR. BOLLOCK: Thank you. And our patients' rights advocate, Ms. Laura Weil?

MEMBER WEIL: Here.

MR. BOLLOCK: Thank you. All right. I confirm that we have -- a quorum is met of at least six members.

Also at the table we have Mr. Zoubir Ouhib and Mr. Richard Green. Mr. Zoubir Ouhib has been selected as the ACMUI therapy medical physicist and Dr. Richard Green has been selected as the ACMUI nuclear pharmacist. Both Mr. Ouhib and Mr. Green are pending security clearance but may participate in the meeting, however, they do not have voting rights at this time.

I'd also like to add that this meeting is being web cast, so other individuals may be watching on line. We have a bridge line available, and that phone number is (888) 711-9833. The pass code to access this bridge line is 93680 followed by the pound sign.

I'd just like to make a side note that we have, as recently as yesterday afternoon, had difficulties with the web cast. I believe the server went down. Our technical staff, the NRC technical staff did a wonderful job of getting it back up for this morning, but if there are issues, I'd please encourage people to make note of the bridge line, because they still will be able to participate through that. So again, the bridge line number is (888) 711-9833 and the pass code is 93680 followed by the pound sign.

Individuals who'd like to ask a question or make a comment regarding a specific issue the Committee has discussed should request permission to be recognized by the ACMUI Chairperson, Dr. Philip Alderson. Dr. Alderson, at his option, may entertain comments or questions from members of the public who are participating with us today. Comments and questions are usually addressed by the Committee near the end of the presentation after the Committee has fully discussed the topic. We ask that one person speak at a time as this meeting is also closed captioned.

I'd also like to add the handouts and agenda for this meeting are available at NRC's public web site.

At this time I'd ask everyone on the call

who is not speaking to place their phones on mute. If you do not have the capability to mute your phone, please press star 6 to utilize the conference line mute and un-mute functions.

At this point I'd like to turn the meeting over to Dr. -- to Mr. Dan Collins, Director of the Division of Material Safety, State, Tribal and Rulemaking Programs for some opening remarks.

MR. COLLINS: All right. Thank you, Doug. And I am not a doctor, but thank you and welcome to all of the members of the ACMUI. I appreciate you taking time out of your busy schedules and traveling to meet with us today. And those of you who had painful Uber experiences, we especially thank you.

So just by way of some opening remarks I'd like to thank you members, all of the members for all of the hard work that you do to support the important work that's being done by the Committee in support of the NRC and our regulatory functions. We wouldn't be successful without your input, so thank you.

Just in terms of some -- before I get to some organizational changes, I also thank you, Dr. Alderson, for your kind words regarding Frank Costello. As you noted, he was a long-time NRC employee and added great

value in everything he touched, and he will be missed. So I also look forward to the meeting in the fall where we can recognize him more formally.

In terms of some other organizational changes, just for folks' awareness in case you haven't heard, we do have a new chairman at the NRC. Kristine Svinicki was designated to be the chairman of the NRC by President Donald J. Trump on January 23rd, 2017. She began as a commissioner at the NRC on March 20th, 2008, and so she has a long history with the Commission, but she is now the chairman and the former chairman Stephen Burns remains on the Commission as a commissioner.

Within the Office of Nuclear Material Safety, State, Tribal and Rulemaking Programs, not the office, the Division of Material Safety, State, Tribal and Rulemaking Programs, we have had some changes. Pam Henderson, who was my deputy, retired on March 31st, and we are in the process of identifying her replacement.

Also, some of you may know that Mike Fuller will be retiring effective May 5th. So we will hate to see him go, but we appreciate everything that Mike has done for the medical team and for the support of ACMUI.

You'll be missed, Mike.

We will be backfilling for him, but we're

not far enough along in the process to make any announcements at this point. But that will be forthcoming fairly soon.

Within the ACMUI many of you know Dr. Langhorst will be rotating off of ACMUI in September of this year.

So, doctor, thank you for everything you've done for us.

We have identified her replacement and I sent out an email on this to everybody this morning. Mr. Michael Sheetz has been selected to fill the radiation safety officer position once Dr. Langhorst's term ends in September. Mr. Sheetz will be joining us for this meeting over the bridge line and we hope to have him here present in the fall.

For those of you who haven't had an opportunity to check your emails, just by -- and for the other members of the public who are listening, just by way of a little bit of short background for Mr. Sheetz, he's currently serving as the director of the University of Pittsburgh's Radiation Safety Office and as the radiation safety officer for the University of Pittsburgh and the University of Pittsburgh Medical Center.

He is a clinical assistant professor of radiology in the University of Pittsburgh's School of Medicine where he provides ongoing clinical teaching and research support. He holds a bachelor's degree in biological science and health planning and administration from Pennsylvania State University and a master's degree in radiation health from the University of Pittsburgh's Graduate School of Public Health.

He is board certified. He received his board certification in comprehensive health physics from the American Board of Health Physics in 1988 and his board certification in medical health physics from the American Board of Medical Physics in 2003.

So we welcome him to the ACMUI and we look forward to hopefully a speedy clearance process for him so he can formally join the --

(Laughter.)

MR. COLLINS: So, always hold out hope, right?

In terms of some other things going on, the members of the ACMUI all know this, but for members of the public who may be listening, there will be an open Commission meeting with the ACMUI tomorrow morning at

10:00 in the NRC Commission Hearing Room. So members of the public will be able to attend that or listen in.

Other activities going on. With respect to patient release, I see on the agenda that you are going to get a more fulsome update from Dr. Donna-Beth Howe this afternoon. But other things going on with respect to patient release, the NRC did publish a *Federal Register* notice in -- on April 11th of this year entitled, "Patient Release Programs." And that was requesting public comments on the NRC's Patient Release Programs. Specifically we're seeking input from the public on whether additional or alternate criteria are needed and whether to clarify the NRC's current patient release requirements. And that information will be used to help develop some recommendations that the staff will be sending up to the Commission in the December time frame of this year.

So we had a public meeting yesterday on that, and that was the meeting that Doug referenced where we had some challenges with the webinar, or with the web cast. And then there's another public meeting that's scheduled for May 23rd, which will also be here at headquarters, and that will be again seeking additional input from members of the public on that

issue. But as I said, Dr. Donna-Beth Howe will be providing additional updates to the ACMUI this afternoon.

With regard to rulemaking, the Part 35 rulemaking is still with the Commission. We are hoping to get the final vote within the next month or so, and Torre Taylor will be providing a brief update for you tomorrow afternoon.

We'll also be providing for you an update on the Agency's Category 3 Source Security Accountability Initiatives that we've previously talked about, but Irene Wu, who's the project manager, will be here today to give you an update on where that all stands. And we recognize that there are some important considerations from both the practitioners and the public's perspectives regarding the Source Security and Accountability Initiatives, so look forward to that discussion.

In terms of other ACMUI upcoming vacancies, we will be, as I said, working to backfill for Frank. And then additionally the staff is going to be looking at those positions on the ACMUI that are due to rotate off within the next year and working on the succession planning for that.

And at this time I will turn the meeting back over to Dr. Alderson. But before I do that, just my apologies, I am triple-booked this morning, so I'm not going to be able to stay for it all, but you're in good hands with Doug and the rest of his team.

So with that, Dr. Alderson, the meeting is -- I'll turn the meeting back over to you.

CHAIRMAN ALDERSON: Thank you very much, Mr. Collins. Any other comments related to anything that -- questions on anything that's been said here?

(No audible response.)

CHAIRMAN ALDERSON: Well, then we're into the old business segment of the agenda and Michelle Smethers will bring us up to date.

MS. SMETHERS: Thanks, Dr. Alderson. It's nice to be here with all of you. For those of you in the back who don't know me, I'm Michelle Smethers and I'm the ACMUI coordinator. During this portion, the next portion of our agenda, we'll be going through the old business, as we do in all meetings, where we recap actions and recommendations put forth by the Committee and noting any changes.

So beginning with 2007. Okay. So all items listed in 2007 are open as -- sorry. All items

in 2007 listed as open are included in the current Part 35 rulemaking, and open and delayed means they will be considered in future rulemaking.

Moving onto 2008. Again, just like 2007 all items listed as open are included in the current Part 35 rulemaking, and open and delayed means they will be considered in future rulemaking.

2009. The two items listed in 2009 are both included in the current Part 35 rulemaking.

Moving onto 2010. 2010 is not included because all actions and recommendations were previously closed.

2011. Items 11, 13, 14 and 15 are included in the Part 35 rulemaking. And then Dan touched on this. Items 1 and 16 have to do with the patient release criteria, and both of these items are pending because there's a patient release effort going on at the NRC in the Office of Nuclear Material Safety and Safeguards. So as he mentioned, there was a public meeting yesterday and there will be another to seek feedback and comments on May 23rd. So that is pending and will stay on there.

Lastly, item 6 is the indefinite action item, the open action item from the Committee to review its reporting structure, and I will be reviewing that

later in the meeting. So that stays on there.

Moving to 2012. All 2012 items were closed in the last -- in the March 2016 meeting, so there's nothing for 2012.

2013. Items 1 through 13 are part of the current Part 35 rulemaking. Some of these charts are less exciting than others. Okay.

Moving onto 2014, all items were closed as well during the October 2016 fall meeting.

For 2015 item 7 is still listed as open as this is an ongoing effort and we are waiting on staff's review and evaluation to revise the NRC's abnormal occurrence criteria policy statement. Item's 12 through 15 have been part of an ongoing effort. You will hear a presentation tomorrow morning from Dr. Dilsizian regarding the Patient Intervention Subcommittee's recommendations on the definition of patient intervention.

And item 22. Like item 7, item 22 has to do with NRC's ongoing efforts with the abnormal occurrence criteria policy statement.

For 2016 -- we're going to move onto 2016. Items 1 through 15 all deal with the Part 35 rulemaking Subcommittee report that had the recommendations

related to the draft final rule. The Part 35 rulemaking package, as you've heard, is sitting with the Commission for vote. And we'll hear from Ms. Torre Taylor tomorrow afternoon for a brief update.

And then for item 16 we will hear from Dr. Palestro later this afternoon for an update on the work done by the Training and Experience for All Modalities Subcommittee.

Item 24 was an ACMUI action to reach out to professional organizations to encourage interactions and communications between professional organizations, the NRC and the ACMUI. And I believe Dr. Alderson will report briefly on this to the Commission tomorrow.

Would you like to keep this on the chart? I think last meeting we decided that moving forward we would, but --

(Simultaneous speaking.)

CHAIRMAN ALDERSON: Yes, I would. And before tomorrow's meeting I want to review with people exactly who's meeting with whom and when so we can convey that to the Commission.

MS. SMETHERS: Great. Yes, we can do that later today.

And for item -- are we on -- let's see, item

38 was brought to the attention of the ACMUI last meeting by Dr. Zanzonico during the open forum of the fall 2016 ACMUI meeting. The open forum provides ACMUI the opportunity to identify medical topics of interest for further discussion, so Dr. Alderson requested that this topic be discussed at this spring meeting to appoint a subcommittee that will report on the nursing mother guidelines for the fall 2017 meeting.

Item 39. Item 39 was the Committee recommendation that staff issue a generic communication or information notice regarding tubing issues such as kinking, connection, hub, etcetera, during the administration of Y-90 microsphere brachytherapy. And staff is still looking into this, so this remains on the list.

Item 41 was an action to reestablish the Patient Intervention Subcommittee, and the subcommittee's new charge was to make a recommendation on what the definition of patient intervention should be. As I mentioned, Dr. Dilsizian, chair of the Subcommittee, will be reporting tomorrow morning.

Items 42 and 43. The working group is developing a draft revision for the licensing guidance, which it intends to send out for public comment this

summer.

And items 44 through 52 all pertain to the NorthStar Medical Radioisotopes RadioGenix Moly-99 Tech-99 Generator System Licensing Guidance. And these items are still open since the comment resolution work is still in progress.

Lastly, item 25 was an ACMUI action to hold the spring 2017 meeting. And since we are all here and holding this meeting, I would like to request that this action be closed.

CHAIRMAN ALDERSON: Are there questions or comments before we vote on that request? Yes?

MEMBER LANGHORST: Oh, on the request of --

CHAIRMAN ALDERSON: To approve. Please, go ahead. Make your comment.

MEMBER LANGHORST: I'm sorry. What was the request? To approve for what?

MS. SMETHERS: To close the action --

MEMBER LANGHORST: Oh, yes.

MS. SMETHERS: -- to hold this meeting.

MEMBER LANGHORST: That was not my comment on that.

CHAIRMAN ALDERSON: Not your comment?

MEMBER LANGHORST: Sorry.

CHAIRMAN ALDERSON: Would you like to make another comment?

MEMBER LANGHORST: I'll wait until we --

CHAIRMAN ALDERSON: You'll wait?

MEMBER LANGHORST: -- decide on that.

CHAIRMAN ALDERSON: Very good. Are there any other people who would like to comment on this particular action?

(No audible response.)

CHAIRMAN ALDERSON: Hearing none, let's vote. All in favor?

(Chorus of aye.)

CHAIRMAN ALDERSON: Unanimous. Thank you.

MS. SMETHERS: Okay. Thank you.

CHAIRMAN ALDERSON: Now, Dr. Langhorst?

MEMBER LANGHORST: Yes, thank you. I did have a question on the item. So with so many items being closed for Part 35, will they all still remain on the list and be discussed as closed next time? Because I think the Committee may want to really be careful in looking through each of those items to make sure nothing is lost that was not part of the Part 35 change, but that

the Committee feels is important to keep in the forefront.

MS. SMETHERS: Yes, we can keep them on there and discuss them next meeting before moving them from the list.

CHAIRMAN ALDERSON: Okay.

MEMBER LANGHORST: That might take a little more time.

MS. SMETHERS: Yes. Yes.

MEMBER LANGHORST: So, thank you.

CHAIRMAN ALDERSON: Good. Thank you.

Other comments?

(No audible response.)

CHAIRMAN ALDERSON: All right. Hearing none, Ms. Smethers, thank you for --

MR. BOLLOCK: Thank you.

CHAIRMAN ALDERSON: -- doing this part of the agenda.

And that brings us to the part of the agenda called open forum. And this is a time when something just like Dr. Langhorst just discussed can actually be discussed, such as any medical topics of interest for further discussion that people would like to talk about before we get into the actual presentations. So the

floor is open at this time for any such items.

Dr. Zanzonico?

VICE CHAIR ZANZONICO: Yes, good morning. We went through a lot of time and effort and thought, and so did the NRC staff, on the -- waiving the Disposal Funding Plan for the germanium-68/gallium-68 generator. And I've gotten informal inquiries, feedback from various individuals saying that at least some of the Agreement States are still requiring disposal plan funding to the point where some institutions are not going to do gallium-68 studies, unfortunately.

And again, these were informal comments/inquiries. I don't know their accuracy and I don't know exactly what was told to various institutions and how the various institutions responded and so forth and so on, but it seemed there was so much effort and so much unanimity of the value of the gallium-68 radiopharmaceuticals and the impropriety of the Disposal Funding Plan requirement as originally appeared that it seemed we should somehow address that, because you seem to be going backwards to some extent after all of that. So I just wanted to bring that to everyone's attention and perhaps discuss what could be

done to remediate that situation.

CHAIRMAN ALDERSON: Yes, Mr. Green?

MEMBER GREEN: I have personal knowledge of that with our licenses. While the financial -- the decommissioning funding plan has been exempted if you ask for it and follow all the requirements that were specified in the guidance, some states are still requiring the financial assurances warranty bond, which doesn't make sense because to get it back to the manufacturer is an $85 FedEx charge but to put a couple $100,000 down on a financial assurances warranty bond doesn't make sense. So part of it was I made a pathway, but part of it's still unclear and some states are requiring that warranty -- financial assurances warranty bond.

MR. BOLLOCK: And I can address all this. Are there any other comments from the Committee or questions that I -- they'd like me to address in this area? And I can touch on all the points that both Dr. Zanzonico and Mr. Green have brought up.

So the issue that was brought to us was the decommissioning funding plan was too expensive, and -- expensive and extensive is what we heard. So we brought -- so we looked at that, went through how could

we get rid of the decommissioning funding plan, because they can -- this is something that needs to be updated. It can be very difficult to -- to get a decommissioning funding plan for just -- just to have these generators, which is what can happen.

So, and it's not just -- some the states actually are -- in order for us to allow our license -- our regions to allow licenses with exemptions to the decommissioning funding plan there was still a requirement for funding assurance, essentially the bond that Mr. Green was talking about. That actually is our requirement and some of the states' requirements.

Some of the other issues are some of the other states because they do not have to follow our exemptions, our exemption comes from our office director to the regional administrators that license NRC licensees. They don't necessarily have to follow exactly how we deal with decommissioning financial assurance. So there are some differences state to state and we are aware of that.

There was also some confusion whether the financial assurance was still required or not based upon our exemption. And as Mr. Green brought up, the fact that if you just ship it back, that's -- it's a very cheap

thing, however, in order to kind of shift the -- I was -- and so I have explained this to the Commission.

I believe I said this in front of -- at an ACMUI meeting previously. We got rid of the financial -- the decommissioning funding plan, but we shifted the -- there is no -- there's a zero sum safety change. The licensees are still required to have that bond so that they can't -- so that we know they can ship it back without any of that -- the financial discussions back and forth.

We had originally looked at other options, and that would -- from manufacturers to pay for it, get it into the book. So we did look at other options, but what we had last summer when we worked through this, the information we had, that is the end result where the exemption was leaving some sort of financial assurance.

Unfortunately, our financial assurances are set in our regulations that 100 and -- I think it's a $125,000 bond for -- it would -- practically equates to one or two generators. And then more than two generators it is -- or, no, it's 250,000 and then 1.25 million for more than two generators is -- is what it comes down to. So that's not right.

And as Mr. Green -- we realize practically

you're shipping back a little generator and what does that cost and why does the bond -- unfortunately, we're working within our bounds on the information that we have to keep -- to allow us to not just on a safety basis and a legal basis be able to allow exemptions.

We did just receive -- I believe this is publicly available knowledge. We did receive a petition for rulemaking to open up the Part 30 table that requires the decommissioning financial assurance. And one of the specific isotopes they want to add to the table which could basically allow for us to address all this in rulemaking, in a petition for rulemaking is the germanium-68.

So we are -- we were working on a direct final rule to address this instead of going by exemption, and we believe now that we may -- still in process, but there is a petition for us to just open up the table and address this issue. So there will be time available or opportunities available in the future to bring up all of these points for us to make a change in the regulations to allow easier access without financial assurance, essentially a bond of some sort even with the exemption or a decommissioning funding plan.

CHAIRMAN ALDERSON: So I'm sure that everyone's happy to know that there is ongoing progress. A couple of questions might be useful.

Dr. Zanzonico, do you know in terms of the states that are still requiring this -- there's something like 37 Agreement States. How many states or what proportion of the states are still requiring some sort of bond? Is this a big problem or is it only a few states?

VICE CHAIR ZANZONICO: Again, the information I received is just anecdotal, sort of a semi-hysterical email.

CHAIRMAN ALDERSON: From one of the Committee members.

VICE CHAIR ZANZONICO: Well, no, just from users out in the field. And I believe they identified two different states.

CHAIRMAN ALDERSON: Two?

VICE CHAIR ZANZONICO: But for the people in those states it's a big --

(Simultaneous speaking.)

CHAIRMAN ALDERSON: Yes, it's a big number. Absolutely.

MR. COLLINS: And just to be -- it's not

just the states. Those states are following NRC -- our exemption -- still requires the bond. It was -- the issue was the decommissioning financial -- decommissioning funding plan, because that -- there are other requirements for that. That was the issue, get rid of that. While we still have -- it's a step down in our regulations of requirements based upon the amount of certain isotopes. So we -- again, based on the information that we had last year we were able to exempt the decommissioning funding plan, however, when we took a step down we were still requiring that, financial assurance was still required.

Mike, do you have anything to add? Mike Fuller.

MR. FULLER: Yes, thanks, Doug. Thank you, Dr. Alderson.

The one thing I'd like to point out; and this is something I think is kind of in the details and folks don't always recognize, our requirements are for decommissioning financial assurance. People sometimes confuse that with decontamination. And so it's not just the cost. We talk about this being a relatively closed system and the potential for contamination is pretty low. Everyone would agree to

that.

But when it comes to decommissioning what we're talking about is actually removing something from a license and/or actually terminating a license. And so our rules are pretty straightforward and pretty clear that there needs to be financial assurance in place; this is the way that we've done it for many, many years, that ensures that folks have the funding in place to properly decommission and then ultimately terminate a license.

We haven't had a lot of these situations, but we've had situations where people, even some medical facilities have gone bankrupt and someone comes in and padlocks doors and there is radioactive material on site. And so in situations like that there needs to be some financial instrument in place to ensure that means can be -- I mean that steps can be taken to have that material removed appropriately and properly and disposed of or returned to someone. And sometimes that costs some money.

And as Doug mentioned, our funding levels under our financial assurance requirements are really set in stone. Everyone would agree that it probably doesn't cost that much money. But again, this is a

default. If we can get the table updated to an appropriate value for germanium-68, that will tend to alleviate a lot of this.

But just wanted to caution folks don't just think of decommissioning -- I mean, don't -- yes, don't just think of decommissioning as decontamination or cleaning up something. It's probably not likely to be contaminated. It has to do more with decommissioning a license or decommissioning a facility and ultimately terminating a license. So keep that in mind, too, as we discuss this.

CHAIRMAN ALDERSON: So again, I think that most people would be happy that there is some progress that the NRC is discussing this. I would certainly advocate that -- and we've discussed this many other times, that this -- these discussions be as timely as possible.

Pat, do you want to make any more comments?

VICE CHAIR ZANZONICO: Yes, I think -- and I understand the regulatory constraints; and they're not unreasonable and so forth, but clearly there's some confusion among users that's significantly affecting patient care and so forth. So I think at the very least there needs to be some formal document, some formal

release from the NRC clarifying exactly what is and is not required at the moment and what the path forward is, because otherwise I think this confusion is going to persist.

MR. BOLLOCK: Yes, and we are actually addressing that because we -- even amongst our -- the other states that want to follow our exemption or something similar. So we -- there's some -- we're going to add one clarifying line to the actual guidance, but then our methods, or communicating our exemption guidance, that confused people because it didn't have all the details. And having the cover sheet that set the actual information didn't get specifically to the point of you still have some financial assurance if -- in the case that Mike said -- an organization went -- bankrupt.

So I'm sure you can send these things back or decommission the site. So there was some confusion in that because that didn't get into those details. And that is an important detail. So we are updating that. And that -- I mean, that -- we are very shortly will be sending that out to try to clarify that amongst the regulators.

CHAIRMAN ALDERSON: So Dr. Daibes from the

NRC has a comment and then Dr. Ennis has a comment.

DR. DAIBES: Said Daibes. Yes, adding to what our branch chief just added, we have three documents in concurrence. It's apparent there's a potential confusion out there with respect to when you request the exemption for the DFP. People were under the impression that that was exempting financial assurance. And we're working with that confusion. So we have something specifically addressing that concern. It's pretty close to being a final product. And that will actually do what needs to be done out there with respect to clarifying.

We have updated guidance and we have updated the memo to add those clarifications so people are not under that impression. So our initiatives will potentially exempt DFP, but we cannot assume that it's going to exempt all financial assurance requirements. And that's very explicitly defined in our new documents coming out. So I wanted to add that.

CHAIRMAN ALDERSON: Dr. Ennis?

MEMBER ENNIS: Thank you. So I'm not surprised there's confusion because I was misunderstood what we had done. So how much would it actually cost an institution to have that bond in place?

MR. BOLLOCK: We -- Said and I have kind of ballparked that, like just looking at it. I mean, this is just us on Google, right? And it was within hundreds of dollars or a thousand dollar a year insurance --

DR. DAIBES: Can I add --

MR. BOLLOCK: Yes.

DR. DAIBES: Yes, Said Daibes. So we went out and we were checking this. Five hundred dollars to actually get a bond that will provide the assurance you need in order to access this financial assurance bond. Four, five hundred bucks.

MEMBER ENNIS: Okay. So to me then that's reassuring that we did accomplish something.

(Laughter.)

MEMBER ENNIS: That seems like a reasonable price.

(Simultaneous speaking.)

MEMBER ENNIS: And then -- and but again, I mean, it's important to hear from someone who has the practice. So, Mr. Green?

MR. GREEN: Yes, it's roughly two percent per annum of the bond amount, but the organization that I'm employed by has 22 sites that currently possess germanium generators. And it's not just the per annum

amount that you pay to the financial institution for the instrument. It's the process of going through your bank and treasury departments and so on to create all the paperwork and all the lawyers involved to do all that. But I'm happy to see that we have a short term solution to dispel the confusion that exists and I hope we have a long-term solution by changing a value on a table.

CHAIRMAN ALDERSON: Yes, Dr. Ennis?

