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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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FALL 2018 MEETING

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FRIDAY,

SEPTEMBER 21, 2018

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The meeting was convened in the Commissioner's Hearing Room, One White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:30 a.m., Christopher J. Palestro, ACMUI Chairman, presiding.

MEMBERS PRESENT:

CHRISTOPHER J. PALESTRO, M.D., Chairman

DARLENE F. METTER, M.D., Vice Chairman

VASKEN DILSIZIAN, M.D., Member

RONALD D. ENNIS, M.D., Member

RICHARD L. GREEN, Member

MELISSA MARTIN, Member

MICHAEL D. O'HARA, Ph.D., Member

ZOUBIR OUHIB, Member

ARTHUR SCHLEIPMAN, Ph.D., Member

MICHAEL SHEETZ, Member

MEGAN L. SHOBER, Member

JOHN H. SUH, M.D., Member

LAURA M. WEIL, Member

PRESENT VIA TELECONFERENCE:

PHILIP O. ALDERSON, M.D., Former ACMUI Member

NRC STAFF PRESENT:

DOUGLAS BOLLOCK, NMSS/MSST/MSEB, Designated Federal Official

RUSSELL CHAZELL, SECY/RAS

SAID DAIBES, NMSS/MSST/MSEB/MRST

MARC DAPAS, NMSS

LISA DIMMICK, NMSS/MSST/MSEB/MRST

CHRISTIAN EINBERG, NMSS/MSST/FSTB

SOPHIE HOLIDAY, OE/EB

DONNA-BETH HOWE, NMSS/MSST/MSEB/MRST

KATIE TAPP, NMSS/MSST/MSEB

CONTENTS

P R O C E E D I N G S

8:42 a.m.

CHAIRMAN PALESTRO: I'll call the meeting to order. Yesterday we began by introducing new members to our committee. Today we come to the opposite side of the coin and we say goodbye to two individuals who are not only stalwart members of this committee, but far more importantly, have become our very good friends.

And so at this time, I'd like to turn the meeting over to Mr. Marc Dapas, who is the Director of the Office of Nuclear Materials, Safety, and Safeguards. Mr. Dapas.

MR. DAPAS: Thank you, Dr. Palestro. I apologize for being late. The Metro didn't cooperate. I have to say it feels a little peculiar sitting in this seat. It's normally reserved for the Chairman of the NRC when she has a Commission meeting with us. So no delusions of grandeur here.

Well, first and foremost, it's a great opportunity to acknowledge the service on the Advisory Committee for the Medical Uses of Isotopes of Dr. Suh. He has served on the ACMUI since October of 2010, and he was renewed for a second term in 2014.

Dr. Suh has demonstrated expertise in the

field of radiation oncology, especially in gamma knife radiosurgery. In fact, he served as Chair of the Subcommittee on physical presence requirements for the Leskell gamma knife icon, and as well as the gamma knife Perfexion and the Leskell gamma knife Icon draft licensing guidance Revision 1. I hope that got that correct.

But we much appreciate the expertise that you were able to provide in supporting that particular subcommittee. He also served on the medical event reporting for all modalities except for permanent implant brachytherapy. And with respect to chairing this particular subcommittee, Dr. Suh provided particular expertise and input to help the Committee in their deliberations.

During the time that Dr. Suh has been on the ACMUI, the staff has benefitted from his expertise in a number of high priority issues, including permanent implant brachytherapy, as reflected in the subcommittee that you chaired.

The hormesis and linear no threshold petitions for rulemaking. The analysis of yttrium-90 microsphere brachytherapy medical events. A review of NRC's medical use policy statement. And then revisions to Nureg 1556, Volume 9, consolidated

guidance about materials licensees, program-specific guidance about medical use licenses.

And most importantly, training and experience requirements, which has been a particularly interesting area of our regulatory engagement, and I know that the Committee is currently involved in evaluating training and experience requirements.

Another area that reflects a broad spectrum of views is patient intervention, and I appreciate your engagement in that area. So would like to thank you again for your extensive, eight years of dedicated service here, and we have a few tokens of our appreciation and gratitude that we'd like to present to you.

So first, we have a certificate of appreciation that was signed by our chairman, Kristine Svinicki, and it says, In recognition of eight years of service and leadership to the Advisory Committee on the Medical Uses of Isotopes, which resulted in significant contributions to the work of the US Nuclear Regulatory Commission, dated September 14, 2018. So congratulations.

MEMBER SUH: Thank you.

(Applause.)

MR. DAPAS: And then we have to present to you a flag and associated certificate. And this flag was flown over the United States Capitol on August 21 at the request of the Honorable Chris Van Hollen, United States Senator. As stated on this certificate, this flag was flown for Dr. John H. Suh on the occasion of his completion of eight years of service on the ACMUI. So here, congratulations.

MEMBER SUH: Thank you very much.

(Applause.)

MR. DAPAS: And then lastly, we have gold lapel pin here for you, so.

MEMBER SUH: Thank you very much.

MR. DAPAS: Thank you again for your service.

(Applause.)

MEMBER SUH: Thank you very much. So, and I was reflecting a little bit about what to say last night and I thought I'd get some inspiration by trying to watch the Cleveland Browns win their first football game, which they did, so. So the city of Cleveland may ask me to return again to get some wins.

But I just want to reflect back on my time here, the eight years on the Committee. And when I think about the ACMUI Committee and what the

NRC represents, it's obviously a really important committee. And I don't think I understood what this committee represented until a few years into being part of the Committee.

And you know, I was looking at the website last night about what the ACMUI represents. It represents the important role of providing policy and technical issues in the regulation of the medical uses of isotopes and diagnosis and therapy. So that's a very daunting task for this committee.

And one of the things that I've really had the pleasure over the past eight years is to really work with wonderful people. This is a very diverse group with various different levels of expertise, some different personalities as well. But at the end of the day, we all get, work together for the common good for the patient, for the public.

And at the same time, not imposing on the practice of medicine. Which if you think about it, those three Ps, it's really hard to balance all that, right. Public, patient, and then also the practice of medicine. I think it's very, can be difficult at times.

With this subcommittee, the committees that I've had an opportunity to work on have a done

a wonderful job with that. I want to take this opportunity to thank a few people. I see Chris Einberg there.

I remember interviewing with Chris, I think it was in 2009. I wasn't sure if I was the right person for the job, because they said, well, we need a gamma knife expertise. I said, well, I can do gamma knife. The other stuff about policies and about regulation, I wasn't sure I was the best person for that. But you know, like anything in life, you learn about what those things mean.

I also want to thank Doug Bollock for his leadership and the medical staff, and also the other wonderful people here on the medical staff. It's nice to see Ashley, who helped introduce me to how to sign on and get on travel and get reimbursed, and then followed by Sophie Holiday, who did a wonderful job as well. So I want to thank them.

I also want to thank Cindy Tomlinson from ASTRO, who I've gotten to know very well through the years in terms of some of the physical process requirements and other medical events requirements we were trying to do within the Subcommittee.

So I'm going to leave with a few thoughts here in terms of my thoughts in serving the ACMUI. I

would really encourage the Committee to continue its excellent work in terms of medical events.

I'm a very staunch advocate for quality and safety, and I think it's really important that this committee continues to remember that quality and safety really needs to be a number one priority for this committee. So I would really encourage each and every one of you to continue that.

The other thing I would also mention is I think as the Committee, it's also important to share best practices. I think sometimes, and I'll be very honest with you, before I became a member of the ACMUI, I didn't know what this acronym stood for. Which, maybe it's part of my ignorance, but I think it's something where I think we need to do a better job in of promoting what the ACMUI represents and also the important role that it has.

Safety culture is also another area I think we can do some good in terms of safety culture. I think as we heard yesterday from Ron Ennis, the fact that we don't do timeouts universally on every patient who undergoes any diagnostic or therapeutic procedure in radiation is something that needs to change. I think that's hopefully something that continued to be messaged as well.

There's also a clear need for data as well. I think sometimes in our deliberations we ask, you know, what's the numerator, what's the denominator. It would be nice, moving forward, if we really had true numbers in terms of what the numerator is as far as the denominator.

And last point I want to make is I think it's wonderful that the ACMUI is reaching out to the professional societies. I had the opportunity to give a brief presentation to ARRO, which is the Association for Residents in Radiation Oncology. I think it opened their eyes in terms of what this committee does, the important work it does, how quality and safety really ties in to policies as well as regulations as well.

So I'd end by thanking everyone who I've the association of developing very keen friendships with. I hope to keep in touch with many of you, and thank you very much.

(Applause.)

CHAIRMAN PALESTRO: John, on behalf of myself and of course the entire ACMUI, I'd like to thank you for all that you've done. And it has been a delight working alongside you. I know that for family reasons you oftentimes are in the New York

metropolitan area, and by all means, if you have time, stop by. The door is always open, look forward to seeing you.

MEMBER SUH: Okay, thank you.

MEMBER ENNIS: I've really enjoyed working with you and getting to know you. And obviously being a great resource as to radiation oncologist on the Committee. And my only hope is that we can continue to work together and stay in touch.

(Off-mic comments.)

MR. DAPAS: I did want to just offer that I do regret that I haven't had the opportunity to interact with you more frequently.

But I do very much appreciate the work of the ACMUI and the considered thought that you provide and the suggested input that you provide to the NRC staff as we're trying to determine what is the best regulatory approach in dealing with a number of challenging medical issues.

I mentioned training and experience. Patient release is another area that there is a broad spectrum of stakeholder views, and I know that my team very much values the input that all of you provide as you give very considered and deliberative

thought to those challenging issues. So thank you on behalf of the NRC staff.

And I appreciate what you said, Dr. Suh, about the support that you did receive from the staff in helping you be successful in your role in the Committee, so thank you.

CHAIRMAN PALESTRO: Dr. Alderson, are you on the line yet?

MEMBER ENNIS: Chris runs such efficient meetings we're always ahead of schedule.

MR. DAPAS: The agenda said nine o'clock, correct? Sure.

CHAIRMAN PALESTRO: John, this isn't really an ACMUI topic, but you brought up the Cleveland Browns winning.

MEMBER SUH: Is this being transcribed?

CHAIRMAN PALESTRO: It seems only fitting that they would beat the Jets. If there is a team who, there is no team more successful at figuring out how to lose than the New York Jets.

MEMBER SUH: I should be very careful what I say, because there could be someone from, well, when you go two seasons without winning a game, it's. But I'm glad that a New Yorker has admitted that, so. Since there are a few New Yorkers around this table,

so that's good.

MR. DAPAS: Oh, well, I enjoyed that Red Sox victory last night. I'm from New England, and I'm a diehard Red Sox fan. So clinching the playoff berth in a defeat over the Yankees is a special day for me.

MEMBER ENNIS: I'm with you, Marc, but I turned it off when they gave up the grand slam to Stanton. So I missed the comeback.

MR. DAPAS: I missed that. I turned it off when it was the eighth inning and Betts hit a home run, I thought, well, that's it, eleven to six, good to go. So I missed a grand slam. Oh, okay.

CHAIRMAN PALESTRO: Dr. Alderson, are you on the phone?

DR. ALDERSON: I am.

CHAIRMAN PALESTRO: Morning, Phil, how are you?

DR. ALDERSON: Very good, thank you.

CHAIRMAN PALESTRO: All right. Again, at this point, I'm going to turn the session over to Mr. Dapas.

MR. DAPAS: Well, thank you. Another opportunity to thank an individual for their service on the ACMUI. Dr. Alderson has served on that

committee since March of 2014. He was renewed for a second term in 2018, at which time Dr. Alderson agreed to stay on the Committee until a replacement member could be selected.

Dr. Alderson was appointed Vice Chair of the ACMUI in January of 2015 and was appointed Chair of the Committee in October 2015. He also had the opportunity to brief the Commission during the public Commission ACMUI meetings on several occasions, including March of 2016, where he provided an overview of ACMUI activities and discussed enhancing ACMUI communications.

And then he also had the occasion to present and speak before the Commission in April of this year and March of this year, where he again provided an overview of ACMUI activities.

During Dr. Alderson's time on the ACMUI, the staff has benefitted extensively from his expertise in regards to, on a number of high priority issues, including the hormesis linear no threshold petitions for rulemaking. In fact, Dr. Alderson served as Chair to the review of the hormesis linear no threshold petitions for a rulemaking subcommittee.

He also provided input on review of the NRC medical uses policy statement and Nureg 1556,

Volume 9, which provides consolidated guidance about materials licenses program, specific guidance about medical use licenses.

He also has provided input on licensing guidance for radioactive seed localization for non-palpable breast lesions. And then also contributed to a review of the staff's evaluation of training and experience requirements for administering radiopharmaceuticals.

At this time, to signify our appreciation for his four years of service on the ACMUI, we do have some things to present. We will be sending a flag to you. I know they say that the check is in the mail here, but I am told that the flag will be mailed to you. I think there was a slight correction that had to be made on the certificate.

But that flag was flown over the US Capitol, again at the request of Senator Chris Van Hollen from Maryland.

I also have a certificate here signed by our Chairman, Kristine Svinicki. It says, In recognition of four and a half years of service and leadership to the Advisory Committee on the Medical Uses of Isotopes, which resulted in significant contributions to the work of the US Nuclear Regulatory

Commission. And that was signed and dated September 14, 2018.

And similar to Dr. Suh, we also have a gold lapel pin that we will be mailing to you. So I hope that both of you, Dr. Suh and Dr. Alderson, have a chance to continue to engage perhaps in the future, and you can share your gold lapel pins here.

MEMBER SUH: I'll start wearing it right away, so.

MR. DAPAS: Thanks. But Dr. Alderson, again, thank you for your dedicated service and the support that you have provided to the Committee as they've deliberated on a number of important issues germane to our regulatory oversight and the beneficial practices of medicine. So thank you.

DR. ALDERSON: Yes, you're welcome.

(Applause.)

DR. ALDERSON: Is it time for me to make a few comments now?

CHAIRMAN PALESTRO: Yes, go ahead, Phil.

