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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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SPRING 2016 MEETING

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OPEN SESSION

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FRIDAY,

MARCH 18, 2016

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The meeting was convened in room T-2B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:01 a.m., Philip O. Alderson, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

PHILIP O. ALDERSON, M.D., Chairman

FRANCIS M. COSTELLO, Agreement State Representative

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

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

STEVEN R. MATTMULLER, Nuclear Pharmacist

DARLENE F. METTER, M.D., Diagnostic Radiologist

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

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

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

LAURA M. WEIL, Patients' Rights Advocate

PAT B. ZANZONICO, Ph.D., Vice-Chairman

NON-VOTING: ZOUBIR OUHIB

MEMBER-SELECT: RICHARD GREEN

NRC STAFF PRESENT:

SCOTT MOORE, Acting Director, Office of Nuclear Material Safety and Safeguards

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

DOUGLAS BOLLOCK, ACMUI Designated Federal Officer

SOPHIE HOLIDAY, ACMUI Alternate Designated Federal Officer and ACMUI Coordinator

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

MICHAEL FULLER, NMSS/MSTR/MSEB

ESTHER R. HOUSEMAN, OGC/GCLR/RMR

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

ANGELA McINTOSH, NMSS/MSTR/MSEB

GRETCHEN RIVERA-CAPELLA, NMSS/MSTR/MSEBKATIE TAPP, Ph.D., NMSS/MSTR/MSEB

MEMBERS OF THE PUBLIC PRESENT:

DEBBIE BENSEN, Elekta, Inc.

BETTE BLANKENSHIP, American Association of Physicists in Medicine

CATHERINE GILMORE-LAWLESS, Elekta, Inc.

LYNNE FAIROBENT, American Association of Physicists in Medicine (AAPM)

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

RICHARD MARTIN, American Association of Physicists in Medicine

CARL MELLERBY, Nordea

ERIC PERRY, Kentucky Department for Public Health

CRAIG PIERCY, Elekta, Inc.

MICHAEL PETERS, American College of Radiology

KAREN SHEEHAN, Fox Chase Cancer Center

ROBERT THOMAS, Elekta, Inc.

CINDY TOMLINSON, American Society of Radiation Oncology (ASTRO)

T-A-B-L-E O-F C-O-N-T-E-N-T-S

P R O C E E D I N G S

(8:01 a.m.)

CHAIRMAN ALDERSON: So welcome back everyone, to the second day of our spring meeting. And I'm going to -- this is Dr. Alderson, and I'm going to turn over the proceedings to Doug Bollock of the NRC.

MR. BOLLOCK: Good morning. We'll start off the morning with a presentation on our staff response to our Office of Inspector General audit of NRC's oversight of medical use of nuclear material.

So if you want me to go over a little bit of background of the audit, the audit findings, recommendations, and our response, and what we're doing moving forward.

MS. HOLIDAY: For persons on the telephone, could you please mute your phone. If your phone does not have that capability, please press Star 6. Thank you.

MR. BOLLOCK: Thank you, Sophie.

Okay, a little bit of background. So our Office of Inspector General is the NRC's internal oversight of our programs. And so they decided to audit our medical program last year.

So the audit objective was to determine

if NRC's oversight of medical use of radioactive isotopes adequately protects public health and safety. So in order to do that, they spoke with NRC staff here at headquarters, NRC regional staff, agreement state staff, and a number of licensees.

So the audit was completed about summer of 2015. And their findings were that the NRC does provide adequate oversight of the medical use of radioactive isotopes to protect public health and safety.

However, opportunities for improvement exist with regard to clarification of NRC's medical event reporting requirements, periodic self-assessment of medical event reporting, and with providing better feedback to the ACMUI.

So their first recommendation was to clearly define the purpose of medical event reporting in a publicly available document and clarify the reporting requirements.

So during the audit they found there was some confusion as to why, what the purpose of medical events or reporting of medical events was. And there are some differences between NRC staff, Agreement State staff, within NRC regional offices. So it was pretty clear that we should have one specific

definition for the purpose of medical events.

Recommendation 2 is to proactively provide all medical licensees with medical event tracking trending information for lessons learned purposes. And I know we spoke a little bit about that yesterday, and Dr. Langhorst had some comments on that. So they recognize, the OIG audit recognized that as well.

The third recommendation was develop and implement policy and procedures that require periodic assessments of NRC's approach to medical event reporting. These assessments should include whether the intended purpose of the reporting requirements are being met and the thresholds of reporting requirements are appropriate.

And their fourth recommendation was develop and implement policy and procedures to guide provision of sufficiently detailed and timely feedback to ACMUI from NRC staff.

So our staff responses - for the first recommendation, we took some actions. And we found what the official purpose of medical event reporting was. It goes back to 1980, back when medical events were called medical misadministrations. But we took that statement and put it on our NRC website. We put

it on the medical list server, sent it out to everyone on the medical list server.

In the current rulemaking, we are planning on adding that in the statements of consideration for the current rulemaking. And what that will do is just update it from, essentially, from saying medical misadministrations to medical events.

And we also sent an RCPD letter to the Agreement States. And I can read to you the official -- out of the statements of consideration for the 1980 rule --le the Commission's purpose in requiring misadministration reports. The NRC was to identify their causes in order to correct them and prevent the recurrence.

The Commission was able to notify other licensees if there is a possibility that they could make the same errors. So that right there is the purpose, to identify and correct, or to correct and prevent recurrence, and to give us the ability to notify the licensees of these events. And that can help them, help prevent from making the same errors.

So the second recommendation, with our second recommendation we have some medical event tracking trending initiatives. Essentially, we are allowing the access to the general public, as I said

yesterday, access to the ACMUI medical event slides. So the slides that Donna-Beth provides once a year and then the ACMUI, in the second meeting, provides that back to us. Those are now specifically pulled out and provided on the public website.

There was some question -- just a little bit more background on that. We had some discussions about how much information we'd get, you know, to find the causes and any actions that were taken. We do share that in the slides when it's known. Sometimes it's not always known, but we do our best, if it is known, to put it in those slides so the public can get that, and the licensees can get that as well.

All right, for Recommendation 3, we'll be conducting an annual self-assessment in the overall effectiveness of NRC's event reporting program. So even though it was specific to medical events, we evaluate on a yearly basis all events as part of our annual assessment review. And so as part of that, we will do a separate self-assessment and looking at some specifics and effectiveness of just medical or event reporting in general.

And for the last recommendation, we have updated our policy and procedures that related to our work with the ACMUI. So our Policy and Procedures,

2-5, basically it didn't need any updating, because that is how we make a decision on what to include, basically major medical policy to include ACMUI but Policy Procedure 6-15 is how we actually implement our workings with the ACMUI.

So we've updated those procedures to enhance our communications, essentially to give the memos and with better rationale behind our proposed actions.

So in the past we've always given, as Sophie did yesterday, the update from all the open action items but now, for anything that we either don't agree with partially or don't agree completely with the ACMUI, we will give in a memo format, response back to the ACMUI with our reasoning why.

All right, any questions?

CHAIRMAN ALDERSON: Would anyone on the Committee like to raise a question? Yes, Dr. Ennis?

MEMBER ENNIS: I have a few actually, if that's okay.

CHAIRMAN ALDERSON: Yes.

MEMBER ENNIS: One, I had a few questions. One, in terms of response from staff to us, could it be more interactive, like a presentation at this type of a venue rather than a memo?

MR. BOLLOCK: We considered, we did consider that, because we have the open, we go over the open action items list. Sophie goes over that. That's an opportunity to ask those questions. So we feel we do have that, or you have that opportunity to ask us questions there.

But in between the meetings twice a year, you know, there's six months. Time goes on. You may or may not think to ask the question then. So it's the in-between we will be providing the memos, just so we have, essentially you have, I guess, an official record of why we decided to go one way or the other based upon your recommendations.

But yes, I mean, we encourage open communication with the ACMUI. But that was kind of the rationale behind why we didn't just leave it to this meeting.

And some other things that we are actually, actually Mike and I were discussing this morning, not necessarily in regards to recommendations but just some of the staff actions. We may just take, five, ten minutes out of the ACMUI meetings and go over what staff has been working on because some of them are based on recommendations or may be tangentially associated with some of the recommendations from the

ACMUI. That's something we plan to do. And that'll be more of the informal, you know, presentation during the ACMUI meetings.

MEMBER ENNIS: All right, great. Yes, that was mentioned. I think that would be great. So I guess the question now for us would be do we want our subcommittee, for example, that works on things and had the reports, when we get a report back from the ACMUI do want to reconvene the subcommittee just to digest that response in some way? Would that be a useful process?

CHAIRMAN ALDERSON: I don't know about that. I think it would depend on the report and the issue. Other people would like to comment on that question? Dr. Langhorst?

MEMBER LANGHORST: I think it would be very important for the subcommittee to review it and provide just maybe some written responses to that. Because it doesn't necessarily, it may not warrant another presentation. But I think it would be very helpful to have the subcommittee then give an assessment for the overall Committee.

CHAIRMAN ALDERSON: Okay. Thanks, Dr. Langhorst. Did someone else have a comment on this particular question?

VICE CHAIRMAN ZANZONICO: Oh, not on this, not on the current question.

CHAIRMAN ALDERSON: Anything else on Dr. Ennis' suggestion?

(No audible response.)

CHAIRMAN ALDERSON: So the Committee's leaving it that, obviously depending the content or whatever, but they have a perhaps brief written response to say this is clear, we understand, or here are a couple of issues that would be useful.

So given that everyone seems to agree with that, then we'll try to adopt that approach. Other comments, Dr. Ennis?

MEMBER ENNIS: Yes. I just have one, I guess one other. So with a more clear statement of what the purpose of a medical event is, combining with our conversations of yesterday, it seems like it's time to really, with the new changes in, you know, the culture of how you get a good quality culture and a good safety culture, we really ought to move more to what Laura has been talking about as an ideal.

And our challenge is how do we transform medical events that are now really, had a significant punitive component to them politically, and how can we or can we transform them into the more just culture

that is prevalent today?

CHAIRMAN ALDERSON: Yes. Well, I think that's a very good question. I don't think that -- and I think it's a complicated question. We're not going to answer it right now.

MEMBER ENNIS: No, no.

CHAIRMAN ALDERSON: It's probably a topic for a future meeting.

MEMBER ENNIS: Yes.

CHAIRMAN ALDERSON: Does anyone want to comment on that before we move on?

MEMBER COSTELLO: Yes. I would think, to the extent we could get -- I'm sorry, that's something I think the Committee should take up as a whole sometime, maybe in a subcommittee or wherever you'd want to do it.

Because a lot has happened since 1980 in terms of therapy. And we've learned a lot in the implementation of this. And I think maybe we can probably put together a rationale that's more timely; it fits better the paramedical practice.

CHAIRMAN ALDERSON: Good. All right, very good. And we'll certainly consider that. Yes, Dr. Langhorst?

MEMBER LANGHORST: I know a few

Commission briefings ago Dr. Thomadsen was talking on safety culture. And I was also bringing up the idea of how NRC can support or undermine a licensee's safety culture.

And I really appreciated the report here. On Page 15 of that report, wait a second, yes, it says, ''Some stakeholders noted that NRC's approach to medical event reporting is perceived to be punitive in nature. Specifically stakeholders opine that the associated reporting requirements are actually a deterrent to self-reporting medical events.''

And so this is NRC's own review of how this could be perceived as not supporting safety culture. It's very difficult, and I know the Commissioners brought it up at that point in time, well, we're the regulator. Yes, we understand that. But maybe in this instance can there be, because medical use is different, because maybe there could be a different model of how you receive medical event reporting and what you do with that in the initial instance of a licensee having that problem.

Now, maybe if there are repeated problems there's another path you have to take. But can it be in a way that, yes, we need this information, we'd like to share as much, and maybe we could share it

with the community and not necessarily name names but give the instance of what's happening, what led to it, how you fixed it, and what the results were.

That could be of tremendous help to medical licensees and especially the smaller licensees that maybe don't have as much resources to devote to all of this. So I just ask that we help advise the NRC and the NRC be open to maybe a slightly different model that we could use to help support this development of a safety culture between licensees and the regulators.

CHAIRMAN ALDERSON: Right. So I think that's a fine suggestion. Yes, Mr. Costello?

MEMBER COSTELLO: And all the persons who work at the NRC.

CHAIRMAN ALDERSON: Yes.

MEMBER LANGHORST: That's why I said regulators, sorry.

MEMBER COSTELLO: That's right. Whatever percentage they said yesterday of licensees that belong to the Agreement States and the approaches taken by the Agreement States are not uniform with each other. In fact, NRC regions aren't always uniform with each other.

It is a very important point, Dr.

Langhorst. And maybe if we do a subcommittee or something to look into it, if it had recommendations that go beyond the language of the purpose of the medical event, and if you go into all that you talked about, you know, perhaps some of these could be anonymous as far as, because of the public.

But I've heard the same thing from licensees in our State that they don't mind reporting at all. But the idea of associating their institution with a mistake they believe is a deterrent.

Now, when they tell me that there's very little solace that I can give them. I can't tell them they don't have to report, and I can't tell them we can make them anonymous. Because that's not how it is. You know, we get the report, we give it to NRC, and the process moves on.

So if we do get a group to look into this, well, we certainly want them to look into revisiting the 36 year-old, you know, definition of medical misadministration. Maybe it can have a broader scope and talk about things that you talked about, talk about safety culture, and talk about ways of implementing it in a way that's more likely to bring about what you're trying to do. Thank you.

CHAIRMAN ALDERSON: Yes. Dr. Dilsizian?

MEMBER DILSIZIAN: Yes. I just wanted to bring the clinical stress when these things happen in medical misadministration.

The first thing we actually do, besides thinking about the NRC, is call our legal counsel. So just to let you know, that we, you know, while this, you know, the culture of safety is an interesting concept. But the stress on the clinicians, and the patient, and the hospital, and legal counsel is parallel if not more stressful.

And so if NRC, in any way, can soften these misadministration concepts that we should be reportable but not necessarily a medical/legal action, it really may help the physicians to report them. I'm just letting you know that it's not just the NRC, it's the other aspects of the medical/legal.

MR. BOLLOCK: If I can address some of these? I think the purpose is, you know, the purpose has got to remain the same. I think the purpose is important that we, like I said, identify them to correct and prevent recurrence and then any information we can disseminate otherwise to help it from happening again. I think that's, as long as we keep that as the goal, I don't think that's going to change the purpose.

However, what you all are speaking on is how do we implement that. And as, you know, Dr. Suh had a presentation yesterday about the medical event reporting. I think in any way that you all can help us with that implementation will help.

You know, fortunately for us in the NRC, you know, we have our regulations. If you're not in compliance with a regulation then, you know, essentially you have a violation. But it's not a, it's legally binding to an extent, but it's not the same things that, you know -- we understand you have other concerns that aren't -- our concerns is not, you know, we're not directly affecting this, well, but we are affecting it because of the regulations.

So we understand that. And we are sensitive to that. And a lot of the efforts going through the whole, you know, our process of we license, we inspect and we enforce, and going through that, we try to enforce such an inspection, and by that the enforcement through performance base.

And how our structure works and how, you know, we understand the good safety culture, and this is a good safety culture going not just from the NRC reactor side. We've got a good hold on that. But if you look at safety culture across any industry, any

field, professional field, there are consistencies of good safety culture. And we do understand that.

So, you know, you should be able to bring up when a mistake is made or something without repercussion. And that is always a sign of a good safety culture. So hopefully that's where we could all get to.

But, because like you said, there are other aspects that you have to consider. We have to be open to that. I think we are, you know, we as the medical staff. And we can communicate that to our management. And I think, with your help, we can get the implementation to get it to work at the best way.

So, you know, my main points are the purpose I don't think is going to change. But you can help us with the implementation to help minimize those crossovers that cause other unintended issues from our part while still working together to get, you know, to get the good information out so that we can prevent it. And other licensees can, you know, it can prevent them from having these events occur and, at the same time, you know, promote a good, healthy safety culture.

CHAIRMAN ALDERSON: Right. So Mr. Ouhib has a comment and then Dr. Langhorst will be next.

MR. OUHIB: Yes. I think this is a great initiative. And let me go back to the purpose again. So what mechanism is in place currently to actually inform the users? And that is whether they are NRC States, I mean, NRC-regulated States or Agreement States.

And the second is how many cases will it take to actually identify that this needs to go to users? Is it two cases, is it three cases, similar?

And then the other item is that unless the information is accurate, it doesn't serve any purpose. So that means there is, like we talked yesterday, there is work that needs to be done on both sides of the aisle. There's from the regulators, perhaps education and training, and then from the users, them also.

That information is really crucial. And why is it crucial? Here's why. We're trying to help and assist others. This is not because we want to get to the nitty gritty. You could help us prevent something. And that's from both parties, that is the regulator and the end user.

MR. BOLLOCK: So the different levels, first the reporting, the reports that come in, they are publicly available on our website. So, I mean,

that's a good and bad thing. But that's one level to get, one step to get that an event happened.