MEMBER ENNIS: Just one thought. When we get to the issue of the table, I'm a little concerned; and this is something we had talked about, there may be another isotope next week. And two weeks from now or a year from now yet another isotope. And if we're going to go back to rulemaking to change the table every time, that's not an ideal solution. So I don't know if we could be more creative about figuring out and anticipating what might be coming in a more generic kind of way.

MR. BOLLOCK: That's a very good point and we are aware of it and that is our plan -- we're in the process. That is actually part of the discussion we had on Monday of this week, that we recognize exactly that. So our first step would be to solicit that. What other

isotopes are out there that aren't in the tables that are used for medical or for other uses, industrial, that can show the need. So that would be the first step and we are aware of that.

CHAIRMAN ALDERSON: Yes, one final comment on this. Dr. Langhorst?

MEMBER LANGHORST: I have a couple comments, if that's okay, Dr. Alderson.

CHAIRMAN ALDERSON: Please.

MEMBER LANGHORST: For people doing financial assurance -- and just a reminder that decommissioning funding planning is when you have a lot of activity and you have to design how much financial assurance you have for your given license. That's where the DFP comes in. There's NUREG-1757 that is very good in telling licensees what are the ways they can get this financial assurance. So a bond is one way, but there are other options. And so licensees should explore that NUREG-1757.

The change in the table -- this is a Part 30, Appendix B table, which is the old table from Part 20 before it was updated in the early 1990s. The table in Part 20 could be referenced instead of this table.

Now if you're changing that -- the proposed

-- or the request for rulemaking was to change the table, is that correct? So that has lots of implications. And it won't go quickly because a lot of people may no longer need to do decommissioning funding planning to do their financial assurance, but maybe it might change others to require that decommissioning funding planning. So that's not a quick fix. So I would hope that NRC keeps going on its proposed plan to have like a footnote on the table for germanium-68.

And the isotopes that are in this table are ones that are greater than 120-day half-life. So that leaves out a lot of medical use isotopes because a lot of them are a lot less -- lower half-lives. So I just wanted to make a few of those comments that -- thank you.

CHAIRMAN ALDERSON: Mr. Bollock wants to follow that up.

MR. BOLLOCK: I just -- and so the -- that direct fund rule with the footnote that we talked about, we're working on that.

MEMBER LANGHORST: Yes.

MR. BOLLOCK: And actually we're very far along. That's not going to be -- that will still require some financial assurance --

MEMBER LANGHORST: Right.

MR. BOLLOCK: -- so it does not alleviate the bond or that level of financial assurance that currently is in our exemption. So if you want further changes, we -- the -- so for our -- at least our NRC licensees there is no -- there would be no change in the -- in what we're doing with the direct final rule. So I just want to make that be known and be clear to you all so you understand that.

CHAIRMAN ALDERSON: Okay. Thank you.

Is there anything else on this subject? Yes?

MEMBER OUHIB: Just a general comment. Do we have a timeline at this point, because there are users sitting out there thinking, well, what do I do now, or how long do I have to wait to make some changes and so on and so forth?

MR. BOLLOCK: So --

MEMBER OUHIB: So, I mean I know you have some corrective actions and so on and so forth.

MR. BOLLOCK: So your options now would be follow the rules as is, which is a decommissioning funding plan, which is -- can take a lot -- this is -- well, it's expensive to come up with one and everything, but if your plan was it costs us $85 to send

back these generators, we only need $1,000 of assurance to -- for four of them, then that's one option.

Or if you're an NRC licensee, request the exemption. You have some sort of financial assurance at our levels. And then the other specific requirements to get that exemption, which is just that you have a contract, that when our generator is expired, we ship it back. And that's -- those -- so those right now are the two current options. If we -- even with a direct final rule change for the -- to the footnote to the table, it would still be that for NRC's licensees. So I want to be clear on that.

To make a change to lower the values, lower that bond rate, make it even easier would take -- and that has always -- that would take a more extensive change to the table now. We are further along the lines when it comes to germanium, but as Dr. Ennis pointed out and we understand, we're not just going to open a table for just that.

There are other -- there could be other uses, other isotopes that could be useful to the medical community that we want to know about and also include those so that we're not doing this all over again with those other isotopes.

CHAIRMAN ALDERSON: So, Dr. Daibes, you had a final comment?

DR. DAIBES: Yes, Said Daibes. I just want to add that when you request the exemption, there's two requirements you need to satisfy, one of them being the legally binding agreement with the distributor that will be supplying that generator. And our memo and guidance has specifics on the components that a legally binding agreement will need to have in order to comply with the NRC's regs. And the other component is a financial assurance certificate for the corresponding amount of financial assurance based on the level of activity or generators you're requesting. So those are the two, just clarifying, to answer your question.

CHAIRMAN ALDERSON: Thank you. I think we'll draw this discussion to a close. I think it's been a very good discussion. Ultimately a lot of these issues are going to relate to the specific venue or the territory in which you work and what that hospital or that state is willing to do. So I think we've gotten a good background on what some of the issues will be. So thank you very much to all of you who have participated in this discussion.

We are a little bit behind time, not badly

behind time. Is there another issue for the open forum that people feel they need to bring forward at this time?

(No audible response.)

CHAIRMAN ALDERSON: Hearing none, I think that we're ready then to move onto the next part of the agenda, which is the -- the representatives from Elekta will discuss the physical presence requirement for the Leksell Gamma Knife Icon. So there they come.

MS. LOHMAN: Good morning. I'm Susan Lohman from Elekta and I have worked for Elekta for two decades. Prior to that worked in a clinical setting with Leksell Gamma Knife.

What I do for Elekta is clinical training and application support. In the role of application support and clinical training I participate at the training centers here in the United States that train customers that are new to Gamma Knife or that will be upgrading a Gamma Knife, as well as on-site training, both for the equipment itself, the machine, and planning software. With the experience that I've had I've probably observed greater than 2,000 Gamma Knife cases, either participating as a clinician while I was working as a nurse or in my role with Elekta.

The presentation today is going to include

four parts: The first is a brief introduction to Elekta as a company. The second is information about the Gamma Knife technology, recognizing that there are various degrees of familiarity with Gamma Knife. The third portion of the presentation will focus on the importance to the patient and the public for access to Gamma Knife treatment and the physical presence requirement. And finally, specific language that is being requested in a modification to the physical presence requirement.

As a corporate overview, Elekta is a medical technology company that is global in its presence. Elekta has -- developed Gamma Knife at the beginning with a physician who was striving to improve patient care. Over the 30-year history of Elekta, Elekta has been focused on improving the quality of patient treatments through advances in technology and additions such as imaging and improvement of treatment planning.

With all of this Elekta is a well-established cancer care partner in over 6,000 hospitals worldwide with 1.5 million people being treated with an Elekta solution every day -- I'm sorry, every year. And then every day greater than 140,000 patients are touched by some sort of Elekta solution,

whether it be with treatment, treatment planning or with an electronic medical record as follow-up.

The Gamma Knife has been through an evolution over these past 30 years. It is a machine designed to specifically treat intracranial lesions, and those intracranial lesions or diseases are often things that are considered inoperable. They cannot be reached with a surgeon's scalpel. The machine uses cobalt-60 sealed sources as its source of radiation for treatment. It is considered a gold standard in radiosurgery. It treats very small locations as well as lesions in critical locations.

If you look at the picture on the top left of the screen, that represents a -- it's a picture of a tumor that is being -- had been planned with Leksell Gamma Knife. The yellow line represents the treatment margin of that tumor. And the two green lines represent a steep dose fall-off, minimal amount of tissue being affected by the radiation that is being used to treat the target.

The small red circles that you see in there are our isocenters or the points at which the radiation is focused throughout the treatment. And I believe in this specific treatment there were 20-some isocenters

used. So different positions at the focal point of the machine during the treatment.

It uses 192 sealed cobalt sources in its treatment. Each one of these beams individually are not strong enough to affect the tissue, to have any negative effects on tissue, however, as these beams converge to a single point is where it becomes effective in treating abnormal tissue.

There are very few moving parts to the Gamma Knife. The sealed sources which are represented by the red dots on the screen are on a plate that moves longitudinally over the collimator body. This collimator body is drilled with different size channels for the beams to pass through, and those channels are what will collimate the beams to one of three different sizes: 4-millimeter diameter, 8- millimeter diameter of a 16-millimeter diameter. Because we're using cobalt-60 sealed sources, the output from the machine is stable and known throughout the life of the machine.

The patient positioning device is the entire couch on which the patient lies. That is calibrated to the focal point of the Gamma Knife treatment unit. The patient is attached to the positioning device through an apparatus, either a

stereotactic frame attached to their head rigidly or through mask fixation with an interface to the patient positioning couch.

There are expanding clinical applications for Gamma Knife treatment. When Gamma Knife first began the large majority of treatments were vascular diseases, however, over the years that percentage has changed and now the majority of treatments that you see being performed by a Gamma Knife are for malignant disease, many of these being brain metastases as patients are being better cared for, advances in medications throughout the cancer care spectrum, seeing more patients with metastases living longer and having more metastases.

So there are greater than a million patients treated worldwide with Gamma Knife, 80,000 of those annually, and there are over 2,500 peer-reviewed papers attesting to the efficacy and safety of the Gamma Knife.

Over 30 years the technology has changed tremendously for Gamma Knife from a completely manual system to a fully automated system for patient positioning. The first Gamma Knife was a Leksell Gamma Knife Model U, and that was in 1987, which happens to

be the very first model of Gamma Knife that I worked with. And this was a fully manual system.

The helmet that you see, the collimator, which is the silver portion immediately around the patient head -- there were four helmets, each with 201 collimators in it that would go -- retract back into the machine and line up with the cobalt sources to deliver treatment. These helmets had to be changed manually using a hoist that was brought alongside the bed, attached to the helmet, lifted off of the machine and moved to a storage table in order to change the helmets.

In addition, the coordinates for each one of the isocenters needed to be set manually by the treatment team on the stereotactic frame. So three coordinates: X, Y and Z. So a total of six coordinates for every isocenter. All of this manual intervention left a lot of room for human error.

So the next model of Gamma Knife changed the configuration of the collimator helmet, but that was really the change there.

In 1999 Elekta released the Model C Gamma Knife, and this was where automation began to come into the picture with Gamma Knife. There was an electronic transfer of the treatment plan, the coordinates for each

isocenter between the Gamma Knife and the planning system. There was also a sensor for the helmet that was in place so that it was no longer left totally to the user to make sure that the helmet was the correct one. The sensor would tell you if the helmet that was on the machine is the one that you had planned to use.

Shortly after that there was an upgrade to the Gamma Knife C that included an automatic positioning system, which was an interface between the helmet and the patient's stereotactic frame which is attached to their head. And this would move the patient between isocenters. There were some coordinates that still needed to be set manually for some isocenters. Others were set automatically. So it was a combination between your manual and automatic.

The next model was a fully automated system. The helmets have been removed. The collimator body replaces the helmets. The collimator body is inside the treatment unit, is stationary and the earlier picture where I showed the cobalt sources in red on plates that move over the collimator body all contained inside this unit. The transfer between the planning system and the treatment unit is all electronic. It is a fully automated positioning system

where the entire patient body moves, not just the patient head, as you move from isocenter to isocenter. There is an integrated QA to the machine for simplicity and quality.

The version of Gamma Knife that we're really focusing on today though is the latest released model, which is a Gamma Knife Icon. And the -- with the benefit of improved technology, the ability to treat a large number of patients with larger lesions over a series of multiple sessions.

The visible changes between Gamma Knife Perfexion and Gamma Knife Icon are pointed out here. The first one is the ability to use a mask instead of a frame for immobilization. The second is the addition of a cone-beam CT. And the last is the addition of a camera and tracking system for motion management.

The planning system has advanced so that it integrates real time information about the patient positioning immediately before beginning the treatment where the patient position can be evaluated, how the dose distribution looks at that time for that position.

Once the planning has been completed, the positioning has been reviewed, the dose distribution reviewed and approved by the authorized user, we then

move into the treatment. And there is a limit set on the amount of movement that is acceptable, and that's a very small amount of movement: 0.5 millimeters to 3 millimeters. That is continuously monitored throughout the treatment through the use of an infrared camera and reference frame. The threshold that is set, if it's surpassed, the machine goes into a safe mode or beam-off position without user interface. That is built into the machine.

This next slide -- yes, I'm sorry.

CHAIRMAN ALDERSON: Yes, this is Dr. Alderson. When that -- when you go into that beam off is there an alarm that sounds or is there some sort of a notification that goes out?

MS. LOHMAN: Yes, there is. There -- on the console itself there is a color change of the representation of the sectors that show they are in a beam-off position. There's also an indicator light that will flash that tells you that the beam is off. And then there's a -- if I go back to that slide, the graph representation that's on the bottom left of the slide, the blue line represents the tracking that's being done of the patient. The red line is representative of the threshold. So you can also visually see if that

threshold has been surpassed. What you can't see on this slide is that there are numbers in the top right corner of that screen that's on the monitor at the console that gives a numerical value for how far off of baseline the patient is. So it doesn't only monitor that they go out of threshold. It also monitors how far off of baseline they are in submillimeters.

CHAIRMAN ALDERSON: Thank you.

MS. LOHMAN: Yes.

Yes?

MEMBER ENNIS: The infrared tracking is specifically tracking what?

MS. LOHMAN: What it's tracking is the position of patient by way of a marker on their nose that is relative to four -- if I may for just a second -- these lines coming in here represent the eye of the camera. And what it's looking at are four sensors, infrared sensors that are built into that mask holder. So the patient is affixed to that mask holder. The camera is monitoring the position of the four fixed reflectors and any movement of the patient relative to those reflectors.

MEMBER ENNIS: So the patient position is essentially by the single point on the tip of the nose?

MS. LOHMAN: Correct.

MEMBER ENNIS: So and what, do you stick something on their nose?

MS. LOHMAN: Yes, a reflective marker is --

MEMBER ENNIS: How big is that marker?

MS. LOHMAN: Approximately three millimeters in diameter.

MEMBER ENNIS: And how is it attached to the nose?

MS. LOHMAN: It's a sticker and it sits on the tip of the patient's nose.

MEMBER ENNIS: And --

MS. LOHMAN: So with the configuration of these four reference points any movement of the patient's nose will be monitored in all directions, not just linearly.

MEMBER ENNIS: Well, you probably just have --

(Simultaneous speaking.)

MS. LOHMAN: Well, you also have rotation because it's where this one hits. So if the marker rotates even, its position relative to the fixed points changes.

CHAIRMAN ALDERSON: Thank you. Let's go ahead with the --

(Simultaneous speaking.)

MS. LOHMAN: Certainly. As I mentioned, this next slide to my taste is a little bit too salesy, but there is one point on it which I do want to draw your attention to, and that is the last one, which is safety through integration. There is a high level of safety built into the Gamma Knife with continuously quality control, with continuous self-monitoring that's built into the system, sensors that are triple-sensored, that there is redundancy in each and every movement of the device.

Gamma Knife has an impeccable safety record. Between the eight years of 2006 and 2014 there has been a review of these medical event records to the NRC. Of the 105,000 patients treated during that time in the United States there were only 17 event records submitted. Of those 17, one of them resulted in user intervention to stop a treatment, and that was because it was identified that the wrong site had been planned. It had nothing to do with the machine itself. It was during the planning process that there was an error made which was identified during treatment.

In addition to the NRC records, Elekta also looked at global reports available to us for that same time period. And what we found is that the need for the authorized user or authorized medical physicist; and those terms vary in different parts of the world, was for intervention to take place in 0.004 percent of treatments that were performed during that time making this the safest therapeutic technology available for radiation.

One of the major concerns for Elekta as well as others is the minimization of radiation to the public, and the Gamma Knife is designed to give very low dose to surrounding tissue as well as to other body tissue during the treatment. And this is documented in peer-reviewed papers that have looked at the scientific evidence with -- between treatments with Gamma Knife and other technology available in the market.

The efficacy and safety has been reported repeatedly. The 2,500 peer-reviewed papers on Gamma Knife represent over 74 percent of the literature available for stereotactic radiosurgery of the brain. This efficacy and safety is part of what has made the Gamma Knife the gold standard for treatment with radiosurgery of intracranial lesions.

Based on the long safety record of Leksell Gamma Knife, the technology to not only deliver precise and accurate treatment with high normal tissue sparing, but also built-in safety features incorporated into the machine, Elekta is making a request for modification to the physical presence requirement.

The current requirement is that a licensee shall for gamma stereotactic radiosurgery units require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit. And "physically present" is defined as within hearing distance of normal voice. And practically what this means in the clinical setting is that the authorized user and authorized medical physicist need to be at the console area of the Gamma Knife.

In order to increase patient access to care providers -- cancer is increasing both in the United States as well as worldwide. The incidence has grown exponentially. And in order to make care more accessible to patients, we feel that releasing the authorized user from being present at the console for the entire duration of the treatment would be a benefit to the patient population as a whole.

The proposed change that Elekta is respectfully requesting consideration of is we will have an authorized user and authorized medical physicist physically present during the initiation of all treatments involving the unit. The authorized medical physicist will be physically present throughout all patient treatments involving the unit. the authorized user will be physically present in the department during patient treatment and immediately available to come to the treatment room to respond to an emergency.

That's a lot of verbiage, so we've split it into two columns of the current requirement as well as the requested requirement.

So at the console at the initiation of treatment we are not requesting any change. Both the authorized user and authorized medical physicist be present. However, throughout the treatment course we're asking that the authorized medical physicist remain present, however, that the authorized user be allowed to be away from the immediate area of the console, but still immediately available within the department in the case of a medical emergency.

The rationale for keeping the medical

physicist at the console. The medical physicist is really the one who knows the most about the machine itself, and its machine safety as well as patient safety that is a concern. And the patient safety comes from the safety of the machine. The physicist does the commissioning, they do the QA throughout the year. If there's any troubleshooting that needs to be done with the machine, it's done by the physicist. So the physicist is the most prepared to respond to any emergency with the machine.

If we look at physical presence requirements throughout the radiosurgery world, the physical presence requirements on the Leksell Gamma Knife are the most restrictive. For linear accelerator stereotactic radiosurgery, there is no physical presence requirement.

In the middle of that, with the ViewRay Guided System there is a requirement for an authorized user or authorized medical physicist to be present in the department. The modification that we are requesting will keep Gamma Knife as the most restricted, however, it will allow the radiation oncologist, the authorized user, to step away from the console. It's the -- Gamma Knife is the most integrated technology,

but the most restrictive.

And with that, I thank you for your attention and allowing us to present this today and will open for questions.

CHAIRMAN ALDERSON: Excellent. Thank you very much.

Questions? Comments about this presentation? Dr. Zanzonico?

VICE CHAIR ZANZONICO: Thank you very much. That was very, very helpful. I'm not personally familiar with this technology, so some of my questions -- I'm a little naïve.

For a typical treatment what is the duration of the treatment? What kind of dose rates are we discussing?

MS. LOHMAN: Well, with cobalt decay, to give a dose rate, when a Gamma Knife machine is first loaded, it's a new machine, new cobalt, the dose rate is typically around 3.4 Gray per minute. The decay of cobalt is 5.26 years, so as time goes on the treatment becomes longer for the same indication, the exact same plan.

Treatments range anywhere from 30 minutes to 3 to 4 hours. A simple metastasis with the largest

size collimation might be a 20-minute treatment. A very complex meningioma or arteriovenous malformation or a patient with 15, 20 or even 30 metastases could be as long as 3 or 4 hours.

VICE CHAIR ZANZONICO: Because the point I'm getting at is sort of what is the tolerance in responding to a catastrophic failure? In other words, is it the order of minutes or less or longer in terms of avoiding some really damaging mis-irradiation of normal tissue? Because obviously the real value of this technology is its spatial precision.

MS. LOHMAN: Yes.

VICE CHAIR ZANZONICO: And that's sort of a double-sided coin --

MS. LOHMAN: Yes.

VICE CHAIR ZANZONICO: -- that if there was some failure, it wouldn't take much of a failure to over-radiate some nearby sensitive structures. So that was the question I was trying to get at, is sort of the response time relative to delivery of some potentially damaging radiation to a normal part of the brain.

MS. LOHMAN: The response time to minimize that would be seconds. It would require -- and in most

instances it would be the authorized medical physicist entering the room, removing the back cover of the machine and manually retracting the sector that was in a treatment position as opposed to in a safe position. That whole process takes less than maybe two minutes, the longest part being getting through the door into the treatment room.

VICE CHAIR ZANZONICO: And so that motion tracking system --

MS. LOHMAN: Yes.

VICE CHAIR ZANZONICO: -- if the patient for example had a seizure and some violent head motion --

MS. LOHMAN: Yes.

VICE CHAIR ZANZONICO: -- I mean, that wouldn't cause the system to fail-safe and automatically shut down?

MS. LOHMAN: No. What it would do is as soon as that seizure began and the patient moved out of tolerance -- and forgive me, I'm going to go into sort of a little bit of detail to better answer your question. If the patient is above that tolerance for three seconds, the sectors automatically go to a blocked position, which means radiation is not being delivered.

If after 30 seconds the patient does not return to under the threshold, the sectors go home, which is a totally retracted position, and the couch comes out.

If didn't want to wait that 30 seconds for that to happen, could press a pause button at the console which would send the sectors home and bring the couch out, at the same time allowing entry into the room in a safe condition for the users.

CHAIRMAN ALDERSON: And what you've described is just true of the Icon, is that correct?

MS. LOHMAN: Yes, the motion management, the tracking is only available with the Icon.

CHAIRMAN ALDERSON: Right, I just wanted to make that clarification because I think they're asking for a change with relationship to the Icon. But there are lots of other Gamma Knifes out there that aren't Icons, and what we're discussing doesn't apply to them. They still need the more rigorous approach.

Yes, Dr. Palestro?

MEMBER PALESTRO: Thank you. I have two questions for you and they're sort of related. And again, like Dr. Zanzonico, I'm not familiar with this sort of equipment. But you indicate that the authorized user; the requested change, should be

immediately available in the department.

MS. LOHMAN: Correct.

MEMBER PALESTRO: Okay. My first question is how is "immediately" defined? To me it's sort of a general term as written. There may be an implied or an understood definition.

And my second question sort of goes along with that: "is immediately available in the department." Initially or at least on first glance that sounds reasonable except when you think about departments that are scattered on multiple floors and in sometimes multiple buildings.

MS. LOHMAN: Yes.

MEMBER PALESTRO: So how is that addressed?

MS. LOHMAN: Okay. So to answer the first part of the question, the "immediately available in the department," what Elekta visualizes that as; and I believe many of the Gamma Knife users would visualize that as, is they could be doing a consult, they could be evaluating a plan for a patient to be treated somewhere else, they could be taking phone calls in their office, that if a page went out overhead, Dr. Authorized User, please report to Gamma Knife, they

could drop what they were doing and respond. They wouldn't be in the middle of a brachytherapy procedure or another procedure that they could not just drop what they were doing and walk away.

In regards to multiple departments spread over various parts of the hospital or various floors, the vision that Elekta has is that the Radiation Oncology Department would be a single floor, a single location, not spread out over multiple floors, multiple facilities.

CHAIRMAN ALDERSON: Dr. Ouhib has a question.

MEMBER OUHIB: Yes, this is Zoubir Ouhib. I think the importance is really what is the role of the authorized users in this treatment itself?

MS. LOHMAN: Yes.

MEMBER OUHIB: And so, let's take a look at two scenarios. There is a device malfunction. Source stuck for instance.

MS. LOHMAN: Correct.

MEMBER OUHIB: Okay? Or there is a medical situation, an emergency with a patient. So I think my first question is that who actually is involved in the patient's set up at the very beginning?

MS. LOHMAN: Okay. So involved in the patient set up at the very beginning varies. There are requirements, regulations that dictate that, but then there are also others who participate depending on individual centers that are not regulated that they have to be there. So by regulation the physicist and the radiation oncologist, authorized user and authorized medical physicist, have to be there, have to be involved.

And then depending on what center you're talking about the neurosurgeon may be involved in the patient's set up, nursing staff may be involved in the patient's set up, and in a few centers in the United States a radiation therapist involved in the patient's set up. But those three individuals are specific to institutions not regulated as such.

MEMBER OUHIB: Right, but to get to the details of it, because this is what will determine why and what. Okay. So we have a patient that comes in the room. The patient will lay on the couch and there's the set up. Does the therapist and the medical physicist get involved in positioning the patient at that point or does the authorized users must be present? What I'm getting to is that in the event that the whole set up

has to be dismantled --

MS. LOHMAN: Yes.

MEMBER OUHIB: -- in an urgent manner, can the medical physicist and the therapist and the nurse be able to do that without the intervention of the authorized user --

(Simultaneous speaking.)

MS. LOHMAN: Absolutely.

MEMBER OUHIB: Okay.

MS. LOHMAN: Yes.