DR. ALDERSON: Thank you. Well, I do want to thank everyone. I really thank the NRC for providing me the opportunity to meet with you today in this long distance approach.

When we last spring talked about

potential dates for a meeting this fall, I had no idea that this would fall at the very same time that my daughter and her husband and three grandchildren, who have lived in South America for the last several years, the only time they could visit at St. Louis was this week. It's actually spring vacation week down in Buenos Aires, where they live.

So when I found that out, and we had already gone through the decision process of my stepping back from the Chairmanship, I really realized that this ceremony being the primary reason for me being there, this probably wouldn't be a time that I could make it. But I really do appreciate the fact that we were able to set up this call in this way.

And I do want to thank all of my colleagues on the ACMUI who have supported the various things that you were just told about that, things that we launched and did during the time that I was with you and was privileged to serve as your Chair.

And I wanted to specifically point out two or three people who I think deserve some special recognition. From the NRC side, you know the NRC staffing changes so often, but Sophie Holiday, I hope you're in the room, Sophie. I mean, you have been a

tremendous support to me during my chairmanship.

Obviously to my predecessors, and you will be to Dr. Palestro and his team as they move forward. It's been a pleasure to work with you, and I hope that you continue to serve for a long time. The ACMUI needs your support.

I wanted to briefly comment on two or three past members of the ACMUI who no longer are with you. It was just a wonderful group that we had. Certainly we all miss Frank Costello. He was a superb state's representative and did great work with us. And always knew how to advise us about how to make things work because he had been such a long-serving person in the NRC and the government.

And no one can forget Sue Langhorst. I mean, Sue Langhorst had, it seemed to me, a virtually encyclopedic memory of all the NRC data books. She could quote chapter and verse of regulation and brought great, great insight. I appreciated her energy on the Committee, and it helped us do a lot of things.

Pat Zanzonico was my Vice Chair, and Pat brought great expertise to the process. And to all of you, and I'm not going to go through and, I decided I could talk about each one of you who served with,

the time that I was on the chair.

But the fact is that then I would inevitably forget to say the right thing about one or more of you, and I really do value each and every one of you. And that's the basic reason I'm sorry that I can't be there today to share these moments with you.

I did want to make a couple of comments just about the fact that I know we all respect radiation. We probably wouldn't agree to serve on this committee, or even be eligible to serve on this committee, did we not share that particular outlook. Sophie, this would be the time to have the slide on the screen that I sent to you, so I hope that that's up there now.

What you see on the screen is the radiation memorial. They exist in Semey, Kazakhstan, which is a place somewhat remote and unlikely common place for any of you to have traveled.

But I had the privilege of traveling there in the spring of 2016 as their guest when we were considering possible associations, affiliations between the medical school that exists there in Semey, one of the five state-sponsored schools in Kazakhstan, and St. Louis University, of which at

that time I was the Dean.

So it was official business and the NRC knew I was going there and we cleared all that before I left. It was a very interesting trip. And this was one of the most interesting sites. This very tall and impressive memorial testifies to the fact that the people in Semey unfortunately suffered from radiation. Semey is at the very far eastern tip of Kazakhstan.

Kazakhstan's a very large country in central Asia, and at just beyond 20, 30, 40 miles beyond Semey is the western tip of Mongolia, to give you an idea of where this is. This unfortunately was about 60 miles sort of west-northwest of the main Soviet nuclear testing site. During the era of the Cold War in the 50s, the 60s, hundreds of detonations about ground were taking place at that testing site.

And the people in Semey and in Kazakhstan, in this area of Kazakhstan, were unfortunately the victims of all those things that happen with fallout, the cancer clusters, the thyroid disease, the birth deformities. And to such extent that they consider themselves a sister city with the cities in Japan that were bombed during World War II.

This memorial, this very tall memorial,

shows the atom at the top with its power breaking through the structure of the protective barrier all the way down to the bottom. And you probably can't see exactly what those images are at the very bottom. That is, the sculptor has created the image of a mother on her knees crouched over and trying to protect her baby from the radiation.

So it really I think makes an impact on what these people suffered. And other people in other parts of the world, and we all know about Fukushima and Chernobyl and places like that.

And even here in St. Louis, we have our own special little problem in this regard, because the Mallinckrodt Chemical Company was one of the agencies of the federal government that agreed to help make materials during the World War II time when the bombs were being created.

And when that was over, there was a lot of residual of those materials. Eventually, those materials were moved out to what was then remote St. Louis County and were buried. Now, you couldn't do that today. I mean, there are too many regulations about these things.

But in fact these areas, what's called the West Lake Landfill, still do exist, and they have

created all the controversies here in St. Louis because now there are some cancer clusters in an areas called Coldwater Creek where some water comes from areas that might have been some seepage.

Well, I'm not going to give you all the details, but the fact of the matter is it's another example of the power of radiation and how we have to always respect that power. And I believe that as members of the ACMUI advising the NRC have to always remember the power of radiation and protecting the public from radiation. That is our primary goal.

And yes, there are other goals that have come out as we have now begun to reconsider the educational process, so what really is required for someone to handle radioactive sources. And well, those things are important.

But I hope that as we go forward and consider the balance between public convenience and availability of therapies with the issue of radiation safety, I think that we, and I speak really now as a member of the general public because my term officially I think ended yesterday or the day before, I think we have to come down with the ratio favoring radiation safety.

And it's that respect for radiation that

I wanted to use with the Kazakhstan memorial to make that point. We just have to keep considering these things and realize that that is our strongest goal.

Well, I don't want to belabor these points. I think that the memorial is a very beautiful and interesting testament to what's gone on in Kazakhstan. It was a pleasure, a privilege to be there and to be able to see it.

And it's been privilege and pleasure to work with all of you. I certainly think now with Dr. Palestro, Dr. Metter in charge, you have a great new leadership team. I know that the NRC is very engaged with the myriad of problems that we've discussed. I think you're on a good track. And I wish all of you, all of you the best and future success in your important work. Thank you very much.

(Applause.)

CHAIRMAN PALESTRO: Phil, this is Chris. You know, you and I have known each other now for more than 30 years, and our paths have crossed in a lot of different ways, a lot of different times. But it has always been an honor and a privilege to work with you, for you, and alongside you. And for that I thank you very much. And I wish you the best in the future.

DR. ALDERSON: Thank you very much, Chris, it's been a mutual pleasure.

VICE CHAIRMAN METTER: Phil, this Darlene. And I'd also like to thank you for all the guidance you've given me over these past, I don't think I've known you as long as Chris, but I've known you for other societies with the American Board of Radiology and the other different societies we've been in.

But thank you very much. You've always been a role model for me, and you've really been a great person to look up to. And thank you, and I wish you the best.

DR. ALDERSON: Thanks, Darlene.

CHAIRMAN PALESTRO: All right, thank you very much, Phil, it's been a pleasure.

DR. ALDERSON: Great, have a great day. Bye bye.

CHAIRMAN PALESTRO: All right, we're going to move along now, and the next topic, Dr. Tapp is going to present on Y-90 microspheres brachytherapy licensing guidance. Dr. Tapp.

DR. TAPP: Thank you, Dr. Palestro. Today I'm going to talk about an update to the yttrium-90 microsphere brachytherapy licensing

guidance. Next slide, please.

I have three topics to cover today. First, I want to talk about the status of the current revision that the NRC and the organization of agreement states are working on, Revision 10 of the licensing guidance. Then I want to talk about an evaluation of medical events associated with the yttrium-90 microspheres that the NRC conducted earlier this year.

And then a future project on comprehensive training and an experience evaluation associated with yttrium-90 microspheres licensing. Next slide.

So to start, we're going to talk about the current work on updating the licensing guidance. As you may remember, last January we submitted the licensing guidance in the Federal Register asking for public comments. This is the first time we requested public comments on a 10 CFR 35.1000 licensing guidance.

In addition, in July, as we all know, the Part 35 rule was finalized and was published, and that is going to become effective in January of this year. So right now the NRC and the Organization of Agreement States Working Group is in the process of

reviewing the public comments that we received from the public comment period and reviewing the final rule to make applicable changes to the licensing guidance. Next slide, please.

In the public comments, we received over 100 letters from different commenters, 103 of these commenters used the same template letter. So we received about 30 different comment letters from different individuals, from societies, from manufacturers, users, and members of the public.

The majority of the commenters commented on the manufacturer training pathway. This is the pathway that allows the manufacturers to provide AUs training to get their status and to become authorized users. This pathway is known as Pathway 2. Next slide, please.

The majority of these commenters recommended the retention of this pathway allowing the manufacturers to continue providing this training to future AUs. Their reasoning is that manufacturers have vast experience and can provide consistent training. They can keep up to date with current events and provide status updates quickly.

They also, commenters stated that the onsite training that the manufacturers provide to the

entire team at the sites promotes patient safety. And they had concern that there is limited training facilities if the manufacturers were not allowed to come to the sites to provide this training and the AUs had to go to find other AUs. There is public concern that there wasn't enough training facilities for that purpose.

For these reasons, again, the majority of the commenters recommended to keep this pathway allowing the manufacturers to provide this training. Next slide, please.

Four commenters did recommend removal of Pathway 2. Their reasoning was to be consistent with other modalities, to ensure the trainers are physicians and not manufacturer representative. And one commenter was concerned that there was too strong of an industry push, and then if you removed the manufacturer training, this would support independent physician practice decisions. These are public comments.

In addition to the training experience Pathway 2 comments, we received public comments on written attestation, that they also had a comment that there's a new American Board of Radiology Board certificate for interventional radiology, and wanted

to update our guidance to capture that.

There were comments on medical events, radiation safety officer training, post-treatment surveys, possession limits, and then other authorized user training requirements. So we received a gamut of comments there, but not as many as the Pathway 2. Next slide, please.

So as I mentioned that the NRC and Agreement States are working right now to review these comments, update the licensing guidance, as well as review the rule and make sure we capture any changes in the rule that could affect the guidance. Once we have a final draft, we will provide that to the ACMUI for your review and recommendations.

We will also at that time provide the final draft to the regions and the states for their comments, and it will be also some time, because we have to do a congressional review on the guidance. So before it's published, there is some more steps we have to take before the guidance will be final. Next slide.

So now I'm going to change topics and talk about the evaluation of yttrium-90 microsphere medical events that the NRC conducted earlier this year. Next slide. This was, the evaluation results

were presented at the Agency Action Review Meeting to the Commission in June of this year.

This evaluation was completed at the request of NRC staff after there was concern that there was increase in yttrium-90 microsphere medical events in recent years. Next slide.

This evaluation examined three specific areas, the regulatory requirements associated with yttrium-90 microsphere use, use of post-treatment imaging determining dose delivery, and potential licensee performance trends. Next slide.

At the conclusion of this evaluation, their recommendations were requiring post-treatment imaging would not recommended. This was something that the ACMUI previously had recommended to the staff, was to not require post-treatment imaging. And there was no change in that recommendation, the staff did not find a need at this time to require post-treatment imaging.

There was no negative performance trends or regulatory gaps identified, and it was also identified, getting some information from the manufacturers, that the number of medical events reported have been increasing over time. But this increase is commensurate with the increase in

yttrium-90 use.

Yttrium-90 use has been increasing over years, and the medical events have just increased with that number. They have not, the incident rate has stayed the same. Next slide, please.

And my final topic I want to talk about today is a comprehensive training and experience evaluation. Next slide. During the public comments that we received, we received numerous comments that stated the manufacturer representatives can provide better training than AUs. So we're allowed, for yttrium-90 you're allowed to either have manufacturers provide training, or AUs train other AUs.

As I stated that the majority of commenters wanted to keep this manufacturer representative training, but the commenters went above that and even stated that that training is better than AU training to AU.

There also was commenters stating that there is a need for onsite training, that this may be something that needs to be done to promote patient safety. So the Working Group wanted to evaluate this further.

And then we have had recent enforcement

actions and inspection insights that show there possible is an AU knowledge gap in written directives ordering medical event evaluation and calibration. So again, the Working Group wanted to look into this further. Next slide, please.

The current training requirements are listed in the 10 CFR 35.1000 licensing guide, and this is a recommended pathway for individuals to become authorized users. In this guidance, it has multiple pathways. This is because there's multiple different types of authorized users.

There's nuclear medicine physicians, radiation oncologists, and interventional radiologist, who would become users for yttrium-90. So there's different pathways depending on what type of position the individual is.

And then they're allowed to either have manufacturer training or AU training to provide the clinical use training. Next slide, please.

For radiation oncologists and nuclear medicine physicians, the general requirements are that they meet the standard in 10 CFR 35.390 or 490, and then they have additional training in the use of the delivery system, the safety procedures, and clinical use for the device.

This can be provided again by the AU, which includes three hands-on cases, or from a manufacturer, which includes three in vitro cases and three hands-on cases. Next slide.

For interventional radiologist, there's a slightly different pathway. They can either be Board certified or demonstrate that they've had three years of supervised diagnostic radiology experience and one year of supervised interventional radiology experience.

This does not have to be an AU-eligible diagnostic radiology experience. This is just they have three years of diagnostic radiology, an experience with use of radiation.

They then additionally have to have 80 hours of classroom and laboratory training for byproduct material, including yttrium-90 microspheres. Next slide.

Like the other pathway, they have to have work experience. And this experience, though, can be provided by an AU or a manufacturer representative. And they also have to have the training in the delivery system, safety procedures, and clinical use.

Again, similar to nuclear medicine and radiation oncology, this training can be provided

from the AU or a manufacturer representative at this time. Next slide, please.

So the NRC and the Working Group may want to look into this further and see if there's any knowledge gaps in these AUs, so anything that maybe we need to look at closer to see if the training needs to change. So right now we're creating an evaluation plan to see how we're going to evaluate this.

The Working Group now has proposed doing an inspection temporary instruction to collect more information. As we know when we get medical events in our NMED, sometimes we don't have all the data there to look and see is it related to the training.

So we're talking about possibly doing an inspection that we can go out and specifically look at knowledge of the AUs involved in these medical events and AUs for yttrium-90, and then report back so the Working Group can evaluate this and see if there is potentially a knowledge gap.