And so that information is available for other licensees, and regulators, and whomever to see that and say, okay, well, this happened and hope, you know, someone with a good, whatever you call it, quality assurance program, what have you, would look at that and say how can we make sure that this doesn't happen to us.

When we see -- one of the other things that we do is we evaluate. Because we get all the event reports that come in. We evaluate for a trend. If we see a trend or a number of issues or issues that are significant, like, that we feel are very safety significant, there could be a high impact, we have generic communications. It's one of our avenues.

So we would take the information that we learned from an event or a series of events and share that in a generic communication. There's different levels of generic communications.

The first one is an information notice. And that simply is just here's the information we have from what has happened, and here is what you can learn from it. And it's just a, you know, it's just information. There's nothing that is a requirement

on any licensee.

The next level is a regulatory information summary which typically doesn't, again, no requirements on licensees, but it may be a little bit more in-depth.

And then there are other levels if we see something that requires some sort of order or action. There are higher levels. I've not seen any of those on the material side at all. But we do have, that's kind of the escalation for getting the information out and what we'd expect from it.

CHAIRMAN ALDERSON: Dr. Langhorst?

MEMBER LANGHORST: To answer your question, Dr. --

MR. OUHIB: Zoubir.

MEMBER LANGHORST: Zoubir. One, you can learn something from one event, because it may be very valuable for your license. So I would say, you know, if you could just give it for all of them, and you have that consistent information, and full and accurate information, that would be great.

Mr. Bollock, I just want to say that a safety culture is not a thing that you write down and then you say, okay, now we're all going to follow it. It doesn't happen that way. And I know you appreciate

that. It is a living, breathing thing. And it's based a lot on trust.

And so trust you have to build. And it can go like that. And when there's a mistake, you have to work hard on the trust that, yes, I can bring this forward. And everybody agrees, yes, boy, we're really sorry this happened. What can we do for this instance, what can we learn, and how do we apply it every place else so that we can get that valuable lesson?

I know licensees do that right now with the information that NRC puts out. I'm not aware of any Agreement States being able to put out like information. But that's helpful for my users to say, hey, this happened over here. You might look at it and see what we can learn from it.

I just would like the NRC to be open, and I know Agreement States too -- when I say NRC, I mean everybody, sorry, Frank -- that we continually talk about this. And because medical use is different, it may require a little different perspective on that give and take between the regulated folks and the regulators.

So it's an area that I think we want to explore. I think it will be very helpful to all of

our patients. And I just cheerlead and encourage everyone to be involved in it. Thank you.

CHAIRMAN ALDERSON: Yes. Ms. Weil?

MEMBER WEIL: I totally agree with what Dr. Langhorst is talking about. And it devolves down to, you know, the inspector, the person who interacts with the licensee.

And something that NRC and States could do is to train those folks to enforce that those folks promote this kind of a culture which is not blame, which is not punitive, hopefully, which is not negative in any way but rather that there's a positive spin. We're here to help you, we're here to help others. And I'm sure that that's not how many inspectors approach their jobs.

MR. BOLLOCK: And that is a very good point. And we do, like I said, you know, we do promote, as an agency, that performance base. So, you know, we are supposed to give credit for licensees that identify the issue and correct it. And, you know, that's how we're, I mean, that is the push for the NRC.

But you're right, it gets down to the individual inspectors, whether they're an NRC regional inspector or they're a State inspector. And then

along with that though is when we do see a non-compliance with a regulation, you know, we have an obligation to identify it. But then what do you do with it?

MR. BOLLOCK: Right. Right. And there are, and now it gets to levels of enforcement, and follow-up action. And this is something that, you know, can be evolving. You know, it's evolved on the other side of the, on the reactor side of the house. It's evolved.

We went from completely compliance-based to the performance-based. They have -- the reactor oversight process has changed from purely traditional enforcement to where you look at significance. And they've got, you know, for violations, they have non-cited violations.

It's basically you get a finding, they correct it, and that's it. It's in a report, it's publicly available, but there's no civil penalty, you know, at that point no potential civil penalty. It's just a very cut and dry, here's your violation, here it explains it. They have to take action to correct it, and we're done. And, you know, like I said, that's really the way the agency as whole is moving towards.

And we do, we do train our inspectors. We do, you know, try to promote that for everyone. So, you know, we'll continue to do that, and hopefully that will help. But there is still, you know, at the end of the day, if there is a non-compliance we will take some action.

You know, whether it's just a report that has a, you know, a severe Level 4 finding, you know, with no civil penalties, but it's still in a report. It's still publicly available. And that, in itself, could have consequences in the medical community, you know.

But we understand that we have to work. And this is why, you know, evaluate changing medical events and what it takes and, you know, the aspect from the medical community, we appreciate that you all bring that to us.

CHAIRMAN ALDERSON: There's enough interest around the table that I think that we should form a subcommittee on this particular issue and follow it. And I don't think that, although I see other hands up now, I mean, we could discuss this the rest of the morning, but I think we shouldn't do that.

We should, in fact, have a subcommittee. And then we should make it our business during the

off times to get together and move this issue forward. I think that, Frank, you should definitely be on that committee because of the State's issue. Vasken, you were interested in the medical/legal side. Mr. Ouhib, would you like to join that committee? I'd like at least a couple of other people. Who else would, would you like to be on that, Sue? Okay.

MEMBER LANGHORST: Can we also, because this is not the ACMUI members' issue, it's also an NRC staff issue. So I would like a few NRC staff to be helping us.

CHAIRMAN ALDERSON: I think that's a great idea. And --

(Simultaneous speaking.)

MEMBER LANGHORST: And I wouldn't mind having maybe a person from the Office of Inspector General be on that to --

CHAIRMAN ALDERSON: Well, we should check on that. But I think the idea --

MEMBER LANGHORST: No.

CHAIRMAN ALDERSON: I think the idea of having staff engaged in this process is a very good one. So, Sue, why don't you be on this subcommittee? In fact, why don't you chair it? Would you like to do that?

MEMBER LANGHORST: I would be so honored.

(Laughter.)

CHAIRMAN ALDERSON: Wonderful. So we probably need one more person on this subcommittee. Who else has a passion?

CHAIRMAN ALDERSON: All right. So I have five right now. I have you as the chair, I have Frank, Vasken, Dr. Ouhib and Laura. Is that -- Dr. Ennis?

MEMBER ENNIS: It has to be six, right?

MEMBER LANGHORST: Yes.

MEMBER ENNIS: I'll be glad to --

CHAIRMAN ALDERSON: Doctor -- yes, absolutely. So Ron Ennis, so you have six. That's the committee.

MR. BOLLOCK: I think we have one too many. Yes, we can only have five. Just because --

CHAIRMAN ALDERSON: Only have five?

MR. BOLLOCK: Right.

MEMBER ENNIS: I thought we could have six. It's less than half.

CHAIRMAN ALDERSON: That's because of the --

(Simultaneous speaking.)

MR. BOLLOCK: Yes, we --

CHAIRMAN ALDERSON: That's because Mr. Ouhib isn't a member yet.

MR. BOLLOCK: Yes, because Mr. Ouhib is not a member yet.

CHAIRMAN ALDERSON: So we'll keep him off. And when he becomes a member, he'll get on this subcommittee immediately. How about that?

MS. HOLIDAY: Dr. Alderson, this is Sophie. While Mr. Ouhib is not a full member yet, meaning he doesn't have voting privileges, he can still serve as, like, a consultant, like he did to Dr. Suh's subcommittee.

CHAIRMAN ALDERSON: All right. So we'll have Mr. Ouhib serve as that consultant now. And then we'll have the other five people that we've named comprise the committee. And it is true that I think we're going to need a lot of interaction with NRC staff when this committee goes forward. So we'll work with Sophie to figure out how we should get that done, if that's acceptable to you, Mr. Bollock.

MR. BOLLOCK: We'll support. But I just want to make sure we understand so I know how best to support what specifically this subcommittee is going to be.

CHAIRMAN ALDERSON: Well, the charge that

you all have been talking about is this culture of safety and how to get there. And so we'll rely on Dr. Langhorst to look at the whole issue of medical events.

We've spent a number of times here discussing medical events, not just the culture but the idea of clarity definition in addition to culture. So I think one of the ways that the subcommittee can get really engaged with this it so somewhat define that agenda in that scope of things.

MEMBER LANGHORST: Yes. This is Sue Langhorst. I think Dr. Suh's group is looking at medical event definition, and understanding, and so on. Maybe we could focus on the application of reporting and that aspect of -- let me think of the exact wording and get that to Sophie. And can we --

CHAIRMAN ALDERSON: Right. It's application, implementation that's --

MEMBER LANGHORST: Implementation and how to foster that safety culture in reporting medical events, and investigating, and then not only, I guess, notification of medical events and then reporting on medical events.

CHAIRMAN ALDERSON: So I think that's actually a very good approach. One could take a very

superficial kind of theoretical approach and probably finish that report in the next 20 minutes.

But the fact of the matter is that if you really go into the issue to try to solve a problem that has seemed resistant to solution, it then is going to take a much more sophisticated and deep effort to figure out how people like Burwick, for example, changed the whole safety culture in medicine from a punitive one to more like it is today.

And so that's going to be a much more difficult problem. And so with Dr. Langhorst leading the team and this great team we've got, I'm sure we'll get there.

MEMBER COSTELLO: One more question.

CHAIRMAN ALDERSON: One more question, and then we'll move to a new subject.

MEMBER COSTELLO: I think I pushed it down. Mr. Bollock, do you think that we have a chance of making the public reports of these medical events anonymous with respect to the hospitals?

I think maybe it's something you need to talk to your legal people about. But I think that could be a colossal step forward. And I know I hear from my licensees. They don't mind reporting to us really at all. They don't want to see it on the cover

of the Philadelphia Inquirer, okay.

Because really, we've got reporters who look at the NRC's webpage reports every single day, every single day, okay. And so if I have a thing saying whatever hospital has had a medical event, it could show up on the next day's newspaper. So if that has a chance of being approved, I think it would be a big step forward.

MR. BOLLOCK: I mean, I can't answer that here. I think there's a possibility just knowing that some of the States have restrictions on that. I believe New York is one of them that they are, by statute, they're not allowed to give specifics. So do I think it's possible? Yes.

CHAIRMAN ALDERSON: Well, this is one of many aspects this Committee --

MR. BOLLOCK: Correct.

CHAIRMAN ALDERSON: -- should look at. So we'll proceed with that. Let's move on to a new topic.

MEMBER LANGHORST: As I always tell my researchers, if it was easy it would have already been done.

CHAIRMAN ALDERSON: That's correct, that's exactly right. Okay. Next topic, wherever we

are, Mr. Bollock. Go ahead.

(Laughter.)

MR. BOLLOCK: Next up is Sophie Holiday and Eric Perry from the state of Kentucky.

MS. HOLIDAY: Okay. Good morning. For those of you who aren't aware, my name is Sophie Holiday, and I work with the medical radiation safety team.

MR. PERRY: And my name is Eric Perry. I work for the Kentucky Department of Public Health as a license reviewer and materials inspector for the Agreement State Program.

MS. HOLIDAY: Okay. So today, thank you, we're here to speak to you about the Leksell Gamma Knife Icon, 10 CFR 35.1000 licensing guidance.

Specifically we'll touch on our working group which is comprised of members from both NRC and the Agreement States, give you an overview of the Icon features and an overview of our licensing guidance.

So to start this off, I'd like to give you a little bit of background. Several months ago the NRC and the Organization of Agreement States Board, or the OAS Board, became aware of several Agreement States who had licensees that notified them that they intended to purchase and install Elekta's

newest gamma knife model, the Icon.

In addition, NRC sealed source and device team informed the medical team that they were close to issuing the SS&D certificate for this particular device.

However, I will note that Elekta had not reached out to the medical team directly. So we had to find out through other avenues. But the Icon was already being marketed to potential licensees at the point by which we found out. So this prompted the very swift formation of an NRC/OAS working group to try to meet the needs of the patient community.

So our working group was formed to complete three objectives. First, to review and evaluate the Icon sealed source and device certificate and any relevant documentation including an owner's manual. Two, determine if the Leksell Gamma Knife Perfexion Unit and the Icon Unit were similar enough that they could be addressed in a single 35.1000 licensing guidance document. And three, if so, develop the licensing guidance document accordingly, whether that be as separate documents or a single document.

So for our working group, there were four members, Eric and myself are the co-chairs. Eric is

from the State of Kentucky. And I'm here from NRC headquarters. Our other members were Michelle Simmons from NRC's Region IV and Ms. Debora Vail from the State of California.

We had our kickoff meeting on December 22nd of 2015. We were joined by a few of the members in the audience, representatives from Elekta, where they gave us a presentation on the overview of the Icon as well as recommendations.

Our working group worked very, very expeditiously at a very aggressive pace. We spent about three and a half weeks developing our guidance. We met multiple times in a week in order to try to get guidance out as soon as possible. And we completed our guidance on January 22nd, 2016.

MR. PERRY: Thank you, Sophie. So the Icon offers a number of different features over the Perfexion unit. However, the source assembly and the overall method of delivering the radiation dose is very similar to the Perfexion; however they've added a couple of features to facilitate treatment of the patients without using a stereotype frame.

And that includes this cone beam computed tomography scanner and this intra-fraction motion management, or what Elekta is now calling their high

definition motion management. And that allows the system to work without the frame being rigidly attached, without a frame at all and with no rigid attachment to the patient.

So as you can see here on the left, we've got a picture of the stereotactic frames that were used, have to be used with the Perfexion and can be used with the Icon. And the other picture shows them setting up for a frameless therapy where they use a plastic mask, a thermoplastic mask, and the mask adapter to immobilize the patient and also monitoring for movement.

Right here you see a more close-up view of that. And this was borrowed from Elekta's presentation.

So the patient lays on the couch. They have a marker on their nose and two fixed markers on the patient couch, and an infrared camera that monitors the relative position of those three markers and can monitor that within about, you know, a point, I believe they said 0.3 millimeters of movement causes a pause in the deliverance of the dose. And so the patient is repositioned to the proper location, and then the dose, the treatment can continue.

And this kind of shows that. I know

that's hard to see, but what that shows is kind of what the user gets from the system, from the monitoring system.

So the picture on the right, you can see the red line on the little screen. When the relative motion exceeds that threshold, that's when therapy is paused, until they basically reset and movement stops. And they can resume the therapy. And it monitors continuously. And it's kind of interesting.

One thing I didn't talk about, and I meant to earlier, what goes along with this is the cone beam CT scanner so that they can image the patient just prior to therapy and do a proper transformation of the treatment volume, from a patient-specific coordinate system to the Leksell coordinate system, so that the patient is properly positioned relative to the focal point of the unit.

And so there's not necessarily -- you don't have to do the imaging, the MR imaging with the fiducial box and things of that nature prior to treatment. It simplifies the process, also allows for a fractionated delivery of the dose which is a pretty big step in gamma radiosurgery.

Because now if you have areas that may be close to areas that you don't want to give an excessive

radiation dose to, you can break that therapy up into multiple fractions and thereby reduce the dose to surrounding tissue.

MS. HOLIDAY: Okay. So moving on to an overview of the licensing guidance. I would like to start by saying members on the Committee were provided with the licensing guidance when the working group completed its work in January of this year.

So what the working group decided to do was to create a single licensing guidance document that merged both the licensing commitments for the Perfexion unit and the Icon unit. And as such, the working group attempted to marry the guidance such that all the requirements for the Perfexion unit are applicable to the Icon unit.

This does not apply to licensees who have a Perfexion unit but are not upgrading to the Icon unit, meaning that they are just retaining their Perfexion unit as is. They do not have to do anything to amend their license.

But if they are licensees who do want to upgrade their unit to the Icon unit, meaning they get the cone beam CT, and the IFMM or the HDMM system, and the thermoplastic frameless mask, then there would be additional requirements for the Icon unit. But as

Eric stated, the Icon unit can use both the stereotactic frame and the frameless mask option.

Our guidance also incorporates, as you heard from Katie's presentation yesterday, general formatting and language that is included in all 35.1000 licensing guidance documents that were issued after 2013.

So what is the current status of our 35.1000 guidance? As I stated, we provided the guidance to the ACMUI. And I would like to note that typically NRC gives the ACMUI 60-days to review and comment on our license guidance document.

However, I had a conversation with both the ACMUI chair and vice-chair in December to discuss the guidance. And since, basically, there are no significant technical departures, meaning the Icon essentially has the Perfexion core, meaning none of the radiation sources are changing, we just have these additional components, the cone beam CT, the IFMM system and the thermoplastic mask, they agreed that it was okay to forego the standard 60-day review period.

So thank you to the ACMUI for accommodating this. So we were able to get the guidance out to the Agreement States and the regions

ahead of time so that we would be able to, again, meet the needs of the patient community.

We did receive some comments from an ACMUI member, so we do appreciate those comments. And the working group is also resolving your comments, Dr. Langhorst.