MEMBER OUHIB: So in that event --

MS. LOHMAN: To clarify that, the release from the unit is a single latch which is sensored. Soit's a depress-a-button-turn-a-latch-all-in-one-movement which will release the patient's head from the positioning device.

MEMBER OUHIB: Okay. And then the patient can be taken out of the room?

MS. LOHMAN: Yes.

MEMBER OUHIB: Okay. That's great. And in the event of a source stuck, we know that the authorized user is not going to intervene in that situation. That will be the role of the medical

physicist?

MS. LOHMAN: Correct.

MEMBER OUHIB: I think what I'm trying to get at here is that what is it that's really critical from the authorized user to actually be present by the unit itself? And in both situations, it doesn't seem to be as critical as one might think. However, there is a need of the authorized user to be present in the department or whatever should a medical situation occur to basically care for that patient. But that patient could be rolled out of that room, taken out to a special room or whatever and then be evaluated and so on and so forth.

MS. LOHMAN: Yes.

MEMBER OUHIB: That was really all my point. Thank you.

MS. LOHMAN: That is correct. Thank you.

CHAIRMAN ALDERSON: Dr. Ennis has a comment.

MEMBER ENNIS: So you alluded to multiple sites or multiple isocenter types of treatment. So --

MS. LOHMAN: Yes.

MEMBER ENNIS: -- I have not had the privilege of working with a Gamma Knife very much. I

have LINAC-based SRS.

MS. LOHMAN: Yes.

MEMBER ENNIS: So when that's done within a Gamma Knife do you physically have to move the patient to a new isocenter position?

MS. LOHMAN: No, that is now fully automated.

MEMBER ENNIS: So what does that mean?

MS. LOHMAN: So --

MEMBER ENNIS: So you do a repeat cone-beam CT or you do --

MS. LOHMAN: No. The --

(Simultaneous speaking.)

MEMBER ENNIS: -- at the beginning?

MS. LOHMAN: The patient is positioned on the patient positioning device.

MEMBER ENNIS: Yes.

MS. LOHMAN: All of the information is electronically fed from the planning system to the Gamma Knife console. The console then controls movement of the positioning device. So the head is rigidly fixed to the positioning device, and the positioning device is what will move to change the isocenters. So the user intervention in setting up a patient is to lie the

patient down on the couch, affix either the stereotactic frame or the mask into the positioning interface.

There's a graphical interface that is visible in the room for things such as a timeout to identify the patient position, correct site, all of those, and interlocks, that side rails are in place, that it is -- the correct gamma angle, the tilt of the patient's head in the unit, etcetera, is all interfaced electronically.

And so once the patient is positioned on the treatment table, all of the other changes are made computerized.

MEMBER ENNIS: So --

(Simultaneous speaking.)

MS. LOHMAN: So the user is sitting at the console --

MEMBER ENNIS: Right.

MS. LOHMAN: -- watching the computer move the patient.

MEMBER ENNIS: So it's then treating a left-sided brain metastasis and then a right-sided one?

MS. LOHMAN: Yes.

MEMBER ENNIS: Does the patient's body move?

MS. LOHMAN: Correct.

MEMBER ENNIS: The patient's body moves?

MS. LOHMAN: So the whole couch will move --

MEMBER ENNIS: Okay. And how does that verify -- who verifies that that's happened correctly?

MS. LOHMAN: It's -- it -- on the -- at the Gamma Knife console there is a display of what the coordinates are that are planned as well as what the current position is.

MEMBER ENNIS: Yes. And --

MS. LOHMAN: And so --

MEMBER ENNIS: -- with your proposal --

MS. LOHMAN: -- it's a visual --

MEMBER ENNIS: -- the authorized user would not necessarily need to be there to check that?

MS. LOHMAN: Correct. Yes.

MEMBER ENNIS: Would need to be to check the first set up --

MS. LOHMAN: Would need to check the set up --

MEMBER ENNIS: -- the first --

MS. LOHMAN: -- of the patient --

MEMBER ENNIS: At the first --

(Simultaneous speaking.)

MS. LOHMAN: -- so that they're positioned, yes.

MEMBER ENNIS: But not later on?

MS. LOHMAN: Correct.

MEMBER ENNIS: And what would --

MS. LOHMAN: If --

MEMBER ENNIS: -- be the logical difference between the first set up and making sure that first position is correct --

MS. LOHMAN: Yes.

MEMBER ENNIS: -- and --

MS. LOHMAN: It's --

MEMBER ENNIS: -- why the second position doesn't need the same --

(Simultaneous speaking.)

MS. LOHMAN: It's not necessarily making -- it's not making sure that the first position is correct. It's making sure that the patient is correctly positioned on the treatment couch. So it's not the movement of the couch that we're talking about at the initiation of treatment. It's that the patient is correctly set up on the treatment couch.

MEMBER ENNIS: Yes. And the cone-beam CT,

that would be done to check the alignment? In your proposal even the first one would not need to be checked by the authorized user?

MS. LOHMAN: That is done before the initiation of treatment.

MEMBER ENNIS: Right. No, I understand that.

MS. LOHMAN: So if --

MEMBER ENNIS: But I'm saying from your --

(Simultaneous speaking.)

MS. LOHMAN: It -- no, it does need to be checked by the authorized user.

MEMBER ENNIS: But then why would only the first one need to be --

(Simultaneous speaking.)

MS. LOHMAN: Because a cone-beam CT is only done before the initiation of treatment.

MEMBER ENNIS: And then you just rely on the technology to make the shifts correctly?

MS. LOHMAN: The shifts are done through the couch and any patient movement out of position from where they were at the time that the cone-beam CT was acquired is monitored by the patient tracking -- the high-definition, correct. Correct. Yes.

MEMBER ENNIS: Okay. So it's really relying a lot on this nose marker and --

(Simultaneous speaking.)

MS. LOHMAN: Correct. If it any time that marker not only moves, but becomes invisible or any of the reference positions become invisible, the patient changes position of their arm and the blanket is up and blocks visualization, it will stop treatment. It has to see all four markers and a consistent relationship of the marker on the patient to the four reference markers.

CHAIRMAN ALDERSON: So before we get into too many micro-details of exactly how people do this, I'd like to point out that what they're asking for, the authorized user is going to be in the department. Could be the contiguous department. And so the NRC doesn't want to regulate medical practice, so the NRC isn't going to say, well, the authorized user has to be here, there or somewhere else. If he's in the department, he or she, they'll practice medicine.

But the fact is that they're asking for some latitude to allow that authorized user, not the physicist, to be steps away or down the hall or somewhere else because their system in the ICON will regulate

that. So I just wanted to make that clear to everyone, yes.

Yes, Laura? Ms. Weil?

MEMBER WEIL: I have a question, two questions.

MS. LOHMAN: Yes.

MEMBER WEIL: The error that was discovered where it was a planning error --

MS. LOHMAN: Yes.

MEMBER WEIL: -- 1 out of 105,000 cases --

MS. LOHMAN: Yes.

MEMBER WEIL: -- who discovered that error and at what point?

MS. LOHMAN: It was the physician that discovered that error during dictation when they were comparing the -- in doing the dictation --

MEMBER WEIL: Yes.

MS. LOHMAN: -- was reading both the patient history and the treatment protocol and realized that one said right, the other said left.

MEMBER WEIL: So that physician was present?

MS. LOHMAN: Was not present. It was someone that was not at the console but made the call

to the Gamma Knife console where the authorized user was to say we need to stop treatment. We're on the wrong side.

MEMBER WEIL: Okay.

MS. LOHMAN: And that may not be the exact verbiage, but that's --

MEMBER WEIL: Okay.

MS. LOHMAN: -- the gist of it.

MEMBER WEIL: That's helpful. Thank you.

MS. LOHMAN: Yes.

MEMBER WEIL: And had a physician not been present at the console when that call was made, the physicist --

MS. LOHMAN: Physicist, nurse, therapist --

MEMBER WEIL: -- could have --

MS. LOHMAN: -- would have pushed the pause button which would have interrupted the treatment and brought the patient out of the treatment unit --

MEMBER WEIL: Okay.

MS. LOHMAN: -- and closed the --

(Simultaneous speaking.)

MEMBER WEIL: The other question I have, you talk about this relaxation of the regulations would

increase patient access --

MS. LOHMAN: Yes.

MEMBER WEIL: -- to this particular intervention. Are you aware that there's a delay in access or are either of your radiation oncologists aware that there's any delay that patients experience because of the regulation that's current?

MS. LOHMAN: It's not the delay in treatment. It's allowing the radiation oncologists to be available to see more patients during the course of a day. So the access that we're talking about is the patient population as a whole, not necessarily patients who will or are even candidates for Gamma Knife treatments, but access for the public population, those who have been diagnosed with a cancer to see the availability of a radiation oncologist to see them in a timely manner.

CHAIRMAN ALDERSON: Yes, Dr. Langhorst?

MEMBER LANGHORST: Thank you.

Ms. Weil, I wanted to let you know in our case our physicians could be looking at our next Gamma Knife patient and getting them prepared for their treatment. And so that's why they would be outside this patient's treatment, to get prepared for the next

patient, to make that a more timely and a better flow, a process for the treatment.

And we have many people in the Gamma Knife facility to respond to emergencies. And so when Dr. Zanzonico was asking about if there's a stuck source or whatever, the physicist, yes, can go in and pull those sources, but that's not the only response. The therapist, the nurse, they're all trained to -- I mean, I as a radiation safety officer am trained to know how to disconnect the couch, pull it out and get the patient out of there. So there's a lot of different things that happen and it doesn't require the authorized user to be physically present, because there's a lot of the team right there to be able to respond to those situations.

I had one question. When you have longer treatments --

MS. LOHMAN: Yes.

MEMBER LANGHORST: -- patients may ask please stop right now, and so maybe they need to get up and move a little bit, do you propose that the authorized user come back to make sure that positioning again happens correctly?

MS. LOHMAN: Yes, because that would be an initiation of treatment.

MEMBER LANGHORST: Okay.

MS. LOHMAN: It's an interrupted treatment --

MEMBER LANGHORST: Right.

MS. LOHMAN: -- but it would be initiating treatment at that time.

MEMBER LANGHORST: Okay. I think that would need to be clarified, too, because that was a question I had, and I think that's the right way that it needs to go.

MS. LOHMAN: Yes.

MEMBER LANGHORST: Thank you.

CHAIRMAN ALDERSON: Dr. Ouhib?

MEMBER OUHIB: Yes, so you have multiple isocenters.

MS. LOHMAN: Yes.

MEMBER OUHIB: Is there verification of the second isocenter is correctly placed by the authorized user?

MS. LOHMAN: The --

MEMBER OUHIB: I mean, is -- I guess the question is there any imaging at that point --

MS. LOHMAN: There is not.

(Simultaneous speaking.)

MEMBER OUHIB: -- to another?

MS. LOHMAN: There is not. The planning is done. The patient is fixed. We're not moving -- we're not repositioning the patient on the treatment unit. The patient is positioned and the whole couch is moving. And so what's being detected is the movement of the couch to the next isocenter. There's not a specific patient intervention to get from isocenter to isocenter.

The way that Gamma Knife works is there is a fixed focal point of the machine and the patient, whatever is prescribed as the isocenter. The X, Y and Z coordinate, by way of stereotactic space, is moved to that isocenter.

MEMBER OUHIB: I understand. So I'm assuming that couch shift is being tested on a daily basis or --

MS. LOHMAN: Absolutely.

MEMBER OUHIB: -- prior to each patient?

MS. LOHMAN: It is tested on a daily basis and it is monitored throughout the patient treatment with triple sensors that -- there's one sensor that monitors it. There's a sensor -- a second sensor that monitors it and then a third sensor that monitors the

activity of both of the previous sensors. So the movement of the couch is triple monitored in the machine itself. And any variation at submillimeter increments will cause a pause of the treatment. It would cause the couch to come out and it would report it as an error, movement surveillance error.

MEMBER OUHIB: Right, but are there watchdogs monitoring the accuracy of the couch itself at the same time in the system?

MS. LOHMAN: Yes. Yes, those sensors are what are monitoring the movement of the couch to submillimeter accuracy.

MEMBER OUHIB: All right.

CHAIRMAN ALDERSON: Are there any final questions on this? Yes, Dr. Metter?

MEMBER METTER: Thank you for your very nice presentation. I don't know much about it either, but my question relates to medical events.

MS. LOHMAN: Yes.

MEMBER METTER: What were the other 16 issues you mentioned? Were there any trends?

MS. LOHMAN: The other 16, the majority of those that were reported were planning errors or errors in imaging which resulted in a mis-definition of

stereotactic space. And by that I mean when the patient was imaged in the MR or CT Department, an indicator box which provides fiducial markers to set up to define stereotactic space was misplaced. It was not attached appropriately.

There was one instance that the patient actually moved. They were able to dislodge the frame, but it was discovered at the end of the treatment. So there were 17 different targets being treated. Between targets 16 and 17 there was a request by the patient for a break. The break was given. Medication was given. Treatment was resumed. During that last target the patient did move quite a bit in the unit and at the end of treatment when they went to remove the stereotactic frame, it was loose. So they don't know if there was actually any misadministration as a result of that, but it was noted that the frame was loose, which meant it could have shifted slightly on the patient's head.

MEMBER METTER: So then the other things you mentioned didn't apply then, or didn't kick in to stop the treatment?

MS. LOHMAN: That was on an older model of the Gamma Knife.

MEMBER METTER: Okay.

MS. LOHMAN: That -- there have been, that I'm aware of, no incidences reported with Gamma Knife Icon.

CHAIRMAN ALDERSON: Ms. Holiday has a comment.

MS. HOLIDAY: Hi, Sophie Holiday. I just have two questions for you. The first is when you went through your presentation you quoted how many treatments were performed worldwide with the Gamma Knife System.

MS. LOHMAN: Yes.

MS. HOLIDAY: Are you aware of how many treatments have occurred in the U.S. with the Icon unit?

MS. LOHMAN: Let me -- Catherine Gilmore-Lawless is here as a consultant for Elekta.

And do you have that -- I know there was information available as of four months ago. Do you happen to know what that number was?

MS. GILMORE-LAWLESS: I think we only have it for -- the global number is over 2,000.

MS. LOHMAN: Okay. Thank you.

CHAIRMAN ALDERSON: Global number is over 2,000 in case people didn't hear that.

MS. HOLIDAY: Thank you. And then another question or point of clarification is it's my understanding that with the Leksell Gamma Knife Icon unit, while there is a thermoplastic mask that can be used as a frameless option, not with the frame, and it's coupled with the cone-beam CT and the high-definition motion management system --

MS. LOHMAN: Yes.

MS. HOLIDAY: -- the Icon also has the ability to operate with the frame.

MS. LOHMAN: That is --

MS. HOLIDAY: So that means the Icon can use the mask, which as you've heard will detect if there is any position difference through the HDMM system, however, if the Icon is used with the frame, you do not use the HDMM system. So I just wanted to clarify that for the Committee.

CHAIRMAN ALDERSON: Well, I'm going to have to ask a follow-up question then. If you're using it with a frame -- by the way, patients don't want to use the frame. The frame is uncomfortable. This move to a mask is a big positive step in the right direction. But are you saying that if they're using the frame there's no automatic cutoff like there is here?

MS. LOHMAN: There is not motion tracking --

CHAIRMAN ALDERSON: There is not?

MS. LOHMAN: -- with use of the frame. The frame is considered a rigid device.

CHAIRMAN ALDERSON: I see.

MS. LOHMAN: It's a rigid fixation to the skull, to bone of the patient. So they're not going to be able to move within that frame unless there is an issue as such where a frame becomes loose. And that you'll -- is not going to be -- that would not be something that could be detected --

(Simultaneous speaking.)

CHAIRMAN ALDERSON: Well, then it might be necessary in any change in wording to specify an Icon system using the mask specifically. All right.

Yes?

MEMBER LANGHORST: I would like to ask how the presence of an authorized user would prevent that. It wouldn't and it wouldn't deter the response to any emergency. And so I believe this works well on the Perfexion unit also. So --

CHAIRMAN ALDERSON: But the only thing being requested is for the Icon, correct?

MS. LOHMAN: Correct.

CHAIRMAN ALDERSON: Correct.

MEMBER LANGHORST: But for the Icon only with the mask --

MS. LOHMAN: No, for --

MEMBER LANGHORST: -- or for the Icon total?

MS. LOHMAN: -- Icon Gamma Knife radiosurgery.

MEMBER LANGHORST: Yes.

CHAIRMAN ALDERSON: Yes.

MEMBER LANGHORST: So I think that --

CHAIRMAN ALDERSON: We're about 14 minutes over. Is there a final -- I don't -- if there's a burning question, you can ask it, but other than that I would suggest that you hold the questions now just in view of the other important items we have to discuss.

Yes, Dr. Suh?

MEMBER SUH: Yes, so, Susan --

CHAIRMAN ALDERSON: That will be the last comment.

MEMBER SUH: So, Susan, thanks for an excellent presentation. There is no question that Elekta should be very proud of the safety record that

the Gamma Knife has had over the many decades, that it's really been a pioneer in terms of how to make treatments more accessible to patients in terms of delivery. And with the current version of the Icon, it's been an advance, there's no question, with the mask-based system.

But in terms of the physical presence requirement, it is something that I would be open to, although the language would need to be very strict about what physical presence involves. As you know, where I used -- where our former Gamma Knife center was it was a 10-minute walk to the department. So although technically I could say that it was within -- physically within the department, it's 10 minutes for me to respond because -- and that's if I ran on a good day.

MS. LOHMAN: Right.

MEMBER SUH: So that language would need to be modified. And again, that's where it's going to be a little difficult in terms of how prescriptive it would be. And what's that distance? Is it 100 meters? Is it 200 meters? Because there's no question, the safety record is something that is -- think about 108,000 cases and 17 safety reported events from an 8-year period. That's very, very impressive. And I think it's very

important that whatever change that any committee or anyone else advises -- I think you want to try to uphold that really high bar in terms of safety and quality, because when patients think about Gamma Knife surgery, the first thing that comes to mind is this is a very, very precise treatment.

MS. LOHMAN: Yes.

CHAIRMAN ALDERSON: Well, I'd like to thank Ms. Lohman for her excellent, excellent presentation. I think we will ask later for a subcommittee to review what's been discussed here, particularly with some of our radiation oncologists on that committee and to come back to us at a later date with their own recommendations.

But thank you very much.

MS. LOHMAN: Thank you.

CHAIRMAN ALDERSON: Appreciate that.

We'll move on now to the next presentation, which is from Dr. Wu of the NRC on the status update on Source Security and Accountability Initiatives.

DR. WU: Hi. Good morning, everybody. Thank you so much for the opportunity to come and speak to you today about Source Security and Accountability Initiatives here at the NRC. I will be focusing my

presentation on specifically the Category 3 Source Security and Accountability Initiatives going on.

Again, I'm Irene Wu. I am a project manager here at the NRC in the Office of Nuclear Material Safety and Safeguards and I am the co-chair of the Category 3 Source Security and Accountability Working Group that is leading the effort on this initiative.

So before I go into what exactly the working group's been looking at and those activities, I did want to give some background on how we got here. So since the events of September 11th the NRC has been enhancing the security and accountability of radioactive sources that pose a threat to the public, and these enhancements have been focused on the most dangerous sources, those with International Atomic Energy Agency Category 1 and 2 quantities of radioactive materials. The NRC has considered expanding these enhancements to Category 3 sources in the past, and most recently in 2009, but concluded that the existing requirements provide adequate protection.

As I will discuss, as a result of recent events involving NRC and the Agreement States, the Commission directed staff to provide recommendations on whether it is necessary to revise NRC regulations or

processes governing source protection and accountability of Category 3 materials to continue to ensure adequate protection of public health and safety.

So what are Category 3 sources and what type of activities involve their use? Category 3 sources, if not safely managed or securely protected, could cause permanent injury to a person who handled them or was otherwise in contact with them for some hours. Category 3 sources are those containing a quantity of radioactive material equal to or greater than 1/10th of the Category 2 thresholds, but less than the Category 2 thresholds.

These sources have a wide variety of uses in industry, medicine and research and include applications such as fixed industrial gauges, high dose rate brachytherapy sources, plutonium pacemakers, research reactor start-up and certain well logging sources. Category 3 sources are also being used by governmental agencies in security screening at ports and cargo terminals. The number of Category 1 through Category 3 NRC and Agreement State licensees affected by this reevaluation could exceed about 5,000.

So in 2007 the Government Accountability Office, or GAO, conducted an investigation into the

NRC's Materials Licensing Program. Using a fictitious company, GAO attempted to obtain radioactive materials licenses from one NRC regional office and one Agreement State. GAO was successful in one of two attempts to obtain a radioactive materials license and used the original license in an altered version to place orders for radioactive material in portable gauges. The investigation demonstrated that GAO could have acquired an aggregated Category 3 quantity of material, although I'll make clear that at no point in the investigation were radioactive materials actually shipped to the fictitious company.

After the 2007 investigation the NRC and Agreement States made a number of significant changes to strengthen the licensing and regulatory processes to prevent individuals who have malevolent intent from obtaining a radioactive materials license.

Later in 2007 staff submitted an action plan to the Commission to address recommendations for enhancing NRC and Agreement State inspection and licensing programs with respect to source security oversight. The Commission approved the staff's action plan which included consideration of expanding the National Source Tracking System, or the NSTS, to include

Category 3 sources plus a subset of high-end Category 4 sources. This proposed rule on the expansion of NSTS was published in the *Federal Register* in April 2008.

In January of 2009 licensees began reporting Category 1 and 2 source information to the NSTS. Staff requested to further -- to defer further expansion of the National Source Tracking System that would have included Category 3 sources to allow staff to monitor the operation of NSTS for one year to apply any resulting insights to inform the decision on -- the Commission's decision on system expansion.

This request for deferral was not approved by the Commission, so in June of 2009 staff requested approval of the final rule amending Part 20 and Part 32 to expand the reporting to the NSTS to include Category 3 sources. The Commission did not reach a decision on the proposed rulemaking and that final rule was not approved as a result of a split 2-2 vote.

Some of the Commission votes indicated that a further expansion of NSTS should be based upon a vulnerability assessment built off of an interagency risk study for sources and that the original recommendation lacked a risk-informed foundation for the proposed regulatory action.

So moving forward, in December of 2014 Congress passed and President Obama signed the Consolidated and Further Continuing Appropriations Act of 2015 that included a requirement for NRC to conduct an assessment of the security requirements in 10 CFR Part 37. This assessment, referred to as the Program Review of Part 37, was expanded to encompass an evaluation of nine review areas which are listed on the slide related to the implementation of the security requirements in the rule.

These areas included the results of inspections conducted of NRC licensees in the first two years of the rule implementation as well as an evaluation of events reported under the provisions of the rule. The Program Review also included consideration of the definition of "aggregation" as it applies to well logging sources and an evaluation of enhanced tracking and accounting of radioactive sources. The results of the Program Review were documented in a report that was sent to Congress in December of 2016. A second report was prepared by staff summarizing the detailed findings of the Part 37 Program Review Team.

In the same Appropriations Act, Congress

required GAO to lead an independent review of NRC and Agreement States' Part 37 implementation upon the conclusion of NRC's Program Review and provide a separate report to Congress by the end of 2018.

So that brings us to the most recent GAO licensing audit and investigation.

So in 2014 GAO initiated another audit of the Materials Licensing Program to determine whether the licensing vulnerabilities identified back in its 2007 investigation had been addressed by the NRC and Agreement States. As part of its audit GAO conducted an investigation that again attempted to obtain radioactive materials licenses from one NRC regional office and two separate Agreement States using fictitious companies.

This investigation went beyond the 2007 investigation in its sophistication and planning such that GAO rented storefront space to demonstrate each fictitious company's legitimacy during pre-licensing visits. The GAO was successful in one of three attempts and acquired a license for a Category 3 well logging source. GAO was subsequently able to place an order for one Category 3 source and then alter the license and place an order for a second Category 3 source.

The investigation demonstrated that GAO could have acquired an aggregated Category 2 quantity of material, although at no point again in this investigation were radioactive materials actually shipped to the fictitious company.

On July 15th, 2016 the GAO published its final report for the material licensing audit and investigation entitled, "Nuclear Security: NRC has Enhanced the Controls of Dangerous Radioactive Materials, But Vulnerabilities Remain," and this report made three recommendations, which are listed on this slide: They are they were to include Category 3 sources in the National Source Tracking System and add Agreement State Category 3 licenses to the Web-Based Licensing System, or WBL.

Second was to require that transfers of Category 3 quantities of radioactive materials confirm the validity of a would-be purchaser's radioactive materials license with the appropriate regulatory authority or use NRC's License Verification System, or LVS, before transferring any Category 3 quantities of licensed materials.

And lastly, consider requiring that an on-site security review be conducted for all unknown

applicants of Category 3 licenses to verify that each applicant is prepared to implement the required security measures before taking possession of licensed radioactive materials.