And then this evaluation is definitely, is being separately done from the comprehensive training experience evaluation for radiopharmaceuticals.

This was more in response to the public comments and looking further into the question is the

difference in training people are receiving from the manufacturer versus training from an AU to AU. This is separate from the comprehensive training experience that we've been talking about in the past. Next slide, please.

The path forward, the Working Group is still continuing on Revision 10, and we plan to issue a draft guidance to the ACMUI in Fiscal Year '19. This is going to be done before we complete the comprehensive training evaluation. We just want to get that out, there's changes that we want to start implementing before we do a further evaluation of the training experience.

I think the next slide is the acronyms. Opening it up for questions.

CHAIRMAN PALESTRO: Ms. Weil.

MEMBER WEIL: Just an informational question. Why is the manufacturer training requires three in vitro cases in addition to three hands-on, while the AU training doesn't?

DR. TAPP: So the manufacturer pathway, the individual can do the three in vitro cases first, then be added to a license. And then the representative comes out and they do the three hands on. Whereas AU to AU training, they do everything

up front, and then are issued on a license. And they don't have any more commitments.

I don't know.

MS. COCKERHAM: This is Ashley Cockerham with Sirtex. Just to answer your question on that, the issue is you couldn't do hands-on training with the product because you wouldn't be licensed to actually possess the product. Does that make more sense? See, at least do a cold run, get the license amendment, and then you can order the product, then you can do the real cases.

CHAIRMAN PALESTRO: Dr. Metter.

VICE CHAIRMAN METTER: Thank you, Dr. Tapp, for your presentation. I think there has been a question in the past that has been brought up that the manufacturer training pathway, let's say they do the cold runs, the three that they do, and they get on the license, and then they never complete or they don't complete the three hands-on cases.

Is there a timeframe, or what do you all plan on looking at that? Because I think that could be a potential, and has been, I believe, a problem.

DR. TAPP: As you remember, the draft that went out for public comments has a timeframe associated with it. I believe it was six months

after they were issued on a license to complete their training. There was public comments on that, and the Working Group is evaluating if that timeframe is appropriate.

But the draft that went out for public comments did have that, and the Working Group is considering a timeframe to ensure that recentness of training is done before they have patients and they do a patient case. So it's six right now, the draft had six months.

VICE CHAIRMAN METTER: So again, being the Devil's advocate in the sense of let's say I did it and didn't do my. What happens to it? Do I get off, do you take me off the license then, or what's the consequences of not completing the training?

DR. TAPP: In the draft that went out for public comment, it stated that they would have to have applied to have more training before they could have a patient case. An acceptable example that was provided in the licensing guidance would be one more in vitro case immediately prior to doing a patient case.

So that was an example given in the draft. But again, there was public comments on that, so we are evaluating that and it's not final.

CHAIRMAN PALESTRO: Other comments? Dr. Ennis?

MEMBER ENNIS: Just a question of whether the Working Group has the ability or has looked at if there's a correlation within the reported medical events and what type of preceptor training was done.

DR. TAPP: That's what we're hoping going out and doing a temporary inspection procedure we could provide more information on that. Because right now, NMED does not have that information.

CHAIRMAN PALESTRO: Dr. Dilsizian.

MEMBER DILSIZIAN: Thank you, Doctor. So in the spirit of the medical events under your slides of evaluation of Y-90 microspheres, it says, Requiring post-treatment imaging was not recommended.

So you know, we do post Y-90 treatment imaging, because all times, because the only way you evaluate whether it was a misadministration, whether it was a radio, a Y-90 microspheres going to the stomach or the lungs is the only way, can only evaluate that by post-treatment imaging.

So I guess I wanted to know what the thought process there was. And is this an official not recommended, because we seem to do it all the time in our institution.

DR. TAPP: First, I should clarify that it's not recommended to include in, as a regulatory requirement. We're not saying it's not recommended to do, it's just not a regulatory requirement.

That position was made, or that decision was made based on an ACMUI recommendation to us that the current post-treatment imaging does not have, is not quantitatively accurate enough yet where it's the standard of care.

MEMBER DILSIZIAN: I mean, I just I would like to hear my colleagues' comments, because the only way you would know whether you delivered the dose correctly in the right organ, the right lobe, is to do imaging. Otherwise, it's leap of faith. I just don't understand what the discussion was, at least I wasn't part of that.

DR. TAPP: And to my understanding as to the Working Group is the catheter placement and verifying the catheter is in the correct place at the time is really the only thing currently under control of the medical team. And then for one of the manufacturers is to continuously do the contrast and check on that.

But the catheter placement is what is in the authorized user's control. So we do require them

to know that they put the catheter in the right place, and then to do a performance base. It's up to the institution to determine how they want to verify that they have put the material in the right spot.

MEMBER DILSIZIAN: No, I understand all of that. I just wanted to say that if we're going to be monitoring medical events, there's no way we're going to be able to monitor medical events if we don't do imaging, that's all. I mean, from a regulatory perspective.

CHAIRMAN PALESTRO: Yeah, this is Dr. Palestro. I just want to echo Dr. Dilsizian's comments. I mean, there are certain medical events that you can monitor, for example, if the activity doesn't make it into the patient for one reason or another.

But catheters do slip from time to time, and the potential for administering the activity to the wrong organ certainly exists. And without the post-treatment imaging, you're not going to know that until such time as the radiation complications develop.

DR. TAPP: I think Doug.

MR. BOLLOCK: This is Doug Bollock, NRC. I can address a little bit further what Dr. Tapp has

already spoken about. So we are, we do recognize that without some sort of post-treatment evaluation, as Dr. Palestro said, we're limited in how we know if something went wrong.

But as Dr. Tapp said, the assurance that the procedures went correctly is the catheter placement. And so that is, that's the assurance under 3541 that you've followed the procedure, that it's gone correctly.

As she also stated, the post-treatment imaging is not standard practice to get the qualitative information. So for we understand with microsphere treatments, microspheres could go to other parts, and it could be one or two percent.

And it could, any standard PET I think is a, a standard PET may just, it'll show in other areas, though it's very, very low levels, and you can't quantify that to know whether it was just part of the treatment, or was it the catheter moved, you didn't get the full--

DR. TAPP: I should clarify, he said PET but its standard SPECT would not provide that.

MR. BOLLOCK: Sorry, yeah. So it's for standard SPECT that you may not get that. But again, we do recognize that, and this is why we ask that the

question came in and we looked into it. Should we consider making it a regulatory requirement to do that post-treatment imaging?

Now, again, we still relied on our initial review, which is catheter placement assures that the treatment is going to get, the patient is going to get the treatment as it's intended. That with the verifying the activity, you know, they got the activity, the dose that was intended by monitoring the vials and checking the waste because that'll assure that the treatment is correct.

With the whether or not there's a scan afterwards would not prevent an event from occurring. Now, we do recognize it doesn't help us in understanding them what happened or not.

MEMBER DILSIZIAN: No, no, I just want to address this. One this is to place a catheter, I understand the procedure. But remember, what we're following is the way the microsphere goes. The cath is in the right place. However, if the dose went to the lungs and patient has fibrosis, lung fibrosis or has stomach ulcer, you would not know that. The catheter is in the right place.

Technically, it was the right thing, but the physician didn't do the right dosing, perhaps, or

it went to the wrong. So patient management and adverse events have something to do beyond just the catheter or where the radiotracer is going.

MR. BOLLOCK: And we recognize that. There are other patient follow-up, and this where we don't want to get too far into the practice of medicine and what the doctors determine what the follow-up will be to determine those type things.

DR. TAPP: As of right now, we leave it more performance-based. So it's up to the institution based on what instrumentation they have, if they're going to do it during a follow-up, or if they're going to do it with an imaging system, or different methods that I don't know of right now off the top of my head. Such the two I know.

But I will say the staff's evaluation was really relying on the 2013 recommendation from the ACMUI. There has been updates to imaging, as we know it's increasing, especially for yttrium-90 post-treatment imaging. So if there was a change here that we would take a different look at it. I do want to focus most of our evaluation was focused on the report from the ACMUI in 2013. So it's.

CHAIRMAN PALESTRO: And Dr. Tapp, I guess if I understand you correctly, and what Mr. Bollock

is saying is that even though we can do the post-treatment imaging, and even though we may appreciate the fact that the activity has gone to the wrong organ or organs, there's no real way to quantify the amount of activity with SPECT imaging, and therefore you really can't determine whether or not it's a medical event. Is that correct, is that fair to say?

DR. TAPP: There are currently, there are imaging capabilities out there and new software that can quantify that is coming out in research and it's coming out now to clinical practice. But with standard SPECT, it is not quantitative.

MR. PALESTRO: Mr. Ouhib.

MEMBER OUHIB: Yeah, there is some work, but I think the dosimetry is not quite accurate. I think this part should be left to the practice guidelines, in my opinion, and that's where it fits properly.

You know, I was looking at requiring post-treatment imaging was not recommended, and I was like say, maybe it should be not mandatory, but suggested or something like that. I think that would be probably much better, in my opinion.

CHAIRMAN PALESTRO: Dr. Metter.

VICE CHAIRMAN METTER: Yes, thank you for

your comments. I understand the ACMUI reviewed this in 2013, and that's been five years now. And initially when Y-90 came out, it was usually to whole liver. I'm not sure what other institutions do, but at our institution we do a fair number of these, and do split livers. And as far as a pretherapy imaging with MAA, is that a regulatory requirement? Or a suggestion?

DR. TAPP: It is not a regulatory requirement. It is, however, we, with our medical event reporting conditions that are in the licensing guidance, we do not require reporting of lung shunting, if a pretreatment evaluation is done in accordance with manufacturer recommendations, which would be the pretreatment MAA.

VICE CHAIRMAN METTER: So I mean in the sense of I'm not sure what other institutions do, but we generally treat one lobe, wait a month, and then treat the next lobe.

And it's interesting, because the pretherapy scanning is only done for the whole liver, and we've seen at our institution is that let's see pretherapy was less than ten percent and we do do post-treatment therapy imaging with planar, which you can kind of quantitate or generally get a quantitative

with the geometric mean, the thing is that we did see significant lung shunting post-therapy after the next lobe was treated.

So I think imaging, I like the idea. Maybe information, a guidance in regarding to not making it regulatory, but information guidance regarding that, you know, would be helpful.

DR. TAPP: And I, technically I have seen that and it is, post-treatment imaging is coming up and is there. Are you recommending that the NRC do a regulatory guidance?

VICE CHAIRMAN METTER: No, well, just an information sort of thing, and the reason is it did help us. Because we, as far as the patient's health, we'd have to follow her lung functions if she was being compromised and things like that. So it does help in the management of care, which we're not involved with.

But I think as far as maybe an information sort of thing is that that can be, that would be helpful in future managements for the patient or something like that. But not making in regulatory sort of thing.

CHAIRMAN PALESTRO: I just wanted to go back to Mr. Ouhib's comment about the phrase not

recommended. It almost sounds, that phrase, as if you're recommending against performing. And I think maybe a better choice of words would be something like is not required.

DR. TAPP: It would have been a better choice of words, I apologize.

CHAIRMAN PALESTRO: Mr. Ouhib.

MEMBER OUHIB: Yeah, it might be a good analogy here, but when you look back to prostate brachytherapy implant, and so you know, when you think about the catheter and you think about the needles sort of side by side, you're putting the needles right into the target, into the prostate.

Now, you have seed migrating. You think about, you know, the same thing happening, is that a medical event or not? Obviously not, as long as you have put your needles or your seeds into the target. Now, you have no control after that, basically. That, what's going to happen is, you know, is out of the authorized user's hands, basically.

So I think this is really, in my opinion, this is why this is very appropriate. My recollection, and I don't want to be held on this, is that in the practice guideline, I think the imaging was highly recommended.

This is, and again, I hate to say it, but this is one item that maybe I'll leave it till later, is that there's got to be a work between what we do and what the practice guidelines are recommending. That they'll be sort of like consistent.

In other words, in putting something in here on yttrium-90 that is not consistent with what the practice guidelines are from ASTRO ACR and so on and so forth, I think we need to sort of sink that so we're not saying that absolutely makes no sense.

CHAIRMAN PALESTRO: Mr. Sheetz.

MEMBER SHEETZ: We do both types of microspheres at the University of Pittsburgh. We do post-therapy imaging. The imaging is qualitative, not real diagnostic. You're utilizing bremsstrahlung imaging or bremsstrahlung photons.

Also, too, there is always a preplanning study that's required by the manufacturer on the FDA package insert with technitium-99 MAA. And so that's for mapping. The mapping is done with MAA particles, the therapy is done with 35 micron microspheres. They have different flow dynamics.

And so we have actually seen, you know, they don't always match where the MAA landed and where the microspheres end up. And you see differences

from the day of planning to day of treatment where the dynamics and flow is somewhat different.

Catheter placement is identical, and all of a sudden, you know, from the planning study, it went in one direction to one area of the lobe and then on the day of therapy it goes in another.

So I would not want that to be a judgement on a medical event. And I think from the ACMUI subcommittee, they recognized this, that if the appropriate planning study is done to look for lung shunting and extra-hepatic flow, and you position the catheter at that same location for the therapy, then that is appropriate in that any variation from that point forward on distribution to different areas of the liver or extra-hepatic that were not recognized would be something out of the control of the licensee.

And so I think it's important to do post-therapy imaging to gather further information. We have seen where it did not go to the appropriate area, and so then we brought the patient back in several weeks to treat again to try to get microspheres to the appropriate area, but I don't think that represents an error on the licensees. So I just wanted to clarify that.

CHAIRMAN PALESTRO: Ms. Cockerham, I know

you wanted.

MS. COCKERHAM: Yes, thank you, just to address Dr. Metter's question earlier. There's actually a part of in Sirtex, for our proctoring program, we actually surveyed our proctors a couple of years ago just when I had joined for that mapping piece. Because as a company we actually believe that planning is critical.

And there was confusion because we would go out and proctor three times, but sometimes one of those proctoring sessions would be a mapping, because it is very important. And when we surveyed our proctors, they unanimously said, yes, we think that we should be there and we should be doing, you know, peer to peer, MD to MD evaluation of that mapping.