So in February, just last month, on February 22nd, we provided the guidance to the NRC regions for a 30-day review comment period. We also sent the guidance to the Agreement States on February 25th, just a few days later, for their review and comments.

Currently, we have received maybe three or four sets of comments. And we've already begun to review and respond to those comments.

Once the working group resolves all of the comments, in approximately three to four weeks, the guidance will have to move through the general concurrence scheme, meaning through management and legal counsel review.

With that, we expect the guidance to be issued in early summer of 2016. I would also like to note, as I said earlier, we pursued a very aggressive schedule with developing this license guidance document.

Typically, working groups that are assembled to address 35.1000 guidance documents take between six to nine months alone to develop the guidance. Then when you factor in the ACMUI's review, review from the States and NRC staff, it can tack on an extra three to four months. So I will pat ourselves on the back. We were able to get this out in just a fraction of that time.

So at this time we would like to open it for any questions.

CHAIRMAN ALDERSON: Excellent report, administrative efficiency, congratulations on that. Are there comments?

VICE CHAIRMAN ZANZONICO: I just have a general question first. How common is an NRC/OAS working group in drafting guidance? My perception is that typically it's an NRC only working group. Is that not the case?

MS. HOLIDAY: No. Actually, in the past maybe four years, every emerging technology has been evaluated by joint NRC/OAS working groups.

VICE CHAIRMAN ZANZONICO: And then a technical question. So there's an onboard cone beam CT. Is that what is used for the simulation? I mean, I'm ignorant about the technology. So I don't know

if they do the equivalent of a simulation for this or not.

MR. PERRY: What they do with the cone beam CT scanner is that allows them to ensure the patient is positioned properly and can be put in a position relative to the focal point. And the focal point lies at the coordinates of 100, 100, and 100 in the Leksell coordinate system, which is relative to the machine. That allows them to position the patient so that that focal point is properly positioned relative to the treatment volume.

I believe in the past, and I'm sure Dr. Suh is much more familiar with this than I'll ever be, but they would attach the frame to the patient's head, make use of a fiducial box and an MR scanner to properly do that transformation. This allows them to do that transformation essentially at the machine just prior to therapy.

VICE CHAIRMAN ZANZONICO: So how would the -- but this isn't used to define the target volume, right?

MR. PERRY: No.

VICE CHAIRMAN ZANZONICO: No, that's done by more conventional simulation?

CHAIRMAN ALDERSON: Dr. Suh?

MEMBER SUH: So in terms of the essential difference between the Icon and Perfexion is you now have onboard imaging. So from a clinician standpoint, you're going to have greater confidence. And what you see on the computer screen is what you're actually going to treat.

So it actually takes into account what the traditional generation oncology -- what they learned excel our base system. For many years now, we've actually had cone beam guidance where, before we treat, we image the patient, then we go ahead and treat the patient.

With gamma knife, we've always gone under the assumption that, with the frame in place, that the image that you obtained, say MR/CT scan and then you do computerized planning, when you put the patient into the machine, you assume that that positioning was -- you have the same fidelity between what you did before versus after computerized planning. This actually will allow you to do it much more in real time, right before you do the treatment.

The other big advantage of the Icon system is that you will be able to better adapt the plan. So if you do some type of fractionated treatment and you see shrinkage of the tumor, and you wanted to

treat the patient a couple of weeks later or a month later, you can actually sculpt a radiation dose better than you can with the Perfexion system.

So it does have some advantages that should allow for better outcomes overall. I imagine you'd have more data for that, but that's what it will allow us to do.

VICE CHAIRMAN ZANZONICO: And all that can be done based on the cone beam CT?

MEMBER SUH: So in terms of, again, we don't have an Icon yet, but in terms of work flow we've still got the MR scanner as kind of our image of choice. And then we can use the cone beam to actually help adapt the plan.

CHAIRMAN ALDERSON: Dr. Ennis?

MEMBER ENNIS: I think, just to answer your question, you're still going to do a pre-CT scan, MR fusion for the plan. And then the cone beam allows you to verify that with your plans you've got the exact same location, head positioning and everything.

VICE CHAIRMAN ZANZONICO: Right. That was my question. It seemed otherwise. Because I didn't, again, so all I knew is that the quality of cone beam CT really was adequate for, you know, state of the art treatment planning. But it's not replacing

--

MEMBER SUH: So the work flow can be a little different. The big change in the work flow is going to be you can get the image values right before treatment. But in terms of the, you know, if you want to use a frame placement, you know, that MR/CT, at this point it would be the same.

VICE CHAIRMAN ZANZONICO: So the cone beam is really more for verification in --

MEMBER SUH: Up front. And you can also perhaps use it for planning. So again, that's where studies need to be.

VICE CHAIRMAN ZANZONICO: For fraction.

MEMBER SUH: For more fractions. Yes.

CHAIRMAN ALDERSON: Mr. Ouhib?

MR. OUHIB: Yes. This is nothing different than what we have seen using a linear accelerator, basically. We went through that transition basically this same way. So, you know, we went from frame to frameless basically and using cone beam CT for SRS and the SBRT patient, basically.

So really the whole purpose, as it was stated previously, is just verification that you are on target basically instead of relying on fiducial markers. And things can happen with fiducial markers

as we know. But I think having the image now, the level of confidence is much, much higher.

CHAIRMAN ALDERSON: Other questions, comments? Yes, Ms. Weil?

MEMBER WEIL: If this is indeed an improvement in technology, would it have prevented the medical events that Dr. Howe reported yesterday where the gamma knife had been serviced and the bed was misaligned? Would this preclude that, those errors?

MR. PERRY: That's very hard to answer because of, I mean, the circumstances around that medical event, I'm not intimately familiar with it, as I'm sure Dr. Howe is.

MEMBER WEIL: There were eight of them, yes.

MR. PERRY: Well, it was eight patients, one event.

MEMBER WEIL: One event.

MR. PERRY: So that's kind of hard to answer. And remember that these changes to the design are more about the patient's position on the couch. You're still relying on the couch to properly position the patient relative to the focal point.

CHAIRMAN ALDERSON: I'll make a comment

too, Laura, and this is strictly from the patient's point of view. If I'm incorrect about this, please correct me. But it's my understanding that one of the disadvantages of the previous version of the gamma knife is the need to wear this frame.

Patients do not like the frame. It hurts. And they will literally go to other technologies, drive a long way to not do it. So the Icon allows frameless. And that is a huge advantage for the patients.

MEMBER SUH: If I could just make a comment. So although for some patients the frame-based system can be uncomfortable and perhaps not be right for some patients, for some situations a frame-based system is going to give you more accuracy than a frameless system.

So if I were doing a functional case for someone with a movement disorder, or Parkinson's Disease, or someone who worked between the trigeminal nerve, I would want to make sure that there is very little chance of me moving him between what you do for pre-treatment versus the actual treatment itself.

So that's where I think the advantages of having these very small focal beams of radiation being pointed to one area. So I think the frame-based

system, although Icon will allow for a frameless type situations, I think there is always going to be a place where you do want to use a frame, just to emphasize that point.

MS. HOLIDAY: Absolutely. So to follow that up, as we were informed, the Icon, you are able to use both frameless and frame. So depending on the patient conditions, the physician will make the determination whether or not to pursue the framed with the bolts in your head, which of course I don't think is very comfortable for many people, or the thermoplastic frameless mask.

So you are able to use either/or. And depending on which mode you choose, whether you go with the frame or the frameless, that will reflect in the work treatment planning.

CHAIRMAN ALDERSON: Yes, good. Other questions or comments? Hearing none --

MS. HOLIDAY: So may I ask a question of the Committee? While we provided the Committee with the draft guidance and the subcommittee was not formed, can the Committee give us any feedback, although not going into the particulars of the guidance since it is pre-decisional and non-public?

Would the Committee endorse the guidance

knowing that we will be addressing comments that I've received, that we've received from Dr. Langhorst? Would the committee consider doing that?

CHAIRMAN ALDERSON: So that question is before the Committee. Dr. Langhorst?

MEMBER LANGHORST: I would feel uncomfortable in endorsing it just because we didn't do a formal subcommittee review in presentation. Not that I am not personally endorsing it, I have questions on it.

I'd still like to see what the final version comes to. Because I was a little nervous in what it was, what the expectations were of Perfexion unit licensees who weren't necessarily changing to the Icon system.

MS. HOLIDAY: Okay.

MEMBER LANGHORST: So I would feel uncomfortable.

CHAIRMAN ALDERSON: All right. So that's one opinion. Mr. Ouhib?

MR. OUHIB: Yes. I think a review of the final draft will be very useful, by a subcommittee perhaps, and make any comments or what not.

CHAIRMAN ALDERSON: I'm going to suggest that we not form a subcommittee, but rather that those

interested parties with that expertise who are members of the ACMUI be provided with copies so that they can review that. And then we can determine in the future whether, at that point, they might be willing to endorse. Yes?

MEMBER LANGHORST: Yes. I would suggest that we don't hold up this, because again, they're licensing guidance, we can make changes and --

MS. HOLIDAY: Absolutely.

MEMBER LANGHORST: -- suggest at any point in time, as nebulous as that seems. So I wouldn't want to hold up in having a full, formal review of that. So that would be my suggestion.

CHAIRMAN ALDERSON: All right. So I think that's consistent with what I just suggested. So the people who would, I'm sure, like to have this would be Dr. Langhorst and Mr. Ouhib. Does anyone else like to get a copy of the full guidance?

MEMBER O'HARA: I would.

CHAIRMAN ALDERSON: Dr. O'Hara would like to get that.

MS. HOLIDAY: Absolutely. We will just send it to the full Committee. And any members that wish to provide comments can do so.

CHAIRMAN ALDERSON: Very good. Okay.

One final comment?

MEMBER ENNIS: Just a question, so I understand the process. Without this final document provided to NRC, are licensees able to actually use it? Or they can't even start using it until the NRC has provided the Agreement States with that information?

MR. PERRY: From the Agreement State standpoint, and I'll speak for my Agreement State, we would be very hesitant to amend a license or to issue a license for this unit without such guidance from the Commission. I know that that's not true of every Agreement State. And I believe that the NRC regions are not going to issue amendments prior to the guidance. And that comes from their management.

MS. HOLIDAY: So I know we all don't understand compatibility, but 35.1000 is a Compatibility D which basically means the Agreement States do not have to adhere to our guidance document. So we are aware of a couple of Agreement States that have already begun the amendment process to add the Icon to their licenses.

CHAIRMAN ALDERSON: So given that limitation on what has, up to this point, been a very efficient process, I would like to ask Dr. Langhorst

and Mr. Ouhib that when you are provided with the guidance, I would like you to promptly respond indicating your support or your lack of that.

And because if support there, then in fact the guidance can be issued and the patients can receive the benefits of this technology.

MS. HOLIDAY: Absolutely.

CHAIRMAN ALDERSON: Yes?

MR. OUHIB: I have a follow-up question based on Dr. Ennis. What about the institution that actually is going to be using the frame? So there's really nothing that has changed, per se. They're not going to frameless. They're going to be using the frame.

MS. HOLIDAY: Are you referring to if they're not adding on the additional components of that, kind of --

MR. OUHIB: And the additional components --

MS. HOLIDAY: Just remaining as the Perfexion?

MR. OUHIB: -- Icon and simply using the frame just like they will be using it in Perfexion, so there's really, other than the additional imaging component that's there, that's all.

MS. HOLIDAY: So this is actually a question that the working group had addressed early on, because it was a question that was brought up by the representatives in the back of the room.

And the working group did not feel comfortable with the notion of adding an Icon to someone's license and saying, you know, we know you're not going to use the frameless option, but you can install it anyway.

It kind of almost defeats the purpose of why the licensee would add the Icon. Because the whole, I guess, the beauty of getting an Icon is to be able to use either/or, frame or frameless. So it's kind of tricky.

There was a question, maybe if we held off on giving the licensee the thermoplastic mask, would that then be okay? But also from a license reviewer standpoint, it was too much of a burden to have to amend the license to add the Icon, to not use the thermoplastic mask, and then amend it again to be able to use it in its full functionality.

CHAIRMAN ALDERSON: Okay. So we are going to get the guidance distributed to the pertinent members of the Committee who will respond promptly. And are there any other comments before we close this

topic? One final comment? I'm trying.

MEMBER ENNIS: I apologize for dominating the conversation. But is the manufacturer aware as soon as there are -- so I'm not quite understanding, but if the manufacturer's aware that users will not be able to use this without guidance being issued by the NRC, I guess it's a rhetorical question, but how is it that they weren't running to your office very early on to get that done so that things weren't delayed in the whole process?

MS. HOLIDAY: I can't speak for the manufacturer. Perhaps the manufacturer would like to speak for themselves. But I can't, you know, tell anyone to do that. So I'm sorry. I can't speak for them.

CHAIRMAN ALDERSON: So hearing no other comments, and unless the manufacturer wishes to speak, they don't appear to be coming forward, so we'll move on to the next topic. Thank you very much.

MS. HOLIDAY: Thank you.

MR. PERRY: Thank you.

CHAIRMAN ALDERSON: All right. Ms. Daibes, oh, Mr. Daibes. Dr. Daibes is going to talk to us about the Germanium/Gallium generator.

DR. DAIBES: Thank you. First of all,

thank you for your time today. My name is Said Daibes. And I will be providing you an update on what's happening with respect to the Germanium/Gallium-68 medical generator.

And just to provide a fast overview, I'm going to be providing some very brief background. I believe that a lot of that information was provided during the ACMUI briefing of the Commission. And I will provide you a current status and the regulatory options that are pursuant.

So I think that one of the key aspects behind the generator that we're currently evaluating and working on is that it has been used in Europe now for a while. So there's quite a bit of data that supports its use.

And right now one of the biggest impacts is that there's a whole lot of data that outlines its use for new and recurring patients. So there's data and peer-reviewed data that supports that.

Right now, the FDA, as we heard yesterday, is currently reviewing an application. And it was provided to the Commission yesterday. So one of the biggest components of this generator is that it's needed in order to create the actual Gallium-68 regulated pharmaceutical that will be used on

patients. So a facility that is planning on using this regulated pharmaceutical will need some form of generator close by or access to it.

So what's the current status? What we have seen today is that, as you're very aware of, that a DFP will be needed. What is a DFP? A decommissioning funding plan.

And why is a DFP needed? Well, basically the parent isotope, Germanium, is a very long-lived isotope, 270-days half-life. Being a long-lived isotope and being an unsealed radioactive material, triggers a DFP requirement due to the fact that, in Part 30 regulations, Appendix B, there's no defined value for Germanium-68. So automatically a 10 millicurie limit is triggered or defaulted to, in that case triggering that DFP requirement.

Some people have raised concerns with respect to this DFP, and I believe everybody is aware in the committee, is aware of this. So I'm not going to go into details.

So what are we doing right now is that, well, we saw the issue, and we're pursuing multiple regulatory options that are currently available in our regulatory framework.

The first option that we have been

undergoing and tasked with is a license-specific exception. And what is that? What is behind this? Well, it will be an exemption, it will be a specific option to accept the DFP requirement for a person that would like to apply for this.

So staff believes that the most efficient and effective way to provide this regulatory relief will be pursuant to this potential exemption.

And how will that be pursued? We're granting or we're working right now in the potential of granting an authority to the regions if a legally binding contract exists that will allow a licensee or a client, a person that requests this generator, to send it back to the distributor or the vendor that provided that generator to that person or licensee.

A document has been drafted and is currently being reviewed by management. So from the last ACMUI meeting, we provided you information that has changed. We informed you that we were pursuing that, but we have completed that. And it's currently under review.

The secondary option that supports that specific exemption under 35.19 is a potential direct final rule that we're currently pursuing a rulemaking plan on. And it's under evaluation by OGC right now.

So what has changed since our last ACMUI meeting is that that rulemaking plan has been drafted, and right now we're under evaluation right now.

So the effort behind this direct final rule will be that it will potentially amend Appendix B of 10 CFR 35.35 to include that limit that does not exist for Germanium-68, disallowing -- or the new license, allowing that a licensee that accesses this generator would not trigger DFP requirement.

So we believe today that the planned action will be sufficient to ensure public health and safety until a more permanent regulatory solution is achieved through rulemaking. And that's currently under the process.

So any questions that -- and I'm sorry, before we proceed, first of all I want to appreciate the service of ACMUI to this effort. All of your guidance and information has been extremely helpful in making sure we can proceed with this, especially Mr. Mattmuller. Thank you for your guidance and help with this.

CHAIRMAN ALDERSON: So Mr. Mattmuller clearly has been our leader in this regard. So we'd like to hear from him today.

MEMBER MATTMULLER: Yes, very encouraged

by this development and very thrilled to see this happening. A couple of comments/questions for you. Can you explain to us the mechanics of how this exemption would work through the different regions?

DR. DAIBES: So that's a good question. So an analysis has been implemented or initiated, seemed to me, of a DFP for this specific case. So through this review or analysis, everything was broken down into components, details, to see if there's buried behind our need for this DFP for this case.