Once notified of GAO's audit and investigation in October of 2015, the NRC and Agreement States took a number of immediate and long-term actions. The immediate actions included the conduct of self-assessments of licenses issued to unknown applicants. Refresher training was developed and provided via webinars on the use of pre-licensing guidance and conduct of site visits for all NRC regional and Agreement State inspectors and license reviewers.

In January of 2016 we stood up two NRC Agreement State working groups and they were commenced to evaluate vulnerabilities identified as a result of this GAO investigation. One of the working groups considered enhancements to the pre-licensing guidance, while the second working group evaluated the need for enhancements to existing requirements or guidance for the license verification and source tracking beyond the Category 1 and 2 thresholds.

The working groups were also tasked with evaluating the GAO final report. The working groups

completed their reports back in October of 2016 and a steering committee evaluated those recommendations that were made by those two working groups. The two reports and the recommendations produced by the working group will play a key role -- and they do play a key role in the Category 3 source accountability reevaluation.

So now to the work that my working group is leading. So given the Agency's operating experience with higher-risk sources and response to the GAO findings, on October 18th of 2016 the Commission issued a staff requirements memorandum on the proposed staff reevaluation of Category 3 source accountability. That SRM issued directed staff to take specific actions to evaluate whether it's necessary to revise NRC regulations or processes governing source protection and accountability. The SRM also required the submission of a notation vote paper that is slated to go to the Commission in August of 2017.

And the evaluation has to include these nine tasks, and they are: to evaluate the pros and cons, different methods of verification of a license's validity, evaluating the pros and cons of including Category 3 sources in NSTS, looking at the GAO recommendations and assess any additional options for

addressing those recommendations, a vulnerability assessment or threat analysis, a regulatory impact analysis of the accrued benefits and costs of any recommended changes, any potential actions that don't require any rulemaking and that can be monitored through the Integrated Materials Performance Evaluation Program, an assessment of the risk of aggregation of Category 3 sources into a Category 2 quantity, collaboration with affected stakeholders, getting that stakeholder feedback, and then lastly any other factors to inform the Commission decision.

As previously noted, it hasn't been since 2009 that we've really looked at enhancing Category 3 source security and accountability, but as you can see from these tasks this reevaluation is a bit different from past efforts in its scope. Not only will the reevaluation build off of the efforts resulting from the recent GAO investigation, but it will integrate the recently completed comprehensive program review of Part 37 and the current threat landscape.

And then the last task that's included on that slide speaks to the Commission's desire for a real -- a broad and comprehensive assessment.

So to conduct this reevaluation of Category

3 source security and accountability we stood up an NRC and Agreement State Working Group to evaluate and make recommendations. The working group took the nine tasks on the previous slide and broke those down and then grouped them into four activities, as you see on the slide. And all of these task are underway. The working group recommendations will be documented, as I said before, in a notation vote paper to the Commission in August of 2017. Clearly a significant amount of work has been done already and there's still left to be done in the coming months, so I'll give you an update especially on the stakeholder feedback piece.

In February of 2017 NRC also did provide the Commission with an information paper to update them on the source security and accountability activities. That's SECY-17-025. And included in that information paper were the recommendations from the two previous working groups formed in response to the findings and recommendations by the GAO materials licensing audit and secondly the initiation of this current working group looking at Category 3 source security and accountability, and then also potential strategies for addressing rulemaking activities affected by materials licensees.

So on that last note about rulemaking activities I did want to include a diagram for you to see; and it is quite complicated, that would summarize the various materials security activities over the last few years that I've been mentioning and how they'll be integrated into this current Category 3 reevaluation.

The red box on the left highlights our activities in response to the GAO audit, where the box on the right highlights -- the orange box on the right highlights the Part 37 Program Review. The middle or yellow box summarizes the Category 3 source security and accountability activities.

Some recommendations from our GAO and Part 37 reviews identified enhancements of our licensing and inspection guidance training and oversight responsibilities. These recommendations will be integrated into our Inspection, Licensing and oversight Programs and implemented in the future.

The GAO and Part 37 reviews also identified the need for changes to the NRC rules and regulations. The Commission will have to approve the commencement of work on the regulations and development of their regulatory basis, which is seen in that little blue box in the middle.

The NRC recognizes the impact for making multiple changes to the regulations over a short period of time and the cumulative effect that it will have on licensees and the Agreement States. So we'll look for ways to bundle any changes to the regulations together. Any rulemaking activities associated with these activities and these initiatives will likely occur beyond 2017, but most important however is that any rulemaking that -- will require input from the regulated community and the Agreement States.

So the main enhancements under consideration by this working group are listed here on the slide. And here's -- the first -- the items here are ones that are currently required for Category 1 and 2 sources. So we're looking to see if they -- the questions that we asked in our *Federal Register* notice and in all of our outreach efforts were asked whether or not that -- we should expand what's being done for Category 1 and 2 licenses to Category 3 licenses and Category 3 sources.

It's important to note that the focus of the working group is source accountability and license verification for Category 3 sources and not all the security areas required from Category 1 and 2 sources.

However, as previously noted the Commission did direct the staff to not limit the scope of this assessment, but for it to be very comprehensive.

So this slide just depicts what is currently being done for Category 1 and 2 licenses and to show how license verification -- how it ties to the other systems I've mentioned: the National Source Tracking System and the Web-Based Licensing System. And we've been using this diagram in our outreach efforts to demonstrate what is being done for Category 1 and 2 and let people see if that is something that they would want us to expand for Category 3.

So an important aspect of this Category 3 reevaluation was and is to solicit input from the affected regulatory community, many of whom have not been subject to enhanced security and accountability requirements. So we published a *Federal Register* notice back in January of 2017 which contains specific questions for stakeholders to consider regarding Category 3 sources. We received 54 comment letters in response to that *Federal Register* notice. And to facilitate feedback on that we also held four public meetings and two webinars that were transcribed.

In addition to those efforts we wrote

articles that were published in the CRCPD, Health Physics Society, and the NMSS Newsletter, as well as gave presentations to industry groups and professional organizations like the AAPM to solicit feedback. And the comment period, we had a 60-day comment period on that *Federal Register* notice and that closed back on March 10th.

There were 22 questions in that *Federal Register* notice that were separated into seven sections that were based on topics and applicability to relevant stakeholders. The seven sections included general questions related to license verification involving transfers of Category 3 sources, general questions related to the inclusion of Category 3 sources in NSTS, and then again questions related to -- more specific to Agreement States, related to license verification and inclusion of Category 3 sources in NSTS, and then sort of another category of questions.

So at the time that I had to finish these slides for this I didn't -- we hadn't -- I don't -- the comment period closed, but we hadn't fully gone through all the analysis of the comments that we received. So I included this general slide to be able to talk with you on what we observed in the comments. So

in general; and I'll step through it first on the comments that we received regarding license verification of Category 3 source -- Category 3 quantities of radioactive material.

In this area majority of people were against expanding license verification, or in this case sort of limiting the license verification options to just having to do those through the LVS or the regulatory authority. In general we heard from stakeholders that they were happy with the existing method of being able to exchange paper licenses with one another and then to be able to -- and then not to have to then do the extra step of going through the regulatory authority.

We did hear specifically from -- let me find my notes here, hold on, give me a second -- from specific medical licensees as well as we did hear from several non-governmental organizations that you would be interested in. AAPM being one, the American College of Radiology and the American Society of Radiation Oncology. And for the medical licensees that we heard from, as well as those NGOs, they mostly again said no for expanding LVS to include Category 3 licenses.

In terms of comments received regarding Category 3 sources in the NSTS, again the specific

medical licensees and the NGOs that we heard from were against tracking Category 3 sources in NSTS. Most of the arguments for why they didn't feel that that was necessary was if there would be no added security or safety benefit and there would be a high burden to do that additional tracking.

Comments received regarding enhancing physical security requirements for Category 3 sources, again as we expected we did hear from medical licensees and the medical NGOs on this and they did not want us to take Part 37 security requirements and apply them to licensees with just Category 3 sources, again for the same reasons that it would be a huge cost, a financial burden, they would have to ramp up staffing.

And then we did hear some aspects of how -- that this -- that having to implement all this and then the higher costs would essentially take away from patient care. It could cause some licensees to stop offering certain medical care. So we are incorporating and reviewing these comments and taking them into consideration for working group recommendations.

And then lastly, we did have some questions on whether Category 3 sources covered under a general license -- if that should be prohibited, if those should

be considered switched from a general license to a specific license. And medical licensees and the NGOs were mostly silent on this. The only -- the few comments that we did get from them were that if NRC did choose to expand Part 37 to apply to Category 3 licenses that they felt that those Category 3 devices that contained -- that were covered under a general license should be then converted to a specific license.

So again, we're taking all these comments right now into consideration as part of the working group and formulating recommendations.

So next steps. Like I said, we are -- we finished reviewing all of the comments we've received from letters and all of the comments in our public meetings and webinars and we're preparing comment resolution documents that will be part of the Commission paper. We've identified some gaps with our current regulations and guidance and are looking at the changes or enhancements needed to close those gaps.

We have done a lot of work on the vulnerability and threat assessment piece. And we are also making a lot of headway on the cost-benefit analysis. The cost-benefit analysis, although somewhat similar to what's done for rulemaking, will

focus on the working group recommendations and the various options. And that will be done at a much higher level. Again, if this proceeds to -- when this -- if this proceeds to rulemaking, then there will be a much more detailed cost-benefit analysis included with that.

And then finally, as I've mentioned several times, staff is preparing a Commission paper with its recommendation, and that's due to the Commission in August.

So I just wanted to end with my contact information. Duncan White, who is also on the working group. We also have a web page that has links to our working group charter, the transcripts and meeting summaries from all of the public meetings that we've had. So we tried to do all this to help facilitate stakeholder feedback and keep all stakeholders informed.

CHAIRMAN ALDERSON: Well, thank you very much for this report. And I have a couple of questions that I'd like to put on the table and then open it up for everyone else.

I think this is an important activity. I am surprised -- but my first question is; and I'm unaware of this, are any members of the ACMUI on the working

group that is looking at this question?

DR. WU: No, so the working group is made up of NRC and Agreement State staff. So it's -- there's no members from ACMUI.

CHAIRMAN ALDERSON: And it's all staff? I mean, the Agreement State people that are on are staff in those Agreement States. NRC staff --

(Simultaneous speaking.)

MS. LOHMAN: Right, so ours -- the Agreement State representatives we have, we have one that is a supervisor of their Radioactive Material Program, and then the other one is staff --

CHAIRMAN ALDERSON: I see.

MS. LOHMAN: -- from two different Agreement State.

CHAIRMAN ALDERSON: All right. So the second question, it's a corollary and I'm going to be the one -- probably all of you sitting around the table at your fingertips know what all the Category 3 sources are that are used in medicine. Your chairman does not. And so I'm going to ask you to tell us what these sources are, most of these sources are. Perhaps Dr. Langhorst will tell us what those are --

(Laughter.)

CHAIRMAN ALDERSON: -- because she has her hand up.

MEMBER LANGHORST: Thank you.

CHAIRMAN ALDERSON: And that will give all of us a little better idea of what impact we might be talking about.

Dr. Langhorst, would you like to help with this question?

MEMBER LANGHORST: Thank you very much. I'd be more than happy to help with this question.

So currently if there are no changes in the Part 20 table of what sources are required for NSTS tracking, it will only impact HDR sources.

CHAIRMAN ALDERSON: HDR radiotherapy sources?

MEMBER LANGHORST: Yes, so the high-dose remote afterloader sources.

So the other sources used in medicine; and I hear Ms. Weil asking about cobalt, those are already Category 1 and Category 2 sources that are already covered. So the inclusion of Category 3 sources only impacts HDR sources at this point in time.

CHAIRMAN ALDERSON: So at this point in time what we would call diagnostic radionuclides would

not be impacted?

MEMBER LANGHORST: That's correct.

CHAIRMAN ALDERSON: And what about blood irradiators?

MEMBER LANGHORST: Those are already more than likely Category 1 or Category 2 sources.

CHAIRMAN ALDERSON: They are already Category 1 or Category 2 sources?

DR. WU: Right, so they are already complying with the license verification requirements in Part 37 and the NSTS source tracking requirements in Part 20.

CHAIRMAN ALDERSON: Good. Thank you very much. That's good context. Given that context, Dr. Ouhib would like to --

(Simultaneous speaking.)

MEMBER OUHIB: Yes, keep in mind on the HDR itself -- now if you have two sources present there of 12 curies, now you are in a different category.

CHAIRMAN ALDERSON: Yes, Dr. Langhorst?

MEMBER LANGHORST: And usually you wouldn't have two sources that are at their maximum.

MEMBER OUHIB: Right, just to be aware of it.

MEMBER LANGHORST: But I do have a couple questions, if I may?

CHAIRMAN ALDERSON: Please.

MEMBER LANGHORST: Ms. Wu, I thank you and your working group's efforts and in particular the seeking of stakeholder comments. I mean, I know that takes a lot and I really appreciate -- and especially with you being under such a tight deadline.

My first question is do licensees have access to the License Verification System?

DR. WU: So currently those who are subject to Part 37, the license verification requirements, that are mostly Category 1 and 2, they can apply for access. And we go through a credentialing process of determining whether they need to have access. We have had instances where lower category licensees who can't aggregate to a Category 2 quantity have applied for access and we've denied them in those cases because they don't have a need to get access to LVS. But, yes, there are licensees currently right now who have access to LVS.

CHAIRMAN ALDERSON: And are those licensees mostly the vendors, because I understood I couldn't get access.

DR. WU: So, yes, they are mostly

licensees. Agreement State and regulated community do have access, but they have a different view when they log in. Like myself, when I log in, I see a different view than when a licensee goes in.

MEMBER LANGHORST: And if a licensee does not have that access, what's the way that they have to do to verify this as far as Part 37 goes and what you're considering?

DR. WU: Okay. Yes, so we prefer them to use the online License Verification System, but we recognize that a lot of licensees will opt to use the manual process, the alternative method, for many different reasons. Right now we have licensees who either are not comfortable -- they did not want to use the computer-based system. Either they don't have a frequency of transfers that would warrant them to then go through that full credentialing process and have yet another password to remember.

So for them, they use -- we have a form, Form 749, which is available on our web site. And what they would do is they would complete the top portion. Basic information. What -- their information, what licensee that they are trying to perform the license verification on. And then it is submitted to our help

desk that we have for all of our IT-based systems to then follow through the rest of the process, send that to the regulatory authority for the actual license verification.

MEMBER LANGHORST: And so are Agreement States set up to be able to do this in a timely manner?

DR. WU: Yes, currently Agreement States are -- we work closely with the Agreement State partners. And this process has been working pretty well with us, the help desk sending it to them or getting to the NRC person responsible for doing that portion of the verification.

MEMBER LANGHORST: In your vulnerability assessment that you all are working on will that be available to the public or any portion of it available to the public?

DR. WU: So the majority of the vulnerability assessment piece and that appendix to the Commission paper will likely be OUO, official use only. We will try our best to include language in the Commission paper that will talk to our methodology, what we looked at to then make a conclusion on the current threat landscape.

MEMBER LANGHORST: And will your

vulnerability assessment also consider what is the negative impact of now including Category 3 sources on Category 1 and Category 2 source security and tracking? Because my understanding is there will be a great many more reporting and requirements on Category 3 sources, and I'm concerned that that overwhelms the 1 and 2 Category sources.

DR. WU: Yes, we did get a lot of that feedback. Mostly the vulnerability assessment is looking at existing vulnerability assessments and inspection and licensing experience with regulated entities and then current threat information. So the feedback we got from a lot of folks on the effects of the Category -- all these additional sources and licensees and how it could affect Category 1 and 2, it will be taken in consideration most likely separate from the vulnerability assessment, but again will be a piece of our analysis.

MEMBER LANGHORST: I encourage you to look at that. I thank you very much.

CHAIRMAN ALDERSON: Good.

Yes, Dr. Ennis?

MEMBER ENNIS: So I think that was a great overview, so I have a really good understanding of

what's going on and good luck with kind of balancing all those risks.

Just I think -- just so people know, HDR is used -- just people from a medical perspective what would be at risk potentially for patients is it's a curative treatment. It's included for the curative treatment for several cancers, mainly cancer of the cervix, cancer of the uterus, and in many centers prostate cancer.

So, and the other key thing about our field and access issues are that these treatments are usually done at least a few times and travel barriers become a big issue. So right now there are centers throughout the country that use this on a regular basis but not all day, every day. And if there are financial barriers to them having this start to make it financially not viable, they will not really be able to offer it and they will turn to alternatives that are not as successful. But that's just -- that's what's at risk if we over-regulate. Even if technically it's still legal, we could end up harming our friends and colleagues by making these unavailable.

I note that the GAO sting both times was only on the issue of getting into the game, and I'm

wondering if that really just needs to be the focus. It's great that you're doing the whole overview, but it does bring to my mind whether the issue is only we need to really, really careful on how we vet people to let them in, but the system itself, once you're in is healthy.

DR. WU: Right, so -- and that is a good point and we did hear that in a lot of stakeholder comments. So the working group has really been focusing on several vulnerabilities that sort of GAO exposed or that as a working group we've talked about, and that is sort of the first one, the ability to obtain a valid license using a fictitious company.

Then there's the other ones which were -- which I think more of our analysis is geared towards, and that's the ability to alter a valid license to obtain more than authorized or falsifying a license to obtain radioactive materials illicitly or say just counterfeiting a license outright.

And then there's the vulnerability of being able to accumulate and aggregate Category 3 sources to a Category 2 quantity.

And then lastly there's that whole general license issue where you have -- here you have

specifically licensed Category 3 sources that go through pre-licensing and oversight and accountability, but then there's this whole other subset of generally licensed devices with the same Category 3 sources in them that don't have any pre-licensing or accountability or oversight.

So I think this group is focused on those latter vulnerabilities, but a lot of work has been done and is going to be done to address that first vulnerability. So this is -- so we are looking at that as an aspect of this.

CHAIRMAN ALDERSON: Yes, Dr. Ouhib?

MEMBER OUHIB: That takes me back to your first question is that should there be some sort of subcommittee to -- from the ACMUI to actually look at this particular issue and make some recommendation?

CHAIRMAN ALDERSON: You would like to comment on that question or are you --

MEMBER OUHIB: Well, no, I'm addressing -- yes, basically should we have a subcommittee? I'm not aware of any within the ACMUI --

(Simultaneous speaking.)

CHAIRMAN ALDERSON: So I'll give you -- since I raised the question, I'll give you a quick

answer. And then I believe Mr. Green was next and then Dr. Langhorst.

I believe that if this -- if and when this activity begins to extend to the point where sources that are medically relevant -- and perhaps HDR is now, but when sources that are medically relevant are involved, then someone from a medical perspective, potentially from this committee, should be involved in those discussions. So that would be my opening answer.

So Mr. Green was next and then we'll go to Dr. Langhorst.

MEMBER GREEN: Thank you, Dr. Alderson. Yes, I think you and I are in the same camp, not knowing exactly where the Category 2s and Category 3s cut off, and HDR I think is one that we can all agree is probably in Category 3.

But I'm currently aware of at least 10 commercial nuclear pharmacies that have 100-millicurie or so cesium-137 sources for survey meter calibrations, and there may be likewise medical institutions who do their own meter calibrations and pocket dosimeter calibrations. And that's within the commercial nuclear pharmacy or in the hospital setting. Plus there's all the private physicist practices that do

meter calibrations. It's not medically related, but we all have to have our machines -- our Geiger counters function to do our medical operations. So it's I think partially involved as well.

CHAIRMAN ALDERSON: Right. It's of concern.

Dr. Langhorst?

MEMBER LANGHORST: So my first response is to Zoubir's question. I think once the process of what the NRC and Agreement States recommendations are, then if there's anything needed for regulatory change, that's where we need to have our subcommittee. I don't think there's anything we can add more that -- what we will at this meeting before that.

If the Part 20 table gets changed, the potential of including high-activity moly-tech generators are there, and that will impact nuclear pharmacies, so that's another question that I have. And I believe that the cesium irradiators that you're talking about for meter calibration is below the Category 3 level.

And, Ms. Wu, you can --

DR. WU: Yes.

MEMBER LANGHORST: -- chime in on that. I

believe -- because, yes, I don't believe that those are included in Category 3.

DR. WU: Yes, the threshold for cesium would be 2.7 curies, or 0.1 terabecquerels. Mostly when we did our stakeholder outreach we did hear that it was primarily HDRs.

MEMBER LANGHORST: Yes. Thank you.

CHAIRMAN ALDERSON: Do we have other questions or comments on this subject?

(No audible response.)

CHAIRMAN ALDERSON: Well, seeing none, I want to thank you again for an excellent report. I believe that the issue remains an open issue for the ACMUI because we want to keep informed and know how this might extend. And if and when it does, then we would appreciate the ACMUI being brought into the discussions.

DR. WU: Thank you.

CHAIRMAN ALDERSON: Thanks very much.

All right. We are at two minutes -- no, we're actually a little bit behind on break time. The break was supposed to begin at 10:15.

So, Mr. Bollock, are we in position to go ahead and have a brief break now?

MR. BOLLOCK: Yes, I think it might be a good time to give everyone a break, and at your discretion for how long you want to give --

CHAIRMAN ALDERSON: Well, I think that --

MR. BOLLOCK: -- but we are about 12 minutes behind.

CHAIRMAN ALDERSON: Let's say that instead of having a 15-minute break, we'll have a 10-minute break. And so we'll be back here and we'll begin the next session at 10:40.

MR. BOLLOCK: Thank you.

CHAIRMAN ALDERSON: Thank you.

(Whereupon, the above-entitled matter went off the record at 10:27 a.m. and resumed at 10:42 a.m.)

CHAIRMAN ALDERSON: All right, well, I think we're ready to reconvene at this particular time. And the issues are Dr. Howe, Dr. Langhorst are going to talk to us about medical related events.

Before we begin, I do want to say that after that last excellent session on source security that I spoke to Mr. Bullock and to Ms. Wu, and suggested, and they agreed, that at our meeting in the fall, with a date still to be determined, that we will get a brief update report from Ms. Wu on the status of the source security

issue and its relationship to the ACMUI.

Okay, we're ready for the next report. Dr. Howe.

DR. HOWE: Thank you, Dr. Alderson. So I'll be talking about the status of medical events for FY2016. And just to put it into perspective that medical events are a very small number. There are many, many diagnostic events that are performed every year, and there are many, many therapeutic events that are performed every year.

And in the past, the ACMUI has asked for kind of a perspective, where have we come from and where are we going. So this time, I decided to give you about a six-year perspective, to start with the number of medical events back in 2011 and carry through to 2016.

So we've gone from 58, we dropped to 48, we dropped to 43. You can see in this slide that there's a distribution of them most, there's an increase in the 2000 -- in the 35.1000, and there were a fair number of 35.400.

And then if you look at the last three years, we hit 46, we're up to 57, and now this year we're at 50. And you'll see that we've shifted, so we don't have as many in 35.400.

We still have a fair number in 35.600, although that changes on a daily basis. And most of our growth is in 35.1000. And you'll see, as I go through the 35.1000s, most of the 35.1000s are in the yttrium-90 microspheres.

So that's how we have progressed through the last six years.

CHAIRMAN ALDERSON: That's excellent. And by the way, I think this committee asked for that sort of trending summary, and I thank the NRC for providing it.

DR. HOWE: Thank you, Dr. Alderson. So let's look at 35.200. This is the imaging and mobilization. We generally have very few imaging and mobilization medical events, because you have a threshold of 50 rem to a given organ, or five rem whole body.

And so, as expected, the medical events that we have for technetium-99m are where people have given multi-dose vials to a single patient, and that would be our first one we're talking here. The staff member failed to verify the dosage. And the licensee has decided that it's no longer going to use multi-dose vials, and that they will only be ordering uni-dose

vials from the pharmacy.

We had another case which was slightly different, and that's where an intravenous port leaked. And because of the leakage, you had technetium on the skin, and the skin exposure exceeded the limits.

You also had failure to verify the dosage. So in this case, they were looking for a filtered sulfur colloid for a lymphoscintigraphy. They got an unfiltered sulfur colloid significantly higher in activity, 2.4 millicuries instead of a half to one millicurie. And you ended up with over 50 rem to the skin.

And in this case, the technologist has now had retraining, and this will be a verbal confirmation of activity and type of procedure so they end up with the right radiopharmaceutical in the right form.

And the final one is the wrong patient, wrong drug. In this case, they were supposed to get a lymphoscintigraphy, and at a half a millicurie. Instead, they got a bone scan injected into the lymphoscintigraphy site at 30 millicuries.

And so you had in excess of the reporting requirements here. And the technologist failed to verify patient identity. It was the same as on the

dosage. So you had a number of events here. One, wrong patient, wrong radiopharmaceutical, and then you exceed the limits.