And so that is actually built into our process. So one of our proctored cases may very well be one of those planning treatments, and then two additional cases would be for the dose administrations.

And then we would have a manufacturer representative being the actual sales rep doing the third case for the purposes of AU, with the caveat that our MD physician has already signed off after a mapping and two dose administrations, if that makes

sense. So that was my first comment.

The second one was, and Mr. Sheetz already kind of talked about this for the post-implant imaging, it was just February of this year, the MIM software was FDA-approved, which is the software that would do quantitative analysis specifically for Y-90. They have a Sure Plan.

So if we're looking at, you know, what is the status of is everyone doing post-implant imaging, sure, but how great is the technology? There's just now an FDA approval for that actual software to do the quantitative analysis. So MIM has theirs with SurePlan, and then there's a second one, drawing a blank right now, RapidSpheres.

So those two are just coming out. We're starting to see those incorporated into our facilities, and they're piloting them, and they're starting to use them. But that's at the big academic centers.

And so this, you know, Y-90 is used across the industry in all different types of settings, it's not just in the big academic centers. So we're just starting to see really the dosimetry piece step up.

CHAIRMAN PALESTRO: Any other comments or questions? Mr. Ouhib?

MEMBER OUHIB: Yes, I have two questions, actually, for Dr. Tapp. Is that, what is the target date for the draft for Fiscal Year 2019?

DR. TAPP: We're hoping for this winter, for the draft to ACMUI.

MEMBER OUHIB: This winter, that means 2000 -- oh, I see, okay. The other question is regarding the data that you stated that there's an increase in the use of yttrium-90, and this is what. It would be great to sort of dissect that data a little bit more and see is there a correlation really users an event?

Or is it manufacturer issues an event or whatnot? I think that would be very, very helpful to see that, where is this coming from. It's just a thought.

DR. TAPP: Okay, thank you.

CHAIRMAN PALESTRO: Mr. Sheetz.

MEMBER SHEETZ: On a different topic, I would like to strongly recommend retention of the manufacturer training pathway. I think it's very important. Both companies have developed teams and programs, both technical personnel and physicians. And they come in and they train the entire Y-90 team, it's not just the authorized user. Again, it's

nuclear medicine technologists, medical physicists, interventional radiology personnel.

And so they take the time to make sure everybody is trained in that. They also all have physicians that come in. They may not be authorized users, but they do have that physician to physician contact. I have no vested interest in any of the Y-90 manufacturers, go on record as saying that.

But I've seen both their training programs. One offers a one-day course, as center of excellence course. The other company I think is developing one. So I would not want to see this go away and have another AU rely on just an AU for that facility to provide all of this training. Thank you.

DR. TAPP: Thank you.

CHAIRMAN PALESTRO: Dr. Martin.

MEMBER MARTIN: I would just reiterate I think what Mr. Sheetz said is very important to realize. It is training the team, and I think that's what gets missed when you just do authorized user to authorized user. There's a lot more to training the team. You need to train the physicist and you need to train the support, the nuclear medicine technologist.

But the whole group needs to be trained,

and not just one authorized user to the other.

CHAIRMAN PALESTRO: Mr. Sheetz.

MEMBER SHEETZ: Additionally, as yesterday we demonstrated that the majority of the medical events with the Y-90 microspheres is the residual activity in the delivery apparatus, and that's another item that the manufacturers will, in the three simulated cases, go over the delivery apparatus and how it works and how it functions, potential errors that can be, you know, that can occur.

And so that type training on the device setup and operation is invaluable.

CHAIRMAN PALESTRO: Mr. Ouhib,

MEMBER OUHIB: Yeah, I like the ask a question Dr. Dilsizian about this, is how often when doing such a procedure you verify the shunt prior to the procedure itself? In other words, there's been a report where something was done a week ago, two weeks ago, and then the second time that things were sort of different.

So is that standard procedure, or does that vary from one place to another, repeating that shunt evaluation?

MEMBER DILSIZIAN: So we routinely do

MAAs to determine what the percent of lung is. Obviously the interventional radiologist accordingly modifies the dose. And there are other decisions that they make, which is in the past they used to be, you know, right lobe of the liver first, then left lobe, now it's more targeted, even segments of the liver.

And so that's where my question comes in. Because in the past it was more left then right, and the error of left and right is, you know, really tough to make. But now we're saying we're going to target specific segments.

If that's the goal, and that's the dose, do we really get there? That was my question. So we routinely do Y-90 PET imaging afterwards, truly fantastic, you know, PET CT imaging, which is really a positron emitter and we get nice images.

And again, specifically says this is the segment it went to. Didn't go to the stomach, or the dose modification didn't impact the lungs. I mean, at least clinically we seem to be very in favor of this.

I understand it may not be regulatory, I got you that. I think that that may be medical decision, and I'm okay with that. I think we've kind

of said about the art of medicine and we shouldn't really have NRC interfere with that.

But from the medical events perspective, I was just trying to get to the point, was that if we're going to follow up Y-90 and the training and whether it's doing the right thing or not, we really don't, we're not going to have the data. That's what I was saying.

I wasn't suggesting NRC should get involved, but I'm simply saying that it's really tough to know with medical events perspective whether this is working or not if we don't do imaging. That's all.

CHAIRMAN PALESTRO: Yes, sir.

MR. PETERS: Hi, Mike Peters, American College of Radiology. Just a quick process question for Katie. You mention the revisions going to ACMUI for review in winter. Is it then going to be released in a draft revision format for public comment after that, or is it going to be released in final revision form and effective immediately?

DR. TAPP: It will likely be released in final. If there's significant changes, it's possible we will have a delay implementation. If they're relatively little changes, it would probably be final

effective immediately.

MR. PETERS: Thank you.

CHAIRMAN PALESTRO: Any other comments or questions? Any comments from anyone on the telephone lines? Dr. Tapp, I have a question for you going back to one of your earlier slides on the medical event evaluations. You said that you presented your data at the Agency Action Review Meeting of the Commission back in June. Is that presentation available to the ACMUI?

DR. TAPP: It is a public presentation and we can get it to you.

CHAIRMAN PALESTRO: Yes, I think it would be particularly important for the Medical Events Subcommittee to have the opportunity to look at it.

DR. TAPP: I will say it was a, the Agency Action Review Meeting is a NRC-large meeting, so it was one slide, I believe. But I can get that to you. And there's a SECY paper associated with it with more details, and we can provide that.

CHAIRMAN PALESTRO: Okay.

MR. BOLLOCK: This is Doug Bollock, NRC. We can also provide you, we had a, prior to that we had a Commission business line meeting that this topic, the Agency Action Review Meeting, this one

slide was kind of a synopsis of the larger presentation to the Commission, and we can share that with you.

CHAIRMAN PALESTRO: Okay, thank you.

MS. COCKERHAM: Dr. Palestro, could I ask Dr. Tapp one more question? So there's going to be a draft version of the guidance that comes out of, this is a follow-up on Mike's question, draft version's going to come out of OAS NRC Working Group. It's going to go to the ACMUI in draft format. Will that draft be publicly released?

DR. TAPP: We normally don't release the draft that goes to the ACMUI.

MS. COCKERHAM: So then when the ACMUI provides comments, how will the public know what their comments are on what draft that they reviewed, to be able to see what's going into the final?

DR. TAPP: They can provide comments on the recommendations from the ACMUI, but they will not be able to provide, the public will not likely see the draft licensing guidance. We don't normally release that as it's a pre-decisional licensing guidance.

MS. COCKERHAM: But we will see the ACMUI's comments?

DR. TAPP: Yes, you will see the ACMUI's recommendation and comments.

MS. COCKERHAM: Thank you.

CHAIRMAN PALESTRO: Any other comments or questions? Dr. Tapp, just again, one quick question. When would you expect that the guidance will be ready for review?

DR. TAPP: We're hoping this winter.

CHAIRMAN PALESTRO: Okay, all right. So then we will be forming a subcommittee to review it, yes, okay. Considering Dr. Dilsizian and Mr. Ouhib's enthusiasm for it, look forward to having you on the subcommittee.

MS. HOLIDAY: Dr. Palestro, I'm sorry, if I could just follow-up to the question that Ms. Cockerham just asked and Dr. Tapp just answered. So we recently engaged in some discussions with our Office of General Counsel.

So actually, by the time that Dr. Tapp's working group is getting ready to provide its draft licensing guidance to the ACMUI, our process is at it goes to the ACMUI for comment. It also goes to our NRC regions and our agreement states for their comment as well.

But because the ACMUI is going to provide

its comments in the form of a subcommittee report in a public ACMUI meeting, we have in our discussions with Office of General Counsel agreed that going forward we will also release that draft licensing guidance, so that members of the public can see the document that the Committee is commenting on.

But that is with the understanding that if members of the public are providing comments, those comments are on the ACMUI's subcommittee report. It is not an opportunity for the public to submit comments on the draft guidance itself. It's kind of a weird do loop.

So when Dr. Tapp released her guidance earlier this year in the Federal Register, I think it was in the Federal Register, that was an opportunity for members of the public to provide their comments to staff. So then the next step from there is her working group has looked at those comments and they're in the process of developing or making further revisions to their guidance.

So then it's that final bite at the apple that goes to the ACMUI, our regions, and the agreements states. The licensing guidance will be posted when the ACMUI subcommittee report is posted, so that members of the public or professional society

stakeholders, when they want to submit comments for the ACMUI meeting, they will be able to provide their comments on the ACMUI subcommittee report. Thank you.

CHAIRMAN PALESTRO: Okay, thank you, Dr. O'Hara. Any other comments or questions? Thank you, Dr. Tapp.

We're a little bit ahead of schedule at this point. Question for you: Can we take care of any sort of administrative work at the present time? For example, identifying the spring meetings dates. Is that possible, can we do that now?

MS. DIMMICK: Sure. Hold on. Okay, we'll move forward, taking a look at our spring meeting dates, and we'll try to -- this is actually March, but we don't see the March header. So I'll give Katie a moment to try to adjust. I think when we did the doodle poll there were no dates in March that were selected or provided an opportunity for to have a meeting based on feedback from the doodle poll.

So let's go ahead and go on down to April. And then April from the doodle poll, it was the 15th and 16th were dates that 11 of the 13, there were, checking with Sophie. Thirteen, eleven? Okay, so there were 11 responses to the doodle poll that had

available April 15 and 16. So those, at this point, would look like the first choice for a meeting.

Keep in mind that we need to have a Commission briefing as well, so we need to have an alternate date as a backup because of -- so before we select an alternate date, my prompter is reminding me I should ask if the 15th and 16th is still an available date for those who responded to the doodle poll. And for anyone that did not, is the 15th and 16th available or not available, if you should know now?

CHAIRMAN PALESTRO: So is there anyone who cannot make the April 15-16 meeting? Presumably everyone can make April 15-16, so that should be our first choice.

MS. DIMMICK: That would be our first choice. The second choice was April 4 or 5, and I believe there was some limitations by some subcommittee members. It was Dr. Metter is not available and one of those days would be a half-day for Dr. Ennis.

Does this date work for everybody else? Would these days work for everyone else? Again, as a backup if the 15th or 16th did not work for the Commission for our spring meeting.

CHAIRMAN PALESTRO: Is there anyone else who can't make those days? Lisa, what about the third and fourth, that didn't work either?

MS. DIMMICK: Sophie has the message up, so I'll.

MS. HOLIDAY: Sorry, guys, this is a little confusing, since I sent the doodle poll out. So based on the responses that I got, Dr. Dilsizian was not available on the third and Dr. Metter was not available on the third or fourth as well.

Another alternative set of dates is April 8 and 9. I mean, either sets of these dates, there wasn't a unanimous vote. So as the Chair's prerogative, by default you would just select one or two backup dates. And pending Commission response we could go from there.

CHAIRMAN PALESTRO: I'm sorry, what did you say about April 8 and 9? I didn't hear you.

MS. HOLIDAY: April 8 and 9 was another date that was a possibility. Again, we didn't get full, unanimous vote on that, so if that's another date that the Committee would like to consider perhaps.

CHAIRMAN PALESTRO: When you say you didn't get a full, unanimous vote, does that mean

that not everybody completed it, or there were some people who couldn't make it?

MS. HOLIDAY: Out of the 11 responses I received, both April 3 and 4 and April 8 and 9 did not get 11 out of 11 yeses.

MEMBER DILSIZIAN: April 3 I can revisit if I'm available. So I can make the fourth, I can make arrangements for the third if it's, if it comes to that.

CHAIRMAN PALESTRO: I'm sorry, you can make the fourth?

MEMBER DILSIZIAN: The fourth I definitely can, I just thought the third was out, but I can rearrange my schedule.

CHAIRMAN PALESTRO: Yeah, I think the third and fourth would be better than the fourth and fifth of April.

MS. DIMMICK: So we could go with the 15th and 16th as the first choice, and the backup as the third and fourth.

CHAIRMAN PALESTRO: And just to point out and really to remind everybody on the Committee that in the past it has happened on occasion that the Commission has identified a date that doesn't correspond to any of these, and the presenters have

had to come in for an extra day. So that potentially could happen as well.

MS. DIMMICK: That's correct.

CHAIRMAN PALESTRO: All right. So just a comment and a suggestion to the members of the Committee, and especially the new members. Do not wait to make your reservations at Bethesda North, or you will not get a room. I can tell you that when I head out of here at lunchtime, that's the first thing I'm going to do.

I learned the hard way my first meeting when Ashley actually called me up and asked me if I had made my reservations and I said no. And she said you may be out of luck, and I was. I wound up staying I think at the Hilton, which is two train stops down. So I am being quite serious, you really should get online.

And I can tell you that I always book both the first and second choices, and once it's finalized then cancel that second choice, okay. So hopefully now that I've given you that advice I won't be locked out of a reservation. Thank you. So that concludes that.

We also had an item that we were going to put in the open forum regarding a, I want to say an

addendum, but a clarification on the Nursing Mothers Guideline. And I know that Dr. Metter had worked on that statement, along with Mr. Green. And can we take care of that now as well?