And that review or potential document, legal document, has been drafted that breaks everything into that very in-detail analysis. And what that allows the regions, if approved, it allows the regions to potentially exempt or exempt when a person files an application or files for access for this generator for the actual requirement of the DFP.

So it will allow flexibility to the region, at their discretion, if the licensee satisfies their requirement, to exempt that licensee from that requirement. And our branch chief would like to say something.

MR. BOLLOCK: Yes. To add to that, so basically when we get, you know, with the approved guidance to the regions, their license reviewers would

then, following that, be able to allow a licensee to come to them with an exemption with the specifics that we talked about yesterday. The specifics being, you know, there are still limits to, even based on the ACMUI report recommendations, limits to how many generators, basically the amount of activity allowed and then also having that assurance that the generators, once they're expired or once they've been used, will go back to the manufacturer.

And our Chairman of the NRC, you know, hit it right on the head. The lynch pin is that legal requirement, and how is that going to be withheld and how can the license reviewers ensure that that's in a license amendment?

So, you know, the licensees would have to come requesting the exemption and prove that they have those specific things in their exemption showing that they meet those requirements.

So, you know, that is important. A licensee can't just come to us and say, well, exempt us from a DFP. They have to meet the specifics on what we're allowing.

DR. DAIBES: If I may, so basically it will provide specific conditions for a license reviewer to be able to amend or basically to allow

access for that licensee.

And it's real important to clarify that even though this may exempt the DFP, it will not exempt a licensee from financial assurance that is required. So the initiative is not to exempt financial assurance but the DFP component that is in the ranks.

CHAIRMAN ALDERSON: Dr. Langhorst and Mr. Mattmuller, together.

MEMBER LANGHORST: Essentially what you're saying is there would be a license condition for that licensee's --

DR. DAIBES: That's correct.

MEMBER LANGHORST: -- license that says you're exempt from this and whatever the stock language would be if they meet all those requirements. So they would have a specific condition in their license for this exemption.

DR. DAIBES: Yes, ma'am.

CHAIRMAN ALDERSON: Mr. Mattmuller?

MEMBER MATTMULLER: A comment, another question. In thinking about the Commissioner's comments yesterday, with further thought on it, it's really from a licensee's perspective.

We're the one that's going to require that they take it back. Because the alternative would be

I've got stores to take care of it, which is a much bigger, complicated, expensive task than just boxing it up and shipping it back to the manufacturer.

So from a practical perspective, it's a minimal issue. Legally it has to be addressed. But there are some big reasons why everyone's going to want to send it back to the manufacturer.

My question would be what about, do we have to worry about a compatibility category for the agreement states when it comes to exemptions like this? And then -- yes.

DR. DAIBES: I believe not. However, that's something that will be brought to our OGC representative. And that person or OGC will define that when that's complete.

CHAIRMAN ALDERSON: Mr. Costello?

DR. DAIBES: We don't believe that's the case.

MEMBER COSTELLO: There are present exceptions though. Compatibility really only applies to -- I'm sorry. Compatibility really applies to rulemaking. So if you talk about exemptions, there's no meeting compatibility there.

I'm sure there'll be some letter to go out to the Agreement States, all the Agreement States,

a letter explaining this. I think that States will not hesitate, really, if the NRC is, you know, recommending that we give exemptions to this. I'm confident that States will follow the NRC's lead here.

In fact, I remember, it reminds me of your presentation, you talked about John Jefferson's comment on it. And that came up in the context of them coming to us and asking exemptions for the -- At that time, we would have loved to give it to them, but we couldn't see a way clear to do it, you know. We needed to find a way to be consistent with the other Agreement States and with the NRC.

But I would not worry so much about the States following this. I'd be very surprised if there were States that would be not following it. But eventually we're going do the direct final rulemaking which I think could --

DR. DAIBES: And that's why I said that we'll need to pass this by OGC. Because we have that direct final rule initiative that is still under review. So we're not fully aware --

MEMBER COSTELLO: This draft is really only a temporary fix, I think, just so we get this thing going. The direct final rule is really the ideal way of doing it.

CHAIRMAN ALDERSON: Dr. Ennis?

MEMBER ENNIS: So what's the timeframe to have it, this exemption -- What's the timeframe for this exemption to be completely in place and available for users?

DR. DAIBES: I will say months. I will not say a specific timeframe, but I will say in a few months we believe that it shall be out. Again, it's still under review by OGC. So we're hopeful, a few months.

MEMBER ENNIS: And second question, for the final rule, are there other isotopes that we should be thinking about adding to the final rule so we don't have this problem again with something else coming down the pike?

Or should we include Dr. Langhorst's formula that she discovered within the final rule so when the new isotope were to come we could just apply that rule and move forward?

DR. DAIBES: Our branch chief will -- Right now for the direct final rule it's just the Germanium. And that actually, that question, I predict will be a question from our management and our Commission, should we bring this up for direct final rule.

Potentially, that could be something that stops this direct final rule and puts us into, the looking into what else should we do to update the table which likely would put us into normal rulemaking, extend the process to get it done correctly with other isotopes that are safe, they are practical, you know, good uses for the public, and again, so in a safe manner.

And that's why we understand that there could be those, so many obstacles to get to rulemaking change that we, at parallel, went with the exemption, basically the guidance for an exemption and allowing an exemption.

At the same time, for that quick fix for this specifically, should we look into that or that be the next steps. Because, you know, anything with rulemaking does, as you all know, it takes a lot of resources, takes a lot of time.

The Commission is very, and the NRC staff, they're looking at everything very closely for any new proposed rules. So because of that, there will be extra scrutiny, even for direct final rule, to get the most -- basically get the most out of the rules.

And so, I mean, you asked a great question. And, like I said, I foresee our

Commissioners asking the same thing if not, you know -- and we look at it as, you know, we consider it as well.

So that may slow up the direct final rule, but open it up a little bit more and be helpful, more helpful in the long run. And, you know, we're not opposed to that either. But again, that's why we had the parallel paths of developing some sort of guidance to our regional offices that we'll share with the States for specifics that we would allow an exemption.

CHAIRMAN ALDERSON: Dr. Langhorst?

MEMBER LANGHORST: For our new members, I'd like to just let you know the reason that we're at this point in the Part 30, Table B, or Appendix B, is that Germanium was not licensed by the NRC at the time that table was developed. It was not under regulatory authority of the NRC, because it was cyclotron-produced.

The inclusion of cyclotron-produced radioactive materials like Germanium came to be in 2009. And this was an unfortunate miss of that full inclusion of those types of isotopes into byproduct definition. So that's why we are where we are.

The NRC does not issue exemptions lightly. But they are exactly for these types of things where

an unfortunate set of circumstances has made a disconnect in the rules in what is needed for public health and safety.

Commissioner Svinicki yesterday mentioned Mr. Mattmuller's images of how much improved the Germanium-68, or excuse me, the Gallium-68 images were and the fact that having this generator out there for medical use empowers many hospitals to provide this kind of imaging agent when they don't have cyclotrons.

It's a generator that allows much more expansion of this type of technology and to the benefit of many patients out there. So this is an enhancement of public health without any diminishment of safety.

And so I commend the NRC's, Said's work, and everybody else that it takes to do this, to get this little glitch, this disconnect of the regulations and what is truly needed out there so that we can get this done quickly and that we can eventually get to those other issues of, you know, bringing the rest of the regulations up to speed.

But I just thank you so much. And it's just such an impact on so many patients. And I just encourage NRC staff, please keep working on it and getting it done. Thank you.

CHAIRMAN ALDERSON: Thank you. Any other comments on this particular topic? Well, thank you very much, Doctor. Very good report, thank you.

And I think we're running a little ahead of schedule. 9:45 is when the next presentation begins. Are we able to begin that presentation now or --

MR. BOLLOCK: No.

CHAIRMAN ALDERSON: No.

MR. BOLLOCK: No, we're not. We're waiting for Scott Moore to --

CHAIRMAN ALDERSON: Right. So we should take a 15 minute recess?

MR. BOLLOCK: Yes. Or five, ten minute.

CHAIRMAN ALDERSON: So we'll begin at, 9:45 is what the schedule here says.

MR. BOLLOCK: That's fine.

CHAIRMAN ALDERSON: That's good. All right, 9:45. And we'll be reconvened for the presentation.

(Whereupon, the above-entitled matter went off the record at 9:27 p.m. and resumed at 9:47 p.m.)

CHAIRMAN ALDERSON: Thanks, everyone, welcome back. We're now getting ready to have Mr.

Moore from the NRC make a special presentation to Mr. Mattmuller.

MR. MOORE: Thank you, Dr. Alderson. It's good to see so many of you, those of you that I know. Those of you that don't know me, I'm Scott Moore. I'm the acting director for the Office of Nuclear Material Safety and Safeguards.

And I am down here to recognize Steven Mattmuller for his service on the advisory committee. I will be back later in the day, and I'll try to get a chance to talk to many of you before you leave.

So Steven Mattmuller has served on the advisory committee since March of 2008, that's eight full years. He was renewed for a second term in 2012, so two terms on the Committee.

He's briefed the Commission three times during public Commission meetings, including in June 2009, October 2010, and then we all saw him yesterday talk about Germanium/Gallium.

Mr. Mattmuller has demonstrated expertise in the field of nuclear pharmacy and represents that specialty well on the advisory committee. He's talked about a number of things. We mentioned the Germanium/Gallium generator issue yesterday, also the advanced notice of proposed rulemaking on the Part 20

regulations on radiation protection standards, and the licensing of radium-223 dichloride, as well as challenges with the domestic supply of molybdenum and revisions to the AO criteria, and the major revisions to Part 35.

So we appreciate Mr. Mattmuller's service to the Committee. He's advised the staff very well. And we appreciate your participation on the Committee. We have some things to give you, Mr. Mattmuller. So if you could join us. Sophie?

MR. MOORE: So first we have a flag that has been flown over the Capital and a certificate from Congressman Van Hollen attesting to the fact that the flag has been flown over the Capital.

(Laughter.)

MR. MOORE: And then next we have a certificate from Chairman Burns in recognition of Steven Mattmuller's eight years of service and leadership on the ACMUI which has resulted in significant contributions to the work of the NRC, signed by Steven Burns on 11 March.

And finally, we have a gold lapel pin with an eagle on it. Sophie, do you want to get in on this?

(Laughter.)

MR. MATTMULLER: Thank you very much.

(Applause.)

MR. MOORE: So congratulations. It's great to see everybody. I'll be back in a couple of hours. And I hope the rest of the morning's discussions go very well. Thank you.

CHAIRMAN ALDERSON: Well, Steve, I think we're ready for you.

MEMBER MATTMULLER: It's worn out.

MEMBER LANGHORST: He's broken it already.

(Laughter.)

MEMBER MATTMULLER: So as I fade away, there we go, all right. Just a reminder, this is Memorial Sloan-Kettering Cancer Center, New York City. This is not my place. In fact, it's my understanding the top floor on the right, that whole level is Pat's office. And also this is a terrific photograph, probably taken by a helicopter.

So this is my place, Kettering, Ohio, in the southwest corner of the state. We couldn't afford a helicopter, so this is actually an artist's rendition.

(Laughter.)

MEMBER MATTMULLER: And my office is on

the back side buried next to the cyclotron. But we do share this gentleman in common, Charles Kettering, who had several profound quotes, and a prolific inventor, second only to Thomas Edison in patents. And his biggest was the electric starter in the automobile.

But I went back through the old agendas for the past eight years trying to pull out a few of my favorite agenda items to comment on. And this one is one of my personal favorites because, as you can imagine I get excited about techniques and generators too, in addition to all generators.

But just to remind us how we get our moly is a very complex process and how we're trying to convert the HEU targets to LEU which really is a factor of five less in production and a factor of five greater for waste. But there are some real challenges in solving that issue. So in the end, LEU moly is always going to me more expensive than what we currently produce now.

So progress has been made, but our reactors on the left are still aging, fading away, so to speak too. So we're still in a very tenuous situation. So this is a topic that is worth keeping an eye on in the future.

Here we go. Well, I did serve on a number of committees. And one issue was metrication, and we came to an issue of trying to figure out an old traditional unit of activity versus the traditional unit of volume.

And we couldn't find that traditional volume, so we substituted one called a firkin which, for those of who know my enthusiasm for informal meetings across the street, this seemed to be an appropriate choice.

This is a picture that's in the lobby of our hospital. And it's a big one. It's about four feet by six feet. And for a number of years of working there, I always thought this was either Wilbur or Orville Wright.

But it's actually Charles Kettering. He was active at the time of the Wright Brothers, had his own aircraft company. And it turns out this picture was taken of him on his way to a committee meeting in Columbus, Ohio. He was going to a committee meeting for the Ohio State University.

So while we may think we're pretty cool coming here to Rockville for an ACMUI Committee meeting, we'll never be Charles Kettering cool. So another profound statement from him, believe and act

as if was impossible to fail, which I took to heart as we worked on this project of trying to get regulatory relief for a Germanium DFP issue and to get Gallium out into the clinical world where it can benefit these patients.

So I had a lot of help with this report and couldn't have accomplished it without the subcommittee, especially with Sue Langhorst and the hours she spent in the law library. But also Laura was very helpful, and Bruce Thomadsen, and their comments to the Commissioners, and past presentations, and of course the staff. The staff was great in working towards getting resolution of this.

And we're not quite there yet, but I'm very confident we will get there. So it truly was a group effort.

So I've been very fortunate in my professional life that I've always been in an environment of great leadership and support. And it's what I found here too. And it's very much appreciated. Excuse me.

And I've also had a lot of support from home, from my wife, Michelle, as her support has never wavered. And even when I had to give a lot of attention and a lot of time to women named Ashley and

Sophie.

(Laughter.)

MEMBER MATTMULLER: Who, she reminded me Wednesday before I left, she goes, you know, I've never met these women. But she does know they do exist. So thank you for the opportunity to serve. And I hope I've met your expectations. Thank you.

(Applause.)

CHAIRMAN ALDERSON: Well, we are quite a bit ahead of schedule at this point. It's 10:00 a.m. And the next item is open forum. So would you like to just move ahead with open forum?

MS. HOLIDAY: Yes.

CHAIRMAN ALDERSON: Yes, let's do that. So, Sophie, I guess that means you. And so if you will -- so we're now going to go to the open forum which is headlined as we will discuss medical topics of interest. And so Sophie, if you'd like to lead us to some that you think we should discuss, we can do that. If not, we'll go on our own. Yes. Or Dr. Langhorst will lead us. Yes.

MEMBER LANGHORST: So having been here a few years sitting next to this gentleman here, I'm going to miss that whispering in my ear while I'm trying to pay attention to others.

(Laughter.)

MEMBER LANGHORST: I do want to encourage the new members. When I first was here I was, like, what in the world is going on? What does this mean, how do they do this? I encourage you to ask your question, and don't be afraid that if you've asked it before and you still don't quite understand it; ask it again.

I am very encouraged by our training we're going to have later today on regulations and how things work. Because as a radiation safety officer, I kind of know a lot of that, but I didn't know a lot from the perspective of NRC.

So I encourage you to understand that if only to support your own RSO back at your place. But don't be afraid to ask questions. Because you'll know half of us are going, yes, I didn't know what that meant either. So I just encourage the new folks to do that. Thank you.

CHAIRMAN ALDERSON: Good. Great advice.

All right. Are there any other items that people would like to discuss? Dr. Ennis.

MEMBER ENNIS: Just a question first. Donna-Beth gave a very good presentation of events yesterday. But I gave a presentation on the same

topic in October. Why is it that we do that? Is seems like one report from NMED, from either NRC staff or from ACMUI would be adequate. Why are we duplicating that?

CHAIRMAN ALDERSON: You believe that it was duplicative, you gave the same medical events that were given by Dr. Howe?

(Simultaneous speaking.)

MEMBER ENNIS: I think it felt -- pretty similar events.

CHAIRMAN ALDERSON: So we'll let Dr. Howe respond to that.

DR. HOWE: The intent of my presentation is to introduce all the medical events, and organize them for you. And then if you see a trend or something you would really like to follow up on. Then that's supposed to be your main focus on the next one. If you don't have anything you want to follow up with, it's not necessary to have another meeting.

Because it's not supposed to be I do it, then you do it again. It's what does the ACMUI, from its perspective looking at these medical events, glean from the medical events? And bring us a new perspective. So the other thing is we used to have two presentations when I did mine.

I did one for medical events. And our medical physicist did one for other events that dealt with medical facilities, loss of sources, spills, those kinds of things. We haven't had that report for a long time. So you may want to consider adding that in. I think Sue would be --

CHAIRMAN ALDERSON: Dr. Langhorst.

MEMBER LANGHORST: So yes, when Ralph Lieto used to do those.

DR. HOWE: Absolutely.

MEMBER LANGHORST: And I know that Dr. Thomadsen asked me, Sue, we used to have those. And so I did put something together for your report last time, which I apologize. Again, I wasn't here to help support you in those.