So those are our four imaging and mobilization medical events.

The next group of medical events are 35.300, which are unsealed material requiring a written directive. We had four of those. We had a distribution between samarium-153, radium-223, and iodine-131.

For samarium-153, they were supposed to give three gigabecquerels. They gave three gigabecquerels instead of 2.48, so they have an overdose. And the dosage from the pharmacy was not correctly calculated for patient's weight. So the written directive was one thing, and what came from the pharmacy was different.

And for radium-223, they administered 119 microcuries instead of 87. The issue was the 119 was for the wrong patient. And because you're therapeutic, you automatically exceed the limits. Then they administered 99 microcuries instead of 980.

I think it's clear from this that most radium-223 administrations are down in the 99-100

microcurie level, and that the authorized user in the written directive wrote the wrong number. And so it is a good thing that they administered 99 microcuries and they did not administer the 980 microcuries.

So the technician failed to observe the difference between the calibrated activity and the prescribed. That probably wasn't a bad thing is this particular case. And they do believe that the authorized user intended to prescribe 98, but got the wrong value.

So they're going to list the activities for radium-223 in microcuries now, instead of millicuries, which is what they normally use for other procedures.

Iodine-131, they administered roughly less than half of the dose. Typical cause, two capsules, only one of them was delivered. They did not check to make sure that it was two capsules and that there was still a capsule left in the vial.

And they didn't realize he had a capsule left in the vial until they were ready to send the empty vial back to the commercial pharmacy. So they've now revised their procedures for transferring of radioactive materials so they can catch these things quicker.

And moving on to 35.400, we have only six medical events last year. One is gynecological and five are prostate. The five prostate ones, we had multiple patients involved in a few of the cases. For the gynecological, they administered roughly half of the dose to the treatment site.

There was a crimped applicator in the lead pig during transport, so they interpreted the resistance during the application is that they had the source in the right place. And then they found out later that it was not, and so the dose to the lower rectum and the vaginal areas received more dose than expected.

For the prostate, we had one licensee with two events in 15 patients. And actually, both of the -- this is one licensee. They had two different medical events. One medical event identified in 2016 involved two patients in the post-implant imaging, and they received 66% of prescribed dose and 71%.

And as a result of that being found in inspection, they went back and looked at their previous records from 2006 up to 2011. And they discovered they had an additional 13 patients that had medical events where the administration differed by more than 20%.

We had a prostate where the ultrasound

images were confusing, and so they didn't get the brachytherapy sources into the prostate gland at all.

Then we had a human error where the dose was 60, about 70% of the intended, the target. And another one with human error was, the activity was about 59% intended.

And moving on to 35.600, these are your high dose remote afterloaders, your gamma knives, and your teletherapy units. As expected, we don't have a teletherapy unit medical event here. We probably only have one teletherapy unit left in the country that's used in medical treatment.

We had six medical events, they were all HDR units, and in some cases, we had multiple medical events for one facility. So we'll look -- and they range from the bronchus to the mandible to the gynecologic to prostate.

So for the bronchus, we had three patients. And in the three patients, you had fractions that were delivered to the wrong treatment site. And you had three fractions that were not delivered to the treatment site at all.

And in this case, there was a problem with the adaptor piece being used when it wasn't supposed to

be. And it was a case of an Elekta HDR-type unit with the adaptors that weren't supposed to be used for that unit. So part of the corrective action was Elekta was going to update the user's manual to warn about this adaptor.

And they were going to put a warning sticker on the applicator packaging and improve the use of training. And we did follow up on that, and they did take all of those actions. So it was a question of incompatibility between old tubes and new tubes in this adaptor being used.

For the mandible, they used a treatment planning time for another patient, so this would be kind of the wrong patient. And they've decided to have a time-out policy to confirm who the patient is, what the treatment information is, and they hope that will prevent them from having future medical events.

Gynecologically, we had two events. The first patient reported to the primary care physician with skin burns on the legs, so that's the first that the radiation oncologists were informed that they had an issue.

And they thought that the second of three fractions was delivered incorrectly. And they

attributed it to human error, using the wrong transfer tube, and applicator interface.

The second one was -- have I got that one right? No, okay. The second one was an equipment problem. Prior to using the third channel, there was friction. It was detected in the applicator check cable. The check cable was drawn and the treatment was stopped.

So that's a good point, you're taking the right medical action. But you have a medical event. So they prescribed 600 rad during the tandem ovoid, and the applicator was permanently removed from use because of its problems.

And then we had two prostates. There was equipment failure. And in this particular case, both of the medical events reported under the prostate HDR are from the same licensee.

The first event happened on, and I'm not sure, I don't have the month. But essentially on the 16th of the month. And there were equipment errors, friction, at the catheter site, so they had to replace, it's actually this one, they had to replace the V-block and the opto-pair. And then they tested the next day, and it was operating.

And then about four to five days later, they had another medical event, and that medical event gave the same error codes, the same issues. And they brought the manufacturer in. They had to replace a lot more parts. So it was equipment failure that wasn't totally corrected the first time. Both of these were the same licensee.

In 35.1000, we have 30 medical events. We have three medical events from the Perfexion. We have one from seed localization, and we have 26 evenly distributed between TheraSpheres and SIR-Spheres for the yttrium-90 microspheres.

For the Perfexion, they got the wrong treatment site. They had a new frame adaptor. They didn't realize that the frame adaptor could be locked, but in the wrong position. And so when they pulled the patient out finally, they realized there was a maximum of two centimeters in one plane of deviation from where the treatment should have been.

They looked at it, it was a non-keyed design, so that it wasn't just one way that the head adaptor could fit into the head frame. So it fit in incorrectly. And the difference in clamping forces was not noticed by the licensee. And also, the operator did

not follow the instructions.

The second Perfexion was a dose to an unintended site. And the treatment was stopped out of 15 and 16 sites to re-sedate the patient, so obviously this patient needed to be sedated in order to get the procedure.

And they stopped it, they re-sedated him, and after they started the 16th one, the patient awoke and moved significantly. And the frame was out of position when the patient was removed from the unit. So they believe the frame moved during the treatment.

And then we had one on human error where they did the incorrect positioning of the isocenter. It should have been on the left side of the brain. It was given to the right side. It was given to the left side, it should have been given to the right side.

And now they're going to look at their procedures and make sure their procedures are correct. And they didn't identify it until the treatment was completed.

And in our radioactive seed localization, there was a patient that was given seeds to a location. She had a stroke in the interim days, and so they made medical decision not to bring her back to take out the

seeds.

We have since modified our radioactive seed localization guidance so that if the patient doesn't return for a given reason, it would not be a medical event. But this happened before that, so this is a medical event. And these are the expected doses to whole body and to the breast.

And now we start the microsphere. So for, and these are evenly distributed between TheraSpheres and SIR-Spheres, and there's a little bit of difference between what the causes are. But most of the causes are very similar.

There's the wrong site, wrong volume determination, there were catheter issues, there was a radiation detector problems, the modified apparatus, unusual resistance, materials remained in the waste and delivery system.

And in both cases, I have one where there was no description or reason for the medical event, just, there is a medical event.

So, let's look at the wrong site. In this case, they had a previously treated segment IV, the left lobe. They hadn't treated the right lobe. They concluded that the catheter moved from patient movement

or breathing, but they didn't perform a fluoroscopy contrast image immediately prior to the treatment to verify the catheter was in the right position.

And so they determined that there was a medical event to segment IV. And they ended up with hepatic and tumor necrosis.

And in the next one, they administered 88% more than they prescribed. It was to the wrong lobe because they displaced the catheter and failed to verify its position during administration. There were inadequate procedures and insufficient training, and they'll use additional imaging techniques to verify catheter placement.

Volume determination. In this case, an image was taken prior to administration that showed a smaller liver volume that was used to determine the amount of the Y-90 administered. But there was also changed work flow, so a second review of the liver volume showed that the liver volume was larger, so they had a medical event.

In this one, the catheter, the post-apparatus readings were much higher than expected. Most of the activity remained within the catheter. The catheter representative thought the catheter apparatus

may not have been fully extended, so there are some questions whether it was a catheter issue. And then they've determined to use a different and newer catheter product.

In this one, there was radiation meter, we've got three of them with radiation meter problems. In this case, they administered 64%, their electronic dosimetry that was attached to the treatment device had fluctuating readings but no low battery warning. The dosimetry readings indicated that all the microspheres had been administered, but in reality, 36% of the activity remained.

The dosimeter was checked and it had a low battery warning. For their corrective actions, they're going to change the batteries in the dosimeter prior to each administration.

Another cause with radiation meter. They administered 71%, stasis was not reached, but the radiation survey meter indicated that all of the microspheres had been delivered. So they thought the patient had received the entire dose. But when they went back and did the waste measurement, they found that 4,000 rads were in the waste.

And another one where there was

administered 62%. At the completion of the radiation survey, once again, they had an indication that all of the microspheres had been delivered. But when they took the delivery kit back to the hot lab for further evaluation, they discovered that 34% of the dose was still in the vial.

And modified apparatus. In this case, the authorized user observed air in the delivery system, and he added a three-way stopcock to the system to collect the air.

And then the radiation surveys indicated that all of the microspheres had been given. However, significant activity was found within the container when they measured it afterwards. And they concluded that the three-way stopcock interfered with the administration.

Unusual resistance. They administered only 25% of the activity during two separate administrations. They got unusual resistance during both procedures. They unsuccessfully attempt to clear the line, and efforts to complete the administration experience both times. And then the administrations were terminated.

The delivery sets were from the same lot,

and both doses of microspheres came from the same lot. So they believe they had a problem with the catheters.

Unusual resistance, another one. They administered 76%, the resistance in the tubing was felt during administration. The tubing was disconnected, it was flushed with saline, and then it was reattached. And in the end, 24% of radioactivity was in the waste.

And now we have really no reason given for what the medical events were, other than the fact that when they made the final measurements of the waste containers, they discovered most of the activity, or a medical event amount of activity, was still left in the waste delivery system.

The first one was 50% of the activity, and so it was determined at completion. The other one with 74% of the activity was given. And they attributed this one to human error, and they're going to provide new training to personnel.

And then I've got one in which there was absolutely no description of any kind. But the patient only received 15% of the intended administration.

Now, moving on to SIR-Spheres, we have slightly different generic reasons. Dose calculation error, wrong site, apparatus tubing, catheter crimping

included, catheter displaced, vials, no description or reason. We have 13 of these.

So for the dose calculation error, they administered 643 megabecquerels instead of 499. That was 29% more than prescribed. The technologist miscalculated the dosage required.

The second one, they administered 77-78% of the intended dose. The authorized user forgot to change the lung and liver estimated doses from the precalculation worksheet, and so the instructions. And their corrective actions is they're going to draw slightly more microspheres than prescribed to account for amounts that they routinely see in the waste.

Wrong site. They delivered to the left lobe instead of the right lobe. They didn't really give a reason why it went to the wrong lobe, but they administered it to the wrong lobe, so. And they attributed it to failure to follow procedures.

The apparatus tubing, I got one of these. In this case, they administered 0.74 gigabecquerels versus 95 gigabecquerels. A large amount of the microspheres were found in the tubing. No resistance was felt, and stasis was not reached. And they believe there was a long time period between the microsphere

preparation and the patient administration.

And they believe that contributed to the cause. So they have decided to draw a little bit more activity than they have in the beginning, and to do the drawing closer to when they give the administration.

They administered only three percent of the intended dose. They encountered back pressure, and they terminated the procedure. They saw microsphere clumping.

They believe there was improper manufacturer preparation of microspheres, and occlusion of the microcatheters used, or collection of air in a three-way stopcock. So they had multiple things they thought could have gone wrong.

Then we have catheter displacement. The microspheres ended up in the patient's catheter chucks and on the floor. They attributed it to patient movement that displaced the catheter in the patient, and disabled treatment to the desired liver.

But, and their corrective action now will be that when a patient moves during treatment, they're going to stop the administration and make sure that the catheters are in place.

Let's see, catheter issues continued.

They concluded that the misadministration was caused by a clogged catheter. The second case, there was significant resistance. Here, we've named the catheter manufacturer, Surefire Microcatheter.

They had low flow in the catheter or target vessels that may allow distal accumulation in the microspheres in the catheter. They've decided to use vasodilators during the administration to give proper infusion in the future.

Vial issues. In this case, they administered 44%. There was a small plug of microspheres were noticed at the bottom of the dose vial. And they attributed this to lack of experience with microspheres.

They didn't mix the dose as close as possible to the delivery time, and they weren't doing routine agitation of the vial, and they weren't adjusting the position of the inlet tube to ensure maximum agitation. So they attributed it to lack of experience for their part.

Another vial issue, residual activity. Adhered to the top of the vial. And they concluded either the needle was not inserted far enough into the vial, or agitation of the vial during administration

caused the microspheres to go up to the top. So their corrective is to increase the amount of activity to make up for the microspheres that don't get through to the tubing.

Another vial issue, 74% was given, residual activity remained in the vial. And then they administered ten percent of the intended. There was a puncture site in the V-vial rubber stopper that was leaking.

They couldn't stop the leak with a dermabond, which is manufacturer-recommended glue. So they aborted their procedure. I don't know if this is FDA-accepted or not. And so, once again, they're going to go, well, they're going to go to a higher gauge, smaller lumen needles, hopefully to prevent the puncture site issue.

And then I have one case where there was no description and no reason given, where they administered a little less than 80% of the prescribed dose. And that concludes my portion of the presentation.

CHAIRMAN ALDERSON: All right, so we have questions. Ms. Weil.

MS. WEIL: So how is it possible, since

medical event recording and reporting is required, how is it possible that some licensees submit no information, or no information about corrective actions? Is there no review and going back to the licensee to require the necessary info?

DR. HOWE: When we get these reports, if they're inadequate, we do go back and ask, and the agreement states go back and ask. But sometimes you just don't get any information. And it's a matter of compatibility.

I don't believe this is the same level of compatibility that you have for other parts of the regulation. They have to be kind of equal, but they don't have to be identical.

MS. WEIL: It sort of defeats the purpose of reporting medical events.

DR. HOWE: And that was one of the issues that the commissioners brought up during the last rulemaking on permanent implant brachytherapy. They wanted medical event reporting to be a category B, which would mean all of the criteria would be the same across the NRC and the states.

But the final resolution, we haven't resolved that rule yet, but we did not take it to a

category B. So it is an issue that continues.

CHAIRMAN ALDERSON: Dr. Langhorst.

DR. LANGHORST: I just want to remind you that these reports come from the NMED database. And so when there isn't information in there, it could be it's not been updated.

And so it doesn't mean that the licensee hasn't provided that information necessarily. I would guess, and I'll ask, that NRC-reported events get updated, I would assume? That's not a rhetorical question, but a question to the NRC staff.

PARTICIPANT: Yes.

DR. LANGHORST: They said yes. Good. But agreement states may not go back and fill in the information. So please don't think that it's totally because they're not getting cooperation from the licensees. That may not be the case.

CHAIRMAN ALDERSON: Dr. Ouhib had a comment, and Dr. Dilsizian.

DR. OUHIB: Yeah, I just, a couple of comments. First of all, the AAPM is actually looking at this, having some consistency in reporting. There's a task group right now that is actually working on that.

I know for a fact that I brought up this

issue about a year ago, that I said that, because I have looked at 13 years of medical event, and while looking at them, was like, there's something that's got to be done here.

And I had proposed that we should have some sort of a form that has to be done across the board. And if you don't fill out that form, your reporting event is incomplete, and it's still sitting on your desk that you have to do this, this, and this and this.

And that's really very important. Regardless of what the AAPM does, in my opinion, and I could be one of the few, that I think we ought to have some consistency and have very obvious items that we need to know for one purpose: to improve patient safety.

CHAIRMAN ALDERSON: Yes, Dr. Dilsizian.

DR. DILSIZIAN: Thanks. I was curious with the center that had the prostate post-implant decrease the prescribed dose, two patients, and then subsequently they reviewed back and identified 13 patients in previous years.

Now, I find this very interesting because, you know, we're balancing both medical errors and medical events and punitive versus reporting, that's been our discussion. Yet, you know, a center like this,

where there was more than one event or error, really going back and identifying that there were actually 13 or 12 patients, I think this is important.

And I was wondering, in this case, I guess the inspector identified it and went backwards. And when should a center who does more than one or two events, we should do a retrospective to identify how often it happens, and what corrective action should we take? Not being punitive, but really being corrective.

DR. HOWE: Normally what happens is, if we get multiple medical events reported from a facility, the regulatory body will go back and say, what is the state of condition? Did you have more? Is this the tip of the iceberg, or is this isolated?

And so they'll ask the licensee to go back and check their records to see if they had others. And so in the last medical event reporting, we've had, especially back about the time of the VA prostate implant issues, you will see a lot of facilities that went back and discovered more.

They were identified, maybe on inspection, because they hadn't really, the licensee hadn't identified them. And then they were asked for the extended condition and they went back and --

DR. DILSIZIAN: What would be typical corrective action? Is there any, just education, or is there any financial also impacts? Because I know MDE here has financial penalties for things that, you know, go wrong. I just was wondering.

DR. HOWE: A medical event is not a violation. But you could have violations that lead to medical events. So if you have violations that lead to medical events, then there is the possibility, if there are a large number of medical events or more than you expect, a civil penalty.

Generally, we look at the licensee's corrective actions, and the licensee's corrective actions are normally training and normally a time-out to make sure they have the right patient, they have the right materials, depending on what their issue is. So it goes both ways.

CHAIRMAN ALDERSON: Dr. Ouhib.

DR. OUHIB: Can I just comment on that, and I'm assuming you're talking about the prostate cases, is that correct? Yeah, obviously, a lot of those cases, when you apply the new rule, most likely will not be a medical event. This was based on the D90 and so on and so forth.

So when it moves to activity-based, you know, we have seen, and I looked at that, that a lot of those are no longer a medical event. So that's why you see this huge number. It's not like somebody does not know what they're doing.

DR. HOWE: But I think you'll see that there's a decrease in the number of medical events we've seen under 400, because of our enforcement discretion policy that's being used. So, many of those medical events that would have been identified purely on D90s are not being identified now.

DR. OUHIB: Right, and if they use the interim rule, basically, most likely there will not be a medical event also.

DR. HOWE: Well, I just want to clarify. There is no interim rule. There is only the current rule, and then we have issued enforcement discretion, because we've kind of interpreted that you could use, activity could be a substitute for dose. But we don't have an interim rule right now, okay. Just to make that clear.

CHAIRMAN ALDERSON: Mr. Bollock.

MR. BOLLOCK: And I can expand Ms. Weil's comments and Dr. Langhorst, with the reporting and how

do we go back. And then also -- but first I'll, just to add to what Dr. Howe responded to Dr. Dilsizian, with, you know, what are, she covered a lot of the common corrective actions that we see.

But it really just depended upon each licensee, what the event was, what they determine the cause to be. But those are the requirements, if there is a violation, they have to take action to correct that violation. So, it is dependent, but Dr. Howe covered some of the common things that we do see.

Now, for the reporting and the follow-up and getting that follow-up information, so all those reports go into NMED. So that we have multiple levels to reach back out and get the updates.

So NMED contractors, they actually go through and periodically look for that, you know, the more information in the record that doesn't have the, you know, the required, you know, what were the actions, if any planned, you know, to prevent and those type things under our regulations.

They will reach out sometimes to the state that it's in to then reach out to the licensee, or they'll contact the NRC regional, the regions, to find out if we've gotten any of that information. Because

it sometimes does take time, especially from those corrective actions, based upon what they found the cause to be.

So event happens, we expect the licensees to do some sort of evaluation to, you know, they want to know what caused it. And that can take some time, and then what actions will correct that cause and those causes.

So there is some time. But we do, my staff, as events come in, if it's something that we think is, you know, we want to know what's going on now because it's a higher priority or we're seeing trends in it, we will reach out to either our regions or our states or our regional state agreement officers to make sure that we're getting that information.

So that, and then when it's in NMED, like I said, NMED contractors, they do go back and check that as well. So there is, you know, there is some looping back to try to get as much information as we can to keep it as consistent as possible.

And we do see, as you pointed out, it isn't always the same. And any time we see that or lack of information, we do try to get as much as we can.

MS. WEIL: But then is that information

about the consequences of the event and the corrective actions that are taken, is that information available so that this whole process can be proactive in promoting safety? Or is it simply retrospective information?

MR. BOLLOCK: So you mean proactive to get it out to other licensees, or more retrospective? Again, there is always some delay in getting that. And actually, Dr. Howe's presentation, getting as much information including those causes and actions that we have now is information from last year.

This is our being proactive. You know, we did hear, we had an audit from our Offices of Inspector General on medical program, and that was one of the recommendations, to be more proactive, get this information out here. So Dr. Howe, yeah, getting this out there.

You know, these slides they go on our public website. Just, I mean, all of these slides, along with everything in this meeting, are going to be on the public website for the meeting.

But we will take this section out, we have done this for the past year and a half, we'll put it also on our website for the public or any other licensees to be able to get this information, and gather, you know,

as much as we have. But unfortunately, there is, you know, we don't always have it in a timely manner. But we are proactive in trying to get it as much as we can.

But, you know, it really does come down to what the licensee shares with, either their respective regulator, whether it's us or the state, and you know, at one point in their investigation, what actions they've been taking.

DR. HOWE: And as far as the public website, they're currently on our Medical Toolkit, which is, we hope, the place that most medical use licensees go to for information.

CHAIRMAN ALDERSON: So I would have what I would call an editorial question. And my question only relates to how information is presented to this committee. Nothing about NMED, nothing about how reports go out. Just how it comes to this committee.

And I was struck this year, as I think I haven't before, by the similarity between TheraSpheres and SIR-Spheres. When you look at, almost there was only one category that was different in the two, the exact same number of events, a very low number of events.

Should there be a consideration to potentially combine these? They have one table with

both things right there so you can look at that. And then go through the information, not with respect to SIR versus Thera, but really the kind of issue that resulted in a medical event.

DR. HOWE: I've tended to keep them separate because the microspheres work slightly differently. One's a much smaller microsphere, generally has no stasis issues with it.

The other one's a larger microsphere that has stasis issues. And I just kind of kept them separate so that people could understand. There's nothing that keeps somebody from just putting them all together and saying, this is yttrium-90.

CHAIRMAN ALDERSON: That's fine, thank you.

MR. BOLLOCK: Dr. Tapp may have something to add.

DR. TAPP: If I may. I'd like to add to Doug's comment on how we proactively get this information out. And it doesn't go directly to the public, but another thing we do is when we see some medical events that maybe you or maybe your inspectors are unaware of, we do webinar trainings periodically as a medical team.

And we give trainings to agreement state and regional inspectors, who then, as they're going to the fields, they're asking the questions, Have you looked for this type of event, or How are you watching for these type of events that we may have seen in the past.

So it isn't publically available, but this is a training for the inspectors who then are going out to the field, as well as we do this with webinars. And every month, we have calls with our regional inspectors as well.

MR. BOLLOCK: Yeah, and if I could add. Yeah, our inspectors are trained to ask for, you know, to ask to look at the corrective actions, but they are trained to look for, as Dr. Howe said, the extent of condition and the extent of cause.

So, they are, you know, they're the eyes and ears for not just us, but the agreement states have inspectors as well. And they're the eyes and ears for us to get that, you know, get these questions asked and kind of start that ball rolling to get the information back to us.

CHAIRMAN ALDERSON: Yes.

DR. DILSIZIAN: Just coming back to that

index case of the prostate, it strikes me that retrospectively, there were six-fold higher incidence of events than they detected prospectively. So should I take that index case and say that what we're presenting here is probably six-fold less than what actually happens in most centers?

DR. HOWE: I don't know if I would come to that conclusion. But I would come to the conclusion that, and it also was kind of a factor in the VA, is that for prostate brachytherapy, many facilities were confused as to what was a medical event. And so they may not have recognized medical events, or they may not have been proactively looking back to see.

And one of the things that we're fixing in this rule, and hopefully it will go through, is that we're saying under 35.40, which is your program to provide high confidence that the administration is in accordance with what was asked for by the AU, that people check against medical event to determine if they have a medical event.

So we think that will add more focus on people understanding what a medical event is for a particular modality.

CHAIRMAN ALDERSON: Fine. Any other

questions on this part of the report? Yes?

DR. SUH: Just a question, so you mentioned, you know, one of the common things you see kind of yearly, is just, in terms of medical event reporting, is that same type of medical event occurs.

DR. HOWE: Yes.

DR. SUH: Universal time-out isn't done, patient's name, birth date, correct site. And so if you look at the Perfexion Gamma Knife case, they treated, I'm assuming with the dose that they gave, a trigeminal neuralgia case, which is a benign condition for facial pain. And they treated, they mistreated the wrong side.

And you mentioned that there was dissemination of this information as a public website. Do you have sense of what percent of licensees actually go to that public website to actually learn about this information?