MS. DIMMICK: Yes, we can.

CHAIRMAN PALESTRO: Okay, Dr. Metter.

VICE CHAIRMAN METTER: Yes, I defer to Dr. Green.

MEMBER GREEN: So this is a draft of the language that we might be putting on that that says, This document was developed in September 2018 and reflects the FDA approved radiopharmaceuticals on the market at that time.

Licensees are obligated to carefully evaluate radiopharmaceuticals that are not encompassed in this document to keep exposures AL ALARA to patients, staff, and members of the public.

CHAIRMAN PALESTRO: Comments? Questions? Any comments from the attendees in the room or on the phone? So I presume we need a motion for this.

MS. DIMMICK: So is there a motion to add the statements provided by Mr. Green to the Nursing Mothers Guideline?

MEMBER OUHIB: This is Zoubir.

CHAIRMAN PALESTRO: Second. Suh. Any discussion? All in favor? Any opposed? Motion passed.

MS. DIMMICK: Motion passed.

CHAIRMAN PALESTRO: All right, we will resume at 10:45.

(Whereupon, the above-entitled matter went off the record at 10:05 a.m. and resumed at 10:44)

CHAIRMAN PALESTRO: The next presentation is entitled Compounding of -- excuse me -- "Compounding of Sterile and Non-Sterile Radiopharmaceuticals" and, Mr. Richard Green will make the presentation.

Mr. Green?

MR. GREEN: Thank you, Dr. Palestro, I appreciate the opportunity. I proposed this to be added to the agenda.

I know talking offline with many of the members of the Committee that some were aware and some were not aware, and this is, I think, literally, once in a lifetime paradigm change. So, I thought it would be appropriate that we discuss this.

I've entitled this using the actual formal title of the chapter and that is

"Radiopharmaceutical Preparation, Compounding, Dispensing and Repackaging," because each of those is a different and distinct act. And, we're using terminology from the FDA.

So, I'll start off by really discussing -- next slide please -- who the United States Pharmacopeia is. They're a private, nonprofit standard setting body for pharmacy and medicine and food as well.

They establish legally enforceable national standards. I often use -- hear other people use the wrong terminology, they're not guidelines, they're not suggestions, they are standards.

And, these can be legally enforced when recognized and incorporated into laws and regulations.

Next slide, please?

So, the mission of the United States Pharmacopeia is to promote public health and benefits practitioners and patients by disseminating authoritative standards and information developed by its volunteers from medicines, other health care technologies and related practices used to maintain and improve health and promote optimal health care delivery.

Next slide, please?

So, USP, I guess the National Formulary and the Pharmacopeia started back in the 1800s and it's published every five years.

Chapters that are numbered above 1000 are termed General Information chapters. They're good advice, good guidance.

But, chapters numbered below 1000 are official and can be enforced by the FDA or other regulatory agencies.

Next slide, please?

So, the USP sets standards, other bodies may enforce those standards. It could be the FDA does the enforcement agency, they seldom visit pharmacies or hospitals or clinics without cause.

If you have a sentential event, they may knock on your door and ask you questions.

In my world, the Boards of Pharmacy are the enforcement agents that come and visit us on an annual basis to make sure we meet these standards.

CMS and their deemed accreditation bodies are the folks at will be visiting hospitals and that could be the HFPA, the American Osteopathic unit or the most largest unit is the Joint Commission.

But, there's several deemed agencies that

are going to come around and make sure that you're meeting the standards established by CMS.

So, those will be the enforcement -- the enforcers of the standards.

Next slide, please?

I wanted to point out that, although we're talking and this title is Chapter 825, radiopharmaceuticals today are currently under USP standards which is Chapter 797.

I've rarely traveled without my well-worn worked up copy. This lives on my desk and I have to frequently review that for all the various State Boards of Pharmacy that I am involved with.

So, since 2004, radiopharmaceuticals have been subject to, I want to just read just a few paragraphs.

The standards of this chapter are intended to apply to all persons who prepare compound and sterile preparations and in all places where CSPs are prepared, hospitals and other healthcare institutions, patient treatment clinics, pharmacies, physicians' practice facilities and other locations where CSPs are prepared, stored or transported.

Persons who perform sterile compounding include pharmacists, nurses, pharmacy technicians and

physicians, anyone.

Next slide, please?

Again, from the current 797 chapter, these terms recognize that most sterile compounding is performed by or under the supervision of pharmacists and pharmacies, but also, that this chapter applies to all healthcare personnel who prepare, store and transport CSPs.

And then, they go on to state, that for the purposes of this chapter, compounded sterile preparations includes any of the following, and you'll notice that radiopharmaceuticals are expressly listed as being included under the standards of Chapter 797.

So, we've been dealing with 797 for since 2004. And, Chapter 797 went out to revision and was released in a draft revision in September 2015 and there was public comment period on that revision until 2016 in January.

USP received more than 8000 comments from over 2500 stakeholders. I personally wrote them a 65-page letter detailing line by line suggestions, comments, grammatical changes and actually, sometimes, even now, kudos a job well done. So, comments were received.

Today, in the chapter, there are six small paragraphs related to radiopharmaceuticals. But, the entire chapter applies to RPs.

So, we are lumped in with everybody else and we have to meet the standards for a hospital that's making an IV add mixture or compounding a drug product that might have a 90-day beyond use date and we have to wear booties, bouffants and beard covers and, you know, get that garbed in a level of cleanliness for, you know, we'd be happy with a 24-hour BUD, a 24-hour use with our radiopharmaceuticals.

So, we realize that we're currently in the chapter, but there are many problems with 797 and that's when we took the opportunity during this open comment period to make comments.

Next slide, please?

As a result of those comments, the UPS held a stakeholder workshop down the road in Rockville, Maryland February 1st, 2017. I was in attendance of that. I was an invitee and they invited folks from the Sterile Compounding Committee that writes 797 as well as members of the Nuclear Pharmacy and Nuclear Medicine Community, SNMMI was present; the FDA was present, USP staff.

And, during that meeting, we expressed the unique nature of radiopharmaceuticals, the short BUD, the requirements for shielding, the use of remote manipulators, all kinds of things that just made us the square peg in a round hole.

And, we were successful in pointing out the uniqueness of the radiopharmaceutical preparations and they consented that radiopharmaceuticals should have a separate chapter.

Next slide, please?

So, they put out the call for experts, and that was done in June of 2017. They received more than 60 applicants for the expert panel.

Next slide, please?

The -- here's the expert panel target candidates characteristics, nuclear medicine expertise in the commercial setting, a hospital setting, an academic setting, experience with Boards of Pharmacy, board certification in Nuclear Pharmacy, members of the Expert Sterile Compounding Committee that currently house those six small paragraphs on radiopharmaceuticals.

And so, next slide, please?

I believe it was August of that year they announced membership of the expert panel, and this is

the membership today.

I've indicated who's on the Committee, the expert -- sorry, the expert panel, who is a board certified Nuclear Pharmacist, who's representative of the FDA and who's on the expert committee for sterile compounding.

I was honored to be selected to be on this expert panel.

Next slide, please?

So, again, here's the breakdown, you can see the Committee with its institutional members of institutional nuclear medicine, commercial nuclear pharmacy, academia, regulatory and consultants.

So, if we can take the next slide, we'll transition into actually talking about this chapter, 825 has been identified the chapter it will be.

And, its scope is to provide clear and effective USP public standards that meet patient and practitioner needs for compounding sterile radiopharmaceuticals today and in the future.

The proposed new General Chapter will delineate compound activities for radiopharmaceuticals and provide standards and associated with these activities.

When complete, the General Chapter will

contain standards for this class of products.

Next slide, please?

So, this charter in its draft form was released for public comment on the internet on July 27, 2018.

Something else I -- I'm sorry -- I don't travel without is the draft.

So, the public comment period is now open and this draft chapter states that this chapter applies to all practice settings where radiopharmaceuticals are prepared, compounded, dispensed or repackaged.

Practice settings consist of state licensed nuclear pharmacies, federal nuclear pharmacy facilities and other healthcare facilities including, but not limited to nuclear medicine departments in hospitals and clinics, nuclear cardiology clinics and other specialty clinics.

Next slide, please?

This chapter applies to all individuals who prepare, compound, dispense or repackage radiopharmaceuticals. Applicable individuals consist of authorized nuclear pharmacists and authorized user physicians as well as individuals working under their supervision.

This includes, but is not limited to student pharmacists, nuclear pharmacy technicians, nuclear medicine technologists, students, physicians, physician residents and trainees.

Next slide, please?

The purpose of 825 is to provide uniform minimum standards for the preparation, compounding, dispensing, repackaging of sterile and non-sterile radiopharmaceuticals.

As a side note, there are separate chapters today. There's Chapter 828, Chapter 795 for non-sterile radiopharmaceuticals or non-sterile drugs which iodine-131 would fit in that chapter and then sterile is under 797 but we're proposing that all RPs, sterile and non-sterile, go in this one chapter. They are unique.

So, it will be sterile and non-sterile radiopharmaceuticals for humans and animals that occurs as part of state license activities.

And so, again, in the chapter, we define the define the different terms of preparation, compounding, dispensing and repackaging.

The chapter goes into the standards for those activities, requirements for the environment, for engineering controls whether they be in the room

or the device, the laminar flow hood that is used to prepare the drugs, the qualifications of personnel involved in these activities and the practices are necessary and balanced to ensure personal safety, environmental safety and patient safety.

Next slide, please?

I've provided with the kind assistance of Ms. Sophie Holiday, the table of contents from the draft chapter. And, you can see it's very extensive.

It's a chapter that has two audiences. One is the practitioner who will meet these standards.

And, the other audience is our inspectors, whether that be a joint commission inspector or a Board of Pharmacy inspector because they don't really know what they're looking at. Now, they'll be given an education. And, we talk about time, distance and shielding.

We talk about ALARA. There's a reason why I don't hold reactive syringes up against the white background and then against a black background to look for things. You do that in an IV bag, but not in a radiopharmaceutical because of ALARA.

So, it goes into the qualifications, the training, the hygiene.

Next slide, please?

Facilities, which would include facility design, environmental controls, microbiological air and surface sampling, HEPA filtration of rooms, of devices, cleaning and disinfecting of rooms, devices, gloved fingertip sampling, gowning and garbing.

Next slide, please?

It gets into the term we use of beyond use date; a manufacturer puts an expiration date on their unopened drug product. But, once prepared and handled in a particular clinical setting or a pharmacy, then that term changes to what's called a beyond use date that may certainly change different from the manufacturer.

You may have a manufacturer's expiry of five months from now, but once you make that drug, depending on your setting and how you made it, you will certainly have to reduce that beyond use date.

But, that's established here as to what beyond use dates could be.

How to document. And then, we get into the different activities of preparation where we're making a commercially available drug product. All of the kits, you know, Tech-99, MAA Kit for the preparation of compound X versus compounding where you are literally cooking from scratch, taking non-

sterile ingredients and rendering them sterile, doing a pyrogen test and making it suitable for human use.

Versus, on the next slide, please, dispensing which is merely taking something that was ready made like F-18 FDG that comes from a manufacturer, dispense it and also repackaging, similar process, so just changing the container closure from the big glass bottle to a patient unit dose syringe. That is dispensing and repackaging.

What quality control measures must be taken as well as glossary and some example diagrams.

Next slide?

We can talk about the time line for comments. So, it was released publically July 27th and it will be open for comment. There will be a -- the USP will host an open microphone session to discuss the chapter on October 10th.

And, the chapter has -- well, will be published in the Pharmacopeia form in the September/October edition. It was released early on the internet to give the community more time to respond and provide comments.

Next slide, please?

So, the time line for comments and when it will become official. So, the comment period will

end on November 30th, 2018, roughly two months from now.

And, in the absence of any adverse comments to the proposed chapter, it will become official on December 1st, 2019.

That 2019 date is a magical date. There are actually four chapters all becoming official on that date. The 795 for non-sterile pharmaceutical compounding, 797 for traditional sterile drug compounding, 800 for hazardous drug or chemotherapy drug compounding, both sterile and non-sterile.

And, radiopharmaceuticals in this Chapter 825.

So, they all will become effective on that same day enforceable official on that same day.

Next slide, please?

So, this presentation is a heads-up to members of the Committee as well as to staff at the NRC that this is in progress. This is a once in a lifetime opportunity to hopefully positively affect the standards of care and the practice.

There may be some licensees that are looking, once the draft gets revised and becomes official in June of 2018, there may be an amendment request to modify facilities or to put infrastructure

in or to change procedures and processes.

So, it's a heads-up to staff.

So, our next slide provides resources. The -- one of the great impetus behind this chapter was a white paper that was made -- authored by SNMMI and that's provided for your review.

And, also, I provided the link to where you could download a draft copy of Chapter 825 if you wish to read that yourself.

I encourage any member of the Committee, or any member of the audience in the room today that if you have concerns, positive comments, negative comments, comments or suggestions for improvement to take the opportunity to make public comment until October -- until November 30th.

And, if you wish, you can attend the open microphone session.

The next two slides are really acronyms used in the presentation and that concludes.

CHAIRMAN PALESTRO: Thank you, Mr. Green.

Comments or questions from the Committee?

Ms. Shober?

MEMBER SHOBER: Yes, this is Megan Shober.

Richard, could you speak to a little bit

more about what some of the changes are that might drive modifications to facilities or equipment?

MR. GREEN: There's a table, Table 7, that addresses beyond use dates. And, let's start with the lowest term is immediate use.

I could prepare a radiopharmaceutical on the counter top ambient air, but it has to be used within one hour because there's been no controls of microbiological contamination.

If I'm going elute a generator, it needs to be in a particular environment of known air quality. And that would require, perhaps HEPA filtration in the room.

If I'm going to prepare a drug inside a laminar flow hood for beyond use date, you know, up to 24 hours, well, that would require the installation of a HEPA filtered laminar flow hood or a primary engineering control.