And so yes, I didn't remember that it was in consort with yours. So, and let me tell you that was a lot of work. And I don't know that I can do it every time, so.

CHAIRMAN ALDERSON: Mr. Fuller would you like to comment?

MR. FULLER: Yes, just briefly. Dr. Ennis, I spoke a little bit about this yesterday. The presentation that you received from Dr. Katie Tapp, on Yttrium-90 microspheres, and the work that one

group has done to make changes to some of the 35.1000 licensing efforts that are underway. That was a direct result of the Committee looking at what Donna-Beth had presented.

And deciding that they wanted to drill into that. So they drilled into it. They got to sort of, identified some things that perhaps were based upon the medical and clinical judgment of the members of this Committee. Decided that you know that's really kind of inappropriate to be reporting, and so forth.

So that's really the intent. That's sort of where we envisioned how this would go. And as Donna-Beth said -- Dr. Howe said, I'm sorry -- if you look at what she provided. And you say okay, well for this year it seems kind of normal. Nothing there that's really striking us as something we want to dig into, or drill into. Then that's fine. You can pass. But really it's not, you're right, I don't think it serves anyone to just simply repeat. Or maybe package it in some different way and do it over.

It's really, we're providing you with the data. And a little bit of information about some of these medical events. And then it's for you to do with that what you deem appropriate.

CHAIRMAN ALDERSON: Mr. Ouhib.

MR. OUHIB: Yes, first of all, let me just say that what Dr. Howe presented yesterday, I find it extremely valuable. But I should add that perhaps we need to define some goals behind that presentation. What exactly we're trying to accomplish with that information, prior to seeing that data?

And then perhaps act on it, or provide some recommendations. But they have to be sort of you know, two or three items well defined. Okay, here's the purpose of this. And it's not only information that we provided, because I looked at it as information. And then from there I started to think like, okay, well why is this happening? And can we do something about this? Or how can we improve this and so on?

But I think if we define some goals, I think that would be extremely helpful.

CHAIRMAN ALDERSON: So it seems that with respect to medical events, in fact we have set out with some things to do. So, Dr. Suh has a Committee that's looking at the clarity or the definition. And then Dr. Langhorst has just taken on the new Sub-Committee this morning, which several of you are on. To really work on the culture, the communication, and

the things around medical events.

So in fact, I think we have responded to the report with some Committee actions.

Dr. Langhorst.

MEMBER LANGHORST: Always what I have felt in our report is that that Sub-Committee can delve into the NMED data, the nuclear materials, event data base. It's not nuclear medicine, it's nuclear materials. And we can do exactly what you're saying. And give that perspective.

We don't always delve into, I know Donna-Beth, excuse me, Dr. Howe gives us that information. But we can delve into it in our own way to look to see, are there other items in the NMED database that are of interest to us.

One question I do have along these lines is whether -- and I realize there is budget constraints -- whether it's possible to get reports on what are the total number of procedures at this point in time? Because it's been about five years or so since we had those data. So we can again look at, it's this many medical events, out of this many procedures that are done per year.

So I wondered if that could be a possible thing that NRC can provide us in the next year or two?

MS. HOLIDAY: Hi, Dr. Langhorst. This is Sophie. Just to follow up on that. I know this is something that the Committee has requested. And as you have recognized, this is a very tight budgetary environment for us.

Staff will always advocate and put the request forth, but ultimately it's up to whether or not we have funds to purchase those reports. Because those reports are several thousands of dollars. And that's several thousands of dollars for just a small piece of a report. Not even a full report.

So when we do have funds, if we have funds, staff will absolutely provide that data to the Committee. Maybe we'll be able to do that at the next meeting because it has been several years since we've been able to purchase a report. I just can't commit to that since it's not my money to play with.

CHAIRMAN ALDERSON: Yes, Mr. Ouhib.

MR. OUHIB: Yes, if I could just add one more comment. It would be helpful and I believe you have done it, is to get that data well in advance, prior to the meeting for instance. For us to sort of brainstorm on that and come up with some sort of recommendations, or plan of actions.

DR. HOWE: Dr. Alderson, also just to

follow up on what Sophie said. The data that we purchase don't come out with, oh, here's the number of procedures for the different modalities. Sometimes on some years they don't even address our issues.

And in other cases they lump it so largely that it's difficult to tease out. So it's not as simple as saying, we want the number of total administrations for this, this, and this. It doesn't come that way.

CHAIRMAN ALDERSON: Okay.

Yes, Frank. Dr. Costello.

MEMBER COSTELLO: A caution about mining NMED data. First of all, those reports often raise more questions than they answer. I mean, how many reports when you look at them, do you find yourself wanting to ask questions? Like, why did that happen? Or why did this happen? Or what was the effects on the patient? And the data, the quality of the data is very, very, variable in that regard.

And just from a simple counting point of view, I think we should all assume there's a certain amount of under reporting-- for the reason that we've been talking about. You know we may discourage people from reporting by the way we handle the reports.

So I think you know mining the data is useful but you have to be cautious about making major conclusions based on data that is inherently suspect. Thank you.

CHAIRMAN ALDERSON: Dr. Metter.

MEMBER METTER: I was just wondering as far as me looking for the denominator on how many procedures are done. Since my understanding of the Y-90 microsphere is that it's a unit or a standard dose when they're sent. Perhaps you could go to the manufacturer and just see how many they have sold as a baseline?

CHAIRMAN ALDERSON: Yes, Dr. O'Hara.

MEMBER O'HARA: If that, many of these companies consider that proprietary, that kind of thing proprietary information. We're using the Y-90 microspheres as an example. One company has a humanitarian device exemption from the FDA, which they're limited to a total number of patients per year. And the other has a PMA, which is the highest review that we give a medical product.

And the company will tell us how many units they have sold in a yearly report, but again it is proprietary. In some cases you can get the information publicly from some of their presentations.

In terms of the denominators, it's something that the FDA is always interested in too. And with respect to using, again, Y-90 microspheres as an example. It's very difficult because they're used off-label so much.

You know the glass microspheres are indicated for primary liver tumors. And the polymeric microspheres are indicated for colorectal masses. But they both have, both companies have investigation device exemptions, ongoing. This is where they're looking at other indications for use.

And there's a large number of physician-sponsored studies going on too. That's where physicians are actually looking at a number different indications. But so we are as challenged as the NRC with our databases. And I would hazard a guess that many of you have tried to look at what used to be called, the MOD database in FDA, and been totally frustrated by it.

And it is changing, that database is changing. It's now called, SUS internally. The general public can't get access to SUS yet, as they could get, they still have access to MOD. But MOD will eventually go away, and SUS will completely take over. And it's supposed to be, it's being designed

to be much more user friendly.

I still can't use it. I don't even have permission to use it.

So, but it's the denominator, and a lot of what I've heard here today from NRC, talking about the problems with these databases. As I said, the FDA database is very vague, very vague indeed. And many times our analysts look at these and they have to start investigating. They have to start to see where a device has failed.

And remember our database is different. Really, we look at device failures. That's what we're looking at. And we regulate the manufacturers. We're not regulating the users, as NRC does. So there's a lot of differences.

But you'll see that coming out of our Division of Radiological Health, you'll see at least three, maybe four different methods that regulatory scientists are using to analyze this subjective data, from these subjective databases.

So you'll see you know hopefully publications coming out. There's at least one that's close to coming out right now.

CHAIRMAN ALDERSON: Yes, Dr. Palestro.

MEMBER PALESTRO: Yes, in response to

your comment, Darlene. I can tell you that I spent a considerable amount of time in preparation for the presentation regarding alpha and beta emitters, trying to get those data for the other beta emitters that are on the market and for the alpha emitters. And it was absolutely impossible.

I contacted the companies, and they referred me to many different people within their organization. And that went nowhere. And I tried looking on line, on the web and so forth to see, but I just could not find the data.

And then several of these agents have gone from one company to another over the years, which further complicates it, so.

CHAIRMAN ALDERSON: Mr. Ouhib.

MR. OUHIB: Yes, just a comment to Dr. Howe, regarding the medical event. It is hard to swallow, the idea that we are still seeing some errors that have significant impact related to the unit. You know, air-kerma strength versus millicuries and all that. And these are really detrimental when you look at a lot of it more in depth, to these errors.

I'm just wondering if perhaps that might be the work of the Sub-Committee. To actually look into that? And it's perhaps time for us to move away

from the millicuries and go to a single unit such as air-kerma strength. And stay away from apparent activity type of thing.

CHAIRMAN ALDERSON: Any other comments on this particular subject?

(No audible response.)

CHAIRMAN ALDERSON: Hearing none, are there other subjects that people would like to raise?

Dr. Langhorst.

MEMBER LANGHORST: As I said, I've been on this Committee a little while and I am still frustrated in not knowing how many medical licensees there are. NRC publications tell how many material licensees there are. I cannot find how many medical licensees there are. Could we get that data? Could we have it?

You know, I know there's Agreement States and there's NRC licensees, but just to know how many -- and I'm not asking number of authorized users -- that will be the next layer. I'm looking for number of medical licensees.

Now I know, in our instance at Washington University in St. Louis, we are medical use licensees, but we're also a big research licensee. If they have medical use approved in their license, that's the

numbers I want to know.

So that would be great. And I really don't mean to diminish the medical team's resources in time added, as far as getting this data. I would think it would be something that you would have already, so please.

CHAIRMAN ALDERSON: So, a clarification. So if you have an institutional broad license, and Washington U certainly does, you would consider that one licensee. Is that right?

MEMBER LANGHORST: Yes. That's all I'm looking for.

CHAIRMAN ALDERSON: A single licensee.

MEMBER LANGHORST: That's all I'm looking, how many medical licensees are there in the country?

CHAIRMAN ALDERSON: Okay, all right.

MEMBER LANGHORST: And how many are Agreement States? How many are NRC? You don't even have to tell me what they are per Agreement State.

CHAIRMAN ALDERSON: Dr. Howe would like to comment.

DR. HOWE: We have to do what's called an OMB approval. And renew these things for regulatory reasons. And one of them is Part 35, and in doing

Part 35 we have to come up with the number of NRC licensees. And we do that by program code. So we know how many NRC licensees we have. We know what their program codes are. They don't always have primary program codes. They may have secondary tertiary program codes.

So we have those data. That is accessible to us. What we do not have is the same level of detail for the Agreement States. So in our OMB clearances, we do have on a yearly basis, the number of Agreement State licensees.

Now that covers all materials. And so it's not just medical. And so what we do is we make an assumption which may not be a safe assumption anymore, that the ratio of NRC medical use licensees should be the same as the ratio of Agreement State licensees.

So we know the total number of NRC licensees. We know the number of medical use licensees. We develop a ratio and then we take the total number of Agreement State licensees, and we multiply by that ratio.

Now when we had more NRC licensees than now, that was a good approximation. I'm not so sure that's a good approximation anymore. But that is how

we determine how many medical use licensees there are. We don't have the ability in the Agreement States, other than using a ratio, to go from NRC modalities to Agreement State.

But that information we can provide very easily.

CHAIRMAN ALDERSON: So you already have the information you just described?

(Simultaneous speaking.)

DR. HOWE: We already have the information.

CHAIRMAN ALDERSON: You just have to look it up? Yes?

MR. BOLLOCK: Short answer is we can get you the number of NRC licensees and give you an estimate of Agreement State or total.

MEMBER LANGHORST: I would love to have just even that shared with the whole Committee.

CHAIRMAN ALDERSON: Dr. Langhorst will be very happy if you provide this information.

(Laughter.)

CHAIRMAN ALDERSON: Mr. Costello.

MEMBER COSTELLO: I can't speak to any States other than Pennsylvania, but we use the same program codes.

MEMBER LANGHORST: Is your mic on?

MEMBER COSTELLO: Yes.

(Laughter.)

MEMBER COSTELLO: I can't speak for any States other than the fine Commonwealth of Pennsylvania, but we use the same program codes as the NRC does. And if someone were to ask us, I'm pretty sure we could give you the same breakdown that the NRC can give you.

Okay, not only the total number, but we can probably give you the total by program code. How many are cardiologists. How many there are whatever they may be.

Far as the other States go, you have to ask. Then if you would ask, you might get information.

CHAIRMAN ALDERSON: Dr. Langhorst.

MEMBER LANGHORST: Maybe will be answered later this morning, or early this afternoon, but is the ACMUI allowed to ask Agreement States if they could give us this information?

MEMBER COSTELLO: I think it would be better if the NRC asked, would be much better.

MEMBER LANGHORST: Are we allowed to ask?

MEMBER COSTELLO: Allowed?

MEMBER LANGHORST: Without a big formal, oh we need to have this --

(Simultaneous speaking.)

CHAIRMAN ALDERSON: Yes, Dr. Bollock.

MR. BOLLOCK: I don't know that we can ask this. We may be able to, but it may be an issue, I think what Dr. Langhorst eluded to is OMB clearance. Typically when we ask questions that aren't specific to what we're regulating, we need an OMB clearance if we ask more than nine entities.

Agreement States are each their own entity. Unfortunately, that may be the case. So in the meantime, we can get you our numbers and the estimates. And you know that gives you know a relative ballpark for denominators for events. And so we do know generally, have those numbers. But yes, we would have to look into it to see if we could ask all the States something like that.

I mean it seems, I know it seems like a simple question.

MEMBER COSTELLO: I think that I, not being bound by OMB requirements myself, I could probably get Pennsylvania numbers myself and just send them to somebody.

MEMBER LANGHORST: Okay, thank you.

CHAIRMAN ALDERSON: Well it would be interesting if we have the data that the NRC already has based on ratios. And then if you were to get some data from, you could at least do a comparison in Pennsylvania and see how close they were.

But you still would have an overall numbers, you know. Just from what the NRC can provide. So I think it's great that that can be provided. And we should go ahead and do that.

MR. BOLLOCK: Yes, we'll get you what we can.

CHAIRMAN ALDERSON: Right and when you have that number, just obviously send the answer around to all of us on the ACMUI.

Dr. Ennis.

MEMBER ENNIS: May as well go to the second layer then, because what about authorized users? We were hampered in our Committee about the alpha/beta emitters with this issue. And we really could not make an intelligent decision in the end.

MR. BOLLOCK: And that is true because not every -- authorized users don't have to necessarily be listed on every license. So for that we could only give an estimate. And there's some other things.

Broad scopes have multiple authorized users. So those numbers getting to that, the number of authorized users, it really does get to where we don't think we can get other than a rough estimate, anything close to an accurate number, unfortunately.

CHAIRMAN ALDERSON: Dr. Palestro.

MEMBER PALESTRO: Yes, I was just going to echo Ron's sentiments. It would be nice to have. And it would have been particularly valuable to the type of discussion that went on over, is there or is there not, a lack of authorized users?

But again, there's no reliable way to get to that information. Because certainly New York, which is an agreement state, our own institution has a broad human use license. New York State doesn't have the individual authorized user data. They have the licensee, but not the AUs.

MR. BOLLOCK: Exactly right. Just, this was a question, as many of you know with the training experience. We actually have going on and answering questions to Congressional oversight staffers, both Senate and Congress, our Commission. And those are questions that we were asked. Because those are some of the points that the pharmaceutical company was making.

And right, we can't get to the number of AUs. But for 35.300 licensees, we have an estimate of about 2500. It's probably low, a low estimate. But about 2500 across the country that you know. And we were able to find that and we used, because we know the number of NRC licensees, and we used that rough ratio to estimate the Agreement States.

CHAIRMAN ALDERSON: Sophie answer, yes.

MS. HOLIDAY: If I may follow up, both Dr. Palestro and Dr. Ennis, also got, we were requested by professional organizations for the numbers as well. And NRC has what is called, Web Based Licensing, WBL. And that's how we our license reviewers input licenses, medical use licenses and such.

And so in that system currently they do not, you're are not able to pull out the specific number of AUs. However, you are able to pull up if someone is authorized under 300, not 390, but 300, or 200, or 400. Something along those lines. So the number that Doug gave you, is how we got it from just the general number of who is authorized under 300.

Now we're also saying, to answer Dr. Langhorst's question, there was a letter that went out to the Agreement States. And I will have to give

credit Dr. Sandy Gabriel, who used to be a member of the medical team. She's apparently listening, because she sent me this lovely document that went out that has the results of the annual count of radioactive material licenses within the National Materials Program.

So I will share that with the Committee because I don't know if this non-public information, but I will send this to the Committee at the conclusion of this meeting.

CHAIRMAN ALDERSON: Thank you.

Dr. Howe.

DR. HOWE: Just to clarify, that number is published every year in the information guide. Yes, that NRC publishes. And so that's publicly available.

CHAIRMAN ALDERSON: Very good. All right.

MEMBER LANGHORST: So if you let me clarify. It's material licenses, it's not medical licenses?

MS. HOLIDAY: That is correct. Just materials.

MEMBER LANGHORST: Thank you.

CHAIRMAN ALDERSON: So that's something

different, yes.

Mr. Mattmuller.