Because one of the concerns I have is, in terms of the education of what types of medical events occur each year, I would assume that there are a number of licensees that are not familiar with the website.

And furthermore, if this information was more readily available and they read this, I can tell

you as a radiation oncologist, I read that, wow, there was a center that treated the wrong side of the brain. I'd better be extra careful next time and make sure that my procedures and policies of how I do a time-out is universal.

And to give you an idea, where I practice, I mark the ear, I ask the patient which side of the head are we treating today? This side. And so there's a lot of time-outs that we do, and maybe we're, say we're more excessive than some.

But I think sharing this information and perhaps sharing of best practices would help to promote this culture of safety and also promote best practice, which is that educational part which, I know it's the practice of medicine, but I think it would serve the public very well in terms of minimizing.

DR. HOWE: And we do have problems getting information out to licensees. We've tended, the NRC website is quite large, and we've tended to put this in the Medical Toolkit. And every time we talk to someone from a licensee, we'll walk them through the Medical Toolkit and show them where they can find the information they're looking for.

And at the same time, explain to them that

we cover a lot of things in this toolkit, this is meant to help you understand your requirements, your responsibilities, and also the information that we're providing. So every time we get a chance, we try to promote the Medical Toolkit, because it is the central location to find information for all the medical modalities.

It gives you inspection information, licensing information, experience information, and regulatory information. And the latest announcements, like our gallium/germanium, like the moly shortages. We put that there.

And it's, you know, and every time we get a chance to talk to somebody, we bring it up and we try to advocate for it. Because otherwise, it could be hidden on the medical -- on NRC's website, and no one would ever find it.

DR. SUH: Sure. And even just from a trainee standpoint, if you want to think about training the next generation, how do you minimize the risk of a medical event occurring, how do you improve quality and safety. Having this type of information would be very important, because, again, I think it's very impactful.

Like for me, one of things that happens

every time I leave an ACMUI meeting is my awareness of quality safety heightens even further, because I read this, and like, well, this could be the institution I practice in and these things could happen.

DR. HOWE: And we're kind of hoping that you as ACMUI members will also take this back to your locations and your professional organizations and talk up the Medical Toolkit and what it provides, so that more people are aware of it.

We certainly put that information out to our license reviewers, inspectors in the agreement states. But if you guys can also disseminate it, I think you'll find this a very helpful place.

CHAIRMAN ALDERSON: So I would suggest to everyone as they begin to further explore this that we are behind time again, so again, if you have questions, let's get them out there. Who was -- we'll let Dr. Langhorst go, she's part of the committee.

DR. LANGHORST: I just wanted to say that RSOs probably delve into the Medical Toolkit much more than anybody else in a licensee location. So I would encourage RSOs, I know I try to send this type of information out to the people who it impacts to help share that information and do just exactly what Dr. Suh

is suggesting, is getting that information to the right people.

And even the Medical Toolkit can be very daunting in trying to find what you're looking for. But I would encourage all the RSOs listening and everyone who then talks to another RSO to please, hey, keep an eye out for these things and share it with the right folks under your license.

CHAIRMAN ALDERSON: Thank you. Dr. Ouhib and Mr. Bollock.

DR. OUHIB: Yeah, I think I share what Dr. Suh just said there, and perhaps the manufacturer can also help. In looking at the TheraSpheres and SIR-Spheres, there were quite a few that appears to be, I'm not going to say they are, appears to be manufacturing issues perhaps. Or training, so that ties the manufacturer there.

And therefore, perhaps they could be instrumental in sending that information, because they have access to all their users. And said, be aware of here's what's been reported, and then provide corrective actions or, you know, additional training.

CHAIRMAN ALDERSON: Mr. Bollock?

MR. BOLLOCK: I mean, we know a lot of

manufacturers do exactly that. And we encourage all licensees to have this information passed along to everybody have, I mean, the bottom line, and we try to share this at society meetings, anywhere we go.

The bottom line is, licensees are ultimately responsible for their use of byproduct material. And we do as much as we can, and we highly encourage everyone to use it. But, and we understand, we cannot go and talk to 100% of everyone who uses it, because we don't -- but we do everything we can to get it out there. We make it available.

So again, just we encourage you all to take it back. And you know, we did listen to a number of things, and clarifying what a medical event is, gave that information out publicly. Passed that information to the agreement states. Same with this information now. So, there are limits to what we can do.

CHAIRMAN ALDERSON: All right, so let's move on to other medical byproduct material events. And Dr. Langhorst at this time.

DR. LANGHORST: Thank you very much. We're doing this a little differently but not really, because this is the model that my esteemed colleague

Ralph Lieto established years ago with Dr. Howe. And I would hope someone will step into my responsibility for a future time.

So just to remind you, these are NMED events that involve a medical licensee or an associated licensee. I learned this year that it should also include the 35.3047 events, which is dose to embryo fetus or nursing child. And it does not include medical events.

And so I'm going to go real quick because I know we're fighting time. So what I've given here were the numbers that were for FY16, and then for a perspective, FY15 that we discussed last fall. I have these categories, and they're not the best, because miscellaneous has a lot of interesting data: leaking sources, loss of materials, shipping issues, and landfill alarms.

So let me go through these. This slide will take just a little bit. But there were four identified, potential occupational overexposures that, none ended up being an overexposure. One was a high dosimeter reading that they later attributed to a potentially contaminated dosimeter. But they couldn't prove that because it was a very short-lived PET

isotope.

Another was extremity contamination. This happened with QuadraMed administration that there was a bit of a blowback during injection. And there was contamination that they estimated was about one to two millicuries. The radiation safety officer was not contacted, even though there was personnel contamination, occupational personnel contamination.

And did not appear that there was cleanup, adequate cleanup afterwards. And so the RSO was contacted the next day. It did not look like people were going to get a high extremity dose, or over the dose limit, but they did not follow their procedure. So please, work with your RSO and have them involved.

Another one was a courier that came to pick up PET, that's hard to say, PET isotope containers to take back to the pharmacy. He accidentally picked up a lead pig that contained two germanium calibration sources. When loading it into his vehicle, the lid slipped off, the sources came out.

He picked them up, just put them on top of the stuff, and he took them back to the pharmacy. They were concerned he might have gotten an overexposure, but it turned out did not.

The fourth one was a group of nuclear medicine staff that had high dosimeter readings, and did not make sense, because one of the higher dosimeter readings was the director, who had not even worked with radioactive material during that time. And the licensee was investigating it as someone interfering with those dosimeters and exposing them to radiation.

Two declared pregnant workers. One had three months of higher readings. Again, that licensee felt that there could have potentially been dosimeters that were intentionally exposed by another person.

The second one was at nine months. The nuc med tech had received just a little bit more than 535 millirem on their dosimeter. And so they were enhancing their ALARA program to look to see that they might change job duties as people got to certain categories, or certain percentages of the dose limit.

Let's see. There was one 35.3047 exposure. The patient was nine days post-conception. The pregnancy test did not identify it, and they said the cause was that the patient did not follow instructions to abstain from sex prior to the therapy. And so that one you will see in the abnormal occurrence report.

There were two suspected public overexposures. One was a patient being treated with low dose rate therapy, cesium-137, and a person staying the night with them, stayed the night with them, laying in bed with them. And so procedures were not followed to make sure visitors were not allowed to do that.

And another person was exposed to 200 millirem who had volunteered to test a cardiac PET scan so that they could gain operational experience. That's not quite allowed. There was equipment failure on an HDR, this is during source exchange, and the service engineer was there and aware. And so that was equipment failure, but in a very controlled manner.

And contamination. One I-131 patient returned to the ER an hour after administration and didn't tell the ER about that. The ER personnel they were estimating maybe got three millirem. So just a reminder that patients, even if you give them a card they can hand somebody.

And then one was an I-131 patient who had trouble swallowing the capsule, and so instead tried chewing it, and later expelled that. So they estimated there was about 3.7 millicuries of I-131 contamination on that one. And then there was no recordkeeping for

this time.

Leaking sources. Most of the leaking sources were identified by the normal sealed source leak test. And so when you exceed a certain contamination level, you have to report that.

There were a couple germanium-68 sealed sources that, one they identified was maybe damaged during maintenance. Another one they were not sure, but these were on PET scanners. And so that they identified that.

And one was an I-125 localization seed that they felt potentially was damaged during a pathology evaluation of the tissue following that procedure.

There were eight lost seeds from this I-125 localization procedures. Lost in various positions along that process. I think that all were identified as being found at the time they were removed from the patient, but were lost either by the time they got to pathology, or some time during pathology, so.

There were two stolen calibration sources. One patient that was released pulled out 11 seeds from a therapy and threw them in his home trash, so that was another one.

And there was one where a licensee could not

account for the generally licensed source that was in a piece of equipment that had not been used for years. They felt that they may have gotten rid of that generally licensed source in the 1980s, but they didn't have any documentation of that disposal, so that was a lost source.

Shipping issues. There was issues with delivery sources. Two carriers mistakenly transferred, or a carrier mistakenly transferred sources to the United Postal Service. And by the time it ended up at the licensees, it wasn't, the sources were for implants, they weren't hot enough to be used.

There was an accident where the vehicle was taken to a tow yard but there was two radioactive packages in there. And so those were found after the vehicle got towed there.

Several shipping package issues with contamination on the outside. So it's very good to make sure you're checking for that. And sometimes the activity, the isotope outside the package was not what was inside. And a couple of them were where the label was stuck on, that maybe contamination when they put that final label on the package. So you'd have to be careful on that.

There was one where the location did not have a license to receive. And this was for a Xofigo shipment. The clinic had had a license and could receive it. They merged with another entity, went under that other entity's license, that other entity didn't have license for that. And so that was understandable. So be careful as you merge and change licenses.

There was an HDR source that was sent the delivery, and I meant to say this at the beginning, at the first one, the delivery was tried after hours. And there was lots of confusion of where the HDR source -- there wasn't confusion where the HDR source was, but it was confusion about how, when they couldn't deliver it after hours, how it was supposed to get there. And there was a lot of sorting out of that.

There was two sources lost during shipment -- excuse me, one lost during shipment. And then another HDR source that wasn't the right source, the vendor had sent the wrong source. And so it was reported as lost, but it was found, and it was the wrong source going to that licensee.

And then, here's my table for the landfill alarms, and tried only to list those that could

potentially be medical. Although I will mention that the I-131s found in landfills could be from veterinary procedures. And so here's the information on that. Again, California has a robust program in this regard.

And that's the end of my presentation.

CHAIRMAN ALDERSON: Do we have questions or comments on this medical event report?

DR. DILSIZIAN: Just one.

CHAIRMAN ALDERSON: Dr. Dilsizian.

DR. DILSIZIAN: Just a curiosity question. The I-131 patient went to the ER. You said the exposure, was that a therapeutic dose, a high dose?

DR. LANGHORST: Yes, yes.

DR. DILSIZIAN: So, as you know, the patient should still have the name label on the wrist and should have radioactive labeled on it, saying that for three days, right, they're supposed to wear the bracelet arm. That's usually the rule, so I was wondering --

DR. LANGHORST: No, there's no rule. There's no rule for that. That may be your process, but no, there is no rule for that.

DR. DILSIZIAN: It's part of our directive to, you know, you're supposed to wear that for three days

just in case EMT or ER.

DR. LANGHORST: No.

DR. DILSIZIAN: That's the purpose. Oh, I didn't know that was --

DR. LANGHORST: That's your local facility.

DR. DILSIZIAN: So we have a good system.

PARTICIPANT: Maybe we should make that part of the rulemaking.

CHAIRMAN ALDERSON: All right, so. Oh, yes, Dr. Palestro.

DR. PALESTRO: Sue, very interesting presentation. One particular case intrigued me was the incident of the I-131 administration to a woman who was pregnant, and it was attributed to the fact that she didn't adhere to the admonitions to refrain from sexual relations.

It's interesting to me because we do several hundred I-131 therapies a year, and that's always a concern. But I wonder how they arrived at that conclusion. And the information isn't there. What was the time interval between the pregnancy test and treatment?

Did they have a document in front of them,

a lab report, saying that the patient was not pregnant? Was this an oral report over the phone, or something faxed to them by another office? Was it a urine pregnancy test, was it a blood pregnancy test?

All sorts of other questions that come up that I think set the stage potentially for failure in these circumstances. And then I think that sort of incident would be an excellent educational tool. And that's it.

DR. LANGHORST: And again, NMED doesn't have all that information. So yes, I understand.

CHAIRMAN ALDERSON: Dr. Ennis.

DR. ENNIS: Just kind of thinking about educational tool and what Donna-Beth said before. And I know she's made a lot of effort and great to do outreach now to the societies like ASTRO and all that. I would suggest a particular focus on residency societies would be really good, like in radiation oncology, there's a society called ARO.

I'm sure in nuclear medicine, there are similar societies. And I think those particular audience where you have your greatest impact, people thinking about getting out. And everyone gets a little bit of exposure from their own practice, but they have

no world view.

And they have no idea of what else is going on outside of generally high quality programs, and where are they going to end up, in a small practice. And all of a sudden they have all this responsibility. And I think bringing some case studies, for example, you were kind of alluding to this could be a great case study, I think you could have a lot of impact for the amount of time.

CHAIRMAN ALDERSON: Do we -- we haven't asked, I haven't asked this morning, but I will ask now. Has there been any member of the public who's been on the listening situation who would like to raise a question in any way, or would like to ask us about some of the events of this morning before we break for the lunch hour?

There's no one on the phone. They're all at lunch. That answers that question. All right, are there any other issues that people wish to bring before us before we break?

DR. OUHIB: Yeah, let's just comment. There has been an effort, I know the ABS just recently, like the last week, I was actually chairing the medical event session, and that was oriented toward residents.

We are doing something similar at the AAPM, the medical event section. And that's oriented toward new graduate or graduate students, or new medical physicists, to actually educate them about that whole process. So there's a lot of effort there to actually educate people.

And the ABS, we talked about it, and having another one which will be more like a few hours session for residents going through eight different places how you prevent it, what actually could happen, and so on and so forth. So there's a lot of work involved.

CHAIRMAN ALDERSON: Good. Given that we just have a moment here, I'd like to go ahead and do a bit of business, which is to talk about the subcommittee that we're establishing to review the Icon Gamma Knife details.

And of course, this is a therapy issue, and I know that John, Dr. Suh is an expert, certainly not experienced necessarily with Icon, but with the Gamma Knife.

DR. SUH: I actually have that experience now.

CHAIRMAN ALDERSON: Good, well, I'd like to suggest that perhaps you would be the chair of this

committee. That Ron, as another radiation oncologist, not with experience, but that you be a member of this committee. I think Dr. Ouhib would be good. He can only be a consultant now, I believe, because he is not fully approved. Yes --

MR. BOLLOCK: Yeah, he can only do it on a voluntary basis.

CHAIRMAN ALDERSON: He would like to volunteer.

DR. OUHIB: I'd be happy to.

CHAIRMAN ALDERSON: Yeah, he's a voluntary consultant.

MR. BOLLOCK: Yeah, unfortunately we cannot ask, and thus you cannot ask him to be an official member to actually do official work.

CHAIRMAN ALDERSON: Well, then if you would like to approach Dr. Suh, you know. Free advice.

MS. SMETHERS: Dr. Alderson, could I just say, so now that we have ten voting members, we can only have up to four on a subcommittee. I thought it was five, it's four.

CHAIRMAN ALDERSON: Yeah.

MS. SMETHERS: The past is okay.

DR. ENNIS: Including consultants?

MS. SMETHERS: Good question. He's not a member, so, yeah.

CHAIRMAN ALDERSON: So we could have up to four. So there was one more member I was going to ask to consider this. And that's Laura Weil, because it is basically a safety, ultimately that's what your questions were earlier, and it is a patient safety issue. So would you be willing to be on this group?

MS. WEIL: Sure.

CHAIRMAN ALDERSON: Okay. All right, so we know that we have Dr. Suh, Dr. Ennis, and Ms. Weil. And other people might want to volunteer to join them, but we will say nothing official about that particular issue. Are there any other comments before be break for lunch? Hearing none, I think we're adjourned until one p.m.

(Whereupon, the above-entitled matter went off the record at 11:54 a.m. and resumed at 1:03 p.m.)

CHAIRMAN ALDERSON: All right, we've reconvened, so if no objections, we'll get the afternoon session underway.

And, then up will be Dr. Palestro and his group on the training and experience for all modalities.

DR. PALESTRO: Thank you, Dr. Alderson.

First, I'd like to acknowledge the efforts and contributions of the Subcommittee Members, Sue Langhorst, Darlene Miller, John Suh and Laura Weil, thank you.

So, the ACMUI Standing Subcommittee on Training and Experience was established about a year ago with the specific charge to periodically review training and experience requirements currently in effect for all modalities and to make recommendations for changes as needed.

We were charged with the review of the training and experience requirements for the uses of unsealed byproduct materials including 10 CFR 35.100, 200, 300 and 1000 as well as for sealed byproduct materials, 35.400, 500, 600 and 1000.

The guiding principle under which we function is that our recommendations regarding training and experience should ensure that, number one, the requirements and provisions in Part 35 which provide for the radiation safety workers, the general public, patients and human research subjects are satisfied.

And, number two, that patient access to these procedures is not unnecessarily compromised.

In other words, we really have a balancing act between maximizing safety and maximizing patient access.

The issues that need to be addressed and are being addressed by the Subcommittee include the periodic review of these training and experience requirements, addressing competency and addressing patient access. And, these really are all very much interrelated.

In terms of what constitutes a reasonable review interval, while it's been about 15 years since the training and experience requirements were reviewed and revised and 15 years, I think is too long, much too long particularly considering the accelerating pace of new developments over time.

At the other extreme, a one year interval is simply impractical. And, the Subcommittee has settle on at least for the moment, what we think is a reasonable, practical and attainable interval of five years.

However, that five year interval does not preclude an accelerated review if circumstances warrant. And, what sort of circumstances might warrant an accelerated review?

The introduction of a new procedure potentially, an increase in the number of medical events or radiation safety events and perhaps other situations that aren't enumerated here.

One of the things that we have or one of the issues that we have encountered is, in going back through the old records and the information available, it's not entirely clear as to how the training and experience requirements were established and what the thought processes were behind them.

And, it's not to suggest that they are wrong or they are incorrect, but it would have been extremely useful, extremely helpful to us, if we understood the rationale for their implementation and for their design.

And so, we've decided that we really need to try to develop a review template to standardize our approach to the review of each of these various categories.

And so, this is a template, a draft template, if you will, that we have developed for training and experience requirements for 35-whatever and classification of the training and experience requirements could be into broad categories such as

appropriate, inappropriate, obsolete even.

But, if we're going to classify them, how are we going to evaluate them? There has to be some sort of rationale behind that classification.

So, we would propose to look at medical events, radiation safety events and issues regarding patient access.

In terms of classifying the training and experience requirements, first, we have appropriate, inappropriate, obsolete even. But, if we're going to classify them, how are we going to evaluate them? There has to be some sort of rationale behind that classification.

So, we would propose to look at medical events, radiation safety events and issues regarding patient access.

In terms of classifying the training and experience requirements, first, we have appropriate. Inappropriate we can further subdivide into insufficient requirements, and, at the other extreme, excessive requirements and then, finally, requiring training and experience requirements and perhaps for obsolete.

So, what would be the definition of

appropriate training and experience requirements?

Well, in evaluating medical events and radiation safety events, few or none. And, how one defines few, I think, is really, at this point, a matter of conjecture. It might be a certain percentage threshold which could be defined as few.

Constant or trending downward number of these events over time and finally, adequate patient access.

What about inappropriate training and experience requirements?

Well, let's take a look at the insufficient category. If there are frequent or many medical events or radiation safety events, again, with those numbers thresholds to be defined or there is an upward trending of the -- in terms of numbers of these medical events or radiation safety events.

At the other extreme or inappropriate are the excessive requirements, few or no medical events, radiation safety events, no upward trending of these events.

But, then, there's inadequate patient access, it's time to reevaluate those requirements to see what can be done to improve patient access without

compromising safety.

Then finally, there's a potential category, obsolete. And, those training and experience requirements would be classified as obsolete, for example, for procedures that are no longer performed or perhaps there are no authorized users.

So, the classification of the training and experience requirements should be based, at a minimum, on an evaluation of medical events, radiation safety events and patient access.

In evaluating and looking at medical events, it's not simply enough to look at the number and the trends, but we really need to try to analyze why these medical events are either increasing in number or trending upward or they are occurring frequently.

And, the analysis could look at, is it a procedural issue? For example, is this a new procedure that's been recently introduced? Is there a problem with the procedure?

It could be a procedure that's already in place where something in that procedure has changed that may account for an increasing number of medical events.

Is it a competence issue? Or, is it equally possible, a combination of both procedure and

competence?

The same is true for radiation safety events, and these are some examples, high occupational doses, lost sources, improper record keeping, lack of instrument checks or calibrations.

Evaluate the number and trending, look at the number of enforcement actions, the type of enforcement actions, and again, with those data in hand, analyze the explanation, the causes.

Once again, is it a procedural issue? Is it a competence issue? Or, in fact, is it a combination of the two?

What about patient access? Do current or proposed regulations limit patient access to procedures? Do current or proposed regulations provide adequate protection from unintended radiation exposure and, in fact, are the pathways accessible and reasonable for individuals seeking to obtain authorized user status?

Competency is an issue that the Subcommittee continues to grapple with. General definition of competence or competency is the ability of an individual to do something, to perform a task, especially when measured against the standard?

The medical definition of competency is that it is a principle of professional practice that identifies the ability of a provider to consistently administer safe and reliable care.

How does one determine or how do we determine competence or competency?

Well, the vast majority of authorized users, obtain authorized user status by passing a certification board -- certification examination given by one or more Boards, such as the American Board of Nuclear Medicine, the American Board of Radiology, that have achieved or have been designated deemed status by the Nuclear Regulatory Commission.

And, that's the simple part.

But, what about the potential alternative pathway for individuals who are not certified by these Boards?

One question that certainly arises is, should there be an alternative pathway? And, that's a question that needs to be addressed.

Assuming that the answer is yes, there is at least being considered, what's the best structure for that alternative pathway?

One is didactics and some practicums with

examinations and so-called hands-on experience with preceptor certification.

Another interesting alternative that was recently brought up, and I suspect that some people -- some organizations will view this as heresy, it is simply a practical examination. That is, there is a course, if you will, for lack of a better term, course outline indicating what the necessary knowledge is for an authorized user.

And, rather than establishing numbers of hours, laboratory, clinical experience, so forth and so on, simply devise an in depth practical examination that would be carried out by an independent examining committee.

And, by that I mean, a situation or examination in which various simulations can be carried out and simulations have become an integral and important part of medical education where you can have simulated medical events, simulated radiation safety events and so forth.

So, under this concept, or under this possibility, there would be no number of hours. There would undoubtedly be a certain number of cases, minimum number of cases in which an individual would have to

participate.

But, the determination of competency and authorized user status would be based on satisfactory passing or completion of this so-called practical examination.

So, this is the review template example. I know that there is a lot of interest and enthusiasm and angst, if you will, about 35.300, but it was clear to the Subcommittee that, at this point, we simply were not ready to try to make recommendations about 35.300 and we chose a much narrower, less complex category, 35.190, which is training for uptake, dilution and excretion studies.

So, when we evaluate 35.190, we found that there were no medical events reported over the past ten years.

Unfortunately, data on radiation safety events are not available and Dr. Howe, please correct me if I misstate what I'm going to state now.

And, the reason why those data are not available is because, apparently, there are no individuals who are authorized users only for 35.190, at least no data available on them. And, hence, these radiation safety events are grouped in with 35.200.

Is that correct, Dr. Howe?

DR. HOWE: We may have one or two somewhere in the country, but not much more than that.

DR. PALESTRO: So, based on the data that we have available to us, we would classify this 35.190 training and experience as appropriate.

Though the Subcommittee acknowledges and appreciates the NRC staff input, particularly with reference to radiation safety events, especially the efforts of Ms. Maryann Ayoade. And, we strongly encourage continued input from not only the NRC staff and the remainder of the ACMUI, but stakeholders as well.

In terms of stakeholder input, we can talk about informal and formal.

Informal stakeholder input is when stakeholders, interested individuals, interested organizations contact myself or members of the Subcommittee or when I or members of the Subcommittee reach out to various individuals and organization and ask for your input.

This is a lot faster than going through the formal review, formal request for stakeholder input.

The downside of this is that it is offers

a potential for bias. And, why do I say that? Because, in all likelihood, I'm going to approach individuals who I know, with whom I work, organizations with which I am familiar and probably to a very great extent have the same mind set, the same thoughts as I do.

So, again, there's that potential for bias.

On the other hand, it certainly is a good way to start.

At some point, if and when we advocate for rule changes, then we'll have to go through the formal stakeholder input which will be slower but will have the advantage of incorporating a broader respondent base.