That may be a change in infrastructure. It won't change their radiological profile at the facility, but it is going to be a change to the facility.

There may be, in some places, depending on the activities that they pursue, they may actually, you know, change walls and divisions within the space.

But, that's why we're giving a heads up to the NRC staff.

CHAIRMAN PALESTRO: Any other comments?

Mr. Sheetz?

MEMBER SHEETZ: Thank you.

Very interesting and thorough presentation, Mr. Green.

Two questions. One, will these standards be applicable to radioactive drugs that are not FDA approved?

MR. GREEN: Yes, they will. There's not nearly -- FDA drugs, they could be research compounds, clinical trial compounds.

For example, Chapter 823 is for positron emission tomography drugs that you're probably familiar with that are going through clinical trials.

There's FDA CGMP, or current good manufacturing practice, standards for manufacturers of positron emission tomography drugs. But, if you are research chemist or a physician doing research in PET drugs, then you need to apply 823.

So, yes, this applies to research compounds as well.

MEMBER SHEETZ: Okay. But, the PET radiopharmaceuticals or PET radioactive drugs will

still be in 823?

MR. GREEN: Yes.

MEMBER SHEETZ: Okay. And then, the other question I had is that these standards would be applicable to animals? Would this apply to animals used in research?

MR. GREEN: That's a good question, never considered that. We do dispense radiopharmaceuticals for non-research animals, horses, dogs, I've done an elephant, it's a big bone scan.

(Laughter)

MR. GREEN: I don't know, that's a great comment. I'd love to have you put that in the -- in a comment.

MEMBER SHEETZ: Yes, because for research to meet these standards would be difficult, it would be challenging.

CHAIRMAN PALESTRO: Dr. Martin?

MEMBER MARTIN: Is there a plan to present this typical scenarios in a question or like frequently asked questions format?

I'm coming back to the earlier question of so it's very obvious what the differences are between say, standard practice today and what a facility would need to change to implement, just like

you said, I'm going to prepare this radiopharmaceutical to use within one hour.

It would be very helpful to see these in different type of scenario presentations and very clearly spelled out so that, (a) you do not have reviewers from outside commissions coming in and they are not going to be at the technical level that certainly you are.

So, some of these frequently scenarios that you encounter could be laid out as to what the differences are and how a facility will have to make changes to comply with that, that would be very helpful.

MR. GREEN: That's a great suggestion, I'll take that comment back. And, I, again, encourage you to make that comment in the formal format.

I can point out that since 2004, we've been subject to the current Chapter 797. And really nothing is getting more severe.

We're able to loosen some of these standards that are applicable in the standards of practice today because we're not going for 90-day expiry. We're just working with nuclides that, you know, poof, they're gone in a day.

So, hospitals are subject to these standards today. Now, they may not have gotten the attention from surveyors because they may be focusing on pharmacy and being going to the cath lab or the respiratory therapy department or the nuclear medicine department, all places where drugs are used.

But, I can surmise that once there's a separate chapter for just radiopharmaceuticals that surveyors will give more attention and we might have knocks on the door of the nuclear medicine department.

CHAIRMAN PALESTRO: Any other comments or questions from the Committee?

MEMBER SCHLEIPMAN: Just a question for clarification.

CHAIRMAN PALESTRO: Dr. Schleipman?

MEMBER SCHLEIPMAN: Richard, you mentioned compounded PET drugs over main in Chapter 823, but I thought the whole purpose was to put all radiopharmaceuticals in 800.

MR. GREEN: I can -- whoops, let me get the right one.

I will read one small part with your indulgence. This chapter shall not apply to radiopharmaceuticals manufactured in FDA registered manufacturing establishments according to 510 of the

Food and Drug and Cosmetic Act.

Radiopharmaceuticals compounded in FDA registered outsourcing establishments according to 503(b) of the FDA Cosmetic Act.

Aspects of positron emission tomography PET drug preparation as defined in the PET Chapter 823 and administration to patients.

So, once the manufacturer makes the PET drug and gives it to me to dispense, then this chapter is applicable.

MEMBER SCHLEIPMAN: Okay.

MR. GREEN: They make it under the mantra of hocus pocus of the FDA.

MEMBER SCHLEIPMAN: Okay, thank you.

CHAIRMAN PALESTRO: Any other comments or questions from members of the Committee?

(No response)

CHAIRMAN PALESTRO: Comments or questions from attendees here in the room?

Ms. Holiday?

MS. HOLIDAY: This is Sophie.

In my role in the Office of Enforcement, I would just like to make a clarification or additional statement.

Earlier in Mr. Green's presentation, you

saw in the time line and he made several references about the term enforceable.

I'd just like to remind everybody that, for NRC licensees and Agreement State licensees, we would not take enforcement action unless a licensee has a commitment or a tie down on their license which makes it a legally binding requirement that they -- if the license says we will commit to following USP standard blah, blah, blah.

So, unless they actually have that on their NRC license or their Agreement State materials license, or at least I can only speak for NRC, we would not pursue enforcement action. That would not be considered a violation.

It may be a violation for other aspects or organizations that they are affiliated with, but for NRC materials licensee purposes, it would not be an enforcement action unless they actually have a commitment tie down on their license that they would be following these standards.

Thank you.

CHAIRMAN PALESTRO: Thank you.

MR. GREEN: Yes, thank you, Sophie. That is a good clarification that the term enforceable in this context was meant to be enforceable by the Board

of Pharmacy or your accreditation organization, not NRC enforceable.

CHAIRMAN PALESTRO: Any comments from anyone on the telephone lines?

(No response)

CHAIRMAN PALESTRO: Thank you for the presentation, Mr. Green.

All right. Next, we are going to move on to medical team highlights. It will be presented by Ms. Lisa Dimmick.

MS. DIMMICK: So, I'd like to offer a few highlights of the medical team's efforts since basically last October. Well, there's a few earlier references in the presentation as well.

Next slide?

The areas that I wanted to just touch upon is work under our areas in Commission papers, rulemaking activities, NRC Agreement State Working Groups and also guidance documents.

Next slide?

So, 2018 has been a year and things leading up to 2018 made it extremely busy, but we did have three SECY papers that we sent to the Commission in 2018.

They were all information papers but they

were -- there was substantial work that went into each of these papers.

In January, we issued or we sent the Commission a paper on SECY-18-0015, "Staff Evaluation of the U.S. Nuclear Regulatory Commission's Program Regulating Patient Release After Radioisotope Therapy," in January of 2018.

This paper was the result of Commission directed work.

The second paper we developed was SECY-18-0037, "Review of the Emerging Medical Technologies Program." We sent that up in March of 2018.

And, this paper was the result of staff initiated work to evaluate our emerging medical technology program. And, I do have a few more slides to talk about those efforts.

And then, the third paper, we're all familiar with. We've heard about it a few times yesterday. It's SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-Ml70817." And, that was in August of 2018.

Next slide?

So, just to recap some of the efforts of

these papers, so SECY-188-0015, again, this was the patient release.

In this paper, we provide the Commission with staff's evaluation of the program for regulating patient release after radioisotope therapy.

It also presents the results from dose modeling calculations, review of published literature and extensive stakeholder outreach.

Staff had concluded that the current patient release program is protective of public health and safety and that rulemaking to change any of the release criteria in the regulations was not warranted at this time.

Next slide?

The paper -- the staff also determined that a comprehensive update to guidance as well as updates to the equations and methodologies described in the guidance for calculating doses to members of the public from patients release was warranted.

And then, last, updating the NRC guidance with current scientific knowledge would lead to more accurate estimates of public dose from released patients resulting in better licensee decisions regarding the timing, circumstances and risks associated with the patient release following

byproduct material administration.

So, that was in essence the conclusions and recommendations staff had and regarding patient release.

Next slide?

The second SECY paper I wanted to discuss was the staff effort in SECY-18-0037 to provide the Commission with our review of the emerging medical technologies.

This paper also identified staff's past efforts with regard to medical -- emerging medical technologies, emerging medical technologies that we might be currently reviewing and emerging technologies that we see coming down the pike.

So, this was a great effort for the medical team to self-reflect on how we evaluate emerging medical technologies and also so that we can start planning ahead what types of things we're going to be seeing coming down the line and so for basically for resourcing purposes.

So, if I could, just a couple of things before -- you can go ahead and go to the next slide.

So, Part 35, Subpart K that's also 10 CFR 35.1000 describes the process to obtain a license, a license amendment or for a new medical use byproduct

material, irradiation from byproduct material which is not addressed in other parts of Part 35.

So, if an emerging medical technology is not specifically addressed in 10 CFR Part 35, Subparts D through H, staff will form a joint NRC Agreement State Working Group to develop licensing guidance describing an acceptable approach for meeting NRC's regulations.

Also, if the emerging medical technology is specifically addressed in Parts 35, Subparts D through H, the staff may provide additional information to assist in licensing and inspection based on the specific risks associated with the technology.

So, a couple of examples of some past -- recent past reviews, we have many more in our past, but it was the NorthStar Medical Radioisotopes RadioGenix Molybdenum-99/Technetium-99m Generator System. That guidance was issued in February 2018.

The Eckert and Ziegler GalliaPharm Germanium/Gallium-68 Generator, Pharmacy Grade Generator, that was actually Revision 2 that was issued in July of 2017.

And then, in 2016, we did the Low Activity Radioactive Seeds Used for Localization of Non-

Palpable Lesions and Lymph Nodes October of 2016.

And then, we also have a Leksell Gamma Knife and Leksell Perfexion Icon from May of 2016.

And then, Revision 9 of the Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres was February of 2016.

So, there are more that predate those 2016 dates, but that's just a few of those samples.

Now, next slide?

That's some past reviews. I wanted to show an example of some past reviews that we actually did not do 35.1000 guidance for, but we evaluated them to determine if they needed additional guidance or if they were, in fact, 35.1000 guidance or not.

And so, in examples here are Lutetium-177 dotatate. We had determined that that could be licensed under 35.1000, I'm sorry, 35.300. And we did that determination in June of 2018.

We also had, last October, evaluated the Salutaris Manual Radionuclide Eye Applicator and determined that this could be licensed -- would meet the criteria under 35.400.

And then, one that was previous a few years ago was the Radium-223 Dichloride. And we determined in 2013 that that could be licensed under

35.300.

So those are examples of past reviews.

Next slide?

So, we have a few reviews in process right now. There are two cobalt-60 stereotactic radiotherapy devices. One is the MASEP Infini for treating brain tumors and lesions.

And then, the other one is GammaPod for treating breast cancers.

So, that's -- so there's an active working group working on both of those devices that will result in two separate guidance documents for these stereotactic radiosurgery units.

We've already earlier talked about the Yttrium-90 Microsphere Brachytherapy working Group that's working to update the licensing guidance to issue Revision 10.

And then, the Leksell Gamma Knife Perfexion and Leksell Gamma Knife Icon, that will be Revision 1 and this is the document that addresses the physical presence requirements.

Next slide?

So, that was current work. Those are actively in process.

So, we have many things that we've

identified in this SECY paper of coming down the pike. But, these are three of the items that are very near future and, near future, I mean before the end of the year.

It's likely that we might look to establishing a 35.1000 working group to determine if we need guidance for any of these three items, one of them being the Phosphorous-32 OncoSil microparticles for advanced pancreatic cancer.

Thorium-227 antibody therapy for treatment of lymph node, prostate and breast cancer.

And then, another one, Radium-224 as Diffuse Alpha-emitters Radiation Therapy. That acronym is DART and that's for the treatment of solid tumors by alpha particles.

So, here is a few 35.1000 -- we'll evaluate if they need 35.1000 guidance so there is -- it's a potential they may not.

But, these are our current emerging technologies that we are starting to evaluate the licensing needs.

Next slide?

So, the last SECY paper I wanted to mention, again, this one we already talked about was the T&E SECY paper.

And, in this paper, staff provided our initial results, status and next steps related to the NRC staff's evaluation of training and experience requirements for administering different categories of radiopharmaceuticals for which a written directive is required in accordance with 10 CFR part 35 Medical Use of Byproduct Material Subpart E, Unleaded Byproduct Material Written Directive Required.

Next slide?

So, those were the Commission papers that we sent in 2018.

I wanted to touch on too, the other area the working group, I'm sorry, the medical team supports are rulemaking initiatives.

So, two rulemakings that I wanted to discuss are the 10 CFR Part 35 Final Rule for Medical Use of Byproduct Material, the Medical Events definition, training and experience and clarifying amendments.

And then, another rulemaking, Naturally Occurring and Accelerator Produced Radioactive Materials that came in as a petition for rulemaking PRM-30-66.

Next slide?

So, we've already talked briefly about we

know that Part 35 Final Rule was published in -- on July 16th, 2018. It was Final Rule and also implementation guidance was issued and published in the Federal Register.

For this rule, the medical team is developing or has developed training that we will be giving to the NRC staff, NRC licensees, the Agreement States, master material licensees and their permitees.

We're going to conduct between October of 2018, probably through March of 2019, webinar training sessions. And, we're planning at least eight more if necessary to roll out the new Part 35, if you will.

So, January 14th, 2019 is when the rule -- Final Rule becomes effective for NRC licensees and master material licensee compliance.

Three years from that date is would be the effective date for the Agreement States.

Next slide?

So, just to recap a couple of the major revision. There are separate requirements now for identifying and reporting medical events involving permanent implant brachytherapy.

The new rule also added requirements to

measure the Moly-Tech breakthrough after each generator elution. The new rule adds reporting requirements for failed technetium and rubidium generators.

The rule grandfathered certain board certified individuals from certain T&E requirements.

And, the new rule adds the Associate Radiation Safety Officer that could be named on a materials license.

And we -- the rule also adds the Ophthalmic Physicist that could be named on a license.

Next slide?

I wanted to mention this rule. And this was a petition for rulemaking. It's the Naturally Occurring and Accelerator Produced Radioactive Materials.

In April of 2017, we received a petition from the Organization of Agreement States, or OAS, to amend 10 CFR Part 30 Appendix B.

Appendix B of Part 30 is used for calculating decommissioning funding requirements. And, in Appendix B, the default possession thresholds for unlisted radionuclides is felt to be too restrictive.