MEMBER MATTMULLER: Now that I'm leaving the Committee, I've lots of ideas for work for you guys.

(Laughter.)

MEMBER MATTMULLER: But I don't know if it's work worth doing. Actually, I just have two. And the first one I would suggest would be an update on the moly-99 supply issue. And I'm not throwing my successor underneath the bus. I've already talked to him and he's agreed to do this, so. I think that would for the Committee to consider.

And then the second topic would be for Dr. Daibes to give us an update on the number of exemptions that have been granted.

(Laughter.)

MEMBER MATTMULLER: An update, I mean -- implementation and success of the exemption program.

CHAIRMAN ALDERSON: Okay. Those are yes, good suggestions. I think that time will be the issue on the implementation. It won't be available immediately. And the update on the molybdenum situation, do you have someone in mind you'd like to do that?

MEMBER MATTMULLER: Yes, Rich. He's agreed.

CHAIRMAN ALDERSON: Oh, Rich has agreed. Okay, good, great. Thank you. We look forward to getting that information. Yes, thanks very much. Okay, good those are actual, yes fine.

Other topics that people would like to discuss today? We are more than 30 minutes ahead of schedule at this particular time.

Yes, Dr. Zanzonico.

VICE CHAIRMAN ZANZONICO: I'm just wondering what efforts can be undertaken by the NRC staff and or by the ACMUI to disseminate regulatory information in particular, updated information, more effectively to the user community?

I think we around this table, and I imagine even more so among the NRC staff, have a skewed perception that people live and breathe the regulations, which believe it or not, they don't.

CHAIRMAN ALDERSON: Right.

VICE CHAIRMAN ZANZONICO: And I think typical AUs who are otherwise very well informed about many things, are often unaware of new developments. And I mean I can account to this personally. You know before I joined the Committee I thought I was pretty

well informed about the regulations.

And then once I was on the Committee, I was surprised how ignorant I was of many of the regulations and the process and so forth and so on.

So it really strikes me that there's a disconnect between what the NRC promulgates and what the users in the field know. And I know there are many mechanisms in place that in principle should be effective. But they are not nearly as effective as the NRC, and as we think they are.

And I'm just wondering what new mechanisms, what efforts could be undertaken to improve that situation? I don't know if -- I'm thinking even perhaps an NRC representatives speaking regularly at professional meetings. But not just with a booth, you know tucked away in the area of the displays where no one goes.

But maybe even speaking at plenary sessions, you know requesting from the main professional organizations and giving periodic updates on regulations and what's changing. What will impact practice?

Because as I said, I think there's a real disconnect in terms of what authorized users day in and day out, are aware of with respect to regulations,

and changes in regulations, and how they impact practice. And what's actually occurring.

CHAIRMAN ALDERSON: And this idea was specifically mentioned in my presentation to the Commission yesterday. And it is part of the communications plan that we're hoping to support here.

The idea suggested there was that ACMUI member or members, along with an NRC staff person, would appear at some of the major meetings. Now you know as well as I, and you do who are in the organizations, that whether you're on a plenary or whether you're in another session somewhere, that that is something you have to organize with those societies and the people who present those meetings.

But the fact is that all of us know people who are running those organizations and can certainly make an impact. So if we agree to go ahead with that -- we've more or less agreed to go ahead with it -- but if we actually move to implementation. Then certain people who are going to be at those meeting will agree to take the lead.

They'll make the contacts, and they'll try to get onto one of those sessions that are probably initially running in parallel. To just to see if any one shows up. And if people are really interested. -

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(Laughter.)

CHAIRMAN ALDERSON: Well, but if your people are interested then you know the interest begins to get greater and then you say well we, perhaps we could be part of plenary at this or that point.

VICE CHAIRMAN ZANZONICO: It could follow, but I mean the thing you want to avoid is you don't want to be in the, on the display floor in the same aisle as the IAEA, and the ICL. Those are the loneliest people at the meeting. EFU, you have to really have a very prominent role in the meeting. This is why I mention something like plenary session or some such thing as that. And that's just a perfunctory appearance.

CHAIRMAN ALDERSON: No, it's not just an appearance, but maybe I didn't clarify. The idea that I had was that you would listed in the program as leading one of the many refresher courses that are at these meetings. And you'd be course number whatever, on a particular day, and a particular room, and a particular time.

And there would be a hundred and fifty seats in the room, and you know you would hope that some people are going to come and want to talk to the

NRC about various things. You'd have an actual program. You would have planned an actual presentation that would cover topics that you would have announced. And then you'd be a Q&A session as well that would probably take an hour or so. And that's the idea.

Mr. Ouhib.

MR. OUHIB: Yes, I think just to let you know that has been used in the last two years within the American Brachytherapy Society for instance. We have had an NRC representative participate in sessions where there were discussions and all that, an update on the rule making. As a matter of fact, Michael perhaps can testify to that. And Sandra was part of it also three years ago and so on.

But I also think the AAPM also has been so very active in that. So there, it's out there with some organizations. I mean no doubt about it. But maybe we just need to push a little bit more.

CHAIRMAN ALDERSON: So Lynne Fairobent wants to make a comment.

MS. FAIROBENT: Yes, Lynne Fairobent with the American Association of Physicists and Medicine. I think it's great that you want to do something like that. But I'm sorry, I think it's the wrong approach.

I think it's up to each of the professional societies when they wish to invite an NRC, or an FDA, or a CMS regulatory individual. We do that. Cathy Haney last year spoke as the lead kick-off speaker at AAPM spring clinical meeting for example.

We have had a variety of sessions, when appropriate, with NRC individuals. Many of the professional societies have government relations experts who do routine updates to their memberships on what's pending in a variety of federal agencies. And State agencies.

I think that, and Sue will probably cringe, but the vehicle for NRC reaching out to the medical community and ACMUI reaching out to the medical community, should have been moving forward with an NRC regulatory issues conference to the medical licensees or to materials licensees.

And there had been an effort for that, and my understanding is it's not going forward at this time.

CHAIRMAN ALDERSON: Yes, that is correct. That was suggested. It was actually discussed by this Committee. And it was felt that it would be better and more efficient, more cost effective for us to go

to the meetings, than to try to have a national meeting and have people come in for that meeting.

I would say that for any of you who -- and I know many of you have your own organizations, but in leadership positions, you've heard many of the old adages about communication. You know you communicate, communicate, and communicate. Sometimes several different ways, several different places and ultimately no matter what you try to do, you're ultimately criticized for not communicating because somebody fails to hear it.

So what I believe what you need to do is to offer your services. You don't wait for somebody to call because then they're angry that you haven't done your job. You actually offer to go to them.

Now if we in fact go to various societies and offer to put together you know a presentation for one of their refresher courses. And they say, no you know, we're not interested. We don't need you. Well then when they have a problem in a few years, we'll be able to point out that we offered and they said, no.

But I think if you don't offer then you aren't doing what you need to do in terms of communication.

Dr. Dilsizian.

MEMBER DILSIZIAN: I want to say that when we organized the FDA panel, that at the SNMMI we thought nobody would show up. But actually it was full house, people lined up. People want to know how the regulations occur and what's new.

I'm not sure if NRC should be separate, or if FDA and NRC combination probably would work well. But to reassure you, the people do like it and do attend.

CHAIRMAN ALDERSON: Yes. Fifteen or more years ago, and I don't remember what the issues were, there was issue in the radiology community with some NRC topics. And I actually was involved in putting together some sessions at that time. And they were reasonably well attended.

I would also point out that the American Board of Radiology came up with the idea several years ago that it might be interesting to put on a regular session at the large radiological meeting, the Radiological Society of North America, RSNA.

And the initial response to that was similar to this. Oh, no, no, you know, no one will come. And no one will be interested but why don't you go out there. It's now become a really popular,

looked forward to part of every annual meeting. And no they don't get a thousand people, but they get a hundred.

And so they're out there telling each year exactly what's going on. It's been very valuable for them.

Dr. Metter.

MEMBER METTER: Yes, I like what you're talking about, reaching out to societies. And for the SNMMI big annual meeting, and we did do an NRC update. Mr. Bollock was there. And it was very well attended. And they had a lot of questions. And I think the issues coming up with training and experience and all that will be a hot topic.

And I believe that many of us who are involved in leadership and involved in future meetings, I think we should bring that up. And I think it would be a definite service to the community.

CHAIRMAN ALDERSON: Thank you. I think that if you just listen to the controversies, you know the discussions that we'll have over issues like the one that Dr. Palestro's Committee will deal with--and over the question of medical events. It seems to me that there are people out there who want to know the answers to these questions.

And we can't provide pat answers, but we can certainly provide updates and get their input as well. And they will enjoy that.

Yes, Dr. Metter.

MEMBER METTER: I think it would be a great opportunity to educate our fellow colleagues in the community about the current ideas about a just culture, the safety culture. And you know put that in. And I think, you know, just starting it now. It'll take years and years for the change.

But having them realize that you know the NRC is a regulator. But we're here to improve. We're doing quality improvement, no blame. We want to improve on what we do. And I think that would be actually a very good starting point to see maybe you know different motivation for reporting.

CHAIRMAN ALDERSON: It will certainly be good for the general public to hear that message. We'll have to be concerned about the fact that they will expect it to happen by the next month or so.

(Laughter.)

CHAIRMAN ALDERSON: And you know that won't be true. But I think it will be a good message.

Dr. Palestro wanted to speak.

MEMBER PALESTRO: Yes, just to say that I

agree with you, Phil. I think it's better to be proactive than reactive. And if the societies are not interested, they'll tell us so.

And I also think that when in fact they are interested, we'll try to identify topics that would be germane to their societies. I think training and experience is probably going to be germane to a lot of societies. I think the technetium shortage, or the potential shortage which it seems to come up periodically, would be another hot topic for something like the SNMMI.

CHAIRMAN ALDERSON: Good, excellent. Thank you.

Yes, Dr. Langhorst.

MEMBER LANGHORST: I just wanted to add one other perspective to this discussion. I think it's important especially in Agreement State licensees for the ACMUI to promote our presence, in that we're an advisory Committee for the NRC staff. But that doesn't mean we only talk NRC.

And while it is frustrating to be able to get information between NRC licensees and Agreement States and all that, what we were discussing before. The NRC is the driver of this bus. What they're regulations say, are primarily what Agreement States

have to implement.

And so I would encourage that the promotion of the ACMUI, and what we do, and why Agreement State licensees need to know and be involved in, I think that's really important.

CHAIRMAN ALDERSON: That is an important topic, I agree. So if we in fact think that we should be out there talking to at least the three societies that were mentioned in our Commission presentation yesterday, which are the physics, the AAPM, the Society of Nuclear Medicine, and the third was ASTRO I believe.

If we wish to move forward to get some ideas, you know how far ahead meetings are planned. So it would be probably very useful for us to have a representative who was going to just you know on our behalf, approach the organization and say, is there a place on your program?

And you may find out that they'll say well, yes sure, but not until you know 2018. But you know, but we have to be out of there starting these conversations in order for something to happen.

So it's pretty clear I think on the Committee, that we have several people who would in fact, be with the physics organization primarily. We

have several people who clearly are related to ASTRO. We have other people clearly who are related to the Society of Nuclear Medicine.

So it would seem that that might be a starting place. But that isn't to suggest that other organizations shouldn't also be approached if in fact this effort moves forward.

So it would be, I think, helpful if Dr. Palestro and Dr. Metter for example talked about how to contact the Society of Nuclear Medicine.

If Dr. Ennis and Dr. Suh talked about how to approach ASTRO.

Dr. Dilsizian also, the Society of Nuclear Medicine, or cardiologic organizations for that matter.

And Dr. Zanzonico, Dr. Langhorst, think about the physics organizations. And sort of pair up and then decide how you'd like to approach the organization? And then approach them.

Dr. Metter.

MEMBER METTER: Another important organization I think is the American College of Radiology because they do the majority of nuclear medicine procedures as far as diagnostic radiologists in the country.

And actually I was just appointed for the next two years for the annual meeting, to be on the Committee. And for the 2017/2018 meeting, they have our annual leadership meeting in D.C.

CHAIRMAN ALDERSON: Yes.

MEMBER METTER: So --

CHAIRMAN ALDERSON: So will you approach them for us, I mean?

MEMBER METTER: Yes, I'm on the Committee.

CHAIRMAN ALDERSON: Good. So I mean, that's perfect. So please, ask them if they would be interested in such a session?

Yes, Mr. Ouhib.

MR. OUHIB: Yes, certainly let's not forget the American Brachytherapy Society.

CHAIRMAN ALDERSON: Absolutely. Who do you think might represent us there?

MR. OUHIB: Well, I'm the Chair of the patient safety, so I could certainly push for that. And we have done it with in the ABS. We have done this, several sessions with NRC representatives in there.

But I think we need to have some sort of a formal relationship there. And have it sort of like

an annual thing. That there is a session on, you know regulatory and cultural safety and so on and so forth. And I think that will improve. Yes.

CHAIRMAN ALDERSON: Dr. Zanzonico.

VICE CHAIRMAN ZANZONICO: This is just a comment for NRC and for all of us as well. I think in these presentations you really have to go to make an effort to avoid citation of CFR numbers, and of abbreviations. I've been to these presentations where you are very knowledgeable people, and they just don't speak in plain English.

It's all acronyms, abbreviations, citation of as I said, CFR numbers so forth and so on. And I think you immediately lose a large fraction of your audience and the people who are most needy of this sort of information.

I mean I think these presentations to people who are not really engrossed in the regulations need to be very much in plain English.

CHAIRMAN ALDERSON: You're absolutely correct. Absolutely correct.

Dr. Langhorst.

MEMBER LANGHORST: I just wanted to ask Mr. Fuller. I think, do members of the medical teams serve as liaisons to some of these organizations too?

MR. FULLER: Yes, that's correct. To some of the organizations, and then you know as folks on our team move on. Then we try to actually replace some of those. To be specific, and I don't know that's it's actually formalized, but I am very much involved on a regular basis with both the American Brachytherapy Society and with ASTRO.

We have a little bit more formalized relationship with the AAPM. We have two folks that are actually members. One of their Government Regulatory Affairs Committee and one with the Therapy Physics Committee. And then the Society of Nuclear Medicine, Mr. Bollock, Doug, has been involved most recently with those folks and has made presentations and so forth.

So and we have team members, several team members who are actually members of the Health Physics Society as well as past members, who are members of the Society of Nuclear Medicine and Molecular Imaging.

So to answer your question, I think I covered a lot of them. I know I didn't cover everybody. I might have missed a few but we work hard and try hard to stay engaged and we have several people on the medical team who wear multiple hats in that regard.

I would like to take this opportunity and I'm just trying to poke fun a little bit here. Dr. Zanzonico, I just made three presentations a few weeks ago to the American Brachytherapy Society and I was trying to be very careful to use plain language. But I did remark that we've got nothing on the medical community when it comes to acronyms.

(Laughter.)

MR. FULLER: I've actually attended many sessions and I was taking so many notes so that on break I could ask folks what does that acronym mean? Or what are those initials for? And so I actually remarked in one of my presentations that, I said to the audience, I said, you folks got nothing on us. I said, I thought we were bad. But it's true.

I mean again, just in fun. We as any other group, if you will, we do have our own jargon. We have our own acronyms. And we have to be very, very mindful of that and not just blurt out the initials as if everybody understands what we're talking about. You're exactly right.

CHAIRMAN ALDERSON: We have a comment at the microphone.

MS. KUBLER: Hi, this is Caitlin Kubler. I'm with the Society of Nuclear Medicine and Molecular

Imaging. I was just texting our education department to figure out if we actually had a spot open for an ED session of our upcoming annual meeting. And I will get back to you with that.

But as far as governance updates go, we are happy to do those at any time. And we would gladly welcome an update from the NRC, especially since there's so much going on with the training and experience requirement issue, as well as Part 35.

I know Doug presented at our mid-winter meeting. And we were very receptive and we were glad that he was there to provide an update.

CHAIRMAN ALDERSON: Excellent and clear. Delighted to hear that. Thank you.

Yes.

MEMBER ENNIS: Just as a professional with ASTRO, you know ASTRO was really engaged with Mike as he mentioned the last few years. We've got a relations Committee that I'm involved in, and in the annual meeting. And I think it's been very well received. I know we had actually, Mike O'Hara also to talk about the issues, which happens to be a lot of equipment issues in that session. You know I got really a lot of good feedback from it.

So I do think the membership you know are

interested in these things. And the more we do, the better.

CHAIRMAN ALDERSON: Excellent.

Yes. Dr. O'Hara.

MEMBER O'HARA: To follow up on that. ASTRO also had invited a few years ago, it had invited the Commissioner of Food and Drug Administration to give a plenary lecture at ASTRO. And ASTRO hid their concern that the request for the Commissioner showed up, ended up with me.

They held their session and they were very gracious but you could really tell that they were a little disappointed --

(Laughter.)

MEMBER O'HARA: -- that the Commissioner wasn't standing there instead of me.