Thank you.

CHAIRMAN ALDERSON: Dr. Palestro, I'd like to compliment you on really outlining an excellent process, you and the Committee. I think this is a process that can be sustainable as you go forward.

But, the question I would start this session of questions with is, so what's the next steps?

So, now that you've got the paradigm and you've looked at one limited category, what's the Committee's view about what will happen next?

DR. PALESTRO: I think I speak on behalf of the Subcommittee that the next step would be to go

through each of the subcategories of 35.

And again, I know that 300 is a, quote, unquote, hot topic but I kind of think that the next one that we would be doing or should be doing is 200.

It's larger than 100, it will give us a chance to flesh out the template, the review template, and perhaps identify deficiencies, if you will, in the template as it currently is.

And, we'll also allow time for input from various individuals, stakeholders and so forth, that will allow us to tackle 35.300, which I think is going to be far and away more complicated.

CHAIRMAN ALDERSON: Yes, but for me, that's a good answer. I think that's a good approach.

Comments from the ACMUI or questions?

Pat? Zanzonico? Dr. Zanzonico?

DR. ZANZONICO: Yes, I think it was an excellent start to what seems like an intractable problem at times. I mean, really well done.

The emphasis, I think, appropriately is on radiation safety. You know, another aspect of this obviously is clinical competency. And, that may be beyond the scope of regulation and so forth.

So, is that implicit in your approach or --

well, that's the question. Is that implicit in the approach that clinical competency is left to the certifying Boards, professional societies, so forth and so on, independent of AU status?

DR. PALESTRO: Yes.

DR. ZANZONICO: Okay.

DR. PALESTRO: Yes, I don't think that we're in a position to judge clinical competency, nor should we attempt to.

DR. ZANZONICO: No, I agree, I think that should be a sub-policing sort of component of all this. But, yes, I think it's a great start and very systematic approach.

DR. PALESTRO: Thank you.

CHAIR ALDERSON: Yes? Dr. Dilsizian?

DR. DILSIZIAN: Again, great presentation, challenging.

And, I understand why the Committee had difficulty with the competency issue.

So, a couple of comments, when you said the primary competency is based on certification, I think where there needs to be clarification is that that's just not just certification, you need to have a predetermined years of training that follows to a

certification.

No one can sit on an internal medicine board unless you've done three years of internal medicine residency.

So, I think that I would just expand on that. It's not just a certification, it's having proper training as defined for that subspecialty which follows by certification.

You want to answer?

DR. PALESTRO: Yes, you know, I understand what you're saying.

DR. ZANZONICO: No one sits on a Board without having proper years of training, no one. That is a requirement.

DR. PALESTRO: You're absolutely correct, but I'm not sure that that's germane to this because ultimately, the determination of whether or not the individual attains authorized user status is whether or not they pass the certification examination.

And, in addition to that, there are some of the Boards that give credit for all sort of different things that an individual has done.

So, that individual may or may not have spent the quote, unquote requisite three or four years

in the training program.

DR. ZANZONICO: And, that's good.

And, then the reason I say that is because, part two, which is your alternative pathway which is a slippery slope.

Because, if you make it so that the alternative pathway, you know, you can just do a weekend course and have some questions answered, why would anybody go through regular three years of training plus a Board certification if I can go through the alternate pathway that happens to be much easier?

So, I mean, just as a thought, I think that there should be equally competent competency. It should be regimented so that there's not an easier pathway that, therefore, the regular pathway which is well-defined becomes minimized.

DR. PALESTRO: Yes, I understand and I and the Subcommittee agree with you that, whatever criteria are established for an alternative pathway, assuming there is one, have to be equally stringent.

But, that doesn't mean that someone necessarily had to spend four years in a program to meet equally stringent requirements.

For example, and again, I say I'm sure that

there are a lot of folks consider it heresy if we say, there are no requirements other than X number of cases but you have to come and complete a very rigorous on site personal examination. That, too, might suffice.

And, I'm not saying that it does, we're just simply putting it out there as an alternative and looking to gain feedback such as from yourself to help guide us as to what the best approach is. And, I'm not sure that we've fully resolved that yet, to be honest with you.

CHAIR ALDERSON: Other questions? Yes, comments?

Mr. Green?

MR. GREEN: I think it's a great template. It's a big issue to tackle and it was an issue that came up at the fall meeting.

I've seen RAM licenses where, for some reason, the licensing agency felt that this authorized user position should be restricted to unit doses only versus someone who has the training experience to -- or the facilities, I'm not sure why, but to have a generator of made kits and a usable bulk tech.

And, I've seen RAM licenses that say, you can use capsule iodine only or you can use liquid iodine.

And, we're looking at the 100 to 200 to 300 and the various other categories in 35 CFR, but I wonder if there's a possibility to take that kind of a spin on limited access? Whether a unit dose user only of certain types of products, if that would allow a different educational path?

You know, a full authorized user position has to know imaging, gamma cameras, quality control, all of that. But, in the beginning of the 300s, you don't have that, the camera, all the imaging aspects of the authorized users dealing with the medicine today.

DR. PALESTRO: That's one of the issues that the Subcommittee and, obviously, the ACMUI will have to deal with when we get into the 300 category which is why I want to proceed slowly and start with 200 because some of the issues you mentioned actually may come up in the 200 series even for diagnostic.

CHAIRMAN ALDERSON: Dr. Zanzonico has a comment.

DR. ZANZONICO: Yes, what I like about this approach is that it implicitly or it may be explicitly, it separates the issues of clinical competency which is a nonregulatory issue from radiation safety competency which is a regulatory issue.

And, whatever the ultimate form of the radiation safety competency is, that shouldn't replace at all or detract from clinical competency and, therefore, from clinical training.

So, I don't think the alternative pathway is, in a sense, a threat to physicians, specialists, who go through that pathway.

It's like it's a different skill set and I think part of the complexity of what we're trying to deal with is that, they've been mixed together.

And so, it's hard to address either one rationally in a sense. But, in terms of what the approach you've proposed, effectively separates out the radiation safety competency and I think it makes it a lot more tractable and so forth.

But, the point I want to make is, I don't think it at all limits or provides any sort of shortcut to specialist in terms of clinical competency. I mean, I think they still would be required to go through a lengthy residency and fellowship program where they learn that clinical specialty.

The question is, how can they meet the requirements for radiation safety competency in a reasonable way? And, I think that's an excellent

approach that you've provided.

CHAIRMAN ALDERSON: Thank you for that comment.

Other comments?

Yes, Dr. Langhorst?

DR. LANGHORST: I think one of the difficulties on the alternate pathway has always been how you judge the clinical competency. And, I think it's always been an uneasiness for the preceptor to sign off on it.

And, we've suggested several statements of really what they're saying and it really comes down to the radiation safety, the regulated piece of what they're doing.

But, it doesn't come down to the clinical competency.

The Boards help support the documentation that someone has had the radiation safety regulatory training. They also address the clinical competency.

So, there's always been that uneasiness with the alternate pathway. The alternate pathway also is hard to judge when you have someone who is practicing, has gone through their clinical training.

But, how do they now step into a new role?

And, what is exactly the competency and the radiation safety aspect of what they need to do?

And so, do they have to go through a residency again? Well, that's crazy. In fact, some people think they don't need to go through all the training that's listed in the alternative pathway.

But, I think the alternative pathway, the emphasis then really has to be on how you meet the regulatory requirements for safety and safe radioactive materials.

Thank you.

CHAIR ALDERSON: I don't see any other hands here at the moment. I'm going to ask if there are people -- there is a hand.

Mr. Fuller?

MR. FULLER: Yes, I would just like to ask, because, up until this discussion today, we've kind of discussed this and with slightly terminology. So, I just want to make sure that I understand and the medical team understand what everyone means.

Because, obviously, we're not clinically trained and so, we need to make sure that we understand what you mean by clinical competency.

So, to put it in different terms, what we've

talked about in the past and what we rely upon the ACMUI for is the patient safety aspect.

So, when it comes to occupational safety with the use of these materials, we understand that and we have that. We have those skills, we have that knowledge, we have that expertise.

When it comes to public health and safety, we've got that.

When it comes to patient safety, that's where we rely upon this body, to help us understand what the regulatory requirements should be in order to ensure that the patients are safely administered the radioactive material.

So, what I'm hearing today is maybe a little bit of a different twist on that in that you're talking about the radiation safety aspects versus the clinical aspects.

And so, it would be nice, I think, for the staff to hear a little bit more about how these slightly differing approaches to this problem either overlap or where the nexus is.

Because our Commission in the past, when we've gone through rulemaking for this sort of this has made it clear that patient safety is also very, very

important and has to be addressed in our regulations.

So, if somebody could help me with that?

CHAIR ALDERSON: That's an excellent comment. I'm going to turn it to Dr. Palestro, because I believe that in listening to the paradigm that you've developed this template that you must have considered that really very difficult question in doing what you did. So, please, Dr. Palestro?

DR. PALESTRO: The answer is, radiation safety events, radiation safety section was incorporated at the recommendation of staff.

And, our concept is that, in order to carry out, if you will, the mandates of maintaining patient safety, public safety and so forth, that an individual has to be quote, unquote, competent, not only in medical or clinical safety, if you want to call it that, but radiation safety as well.

It's not enough to understand how to prevent or how to manage a medical event when you don't know how to deal with a radiation safety event.

Some of the examples that we gave, the lost sources and so forth and so on.

So, I think it's a broader scope than what we originally focused on because I certainly, as the

Chair of the Subcommittee, wasn't thinking about radiation safety events. I was thinking about medical events because I deal with the patient on a daily basis.

And quite frankly, our RSO deals with the radiation safety events.

But, I think if want to approach it from a more complete aspect and remember that, in the majority of institutions in this country, often times the AU is also the RSO. That individual has to be cognizant not only of medical events, be aware of capable of clinical competency, but also has to be aware and capable of managing radiation safety.

I don't know if that answers your question.

MR. FULLER: That helps, thank you.

CHAIR ALDERSON: Yes, Dr. Ennis?

DR. ENNIS: I haven't had a lot -- I obviously haven't really had time to think about this, but that much, but Mike's question, I think is really actually very insightful.

And, it makes me feel like I don't really agree with the dichotomy that you, Pat, suggest. I'm feeling like they're completely intertwined, they are not separate.

How can I be trained in the regulatory

aspects of I-125 brachytherapy, for example, without understanding the clinical aspects of how that radiation interacts with the patient?

And, the -- by authorization to use I-125 isn't just because I know how to use a survey meter or do a dose calculation or have memorized the half-life or --

But, it's how it interacts with the patient which is in part clinical. And, this is probably why this committee is always struggling with what's regulatory versus clinical.

But, the formulation I think I heard, it didn't really dawn on me until Mike articulated it, but feels very much like a Radiation Safety Officer job as opposed to a nuclear medicine physician or a radiation oncology physician.

And, which I think NRC has turned to the Boards to kind of give the authorization because they are the ones who can kind of do both pieces of that as an integrated unit.

And, it feels to me like that's what needs to be. And, we cannot separate radiation safety aspects of a medical physician's practice using radioactive materials from the clinical aspects, unless

the clinician is doing non-radioactive treatments like I do treat patients without radiation sometimes.

Follow ups, I do check ups, I do hormone therapies. So, that is obviously medical, but not radioactive.

So, I don't see that dichotomy working which obviously makes it very problematic for this alternative pathway.

Because, with what I'm articulating, then how do you come up with an alternative pathway outside of a Board? And, I don't know, maybe the answer to that is you cannot or the Boards need to come up with an alternative pathway that we can then use.

But, anyway, those are my thoughts.

CHAIR ALDERSON: Well, since I don't see another hand, do you want to comment on that? I'll be glad to comment on that also.

DR. PALESTRO: Yes, I understand what you're saying, but I think determining whether or not an individual is quote, unquote clinically competent to manage a patient is way beyond the scope of what the NRC responsibilities are.

And, our paradigm, our template looks at what looks at the NRC requirements and they have nothing

to do with managing the patient clinically.

And, I have to tell you, to use myself as an example, when I administer I-131 for thyroid cancer or for hyperthyroidism, I don't manage that patient. That patient is turned back to the endocrinologist for subsequent follow up and managing.

I understand administering activity. I understand what the consequences of the activities. But, I do not turn that -- I do not manage those patients.

You know, there's lutetium-177 DOTATATE I think that will undoubtedly be available in the not too distant future for treatment of neuroendocrine tumors and I look forward to my division being actively involved in the administration of the treatment -- of that treatment to those patients.

But, there is no one in my division, and I think for most nuclear physicians in general, who are in a position to manage those patients after the treatment.

CHAIR ALDERSON: So, I think that's a very fair answer.

I think it's sort of an issue of semantics, but obviously, eventually, you have to have the whole package in order for the patient to be safe.

But, quite right, the NRC is not in the business of regulating the practice of medicine.

So, in the alternate pathway, I'll just move right to that alternate pathway, the Committee may come back with a recommendation that there has to be in the alternate pathway, another standard.

And, if one has the Boards or something like that, well, that's easy, that's the easy part of that. That's fine, that works.

If they don't, then conceivably, for example, the NRC could say, just like people issue RFPs, they could say, well, we're prepared to go forward in this, but for certain groups, we don't have an effective alternate standard and we invite the comments of people from the public or other places to recommend a standard that at least the NRC could find acceptable without itself actually managing that medical side of this question. That would be one way to approach it.

I think the fact that they've somewhat separated the safety from the clinical competence is actually a good way to get started down the road, which didn't quite exist before.

Now I see several hands up. Ms. Tapp, Dr. Tapp hasn't commented yet, so Katie Tapp?

DR. TAPP: I actually had a question to follow on what Dr. Palestro just said.

You said that you don't manage patients following administration in internal nuclear medicine. But say a medical event were to occur, I would say nuclear physicians would usually be the ones trained to know if a medical event occurred and then what to do, not the endocrinologist, but maybe the nuclear medicine physician what to do if the medical event occurs, how you would --

DR. PALESTRO: I guess the question is when did the event occur?

DR. TAPP: If it occurred during your treatment?

DR. PALESTRO: That's a different story.

DR. TAPP: And, that is part of the training you need, what to do and --

DR. PALESTRO: I would know what to do and I would certainly know what step to take next.

For example, if the patient went into cardiac arrest, the first thing we'd do obviously is call a code, right, and take whatever other measures we needed until the individual, the appropriately trained individuals came to nuclear medicine and took over.

So, yes, that's the sort of thing that we can manage. I'm not referring to that, I'm referring to the ongoing care of the patient after the fact.

DR. TAPP: Radiation NRC medical event.

DR. PALESTRO: I'm sorry, I misunderstood you, yes. Yes.

CHAIR ALDERSON: Dr. Dilsizian had his hand up.

DR. DILSIZIAN: I -- maybe I don't have to persist on this, but the alternative pathway, it actually exists for certain occasions. As you know, it can be really a nuclear medicine physician like me being a cardiologist and doing one year of nuclear medicine training and be Board certified to do radiology, radiation oncology. But they're different pathways that's already there.

The ultimate test of competency has become the certification Boards. So, whatever training pathway you're going to come up with, ultimately, I think there's got to be some certification that says this person passed this test and therefore is competent. That's how we judge ourselves right now.

So, whatever you design with this alternate pathway, I think ultimately it has to have some type of

objective testing just like we've all gone through that says you're competent.

So, right now, it's done through the clinical pathway and ends up with Boards. I'm not sure what you're going to come up with that's not going to end up in some type of Board certification.

DR. PALESTRO: The answer is, if you go back and look at the slide on the alternative pathway, it says with satisfactory or with satisfactory completion of an examination of one sort or another. It doesn't necessarily have to be sponsored by a particular Board. It could be an independent committee of quote, unquote qualified individuals who conduct the examination.

But, we didn't say there should be no examination and that anyone under the sun can become an authorized user. What we're looking at and just sort of suggesting were different ways of attaining AU status alternative pathways.

And the two that we mentioned both included one sort of examination or another. So, yes, that is there.

CHAIR ALDERSON: And, Laura Weil?

MS. WEIL: We should recognize that there

is an existing example of this alternative pathway with endocrinologists being certified as authorize user for iodine-131.

And, that's with only 80 hours of training and experience in addition to their clinical degree.

We could assess whether that works or whether it doesn't work and use it as a cautionary model for going forward.

DR. PALESTRO: There is -- you're correct. There is a -- they call themselves the American Board -- there is a Board, an endocrinology Board, and I apologize, I don't recall --

CHAIR ALDERSON: Dr. Howe may know.

DR. PALESTRO: Dr. Howe may know the name for endocrinologists who undergo certification and that particular Board has deemed status with the NRC. So, that's how they attain it, yes.

DR. HOWE: Yes, that particular Board came in and asked for us to recognize them and they had to demonstrate that they met the criteria for a Board under 35.392 and 396. There are criteria there.

They happened to be essentially the same criteria as the alternate pathway. And then, we recognized them.

CHAIR ALDERSON: Yes, Dr. Ennis?

DR. ENNIS: Just a follow up on the conversation.

So, if there's an isotope that a patient is referred for, but they shouldn't get it because of some medical condition they have, that is something that would be under the purview of the nuclear medicine physician?

DR. PALESTRO: It would be under the purview of the authorized user, whoever that is, that's correct.

DR. ENNIS: Right, okay. So, that is a clinical decision, not a radiation safety decision, to make my point.

And, that shows to me how they're so intertwined and to separate them out and to make it only about radiation safety, I think misses the point of what we're doing.

CHAIR ALDERSON: Yes, Dr. Ouhib?

DR. OUHIB: Yes, you know, we have proven Boards with records and all that, it just makes me nervous that we're looking at an alternative pathway and looking at these group of people that decide that they can examine an individual and handle this delicate --

you are good to go. It just makes me nervous.

Like somebody said, you know, this is a slippery area. I will echo that same sentiment that this could be -- that could come back and bite us actually.

CHAIR ALDERSON: Yes, Mr. Bollock?

MR. BOLLOCK: I just wanted -- you know, we are at a hard position here because we don't want to interfere with the practice of medicine, but as Mike pointed out, we are -- we still regulate the safety of the patient as well.

So, something Dr. Palestro pointed out to kind of like where we get to that grey area is understanding the consequences of administration of the radiation to the patient. That is patient safety under our purview.

So, that is important and it -- so there is a clinical tie. It's like anything -- even the other things that we regulate or anybody regulates. There's always like this on the job training of some sort and, you know, there's some expectation for different certifications and like I said, any other --

And it's not just us, it's across the board in other practices, professional -- any professional

society or professional groups.

So, there is a tie because that clinical -- a certain level of clinical that's in the medical decision and some of it is that helps the protecting the patient on the radiation side as well. I mean there is a tie.

And, as Mike said, that's why we rely upon the advice of you all in making sure that we're not overstepping our bounds, but still meeting that, you know, the safety requirements for the patient in that administration.

CHAIR ALDERSON: And, there would have to be not only a way to initially determine that a particular external organization fit the criteria for a Board, for whatever.

But, there has to be a way, I think, to continue the maintenance and certification idea to determine, over a period of time, that whatever physicians were eligible are eligible to be the AU or whatever persons, those people have to maintain that same level of competence, I'll use that word, in the future just as all the Boards say physicians have to now.

And, that's another aspect to this. So, I don't think these problems are necessarily going to be

resolved, you know, extremely quickly and that's why we have a standing committee and they're looking at these issues in a stepwise fashion. And, you may be able to develop these templates as you go forward and, you know, solve the harder problems after you've had a little experience.

But, all these issues have to be included.

Dr. Langhorst?

DR. LANGHORST: Thank you.

I don't remember what the NUREG is, but the NRC has a NUREG document on medical licenses and what they consider the basis for these licenses.

And, it's a three-prong basis for a licensee who has a medical license. It's executive management. It's the Radiation Safety Officer. And, it's the authorized user.

And, the three of them have to understand the license requirements, commitments and have to be part of that.

That's why it's so important to make sure the training of the authorized user is appropriate, is adequate to help support that triad.

That's why, if you have a physician who works in a different area and now there's a radiation

radioactive drug, let's say, that treats something in their purview, well, they just want to be able to use it and administer but they can't because they need to have that broader, and if you want to say radiation safety, I mean, it's operative to say that it's a cut and dry thing, they have to have that whole understanding of the regulatory environment and their commitments to it.

That's why, I mean, When we talk about alternative pathways, we have alternative pathways already. So, we're not talking anything new, it's just the way of how do you judge a person meets both the clinical and the regulatory, let's say, radiation safety, whatever you want to call it, aspect of using these radiation sources or radioactive drugs.

And, it's not so easy, but I think it's very easy to explain it to outside physicians that think they can just, oh, I want to add this drug to my use now. You can't do it because you have to have a whole different license to be able to do that kind of work.

That's the difficulty in trying to figure out how you bring people who are already practicing medicine into the fold or you don't bring them into the fold or what are the competencies they have to have to

meet in order to work with that.

CHAIR ALDERSON: Absolutely. That's why we asked Dr. Palestro to lead this committee.

(Laughter.)

CHAIR ALDERSON: He has a comment today.

DR. PALESTRO: Yes, I'd just -- I wanted to respond to Zoubir's comments in particular.

The Subcommittee is not necessarily advocating for or against alternative pathways. We've simply indicated a couple of potential alternative pathways.

I think to unilaterally and perhaps arbitrarily say, that alternative pathways or there should not be any alternative pathways, is to turn the blind eye to what is going on and what will continue to go on around us.

If, in fact, we feel that alternative pathways are harmful or shouldn't exist, we should in some way be able to back that up with facts and not just say, well, we think that it doesn't belong. Because, after all, we need X amount of training and so forth.

So, I think it needs to be investigated. I don't have any preconceived, at least I'm trying to avoid, preconceived notions about whether or not they

exist, but I don't think the issue can be ignored.

Because, quite frankly, it's not going to go away.

CHAIR ALDERSON: Right, absolutely.

I'd like ask, are there any people on the phone? Do any of you know if there a person on the phone?

He's checking.

PARTICIPANT: Yes.

CHAIR ALDERSON: We'll move along with our discussion then, but I would like to make sure that during this segment, particularly, that we are sure that if anyone's out there that they get to make comments.

MS. SMETHERS: Are the lines open?

CHAIR ALDERSON: Well, while we're waiting for the answer to that --

MR. BROWN: The line's open.

CHAIR ALDERSON: The line is open. So, we must ascertain then that there is no one there who wishes to comment or ask a question about this issue, is that correct?

People seem to think that is correct.

Is there anyone in the room want to make a comment? No one, okay, so it's fine, it's back to us.

We've tried.

Yes, Sophie?

MS. HOLIDAY: If you're on the bridge line and you wanted to ask a question or make a comment, you may have to dial star six if that's what you used to mute your phone so that you can unmute it.

CHAIR ALDERSON: All right, we'll sit just a moment and see if anyone happens to dial star six and speak up. But after we've waited just a brief few seconds, because they can do that right now if they're listening in, then we'll go back to our own discussion and I will feel like we have done the appropriate thing to be sure that the general public has as opportunity to discuss this particular issue.

Is anyone there?

(No response.)

CHAIR ALDERSON: Hearing none, Dr. Zanzonico would like to speak.

DR. ZANZONICO: I think it's important to bear in mind what generated this latest incarnation of characterizing training and experience. It was the Bexar issue.

And, I think the specific issue there was the necessary training in the number of hours of

training, specifically in nonclinical areas, in radiation physics and radiation safety and so forth.

And, I thought that was the scope primarily of this Subcommittee. I think it's beyond the scope of the Subcommittee to address overall competency and, you know, that's left to the certifying Boards, professional societies, et cetera, et cetera.

And so, my earlier comment, in terms of the approach of the Subcommittee was in relationship to defining some reasonable number of hours of training in the technical aspects that authorized users need to be competent in.

So, I think we've got it -- we've expanded the scope in terms of trying to define clinical competency and overall competency rather than just trying to define some numbers of hours.

And, I think the approach the Subcommittee used in addressing that specific question is very reasonable.

I think the broader question of clinical competency, alternate pathways, et cetera, et cetera, may be beyond the scope of what was originally intended and complicates things maybe intractably in the short term.

CHAIR ALDERSON: Dr. Palestro?

DR. PALESTRO: Yes, going back to the -- it was actually the Zevalin.

DR. ZANZONICO: Zevalin, I'm sorry.

DR. PALESTRO: That was a separate Subcommittee that was formed to look at that and to try to make a determination of whether or not the decrease in use of that radiopharmaceutical is related to a lack of patient access.

That Subcommittee concluded the ACMUI agreed that there was evidence to support that.

Subsequent to that, it was decided that a new Subcommittee should be formed, a Standing Subcommittee, to look at the training and experience requirements for all modalities.

There was nothing in that that focused specifically on a number of hours of training. And, in fact, that was one of the major issues that came up is hours in and of itself, a good way to approach education.

And, in the current milieu, the educational paradigms don't focus on hours of training.