In 2005, Congress had authorized the NRC

to regulate discrete sources of naturally occurring and accelerator produced radioactive material, or NARM.

NRC did not update Appendix B at that time to add these NARM radionuclides to the table. And, as a result, regulators feel that they must apply burdensome decommissioning funding obligations or evaluate exemptions that hinder the introduction of new technologies and adversely affect patient care.

So, the petitioners in this case asked the NRC to amend Appendix B to add appropriate nuclides and their corresponding activities as determined by a rulemaking group.

Next slide?

So, NRC is taking action on this petition. In August of 2017, the NRC noticed the petition in the Federal Register and requested public comment.

Twenty comment letters were received. No one opposed the requested rulemaking.

And then, in April, staff did formulate a recommendation and conducted a Petition Review Board.

So, currently, staff is preparing the recommendation and Federal Register Notice for

Commission review and decision.

I included this rule because I wanted to point out that we do have medical team staff who do -- are supporting this rulemaking effort with our rulemaking division.

So, that's another role of the medical team are to support any sort of rules that touch in the area that touch the medical areas.

Next slide?

So, just a few things on the NRC Agreement State Working Groups.

Next slide?

So, we currently have several active NRC Agreement State Working Groups. I kind of already mentioned this, but we do have NRC Agreement State Working Group working on the MASEP Infini GammaPod stereotactic devices.

This could be a cue for ACMUI that, down the road, maybe next summer, you may see these draft guidance documents coming your way for review. So, that's something that's coming down to ACMUI probably next summer.

The -- it is a NRC Agreement State Working Group working on the Yttrium-90 as well as the Leksell Gamma Knife.

And then, another one that we haven't talked on and I'm going to give a little more information in a moment, but that's the Regulatory 8.39 -- Regulatory Guide 8.39 Release of Patients Administered Radioactive Material Working Group.

And then, continued efforts by the NorthStar Working Group as well.

Next slide?

So, in addition to the guidance documents that might be put forth by those Working groups, we have some other guidance documents I wanted to note.

So, go ahead, next slide?

So, the first one is the Germanium-68/Gallium-68 Generators. Currently, the current guidance for this generator is specific for the Eckert and Ziegler GalliaPharm Ge-68 Gallium-68 Generator.

And, NRC foresees that there will be other generators coming down the pike and that we need to provide guidance for other generators as well.

So, we modified -- the medical team modified this existing guidance document to be a non-specific manufacturer licensing guidance.

The modifications really included minimal word changes to create more of a brand neutral guidance so that we would not have to always create

a new guidance document that was manufacturer specific if the guidance could apply to all types of Gallium-Germanium generators.

So, no changes were made in the revision that staff -- in the revision staff took. No changes were made in the commitments, the breakthrough limits, radiation safety to follow for the operation of this generator.

And so, where we are with this now, we have issued a radiation control program letter -- radiation control program director letter to the Agreement States asking for comment. And, this is one we will be looking to ACMUI to review as well so that will be another subcommittee that we'll be looking ahead to.

And, I think we're going to talk about that later today.

But, anyway, so this guidance is, again, intended to be not specific to a manufacturer so that we won't hold up people from using other generators that might come down the pike.

Next slide?

The Volume 9 and Volume 13 of the NUREG-1556 series documents, so these have been in process and under revision for a while.

But, one thing that we were able to do is amend or add revisions to both of these documents that comport with the Final Rule.

So, the working groups that were drafting these revisions that have been -- because these have been in process for a couple of years.

So, as the rule was becoming final towards completion, the working groups were able to begin incorporating or identifying what would need to change with these guidance documents so that they comport with the Final Rule.

So, when these documents are released, hopefully, sometime in early 2019, but they're currently in the concurrence process.

But, once these are finalized, they will comport with the Final Rule. So, they'll be current with the Final Rule which is nice so we don't have a situation where these guidance documents got way ahead of the rule and got published and then having to issue and addendum to them to align with the Final Rule.

So, but when they are issued, they will comport with the Final Rule -- Part 35 Final Rule.

And, I think that's all I have for updates for the medical team.

CHAIRMAN PALESTRO: Thank you, Ms. Dimmick.

Any comments or questions from the Committee?

Mr. Sheetz?

MEMBER SHEETZ: I have a question. Currently, the Part 1000 uses have a Compatibility Level D with Agreement States. So, if a new medical device comes out, say, DART, and an Agreement State starts to do an evaluation, how is that coordinated with the NRC with respect to deciding on what category it should be licensed under?

Because, DART, I could see it licensed under Part 1000. I could also see it under 35.400.

So, that's from how that's evaluated?

MS. DIMMICK: So, we have pretty good communication with the Agreement States. So, typically, when an Agreement State sees a new technology, especially that might be coming for their -- to license it, they'll contact us to discuss, are you planning 35.1000 guidance or, you know, what and to move forward.

So, once we start to see where they are with ready to license something, that will help us to know when we might need to start a 35.1000 guidance.

While 35.1000 is not a compatibility requirement for Agreement States, they can use it if they end up tying their licensees to that licensing guidance. And, that's often what they do because they might look to see how NRC would license that product.

MEMBER SHEETZ: But, are they obligated to engage you in that working group discussion?

MS. DIMMICK: No.

MR. BOLLOCK: Yes, they can -- the States can independently, if a new technology comes in, they can independently license that for use in their State.

I don't know if you have anything else to add, Megan?

MEMBER SHOBER: Yes, this Megan Shober.

From a practical standpoint, I don't think there's any State out there that has enough technical expertise to really come up with one of these -- a complete guidance set with our in house staff.

So, we really have to pool the resources from across the country and from the NRC to come up with a good workable product.

And, I think that States want that -- we want to work together to do that.

MS. DIMMICK: If I might add, that with many of these technologies, the first sites or licensees that are using them are the medical broad scopes. And so, there's enough flexibilities within the medical broad scopes that they are able to evaluate how they would use these sources and devices in their facilities under -- with their broad scope program.

CHAIRMAN PALESTRO: Any other comments or questions from the Committee?

(No response)

CHAIRMAN PALESTRO: Comments or questions from attendees in the room?

Dr. Ennis, I'm sorry.

MEMBER ENNIS: So, if everyone kind of collaborates and cooperates, why not make 1000 Compatibility C at least? It makes me anxious a little bit to think that a State could go rogue.

You know, who knows? Some manufacturer who's got deep pockets or connections might get a State to go along with something that we would be uncomfortable with.

MR. PETERS: Sorry, Mike Peters, ACR -- do you want to -- sorry.

MS. DIMMICK: I'm trying to think how

best to maybe -- we'll just take the comment in that sense.

I don't foresee that sort of thing. States will have a process. They might be able -- they have some flexibility as to how they could identify how some things could fit in another area of the regulations or how their regulations are written, they might have a way that they could incorporate some of these.

Because many of these technologies are similar to other of the categories, but there just might be some exceptions.

So, they might issue the -- go ahead and issue it under another category with some level of exception. I mean, there's just different ways that they could do it.

MR. BOLLOCK: Right. And, I could add an example, the Germanium Gallium Generator, the reason it's not licensed under 200 is because there's not a breakthrough limit and 200 has specific breakthrough limits for the Moly generators and Rubidium generators. It doesn't have it for Germanium Gallium.

So, a State, maybe in theory, I think a State could, for that type generator, I'd be confident

that Megan could approve that with -- as a licensed reviewer with, you know, some basic information received from the, you know, in coordination with the FDA or the manufacturer to safely license that.

So, there are, you know, that's right there a real world one where I think there is the capability of a State to do it. That may be the reason why 1000 is, I don't know the reason why it's in the regulations as the rule is written. It was determined that the category was.

But, that right there is just a real world, I mean, a reasonable example of why that could be or in a situation where it would make sense and be safely licensed.

I don't know if that helps, but the reality is just the way the rule is written and the determination for the compatibility was determined to be, I think, give the States flexibility to do things like that.

CHAIRMAN PALESTRO: Mr. Peters, you --

MR. PETERS: Sure, so I guess this is more a question about the ACMUI interface with the NRC and Agreement State work groups that work on the licensing guidances.

Historically, it seems like controversy

comes when those work groups differ from ACMUI recommendations, at least as far as the medical community is concerned.

Is there a reason, a technical reason why ACMUI can't be more involved with the licensing guidance draft revisions and stuff in a preliminary fashion before they're actually drafted so that we can lessen the controversies that pop up like we saw with the Y-90 draft Revision 10?

MR. BOLLOCK: Yes, I can respond to that, I don't know if Megan wants to chime in or some ACMUI members.

We have actually frequently engaged with specific ACMUI members who have expertise with the technology, knowledge of the technology or, you know, have constituents in their fields that can help provide that information.

I know we've reached out to Ms. Weil on a number of occasions, you know, Mr. Green, a number of others on the Committee for -- to help us in that development.

Recognizing, like you said, with -- there is Y-90. The working group has an idea of something, I think it's the pathways, right, which should there be manufacturer pathway. That can still happen even

if -- even with understanding what the ACMUI feels the States have.

The working groups, typically, we get a number of representatives from the States. They have their way of doing things. There's kind of the precedence for, you know, AUs. The precedence is, once the -- if you have an established modality, AUs train other AUs. Right?

That's looking at everything else, that's the precedence that could, you know --

There are other reasons besides that. We do -- but we do, staff absolutely does reach out to our ACMUI members to get that insights in the early stages in development. And then, we'll bring that -- our staff members will bring that to the work group.

MR. PETERS: That's comforting to know. And, I wasn't trying to volunteer these poor people for additional work or anything like that.

(Laughter)

MR. PETERS: But, certainly, we like to see ACMUI recommendations be sort of the standard that the work group develops their licensing guidance draft revisions and stuff around.

MR. BOLLOCK: Yes, we -- I mean, we definitely take very seriously and that's why we have

the Committee to advise the NRC staff. They advise the staff, they advise through the staff to the Commission.

The Commission makes the final decisions or with the licensing guidance staff, you know, through a review and our general counsel review, we make the final decision on the licensing guidance for the specific licensing commissions.

However, we don't always align exactly with ACMUI, but we are -- I think the number is somewhere around 85 percent, we accept about 80 percent fully accept what the ACMUI recommends. And somewhere in 10, 14 percent of at least partially accept what the ACMUI recommends to staff.

So, it is very rare that we -- that staff does not agree with the staff or the Commission doesn't agree with the Committee.

CHAIRMAN PALESTRO: Mr. Sheetz?

MEMBER SHEETZ: I guess I would like to go back to Dr. Ennis's stated concern, and the same concern I have, although I would just ask the question and was dancing around it.

But, I'll bring up again, are we comfortable with the current working relationship between the NRC and the Agreement States for new

technologies coming out?

My feeling is, the NRC should be involved right up front with all of these because they have the technical expertise and resources and they also have the resources of the ACMUI to evaluate these new technologies.

So, I guess my concern is, as Dr. Ennis was pointing out, maybe an Agreement State would just want to go alone and do their own thing.

And, they really have no obligation to engage the NRC and they could pick the category and license that under whatever category they wanted.

Some little concern, but I'm new to this, and so maybe that concern is not founded.

MR BOLLOCK: In my experience, and this is just my experience, it's very rare that we -- that the State wouldn't share information with us at some point. Right?

Because a lot of these technologies, they're going through FDA approvals. They're only at broad scopes. Right?

And, we learn, and actually, in the SECY paper that Lisa referenced in her presentation, we go through all the different ways that we, the NRC, hear about the new technologies.

And, the States are one of the primary ones, the FDA is another one. ACMUI members are another resource and then the manufacturers.

They come, you know, some manufacturers know to come to us if they're --

And so, we do, you know, we're open to this. This is why one of the reasons we have the Committee.

Understanding the, I guess, the fear that there could be a licensee that goes to a State, it'd be rare that we're not, like I said, it's very rare that we're not aware of that.

MEMBER SHEETZ: Not so much that they wouldn't engage you, but they may engage you too far down the road which is one of the concerns from the ACR.

MR. BOLLOCK: And, so, again, back to yesterday's presentation or one of yesterday's discussions about the IMPEP reviews. If a State was -- I'm not going to -- I'm just going to -- if they went rogue, for whatever reason, and they were doing something that wasn't -- that was outside what their program is supposed to be, IMPEP reviews are one of the -- is kind of the balance.

And, all the States, and even our

regional -- the NRC regions are under the IMPEP program and get reviewed in how they license and how they inspect and how they enforce among their programs.

So, that's -- I mean, there are checks to that if those type things were occurring.

But, you know, the States are -- they are Agreement States, they license their products in the States. Again, it's, you know, we have a good relationship with them and, you know, we typically do work as a team.

Every one of these working -- the reviews that the ACMUI of our 35.1000 guidance has come from a working group with rare, rare, rare exception.

If there is a minor tweak update to a revision, we may not go to the States. For instance, the Germanium Gallium Generator, we just made it brand neutral.

We shared with the OAS, said, are you okay if we just make it brand neutral? You'll get a chance to look at it, which they are -- all the States are.

But, in almost every other case, they have representatives on our groups that develop the guidance. And, again, the guidance is specific

license conditions that we deem necessary for the safe of those modalities.

CHAIRMAN PALESTRO: Ms. Holiday?

MS. HOLIDAY: Did Megan want to speak before?

CHAIRMAN PALESTRO: Ms. Shober?

MEMBER SHOBER: The thing that I just want to add about the -- any of these licensing guidances are major efforts to research and pull together.

And, quite frankly, NRC doesn't have the staff to do that by themselves. So, you're talking like, I don't know, what do you have, six people, maybe?

MR. BOLLOCK: When we're fully staffed we have six.

MEMBER SHOBER: Yes, when you're fully staffed?

And so, by drawing from Agreement State resources, there's 150 people that could jump in and provide substantial help in doing that.

So, it really is a national effort to come up with a product like this.

MR. BOLLOCK: Yes, and there's a lot of thought. Right? We try to work as a -- as one

national program.

You know, everyone working together to have, you know, put our best foot forward.