CHAIRMAN ALDERSON: Dr. Langhorst.

MEMBER LANGHORST: And I can understand that because it's not just the talks or the lectures that are given. It is the opportunity to mingle and interact with people on a one-on-one basis, which I know is not real effective at those booths. But that is an opportunity not only for the societies to learn about the regulators, but the regulators to learn about the issues important. And what is on the minds

of those people, so.

CHAIRMAN ALDERSON: Absolutely.

We have another comment at the microphone.

MS. TOMLINSON: Hi, this is Cindy Tomlinson from ASTRO. I'm guilty of inviting Dr. O'Hara and Mike Fuller to our Government Relations Council Meeting last, at our last annual meeting. We are working with Mike Fuller to figure out ways of engaging our membership with the NRC. And our annual meetings really are focused on science and it's very hard for us to get folks to policy type discussions.

So we are working on other ways to engage with NRC. We will likely -- Michael O'Hara you're learning this for the first time -- also engage with FDA as well. But outside of our annual meeting. Sometimes it's just too difficult to get those things in.

CHAIRMAN ALDERSON: Absolutely. Well that's the start of a fact finding that we'll discover as we move forward with this initiative.

Yes, Dr. Suh.

MEMBER SUH: So one way to try to help with awareness and communication, perhaps expectations as well, is that actually to make change in any culture, we're talking about the just, safety

culture we were talking about, and how do we -- the transparency through to medicine is.

I think that one of the things to consider is also to start at the grass roots of actually the trainees, the residents. Because I can tell you during my residency, I didn't even know that NRC really had any impact in terms of what I would do in my career.

I had no idea of the ACMUI just until I started getting these phone calls. Hey, John would you like to serve on this Committee? So I think those are the type of things which I think, just to help increase that awareness. And I know there are several residents which are actually very interested in policy.

I mean some of them have their MBAs and MDs. So I think if they were aware that this is a potential opportunity, just to increase the awareness. I think that would also be very effective as well because I think just the transparency of sharing what type of medical events have actually occurred.

And if that was shared with residents, they'd think wow, I really need to pay attention to which side of the brain I treat when I do radiosurgery. I really need to pay attention to making sure I do a

time out, ask for their name, and their birth date before I treat the patient.

I really need to you know pay attention when I put in an applicator in a GYN patient, it doesn't slip. I mean all these things if you read about it -- and I'm just a big believer that the more you see, the more you do, the more you hear, it becomes part of your habits.

I think that's where, I think as a Committee -- I mean one of the valuable efforts we can provide to our patients which is why we're here for, is to make sure that we provide best care possible.

And I think we start from the grass roots level of the residents and they're aware of it. And they're saying, you know the NRC is not the enemy. They're here to help facilitate. You know with your education really to keep you out of trouble. I think that would go a long way.

CHAIRMAN ALDERSON: Well John, I think that's the first time I've heard that idea. I think it's a fascinating idea actually. I'm just trying to think of the various ways one could approach it.

I'll ask you one follow-up question. Do you think in that context, which would be, or is either

of these the correct answer? Would you think that you would try to organize something like this, or approach this through the Accreditation Council for Graduate Medical Education, the ACGME? Through the American Board of Radiology? How would you approach the trainees?

MEMBER SUH: No, so I think you could use that approach right now. I was thinking more of a grass roots you know in radiation oncologists, called ARRO, -- there's an association for radiation oncology graduates.

CHAIRMAN ALDERSON: There is?

MEMBER SUH: They meet every year. They meet this Saturday before ASTRO. And maybe a possibility of approaching their leadership to say, we would like to do just a very short presentation about what the NRC does.

CHAIRMAN ALDERSON: Okay.

MEMBER SUH: What, how this may impact you as you're talking about experience, we're talking about competency. Just let them start thinking about competency. It's not, just because you finished a radiation oncology residency does not give you perhaps in the future, the right, or the authority to say, okay, I'm going to go ahead and be the expert in this.

I mean it's kind of self-regulated as well. And I think that one of the ways you try and keep yourself out of danger is to know what your limits are. So if you've really not been formally trained in procedure X, it's probably not a good idea to say, okay, let me just watch a video and I'm going to try this on this patient.

So I think there's multiple facets of how to approach this. But one I think is to just increase the awareness and I think now that -- when I read these medical events I always scratch my head like, wow, this is, I wonder why this happened? And if this was shared more openly with the trainees I think it would be very impactful.

Because they're like, that would never happen to me. Well, look this has happened 20 times now.

CHAIRMAN ALDERSON: Right.

MEMBER SUH: So I think they'll start to see that.

CHAIRMAN ALDERSON: I think that it's just a great idea. Potentially very impactful. I hope that we can pursue this idea with you.

Dr. Metter, next and then --

MEMBER METTER: I think that's an

excellent idea. And most of these societies do have organizations for trainees or young professionals. Like the ACR has young professionals and the resident and fellowship section. The Society of Nuclear Medicine has their own group too.

And the other people I think, that is another layer, would be the program directors. Because they are there, quote, ''parents during the training period.'' And if you can get the idea of the safety culture you know starting to happen. Then they'll say well you know we're doing this to help with our patient care. So it doesn't happen again.

And so I think like the Nuclear Medicine Program Directors. It's a great organization and the Association for Program Directors in Radiology, a large group of people. And I think if the NRC comes to these meetings, they can meet with those groups too. And so it could be you know something that would be you know more than one audience for that visit.

CHAIRMAN ALDERSON: Mr. Ouhib.

MR. OUHIB: And I think not only the new graduates will benefit from that, but even senior practitioners because there are emerging technologies coming. And we're seeing some errors happening. So I think it would be great to have some sort of

refresher course per se. And update, you know the organization about what's going on. What this modality or what this technology, and so on and so forth.

And then you know, it's an opportunity to sort of share what kind of errors are happening. And how can these be prevented? Maybe there's some feedback from the attendees. And so on. So it would be like a discussion, not just simply a presentation type thing.

CHAIRMAN ALDERSON: Interesting. So as we begin to expand and explore this idea, it's quite clear that it has many tentacles moving out into various different directions, valuable directions.

So I believe, that we have discussed the idea of communication more or less in the abstract thus far. I mean now we're really beginning to discuss how we would get it done. And it seems that we're sort of a Committee of the whole.

So that the question that I'm wrestling with, please help me with it right now in this discussion, is should we move ahead with our communication initiative, which was well received by the Commissioners?

Should we move ahead with the

communication issue as a Committee of the whole? That is the whole ACMUI is going to focus on this issue and work on it together through our various societies. Or should we actually appoint a Sub-Committee on communication, which would require that there would be people on it who basically represent different facets of the ACMUI? I'd just like to have your advice on that question.

Dr. Zanzonico.

VICE CHAIRMAN ZANZONICO: Well I think it would be most effective if the entire Committee was engaged in it simply because by definition the membership is defined to represent all different stakeholder groups in the regulatory environment. And we don't want to miss any by not including them on a Sub-Committee. So I think if everyone was engaged that would be the most effective way to go.

CHAIRMAN ALDERSON: Okay. Other opinions?

Ms. Weil.

MEMBER WEIL: I hate to take over Sophie's spot but I think that the entire Committee cannot act except in a public forum, whereas a Sub-Committee can.

CHAIRMAN ALDERSON: Where did she go? Oh, there she is. You're hiding.

MR. BOLLOCK: I mean yes, so it would we could probably --

CHAIRMAN ALDERSON: Technicality for Sophie.

MS. HOLIDAY: Technically speaking, the Committee, if you're taking on a full action, each individual member is reaching out to their respective organizations. That's fine.

It's just a matter if you guys are deliberating on an item. An item that needs a vote, or Committee consensus if you will, that's when we get into the whole public realm type issues. That's a fact of governance.

So it's here while we're in the room discussing and Dr. Alderson put up a suggestion, or Dr. Zanzonico put up the suggestion that we look at this as a whole. That's saying that each individual member on this whole Committee will go do something with their respective organizations. That's fine. If all of you agree, that's your public discussion.

You only need a Sub-Committee if I guess you're doing a report, or you're putting up formal recommendations. Something along those lines to NRC staff, which will eventually end up as a vote from the full Committee, or an endorsement. In this case

I think what you're pursuing is absolutely acceptable.

CHAIRMAN ALDERSON: Mr. Costello would like to comment.

MEMBER COSTELLO: If we were to meet as a Committee in the whole, which I would recommend by the way. And sometime down the line we want to have a conference call where we've all discussed it. If that were made public that wouldn't bother me.

You know, we have phone conferences that are made public and I think that we are all candid and effect during these phone conferences. And if we had teleconference of discussing communications, it would be public. That might even be a benefit. There might be people who would learn something about our communications effort by looking into our -- why to anything would you want to keep an effort at communication secret?

You know, we keep that laying in our bushel basket. So maybe if we did, you know sometime accomplish -- we're deliberating before we go forward. I'd be happy to have the public see that, and think that we're doing our jobs.

CHAIRMAN ALDERSON: Good. All right. Now that's two opinions that we, that it is appropriate for us to look at this issue as a committee

of the whole. And two opinions that that would be the right thing to do.

Ms. Weil.

MEMBER WEIL: If we want to be nimble and able to act in timely way, as a full Committee, then we have to be aware that that kind of a public teleconference requires notice in the federal register. And you know there has to be, we just need to keep in mind the process, which takes time.

CHAIRMAN ALDERSON: Yes, Dr. Ennis were you going to comment on that point?

I would say that as we get this effort started working as a committee of the whole, that we would just communicate with one another, rather than have you know Committee Y, you know teleconferences. And we would work on the individual sort of initiatives that we discussed this morning. And then we'd come back here and discuss them as part of our group meetings. So that we wouldn't raise that particular technicality in process.

Someone else had their hand up and I forgot who it was. Yes, Dr. Ennis.

MEMBER ENNIS: This is for Doug, and Sophie and others on staff. It sounds like we may be asking you to make a fair amount of trips and

presentations. Do you need us to say that in some formal way so that you can go to your funders and say, hey, we need funds to be able to carry out our requirements the ACMUI expects us to do?

MR. BOLLOCK: It wouldn't hurt.

(Laughter.)

MR. BOLLOCK: And I envision all this discussion and we are, I know I've spoken with the medical team. And Mike and I have many discussions, and discussions at the last meeting with Dr. Alderson. We are 100 percent behind all this you know. We fully agree with you. You know outreach is very important, communication is important. And we have just amongst ourselves planned and have been -- you know Mike's gone out to ASTRO and Donna-Beth, and that's why I'll go to FICA. It's another important outreach to get the patient aspect.

I was at SNMMI two months ago. So we do you know, plan on doing that and that outreach. But like you said, it is, you know we do run on a budget. So our, and funds are limited, and travel funds to get out there because you know we are right now we're in a constricting budget environment in NRC. So less and less travel funds.

But we still have a plan I discussed with

the medical team, and my branch as a whole. Like we still would get at least one person to each of the meetings that is important to get out to. And that will be our goal. And I can sell that to management. And kind of as a whole, put that as a higher priority.

So you may not see, I may not be at the next SNMMI meeting, but Said will be there. And he'll be able to speak on all the topics, or you know Mike will go to ASTRO. Sophie will be at HPS. So you know we will still, we still plan to continue that. And be nimble with our, conservative with our travel funds.

But any input that you can get to us. Any other subjects or topics prior to these meetings that are important, that you know you feel are important to your community that we can speak on, we feel that's greatly appreciated. Helps us deliver the message, answer questions, be prepared.

And then kind of what like what Mike and I call it, like just happen to ask the regulator, just a chance for us to say, this is what we're working on. And I think we have seen it you know be beneficial at SNMMI. You know made them aware of training experience issues that were going on.

Because it wasn't necessarily in the

public forum other than you know the Sub-Committee was doing their work and they're given the recommendations. But there was a lot more going on behind the scenes. Not just from the NRC, but the political pressure. And so there are definite benefits. We see all the benefits and we will strive and work to be able to do that as much as possible.

So you know if, any recommendation, yes it can't hurt to say well, you know help. We should be able to fund this communication with whatever travel is needed.

CHAIRMAN ALDERSON: So in front of the Commission we mentioned three meetings. It was just for example, but we mentioned three meetings. And so it might be useful to go back to the funding side and for the NRC, to say to us, well we think that in our current fiscal year, the next fiscal whatever, we can afford each year to go to three meetings, five meetings?

There are other ways to handle this problem. Once you establish a communication pathway, then probably at sometimes there can be one or two members, usually two would be better ,, who might create you know a reasonable communication pathway with another organization.

There's also all sorts of electronic mechanisms that can be brought to bear this day and age in the right sort of facility, where if certain people could be in present and others could be on a video conference. But I think Dr. Langhorst's comment was very useful. It isn't just the session, it's also the mingling and them getting to know you. And being more comfortable.

So as much as we can in the early going, I would hope that we'd be able to have a representative who would be along there with a member of the ACMUI.

MR. BOLLOCK: And Dr. Alderson you hit it right on. You know it may become where we have to kind of one year go to, one year represent this meeting, the next year this meeting. Hopefully we can get to the ones that have the more, you know signs that we have, already have very good relations with. You know those will probably still go to every year. And we will work to prioritize. And that's on us, and that's on me with budgeting the staff and making sure.

And that's actually something that we have to think about going forward. But we fully support and we recognize the importance of it. And so does my management. And so any support or any direction

that we can get from ACMUI and can help us with the message back and forth, you know. Help us help you, help us.

CHAIRMAN ALDERSON: Very good.

MR. BOLLOCK: We appreciate that.

CHAIRMAN ALDERSON: Dr. Langhorst.

MEMBER LANGHORST: I appreciate Dr. Zanzonico's comment that he's learned a lot being on this Committee. And from our profound comments by Mr. Mattmuller, how it gets into your heart. So I wanted to point out a resource ACMUI members have that staff put together for us a couple years ago.

I asked that staff give a history of who has served on ACMUI. I invite you to look at those lists and have those people help you at your societies. Because they know. They know already and I think they'd be thrilled to help promote this too. So I just wanted to point out that's on the website. And use that. Because I think that's a very valuable tool.

CHAIRMAN ALDERSON: Good. Thank you.

MR. BOLLOCK: And if I could also, to go back to a half an hour ago when we began this conversation. Dr. Zanzonico brought up a good point about you know, when we get new guides out. We do

you know, we try our best to pass on any new guidance as best we can. We put out communications, send them out to the States. And then the States are to pass it on to their licensees. We sent out --, you know, mail out to our licensees.

We sent out medical List servers, something that we highly encourage people. Anybody can sign up I believe and that just, when we add something to the medical List server, they'll get the update. And they'll see that this new guidance is out, or what have you.

So there is actually a lot of information on the public website. Such as the information Dr. Langhorst is bringing up, and among many other things. So that is helpful and you know I encourage you all to communicate that out to your societies, to your peers. And hopefully that will help. Because you know we recognize there is only so much we can do.

CHAIRMAN ALDERSON: Right. So as we promulgate this, it may be that you know we wind up in the beginning, getting NRC people physically at the meetings for the major societies. And the ones not as large, but hopefully eventually you'll get there.

So I want to go back to when we talked

about like who's going to contact whom? Because that's the first step. You have to contact.

We've already heard some things. Because we have people in the audience from SNMMI and from ASTRO. So we've learned for example when you make a contact with ASTRO, that they want to meet, but they don't want it to be at their scientific meeting. They want it to be at a meeting of the government group. So that's something with which we'll have to adjust.

In each case we ought to contact and find out that we can make a schedule, yes this year, and this is where it is. And maybe the Society of Nuclear Medicine will say, they would rather have it at the mid-winter meeting than the main meeting. Who knows?

Then the content, and in part they help define the content. What, you know we say to them, what is it? Here's some things we're thinking about, what do you want to hear about? And then you begin to develop a content that you know the audience is interested in. And then you sort of create your educational or communication objectives and then you get into the details of how you're going to present it. And so on and so forth.

So we've got to go through that particular set of steps, so for ASTRO, Ron Ennis and John Suh

were going to be involved. And you've got this great idea about the trainees, and please I hope we can pursue that. And we don't know exactly where that's going to go yet.

For SNMMI Chris is going to represent us. Darlene you can be involved there too, but you're clearly going to ACR and talk to them for us.

Who's going to AAPM? I don't have that clear. Who --

MR. OUHIB: I'm a member of the AAPM of course. And a member of the ABS by the way.

CHAIRMAN ALDERSON: Okay, so you would contact them. And we've also heard from AAPM that they may not be as interested in this as some of the other organizations, but --

MR. OUHIB: But the clinical symposium is an opportunity.

(Laughter.)

CHAIRMAN ALDERSON: She wants to make a comment, Lynne Fairobent.

MS. FAIROBENT: Lynne Fairobent from AAPM. Dr. Alderson, my point was not that AAPM isn't interested. We already have a mechanism in place that we have used successfully multiple times with NRC and other federal agencies. And far as that goes, you

did hear from Mike for example, we have had historically NRC staff as liaisons formally to our appropriate scientific as well as our government relations Committee.