So, yes, the charge committee -- the charge to the Subcommittee has been greatly expanded or is very, very comprehensive. And, it's not easy.

The members of the Subcommittee will tell you, but that's sort of what we're left with.

CHAIR ALDERSON: Dr. Howe and then Dr. Dilsizian.

DR. HOWE: Just from a historical perspective, you're talking now about the Boards and saying that you may just go exclusively to Boards. That would be a tremendous shift in where NRC has been historically.

Because the Boards are the second group that came in to be recognized. The first group were the alternate pathways now. They were the only pathway when we started regulating medical use of isotopes.

And, in 2002, one of the issues that we had to deal with was, are the Boards focusing on radiation safety? Or, are they focusing on other issues that are important for medical care, but not radiation safety?

And so, in 2002, the Commission decided that, if you were a previously recognized Board in Subpart J, you were not going to be recognized when the 2002 rule went into effect because you may not have been asking questions on your Board that pertain to radiation safety and the radiation protection of patients and workers, et cetera.

And so, there was a shift at that time to make sure that the Boards were asking questions that we were concerned about.

And so, I think as you go forward, you have to keep that in mind that, if you just go to the Boards and you don't have criteria to keep us as part of that examination process, you may have lost what we gained in 2000.

CHAIR ALDERSON: Yes, and I would -- I just I agree with what you said, Dr. Howe. And, but I do want to make a comment on one aspect of it.

I don't want anybody to get the impression that right now, at least as I am hearing this, that the Committee is suggesting that Boards will be the only way to get this resolved. That was not said.

There is a huge spectrum of approaches that will have to be worked out over the months or perhaps years to come with this Committee, but that is not the conclusion that has been drawn at all at this time.

And now, there was another hand over here. It's Mr. Green and then Dr. Palestro.

MR. GREEN: I'd like to follow upon Dr. Howe's comments.

It's very astute that the alternate pathway

for a nuclear pharmacist is the primary pathway. You -- there are only five legacy schools today that have collegiate training in nuclear pharmacy.

Unless you go to one of those schools, you have to take a post-graduate program, a one offered after you get your pharmacy license.

And so, you become an authorized nuclear pharmacist and then you're required to work 2000 hours and then be eligible to sit for a Board certification of the pharmacy.

There's, the number's kind of fuzzy, one and a half, 2000 nuclear pharmacists in the United States today. There are 431 Board certified nuclear pharmacists.

I am the Chair of the BPS Nuclear Pharmacist Specialty Counsel for the next two years. I'm very aware of how many there are. It's a very small number.

But, in, at least with nuclear pharmacy, it's the alternate pathway that leads and then the certification follows.

CHAIR ALDERSON: Dr. Palestro?

DR. PALESTRO: Yes, I just want to emphasize to Dr. Howe and to everyone that the Subcommittee is not recommending against the

alternative pathway. We're trying to remain as impartial as we can without any preconceived notions of whether or not an alternative pathway or pathways are good or bad, but they need to be looked at and eventually when we're able to assemble the data based on input from all the various stakeholders, we can come to a conclusion.

But, the Subcommittee under no circumstances has taken or is taking a position that the alternative pathway should be done away with.

CHAIR ALDERSON: Are there any other comments or questions?

Let's have one final comment and we'll wrap up this discussion.

DR. DILSIZIAN: So, I know that this has been said many times, and I'm sure you don't mean that when you say hours are no longer the way to deal with competency. I don't think you mean -- I know you don't mean that.

Because GME wants hours followed by competency. So, whatever we do, it's number of years or 200 hours, 80 hours or, you know, of classroom work and then competency.

So, it's not GME is not saying just

competency, it's training followed by competency that whatever you did during your training period actually translates to knowledge.

So, I just want to clarify, you keep saying hours is no longer, I don't think that's true.

DR. PALESTRO: I'm not sure I understand you when you say GME. What do you mean GME?

DR. DILSIZIAN: I'm just saying Graduate Medical Education, all those rules, isn't just on competency. They want you to, when we evaluate students, it isn't just on competency, it's that they spend a certain number of hours in our rotation and then you say, are they competent based on that four weeks or four months.

It isn't that --

DR. PALESTRO: But the hours -- when you're talking about -- if you're talking about in order to obtain authorized user status?

DR. DILSIZIAN: No, anything, any education requires a certain number of classroom hours, education, training and then you -- just like surgeons, you can't operate unless you a certain number of cases. And then you say, are you competent to do the operation?

DR. PALESTRO: You know what? I've been

off the review committee for nuclear medicine for a couple of years. But, it is my recollection that the last time we did the program requirements, that while we listed topics that needed to be covered, that there was no specified number of hours, didactic hours that had to be included, that we listed specified topics.

You can check and see, I don't think I'm mistaken because I had the misfortune of being in charge of rewriting those requirements.

So, if I said doing away with perhaps, I misspoke. I think a more appropriate term would be de-emphasizing hours, all right, that there are, and I'm sure we could probably all sit down and agree, a majority of us, agree on the topics that should be covered very easily.

Arguing whether they should be covered in 10 hours or a 100 hours, then becomes the debate.

And, what I am suggesting, and I think what the Subcommittee is suggesting is that maybe it's time to de-emphasize hours, focus on topics with the ultimate criterion for competency being the examination. That's really what I mean.

CHAIR ALDERSON: Well, thank you, Chris, I think that's a great overview statement on which to end

this discussion.

So, I want to thank the Committee and Dr. Palestro again for their excellent work.

And, I think as the meetings go on of the ACMUI that we'll expect at least for there to be a brief report each time about what the Committee's been doing, where it currently is and its progression through the paradigm that it provided to us and we'll continue to discuss these interesting issue.

So, thank you, again, for an excellent job.

All right, that brings to the next topic which is Patient Release Project Update and Dr. Howe is going to help us with that.

DR. HOWE: Thank you, Dr. Alderson.

The Patient Release Project has been a many year and multiple project endeavor.

The one I'm going to be talking about started with a Staff Requirements Memorandum in April 28, 2014 and the topic was the background and proposed direction to NRC staff to verify assumptions made concerning patient release guidance.

The Commission wanted input from a wide spectrum of stakeholders, public, patient, patient groups, physicians, professional societies, the ACMUI

and Agreement States.

And, in order to get the public input, we had to, in some cases, go through the Office of Budget and Management Clearance to get it on the clearance to be able to ask the public questions.

We had to publish in the Federal Register to let people know that we were looking for information. And, we had public meetings.

We've had two parts to this. The first part was to collect information and the reason we split it into two parts, because the second part had more to do with the possibility of looking at -- to see if we were going to do any regulatory changes.

And, we felt that, if we put the possibility of doing any regulatory changes in the first set of public participation things, we would never find any information that we were looking for the patient side of things.

So, our focus on -- so, that's why we split it into two parts.

And, the first part was information that patients believe would help them understand their I-131 treatment and the SRM was primarily focused on I-131, and at the later part, to the SRM it says, well, we'd

like to have you modify guidance on all isotopes, not just I-131. But, that was the major focus.

And, they wanted information on physicians and licensees best practices when making an informed decisions on releasing I-131 patients.

So, we had four basic questions. The next one was information provided to patients on how to reduce radiation dose to others. And, if a patient advocacy group or medical professional organization, licensees or other individuals had brochures, that would address much of this information in an already published form.

So, we got out OMB clearance and we published in the Federal Register November 16th, 2015 with a 60-day comment period. And, we held two public meetings December 2015 and January 2016.

And we got a number of comments and we've been working through those comments and we're getting ready to publish an Information Notice for one set of comments on best practices.

Who did we get comments from? We got them from everybody. We got it from individual physicians, we got it from clinics, hospitals, professional societies, patient advocacy groups and individual

patients. So we really got a good, broad spectrum.

And, the best practices that we're going to be using are in a generic communication which is the Information Notice that should be coming out in the summer of 2017.

And, as part of this information collection, we identified two items that we thought should be included in part two of the Commission Directive.

And, part two was we were asked to evaluate whether significant regulatory changes to the patient release program are warranted.

We were not told to make changes, we were asked to evaluate whether changes were warranted. So, we are really in early stages here.

And we were to explore with the public, licensees and stake partners whether we should change 10 CFR Part 35 for specific reasons.

And, these are the things that we were asked to look at, should -- and we've published a Federal Register Notice April 11th, 2017 on this.

And, they are -- and we have six questions we are asking for public input on.

The first one is, should the Agency change

35.75 to require an activity-based patient release threshold under which patients would be required to maintain -- be maintained in a clinically sponsored facility, that would be a medical facility or facility under the licensees control, until the standard for release is met?

The second question we have is, should we clarify the time frame for the current dose limit in 10 CFR 35.75(a) for releasing patients?

The 500 millirem dose limit is just stated as 500 millirem. It does not say it's per administration or per year or per other time.

Third one was, should the NRC continue to apply the same dose criteria of 5 millisieverts, .5 rem to all members of the general public including family members, young children, pregnant women, caregivers, hotel workers and other members of the public when considering the release of patients?

So, should we have the 500 or should there be a differentiation between different groups? And, it could go up or it could go down.

And, question number four was, to have a new requirement for the release of a patient who is likely to expose young children or pregnant women to doses

above the 10 CFR Part 20 public dose limit?

Right now, we have the 500 millirem limit. And then, if you're going to expose somebody in excess of a 100 millirem, you have to provide instructions, including written instructions to keep doses as ALARA.

And, the two that we have added based on the information received from the part one public comment period and information collection was, should we have a specific requirement for licensees to have a patient isolation discussion with the patients in sufficient time prior to administration to provide the patient time to make an isolation arrangements or for the licensee to make plans to hold the patient if the patient can't be immediately released?

And, during the public comment period for phase one, we had more than one patient that called in and said that they were going -- undergoing I-131 treatment in the next two weeks and no one had talked to them at all about whether they had to be isolated. And, they had small children.

And so, they didn't believe they were going -- if they hadn't looked at a website, they wouldn't know that they needed to make arrangements.

And, our last question is, should NRC

explicitly include a time frame for providing instructions in the regulations and somehow indicate that the instructions should be provided prior to a procedure?

Because we heard from a number of patients that they received their instructions after they got the I-131 treatment and it may have been in a packet of release papers and there really had been no discussion or pointing out that this was what they were needing to follow or question whether they could follow it.

So, these were the six questions that we have asked in the Federal Register. And, for -- we want them to give -- we want people to give us open ended responses.

But, we want to make sure that, if we've asked for whether a change is needed or not, people respond with no, you don't need to make a change and explain why we don't need to make a change.

If they think we do need to make a change, they should provide the criteria that NRC should use and explain why we should make a change.

And, if there's specific groups involved, we want them to specify the groups for each criteria.

And, in all cases, we're really looking at

health and safety. So, we're asking people to provide us with information on what they perceive as the health and safety benefits or lack of benefits to individuals being released, the licensee and to individuals members of the public.

So, this is the kind of information that we're asking.

And so, we've published our Federal Register Notice. We asked these six items. We have the three questions below.

We are in the middle of a 60-day public comment period. We have gotten one request to extend the public comment period. We are considering that. We believe we will extend the public comment period for 15 days. And, if we do that, we will be publishing that in the Federal Register to let everybody know.

We plan to have two public meetings. We had one public meeting yesterday and we are going to have the second public meeting May 23rd. And they're going to be at NRC Headquarters.

We're going to be webcasting the public meeting and we're also try to webinar so that we have a backup system and then we'll have a telephone conference line.

And, if anybody checked in on our public meeting yesterday, you would find out that NRC's webinar has been down for over a week. And so, that backup system wasn't working and halfway through the meeting, our webcast system server crashed.

And so, we had no more visualization on it and we were left with our telephone lines. But, we had to go -- but at least we had our telephone lines open.

So, you know, you plan for these things, and yesterday, it all hit.

And, what are we going to with the results of this? Well, we're going to take the public comments and we're going to be forming a SECY paper to the Commission and we're going to give them our view of whether we should pursue changes to 10 CFR 35.75.

If we decide we aren't going to -- we don't believe we should be making changes and the Commission agrees, that's the end.

If we decide we are going to make changes and the Commission agrees, then we'll certainly go into proposed rulemaking and the whole rulemaking process. So, there'll be plenty of opportunity to comment afterwards if that's the direction we take.

At this particular point, we're still

collecting information and so, it's too early to say one way or the other.

Are there any questions?

CHAIRMAN ALDERSON: Yes, thank you, Dr. Howe.

Yes, Dr. Ennis?

DR. ENNIS: I'd suggest an additional possibility to be considered is whether the training and experience requirements for the authorized user should be changed.

I must say that I'm struck by every time we've had this conversation, it seems to me, the core of the -- these are symptoms of a more core problem in that the authorized user who is treating the patient is not sufficiently sophisticated to convey to the patient or understand what the issues are.

These -- I mean, I'm flabbergasted that patients could be going around getting these treatments and not being explained to them that they're radioactive and all this.

So, to me, these are just symptoms and putting out the little fires.

The core issue, seems to me, is likely in many situations, it's just the training requirement of

the authorized users is inadequate, that they don't really quite understand what they're doing and what they're using.

CHAIRMAN ALDERSON: Ms. Weil?

MS. WEIL: I'd certainly like to echo that sentiment. But, can you just informally give us some sense of what happened at yesterday's meeting?

DR. HOWE: Okay, we had a public meeting. We elected to give an hour for each one of our questions. And, we had an agenda and we stuck to the agenda.

We had a total of 37 people on the phone for the morning session and we had 57 for the afternoon session.

We had hoped we would get a lot of dialogue and comments. Most people on the phone were silent. We did get comments from Peter Crane and eventually, other people would give their comments, too.

But, we had very long periods of where we had to break because we just didn't have anybody commenting.

So, we tried as best we could to get people to talk. So, if we had a subject on for an hour and in the first 15 minutes, we had no more people on the telephone to ask us or to give a comment, then we took

a break and then before the hour was over, we came back to that question in case we had somebody join us later and that helped. We got a little bit more discussion going.

So, in the afternoon, we got some good discussion going but we didn't have the participation on the lines that we expected.

MS. WEIL: Was it primarily patients or were there clinicians?

DR. HOWE: We had probably a mixture because we did have patients that were talking to us and making comments. And, we also had Radiation Safety Officers from medical facilities that were talking to us, too.

Now, yesterday's meeting was fairly close to when we published the Federal Register Notice, so the word really may not have gotten out as well and we'll have to work on publicizing it a little better for the next meeting.

And, based on our output for yesterday's meeting, we may shorten the meeting.

CHAIRMAN ALDERSON: Dr. Langhorst?

DR. LANGHORST: I want to make mention, again, on 35.75. While the dose does not have a time

period in the final rule, it is stated explicitly that it is a per release limit.

And so, I see there is no confusion over what it is. The final rule stated it was a per release limit.

I'll also remind the Committee that 35.75 patient release is not specific to I-131. It includes all radioactive materials.

If the dose to any given group or dose to over a time period is set, how do you administer that? I mean, if someone is -- someone's had a lot of therapy and they've had many nuclear medicine procedures, are they almost the end of the year, you can't give them that next diagnostic test because it might put their family member over 500 millirem?

And, how do you know? That's only if you're taking care of that one patient and you're the only one taking care of them. I mean, I don't -- it's impossible to do unless you just maintain it on a per release basis.

Thank you.

CHAIRMAN ALDERSON: Dr. Ouhib?

DR. OUHIB: I'd just like to echo Dr. Ennis -- sorry. I would just like to echo Dr. Ennis' comment

that it almost sounds like this is, you know, based on explicitly on the iodine-131.

This is more like a practice guideline issue and maybe someone from nuclear medicine can tell me if there is one or if there isn't, maybe it's time for such a thing can have practice guidelines for authorized users on how to actually administer, not necessarily just iodine-131, but these types of isotopes and what should be in place basically.

And, I think that might correct part of the problems.

CHAIRMAN ALDERSON: We have someone at the microphone?

MS. KUBLER: Hi, this is Caitlin Kubler with the Society of Nuclear Medicine and Molecular Imaging.

I just wanted to comment on Donna Beth's mention about the webcast and we did have a few members that participated. It was simply the timing that we couldn't get together and formalize our comments in time to share them yesterday.

But, we will be participating either in person or on the webcast on the 23rd of May and we are going to, you know, make our comments available.

Thank you.

DR. HOWE: Thank you.

CHAIRMAN ALDERSON: Thank you.

Dr. Ennis?

DR. ENNIS: Just a brief follow up.

Again, I wish we could verify this, because my suspicion is not about nuclear medicine, Board certified nuclear medicine physicians. [INAUDIBLE]

I'm concerned about the alternative pathway endocrinologists, specifically. And, I wish we could actually verify that but this is what it smells like to me and that would be very informative for us in terms of our other committee conversations.

And, it would really be quite helpful. But, that's what I was getting at.

DR. HOWE: In our public comment period, in our public meetings last year, the two individuals were going to very reputable hospitals.

CHAIRMAN ALDERSON: I'll ask a question and make a comment and, it may be that this is no longer the extant, but I have to ask it.

With respect to what's in the rule 35.75 or whatever the appropriate rule is, if it is not particularly definitive in terms of the issue at hand,

particularly, I think I-131, that being the most common one.

What I experienced a few years ago as these things were changing and I was still involved in the clinical side of the picture a bit more, was something that you can't control and for which you're not responsible. It was whether an insurer would pay for the room in the hospital to keep the patient.

And so, as the rule became less definitive, the insurers said, well, this doesn't say X. This allows latitude, we've look at this and we're not paying for this room anymore. And, out the patient would go.

So, if that is still a problem and having experienced a number of insurers without being too negative, I would say it probably is, I think that I would just encourage you, the more definitive you can be about the sort of thing that should require a patient to stay in the room, the more likely there'll be someone to pay for that room.

So, that is just an additional problem.

Yes, Dr. Langhorst?

DR. LANGHORST: We are working through such an issue with high plaque patients. Okay? And, it's not just the insurers, it's oh well, if you do it

with this patient, then you should do it with this patient, too. And, you shouldn't treat them differently.

But, one of the things that you have to assure is that you believe your patient can and will follow the rules. Not that you guarantee it, but, if you don't think a patient is capable of doing that, then you need to keep them in the hospital no matter whether it's high plaque or --

CHAIRMAN ALDERSON: Yes, I heard that.

DR. LANGHORST: So, it's not just -- I mean the insurance is one thing, but you have to have a patient who's cooperative and willing to do what you hope understands.

And, that's why it is so unbelievable that you don't have a discussion with your patients on what this all means.

CHAIRMAN ALDERSON: Dr. Zanzonico?

DR. ZANZONICO: I think my feelings on this topic are pretty well known. But, I find it -- I am really very surprised that question one is still on the table.

There's no question that an activity-based release criteria is wrong science and for the

radiation safety.

We know, for example, that individuals around a hyperthyroid patient treated with 10 millicuries will get substantially higher doses than a thyroid cancer patient treated and released with several hundred millicuries. I mean, that's settled science.

And so, I just don't understand the rationale why this is still an issue and why opinion is still being solicited on that point.

DR. HOWE: This was directed by the Commission. It was a Commission Memo from then Chairman MacFarlane and Commissioner Magwood.

And so, they -- these are specific questions one through four that they wanted the staff to look at. And, it can be that it came because we get letters or we at least did get letters until this SRM came out routinely about activity versus dose. So, this may be a way to answer the question, answer the mail, put a period.

DR. ZANZONICO: But, I mean, presumably, the Commission must be aware that, I mean, there's no scientific basis for an activity-based release criteria being more protective of public safety than a dose-based

release criteria.

DR. HOWE: We cannot answer for the Commission.

MR. BOLLOCK: But, and not to answer for the Commission, but to give a little bit -- as Donna Beth -- as Dr. Howe just stated, prior to that time, they had heard, you know, letters basically saying, go back to the way it used to be.

We haven't received those since that time frame.

But, and then, just another kind of background information as to why they're asking or possibly why their asking again, just something else we didn't know is that internationally, the international standards for patient release are not what the U.S. standards are in a majority of the European countries.

DR. HOWE: They're still activity -based.

DR. BOLLOCK: They're still activity -- right. So, that's another -- so they had that information. We've provided that information for them about that time frame.

So, it -- they have information saying the U.S. is different from a majority of the rest of the developed world. You know, so why are we different?

So, there is -- there are reasons why they did it, you know, that are, I guess on a just straightforward --

DR. ZANZONICO: Just not scientific reasons.

MR. BOLLOCK: Logical apples to oranges, you know, why are we -- so, there were things that went into the, you know, the asking this. But, yes, no, we have not, to my knowledge, we have not received any other -- or the Commission hasn't received any other letters advocating to change back in the sense that this has gone.

DR. HOWE: Since this came down, so everybody's kind of waiting for this SRM to be resolved.

CHAIRMAN ALDERSON: So, the next step will be the second meeting and an additional attempt to get public and other input on this question.

And then, after that, you'll I guess come back to the ACMUI, among others, like perhaps at the next meeting and say, here's where we are.

DR. HOWE: As we'll be developing a SECY paper and as a part of our process, when the SECY paper is going through concurrence, we will give the ACMUI a chance to review it and comment on it.

And, we are having the public meetings but the actual official comments have to come in through the -- electronically through regulations.gov or in writing to our Office of Administration. And, that information is in the Federal Register Notice.

So, we are having discussion in the public meetings but those are not considered the final comments. And so, if there is a group that hasn't formalized its formal comments but they still want to discuss and get questions answered, the public meeting is the perfect place to do that.

CHAIRMAN ALDERSON: Well, I think that we all would appreciate hearing how this area evolves and where we come out perhaps at the fall meeting of this Committee.

Are there any other comments people would like to ask at this particular time?

Yes, Mr. Bollock?

MR. BOLLOCK: Just as Dr. Howe just said, you will see this.

CHAIRMAN ALDERSON: We will see this?

MR. BOLLOCK: You will see it, yes, you will get to see what we are going to tell the Commission in the SECY paper. You will have a chance to review it

and so, to give you a heads up, we likely, we will want ACMUI's opinion, which could mean Subcommittee, you know, as the middle of the process to get back. So then, we would include that and your recommendation or your thoughts on our SECY.

CHAIRMAN ALDERSON: Yes, well thank you. We think that's appropriate.

DR. HOWE: And, we may be under a very tight deadline.

CHAIRMAN ALDERSON: Time line.

DR. HOWE: So, we may want to think about having a subcommittee that's ready.

CHAIRMAN ALDERSON: I see. Perhaps appointing a committee now to be ready for when that comes out? Okay, thanks very much for that.

Yes, Dr. Langhorst?

DR. LANGHORST: I have -- remind us when are comments due?

DR. HOWE: I haven't looked at the calendar yet, but the -- if you look at the Federal Register, add 15 days from then. I think they're due in May.

MR. BOLLOCK: No, mid-June, June 11th, yes.

DR. LANGHORST: Okay, thank you.

DR. HOWE: They're supposedly due right in the middle of the Society of Nuclear Medicine meeting and so we're going to extend it 15 days, then the 12th.

DR. LANGHORST: My question is kind of a logistical question and probably for you, Doug. And, you may not be able to answer it right now, but I'll pose the question.

On the Category 3 source comments, it took forever for those comments to be posted on regulations.gov. Is -- and I was told it was because NRC doesn't have the staff to put those comments up as quickly. I just wondered will we have the comments available for the public to review soon after they're made?

MR. BOLLOCK: This is a --

DR. HOWE: All I can say is the experience we had last year with the public comments and they went up pretty fast. They would send them over to us to make sure there was nothing that couldn't be put up, yet everything was put up-able. So --

DR. LANGHORST: And, it might have been because it was Category 3 sources that it took extra time, but that was extremely frustrating to not be able to see those comments as they were being made.

MR. BOLLOCK: Yes, we -- I don't know if we really control that. I mean, we can -- we checked on it, we work with our other staff that works towards that. And they, yes, we haven't had issues in the past, but --

DR. HOWE: We have no knowledge.

MR. BOLLOCK: -- again, if there's -- we --

DR. LANGHORST: It took a long time.

DR. HOWE: And, I think in our last public comment period, we had people that responded directly to regulations.gov and those went up.

We had people that emailed us, those had to come into whoever they were addressed to and then get sent to ADAMS and then regulations.gov.

Sometimes, they came in to other people and had to be recognized as a comment on it.

So, it depends on the pathway things come in as to how fast they go up.

DR. LANGHORST: Okay, thank you.

CHAIRMAN ALDERSON: Are there any other comments before we close the open session of the meeting today? It's about time for us to do that.

Are there any people in the audience who wish to comment? People on the phone line who wish to

make a comment? Here at the table?

(No response.)

CHAIRMAN ALDERSON: Seeing or hearing none from any of these sources, I think we will now go on to break. This will end the open session and we will reconvene at 3:00 p.m. for the closed session.

(Whereupon, the above-entitled matter went off the record at 2:33 p.m.)