We have had the Chairman of NRC speak at AAPM's meeting. We have had several office directors and several staff. So it's not that we're not interested.

My point was that there are already mechanisms in place for various societies. And that those mechanisms should be what ACMUI or federal agency staff work through. Not to create a new thing.

And as far as AAPM, I am the point of contact for AAPM for any federal agency, for any issue. And that was the point of my comment earlier.

CHAIRMAN ALDERSON: Okay, thank you. I stand corrected. And Mr. Ouhib will be in touch with you shortly. Okay.

So basically we'll work in this way with, and there are other people here. Good people who probably are related to other organizations and you should be thinking also about what contact might be there. But we have to watch out for that tendency to sort of go from nowhere to all of a sudden we're reaching out to 15 organizations. And then it just

becomes an overwhelming task. And the NRC can't quite keep up. So we have to balance our enthusiasm with pragmatism.

Yes.

MEMBER COSTELLO: Philip, since I'm a member of the Committee, it's not addressed to the medical practitioners. But I do update the Organization Agreement States and activities of the ACMUI. Now for the most part, they're pretty familiar with the regulations. But all these parties are interested in what we do here.

I'm on the agenda every year, and I update them on the many issues that you listed for the Commission yesterday. And I do it every year.

CHAIRMAN ALDERSON: Good, great. Well I think that we have a starting point. That is the point of contact. We have already made some contacts and learned some things. So in fact I would hope that the people that we just talked about and named would actually begin to make those contacts.

And then I would say that if you would work through Sophie and myself on how these things are evolving. Just email us and so on and that should suffice. And then we can see where we do from there.

And Mr. Fuller would like to comment.

MR. FULLER: Thank you Dr. Alderson. Mike Fuller with the medical team. I just wanted to share a little bit about my own personal experience with how successful this can be. This is also very, very, this communication, this two-way communication or this effort to continually open up these lines of communication is very, very beneficial to us when it comes to specifically the emerging medical technologies.

If we follow a normal process, which means a normal fulcrum or process, where we don't really know about new technologies until someone applies for it. We have, I mean there's no better way of saying it. We have failed. Because we will be in the way. We will be the deterrent or the obstacle.

So through these communications, and I could give you many, many examples in the last few years, where we have sort of under our own initiative, but at the invitation of various professional societies -- and I'm taking another opportunity because this is a public meeting. The earlier that we know of something that's in the pipeline or coming down the road, the better.

I can give you examples, I'm not going to name names, but I could give you examples of how this

has been extremely successful in my opinion because I found out about something at a national meeting. Simply by going on the exhibit hall, and walking around, and asking questions.

And then I could give you examples of where we found out too late about something. And by the time we got our, we kind of got up and running and got focused on it, that perhaps the medical community could have benefitted from the availability of this newer technology, or a new drug, or what have you, sooner.

So I just applaud this. I think we all on the medical team and NRC staff would agree that there's really nothing negative that can come from this initiative. And I thank you for the effort and the initiative.

CHAIRMAN ALDERSON: Thank you. Well I think that we have a plan about how to move forward at this particular time. Let's implement that plan.

We have actually run over our allotted time for the open forum by just a few minutes. And Sophie is prepared to provide some important logistic details in what we call the Administrative Closing. But remember we still have a very important session coming up from Esther Houseman. So we still have some

good things to do here.

MS. HOLIDAY: Okay. So to follow-up from my presentation yesterday. This is your second most important presentation that you'll hear.

(Laughter.)

MS. HOLIDAY: And that is planning for your next meeting which will be the fall meeting. And as we stated that is typically held in September and October. And then prior to this meeting I do send out a meeting wizard to pulse the Committee on their availability.

I am happy to say that all members said they were available September 14th and 15th. I'd like to confirm that that has not changed. It's very hard to see. It's the very last page in your packet.

VICE CHAIRMAN ZANZONICO: Sophie, just from the 6th through the 9th, actually through the 10th is the World Molecular Imaging Congress meeting.

MS. HOLIDAY: Okay.

VICE CHAIRMAN ZANZONICO: And I'll be there. But I don't know if other people will be there.

MS. HOLIDAY: Sure.

CHAIRMAN ALDERSON: The dates again, Sophie that you were proposing?

MS. HOLIDAY: September 14th and 15th that is a Wednesday and a Thursday.

MEMBER LANGHORST: So that is not a time I can be here.

MS. HOLIDAY: Not for you.

MEMBER LANGHORST: And I think I said that.

MS. HOLIDAY: Okay.

MEMBER LANGHORST: There is a meeting in St. Louis on moly-tech supply. And I really want to be at that meeting.

MS. HOLIDAY: Okay. Then I stand corrected, I think that's the only day that only had one conflict. Sorry, Dr. Langhorst.

MEMBER LANGHORST: That's okay.

MS. HOLIDAY: With that being said, that's the only date that only had one person as a conflict. So I think as it stands that might still be the Committee's first choice. I know not preferable.

The only other options I had in yellow although there some that Dr. Zanzonico said, the week of the 4th is out of the question since there is a conference going on that week.

I had responses for September 1st and 2nd. And then October 6th and 7th, so I'll start with the

September 1st and 2nd. Does anybody have a conflict for September 1st and 2nd?

(No audible response.)

MS. HOLIDAY: Okay. Likewise does anybody have a conflict for October 6th and 7th?

MEMBER ENNIS: Those are my -- I think Friday would be difficult for me. Friday is my wife's birthday. If home for it. But I don't have --

MEMBER LANGHORST: Sophie, just to clarify, the 1st and 2nd is the Thursday, Friday before Labor Day weekend. But that's okay with me. And the 6th and 7th is before, in case anybody has that day off, Columbus Day.

MS. HOLIDAY: I mean you don't want to spend your last few days before a holiday with me?

MEMBER LANGHORST: I have no problem at all because your name is Holiday.

(Laughter.)

MEMBER COSTELLO: I think I just said to you one day, but I can't recount now though. I forget what my one day is.

MS. HOLIDAY: Okay. Dr. Langhorst if I may ask, is your meeting on the 14th and the 15th, or just the 14th?

The other option I had was September 15th

and 16th.

MEMBER LANGHORST: The meeting that I have conflict with starts on the 11th and goes through the 14th.

MS. HOLIDAY: Okay. So that means there's high likelihood that you'd not be able to make for the 15th and 16th meeting.

MEMBER LANGHORST: Not on time.

MS. HOLIDAY: Yes. Okay, so then it sounds like we can either go with our first choice as September 1st and 2nd with a conflict for Dr. Ennis.

Or September 14th and 15th which is a conflict for Dr. Langhorst.

Or did anybody have an issue with coming October 6th and 7th? Understanding that that is Mrs. Ennis' birthday weekend.

MEMBER ENNIS: I could leave early --

MEMBER LANGHORST: We could have Dr. Thomadsen send her flowers.

(Laughter.)

MR. OUHIB: It's actually becoming Mattmuller's responsibility to go.

CHAIRMAN ALDERSON: So either of these dates that you're talking about is fine with me, but I didn't understand the discussion about the 15th and

16th. Because your meeting ran from the 11th to the 14th, right, so?

MEMBER LANGHORST: Actually it goes through the 15th.

CHAIRMAN ALDERSON: Oh, it goes through the 15th. I'm sorry.

MEMBER LANGHORST: The 15th, okay, sorry. I was --

CHAIRMAN ALDERSON: I missed that part. All right so that's fine.

MEMBER LANGHORST: I would prefer October 6th and 7th.

MEMBER LANGHORST: Sorry, but --

MEMBER ENNIS: Okay if everyone would be okay with me leaving at noon? And that works in my personal area.

CHAIRMAN ALDERSON: And the meeting is usually over in the early afternoon.

(Simultaneous speaking.)

MS. HOLIDAY: No, the fall meeting is our longer meeting, since that's when we have all of our annual required training such as ethics, allegations, and information security. We can plan that for the first day, that you can meet your annual required training. It's too early to kind of plan when the

meeting will actually end.

But given that we can plan around that, so I guess with that being said. Perhaps our first choice then will be October 6th and 7th for the Committee.

And then your second, your backup date would you like that to be either Sept 1st and 2nd or September 14th and 15th?

CHAIRMAN ALDERSON: 1st and 2nd. I think we should try to have Dr. Langhorst here.

MS. HOLIDAY: Okay. So then to confirm, I have our first choice for the fall meeting as October 6th and 7th. And our backup date as September 1st and 2nd.

Okay, so at this time I would like to go over the new recommendations that were mentioned during this meeting.

As you will see on the screen -- I will provide this electronically and hard copies to the Committee prior to your departure today.

Item 16 was not on there before, but since Dr. Alderson mentioned it during yesterday's open forum, this is when he formed the Sub-Committee to review and evaluate the training and experience requirements for all modalities in CFR Part 35.

Sub-Committee members include Dr. Langhorst, Dr. Metter, Dr. Palestro as the Chair, Dr. Suh and Ms. Weil.

Are there any comments or questions about Item 16?

(No audible response.)

MS. HOLIDAY: Okay. Moving on, Item 17 and 18, and also Item 19 on the following page, have to deal with the teleconference meeting that we had on last Thursday related to the training experience requirements for authorized users of alpha beta gamma emitters and their 10 CFR 35.390.

Those items were not on your lists earlier, so I've added them now that our meeting is in session.

So Items 20 through 22, relate to the spring meeting that we have had these past two days. Item 20 is the action item that Mr. Fuller suggested. That NRC staff will provide data to the ACMUI for medical events reported over a five year span, for training purposes. And I will provide that data to you prior to the fall meeting.

Item 21, Dr. Alderson formed a Sub-Committee today to 1) explore the impact of medical event reporting and its impact on self-reporting

safety culture, if you will;

2) identify potential ways to improve effectiveness of self-reporting in support of a culture of safety, and 3) suggest ways to share any reports and lessons learned with the medical community to promote safety.

I'm sorry, I forgot to list the Sub-Committee members.

CHAIRMAN ALDERSON: Dr. Langhorst is the Chair. We certainly remember that.

MS. HOLIDAY: Dr. Langhorst is the Chair. We have Ms. Weil. I believe we have Dr. Suh.

CHAIRMAN ALDERSON: I've got it, it's Sue Langhorst as the Chair. Frank Costello is on for States. Vasken, and Susan M is on for medical, legal whatever. Laura Weil is on, Ron Ennis is on. And Mr. Ouhib is going to be a consultant at this time. That is the membership.

MS. HOLIDAY: Excellent. Thank you.

Item 22 is that NRC staff will provide the ACMUI with a draft final 35.1000 licensing guidance document for the Leksell Gamma Knife Perfexion and Leksell Gamma Knife Icon. Interested members will be encouraged to provide comments to the working group, understanding that it will be on an

abbreviated time schedule so that we can issue the guidance as early as possible for the patient community.

The last item I believe, Item 23 is that Dr. Langhorst requested that NRC staff provide the ACMUI with the total number of medical use licensees within the United States. This includes NRC and Agreement States.

I did forward that to you guys during this meeting. So that will be waiting on you in your email. And since I did send it, I am asking if can close this item as it is now sitting in your email in-boxes?

MS. HOLIDAY: Just to clarify, the document that I provided breaks down all materials licenses including industrial, medical, and academic. So that document does include the data that you're looking for.

So does anybody agree to my closing Item 23?

MEMBER LANGHORST: I'd like to just say I want to see it before it closes. Sorry, I can't. I'm not ready to do that instantaneously.

MS. HOLIDAY: Sure I can tell you that Ms. Weil's pulled it up in your email. But it does

include the information.

MEMBER LANGHORST: I'd like to look at it and think about it. So if you don't mind, I think that we could close it next time.

MS. HOLIDAY: That's fine. I'll just follow up at the fall meeting to say that I provided it on the 18th.

MEMBER LANGHORST: That would be great.

MS. HOLIDAY: And then Item 24, obviously not listed is that we have planned the fall meeting with a first choice as October 6th and 7th. And your second choice, or backup date as September 1st and 2nd.

CHAIRMAN ALDERSON: I think you should have an item in here about this extensive discussion we just had on how we're going to begin to implement the communications plan.

MS. HOLIDAY: I didn't include it because typically items that we include are items that staff will be doing, or providing to the ACMUI and then if the ACMUI requests something from the staff, or a Sub-Committee is formed, or a recommendation is passed. If you do feel that this is an action item, and it should be captured. I'm more than happy to add that.

CHAIRMAN ALDERSON: Well that's an action

item because as we make contacts and this effort evolves, we're going to come back to you and to Mr. Bollock and look for your availability to join us in this implementation plan. So there will in fact be items for the NRC. And there will be budget impact, although modest, there will be budget impact.

MS. HOLIDAY: Okay, so then the action item will be, the ACMUI will contact their respective professional organizations for possible interactions between NRC staff and ACMUI members with their societies.

CHAIRMAN ALDERSON: Yes, that's fine. I accept that.

MS. HOLIDAY: Okay.

MR. BOLLOCK: Can I just --

MS. HOLIDAY: Sure.

MR. BOLLOCK: As you know Lynne pointed out, we already in a lot of cases, we do already have a lot of conferences, right. So we can, we do have contact information that work with us, ASTRO, SNMMI, so we do already have a lot of those contacts. So you don't have to reinvent the wheel. Or --

CHAIRMAN ALDERSON: No, we won't. Right.

MR. BOLLOCK: So we'll provide you with that, who we have just so that the ACMUI members are

talking to the same people that we talk to.

CHAIRMAN ALDERSON: And so the people who are going to talk to those respective organizations, you need to be in touch through Sophie, with Mr. Bollock, and work in particular way.

And the wording that Sophie just used was sufficiently general and vague that it allows us to do those sorts of things. That's the reasons for it.

MS. HOLIDAY: I think you have a comment from Dr. Howe.

DR. HOWE: It's not about this one, but one of the earlier ones --

CHAIRMAN ALDERSON: Microphone.

DR. HOWE: Not about this one, but one of the earlier ones. I believe when you were, when I was giving my medical event, that you wanted to see the five year on --

CHAIRMAN ALDERSON: That was mentioned.

DR. HOWE: -- every time I give it.

CHAIRMAN ALDERSON: Every time you give it?

DR. HOWE: Yes, and when I give it you want to see five years. And then I go into the rest of it.

CHAIRMAN ALDERSON: That's correct.

DR. HOWE: Sophie was entertaining that it was like a one-time thing that she would provide information.

MS. HOLIDAY: I didn't define it as a one time. I just said that they would have the data before the next meeting.

It wasn't conclusive to say that they would only be getting it at the next meeting and that would stop.

DR. HOWE: So --

CHAIRMAN ALDERSON: It's assumption based on the discussion we had when Mr. Fuller pointed out. The word for something like this, well it might be a little hard the first year, but once we get the data put together it'll be really easy to do it year after year.

MS. HOLIDAY: Exactly.

DR. HOWE: So the expectation is every time I give the medical data, I include that, not that I have to do something separate for the fall meeting?

CHAIRMAN ALDERSON: That's right.

MS. HOLIDAY: That's correct.

DR. HOWE: That's fine.

CHAIRMAN ALDERSON: That's good.

Yes.

MEMBER ENNIS: Mike Fuller had offered much more than that slide gave us.

DR. HOWE: He had indeed.

MEMBER ENNIS: So I just want to be clear, what we --

(Laughter.)

MEMBER ENNIS: Are you talking about giving five years, or are getting decades' worth of data going forward.

MR. FULLER: The way I took the action, that I read up there, is that we'll provide a minimum of five years. How's that?

MEMBER ENNIS: Sounds good.

MR. FULLER: I want to give, what we want to do is take a look at what we have frankly, and let's provide you with the most meaningful and beneficial information and data that we have. And present it in a way that's most helpful. So at a minimum it will be five years. And then we'll see what else we can do.

CHAIRMAN ALDERSON: Yes, I think as you lengthen out the years, you sort of magnify the denominator problem. And maybe five or six years doesn't make a difference. But something that hardly anyone ever talks about when they talk about all these

issues going on in medicine, is we have about 30 or 35 percent more people in the United States now, than we had just 30 years ago. And it makes a big impact in a lot of different ways.

So as you go out too long, then the denominator problem becomes really complex. So I think a minimum of five years is a very nice way to start. If that's all right with you, Dr. Ennis?

Thank you.

MS. HOLIDAY: Thank you. Then that concludes my administrative closing portion. This is also our time and labor week. And generally I would have sent you an email to tell you to give me your hours. But since you're here, you may write your hours down on a piece of paper. And we'll let you officially adjourn the open session before our session this afternoon.

CHAIRMAN ALDERSON: All right. Are there any other items, new business to come before the meeting before we officially adjourn the open meeting?

(No audible response.)

CHAIRMAN ALDERSON: Hearing none, a motion to adjourn. All in favor?

(Chorus of aye.)

CHAIRMAN ALDERSON: Thank you. We are

adjourned.

(Whereupon, the above-entitled matter went off the record at 11:37 a.m.)