And so, as Megan stated, you know, we have medical team staff of six people for all these reviews. So, we do rely on the Agreement States to help us.

They also have, you know, they've got licensed inspectors that are out there seeing this review, this. They're very familiar with it.

We also use our regional staff. So, out of the three regional offices, we'll use because we have our NRC license reviewers and inspectors.

So, that's how we get the -- another way we get the resources to do these technical reviews.

And, as I said earlier, we will consult with our ACMUI members to also help us fill us, you know, fill the gaps.

And then, we'll -- and we do reach out to the manufacturers and get the technical information needed.

CHAIRMAN PALESTRO: Ms. Holiday?

MS. HOLIDAY: So, I'm got to try to give my comments with respect to everything I've heard from the Committee, from Doug, from Lisa, as well as

Mr. Peters from ACR.

So, because there are newer members on the Committee, a couple of years ago, I gave a presentation to the Committee related to how it is that we go about licensing 35.1000 modalities.

And how we also obtain information about these technologies.

And, as Doug alluded to, there are various ways that we learn about these technologies. It could be through our MOU with the FDA. It could be that the manufacturer comes directly to NRC and informs us that they're getting ready to, you know, develop some new technology.

It could be through an Agreement State where they have the sealed sourcing device registration within their State or they have a licensee that has reached out for them, or potential licensee asking to add it to their license.

It could be through one of our NRC States where, you know, they are coming to us telling us that they would like to get a license for this modality.

So, once we get that information, it could prompt the development of a joint NRC Agreement State Working Group. It could be that if it starts

from an Agreement State, they could come to us and maybe ask our opinion about if this is how they should go about licensing.

Or, ultimately, they may come to us and say, hey, we are not sure how we want to do this, can we start an NRC Agreement State Working Group?

You may have heard or you have heard over the years about the importance of a national materials program.

And, what that essentially is, is our relationship with our co-regulators in the Agreement States.

NRC currently has 13 States and there are 37 Agreement States. Come October, There will be 38 Agreement States and 12 NRC States.

So, really it -- a lot of our licensees or a lot of the materials licensees are in Agreement State space.

That being said, 35.1000 licensing guidance or 35.1000 period, is the Compatibility D. That does mean that Agreement States do not have to follow NRC's 35.1000 licensing guidance.

As Megan said, you know, often times, Agreement States do not have those resources to develop their own guidance or how they would like to

approach a certain modality.

So, they do tend to lean on the concept of an NRC Agreement State Working Group.

However, there have been times where Agreement States do go ahead and issue their own licensing guidance or pursue how they want to license a particular modality ahead of the NRC's guidance or the NRC Agreement State's product being developed.

That has happened. That happened at least for the Germanium Gallium-68 Generator where I believe it was the State of Virginia that licensed it ahead of us.

I mean, there are places like that. So, I won't say I feel like rogue is a very strong word, but, as we all have discussed in these meetings, often times, the problem that physicians have is that, if you are licensed to practice in one State, that is an Agreement State, for example, New Jersey and New York.

The requirements in New Jersey may be different from New York. And, the reason for that is that, you know, at NRC, we have granted these agreements with these states, hence, Agreement States.

And, we have given them certain regulatory authority for their program. So, you

know, while it would be very ideal if we could have a very uniform set of how we approach regulations, because we have granted these authorities, it's just not realistic to expect that.

Although, by default, as you heard from Megan, very commonly Agreement States will wait for these licensing guidance to be developed and they just piggyback off of ours or they tailor it to fit their needs.

But, often times, 80-plus percent of the times, it is essentially our licensing guidance that Agreement States will use.

Hopefully, that addresses everybody's comments.

And, also, before I forget, Mr. Peters brought up the notion about how we should be proactive in engaging the ACMUI and that ACMUI's recommendations should be the standard.

But, I would also like to remind you guys that at ACMUI, you are an independent advisory committee. The working group, the NRC Agreement State Working Group is an independent working group in itself.

The working group, in their charters, it has language in there built in that they can reach

out to the ACMUI should they need information or advice or recommendations.

We also have the ability to reach out to manufacturers if we have questions. And we often times have done that.

I know, for example, for my Perfexion Icon Working Group, we reached out to Dr. Suh several times because, again, the purpose of this Advisory Committee is that we do not have that medical expertise on staff. That is why you guys are here. That is why you are important.

So, yes, we do reach out to the ACMUI. But, just like anything, ACMUI's recommendations are independent. You advise staff, but ultimately, we make the decision. We consider everything that you inform us.

And, as Doug said, I mean, compared to all of the federal advisory committees across the U.S. government, we accept a lot of the Committee's recommendations.

Many FACA Committees, agencies only accept or implement less than 50 percent of their recommendations.

So, that is to let you know that we highly value your input and your advice.

Thank you.

CHAIRMAN PALESTRO: Thank you, Ms. Holiday.

Any other comments or questions from the Committee?

(No response)

CHAIRMAN PALESTRO: Attendees in the room?

(No response)

CHAIRMAN PALESTRO: Attendees on the phone?

(No response)

CHAIRMAN PALESTRO: All right.

All right, the next topic and final topic before lunch is the open forum.

Anyone have any issues they'd like to have addressed?

(No response)

CHAIRMAN PALESTRO: Have just one comment that I would appreciate it if, and not before the end of the meeting, but certainly in the next week or so, and you've done it in the past.

If staff would put together a list of all of the members of the ACMUI with their contact information as well as what category they represent.

It would be very helpful for all of us if we want to contact one another. But, particularly, for the Chair, me, when I have to put together subcommittees, I can look at the various areas of expertise.

And, along that line, with respect to the radiation oncologists, I know there are some subdivisions, brachytherapy and I forget the other one off the top of my head, but I'd like to see that in the list.

Mr. Bollock?

MR. BOLLOCK: Yes, we can get that for you.

CHAIRMAN PALESTRO: Thank you.

Not just for me, I'd like to have it distributed, obviously, to everyone.

MR. BOLLOCK: Right, we can distribute that to the ACMUI members.

CHAIRMAN PALESTRO: Anything else before we adjourn for lunch?

MEMBER SHEETZ: Yes, I do.

Yesterday, Dr. Metter presented the final subcommittee document on breast feeding guidelines and recommendations.

And there was some discussion on where

that could be referenced or published or so forth. So, I wasn't sure, one thing I saw was maybe it could be referenced in the new 8.39 regulatory guide or somewhere.

MR. BOLLOCK: Right, that's -- so, I was going to remind the Committee, and thank you, Mr. Sheetz, for that.

There are, yes, there are two things from the Nursing Mother's Guide. I think the Committee accepted a report, but there was specific -- there was some discussion of specific language to say this is -- this report is -- or the isotopes or radiopharmaceuticals listed in this are -- that this -- or these numbers are only for those listed in this guidance.

CHAIRMAN PALESTRO: Yes, we acted on that before.

MEMBER SHEETZ: Yes, that was acted on this morning.

MR. BOLLOCK: Oh, I must have been -- sorry.

CHAIRMAN PALESTRO: That's okay.

MR. BOLLOCK: Yes, and then second, the second one was, if the Committee has a recommendation for staff on what you would like staff to do with the

Nursing Mother's Guidance, is that correct, Mr. Sheetz?

MEMBER SHEETZ: Yes, I think it's important that it is referenced somewhere or included as an attachment. I just don't know what documents practically that could be referenced or attached to it at this point in time without waiting multiple years.

MR. BOLLOCK: Right. So, we are working on updating a draft for Reg Guide 839 which is the regulatory guide for patient release.

So, that is -- that's one appropriate place for it. And, staff feels we're working on that draft. It's a consideration because that's something that's open now and we're working on.

And, that would be one appropriate guidance document to attach that to.

But, if the Committee has any recommendations, again, at the very least, the report is on our ACMUI public website so people who want to use it as a resource can find it.

And then, we can, you know, we can either make it its own Reg Guide or we can attach it as, I think we would probably prefer, it's much easier to have it as an attachment or an Appendix to the updated

Reg Guide 8.39.

Saying that, the -- how the Reg Guide process works, we -- staff will draft the Regulatory Guide and I know Said Daibes leading effort with an Agreement State Working Group, that Agreement State and Regional Working Group.

That'll then go to our Office of Research that just runs the process of regulatory guides. It will go out for public comment. So, there will be a 60 day comment period.

And if -- and that -- so then, the Nursing Mother's Guide would be included as a -- if it's included in the Reg Guide, it would be open for public comment.

So, just for your awareness.

CHAIRMAN PALESTRO: Any other comments or questions?

DR. DAIBES: yes, Said Daibes.

With respect to the question that was raised, we have a section in Reg Guide 8.39 that will address your raised concerns. So, we'll have a section on guidance and some extractions of the report that will be referenced back to the report, yes.

MR. BOLLOCK: Yes, in your working group's draft guidance.

DR. DAIBES: Yes, so that was determined by the working group. And, we're Working on it.

CHAIRMAN PALESTRO: All right, thank you.

Any other comments or questions?

(No response)

CHAIRMAN PALESTRO: All right, just before we adjourn, two quick items.

Number one, when you are making your reservations at the Marriot under Group Code, make sure you use N-18 so that you get the NRC rate.

And, number two, if before we leave, take a couple of extra minutes here, need to get a group photo.

Thank you.

MR. BOLLOCK: Thank you.

And so, is that -- so, what Dr. Daibes shared, does that satisfy the Committee? No --

CHAIRMAN PALESTRO: I'm sorry, I didn't mean to --

MR. BOLLOCK: -- for the Reg Guide, for the Nursing Mother's Guidance, the work group's decided that they believe it should be part of the Reg Guide 8.39. Is that satisfactory to the Committee?

MEMBER SHEETZ: Would you like a motion

from the Committee?

MR. BOLLOCK: We don't need to do that. That's the action we're going for.

MEMBER SHEETZ: That's great.

CHAIRMAN PALESTRO: Thank you.

(Whereupon, the above-entitled matter went off the record at 11:57 p.m. and resumed 1:05 p.m.)

CHAIRMAN PALESTRO: All right. We're going to reconvene now. Next topic on the agenda is ACMUI Subcommittees, NRC Staff, NRC Management, How the Team works under FACA.

And Mr. Chazell and Mr. Bollock will discuss and present this.

MR. CHAZELL: Okay. Am I working? All right. Hi everybody. My name is Russell Chazell. I'm happy to be with you today. Thanks for the invitation.

I work in the Office of the Secretary. And I serve as the NRC's Federal Advisory Committee Act, FACA, Committee Management Officer.

My role as CMO is to monitor the activities of the NRC's three advisory committees. The ACMUI of course, the Advisory Committee on Reactor Safeguards, and the Licensing Support Network

Advisory Review Panel.

So, those are the only three FACA committees that the NRC has. There are other agencies that have a lot more.

My job is to ensure that the three committees comply with the requirements of FACA. And Doug Bollock, who you all know, serves as the Designated Federal Officer for ACMUI. And as the DFO, he ensures that ACMUI complies with FACA.

So today I'll provide an agency level overview of FACA. As well as discuss some ACMUI history. And Doug will address some specific topics later.

And I apologize if you've all heard this stuff before. Hopefully you haven't. Hopefully it's new to some of you. But, I guess we'll find out.

So, Congress when they passed FACA back in the '70s, I think it was, intended for FACA committees to do three things. Provide advice that is relevant, objective, and open to the public.

Act promptly to complete their work. And comply with reasonable cost controls and record keeping requirements.

Further, the committees operating within the confines of FACA, serve the public interest when

they provide federal officials and the nation with expert information and advice on a broad range of issues affecting federal policies and programs. And they participate actively in the federal government's decision making process.

So, as you know from your own selection processes, the NRC goes to great effort to ensure that committee members can provide the kind of expert advice sought under the auspices of FACA.

And because taxpayer resources are being expended, FACA committees must comply with not only FACA, but other federal laws such as the Government and the Sunshine Act. And I've got the citations there if you need a little -- if you're having insomnia and you need something to put you to sleep.

There's Public Law 92-463 is FACA. And Public Law 94-409 is the Government and the Sunshine Act. And if you Google those, they'll come right up.

Additionally, FACA committees must comply with regulations promulgated by the General Services Administration, because they're the government-wide program manager for FACA, and then the NRC.

So, implementing rules for GSA are 41 CFR Parts 101-6 and 102-3. And those are the rules that lay out details like you have to announce your

meetings 15 calendar days in advance. And they have to be published in the Federal Register and all that kind of stuff.

And then the NRC's FACA implementing regulations can be found in 10 CFR Part 7. Which is in these books here.

So, in order to comply with FACA, each committee must have a Designated Federal Official, which in our case is Doug Bollock, pursuant to 10 CFR 7.11. And the DFR will -- the DFO will approve meeting agendas, convene the meetings, attend the meetings, adjourn the meetings, chair the meetings when directed to do so, and ensure compliance with laws and regulations.

So, next slide. This going to go really quick. So here's a little history on ACMUI.

It was established on July 1, 1958. And the Charter renews every two years. And one of my jobs as CMO is to process the Charter renewals through GSA.

And we sent up a SECY paper to the Commission saying we want to go two more years with this Committee. Do you approve?

And then once they do that and we consult with GSA, then we file the Committee with GSA. And

send copies of the Charter to the House of Representatives, and the Senate, and the Library of Congress.

ACMUI reports to the Division of Material Safety Security State and Tribal Programs in the Office of Nuclear Material Safety and Safeguards. And my understanding is that the current MSST Director is Daniel Collins. And the Deputy Director is Sabrina Atack. So I presume you guys have already met them, so.

There are 13 Committee members appointed. You're all special government employees, which is a special type of employee in the federal government that limits your work effort to 130 days in any 365-day period. And your pay is capped at the daily rate for Level Four of the SES Schedule.

One of the requirements that we have from FACA and the GSA implementing regulation is that we provide them with a membership balance plan. And so have to go through every two years when we renew the Charter, and we just did that -- did this earlier this year.

We have to provide a copy of that membership balance plan to GSA. And it gets posted on the GSA's database. Another thing you can look

at if you have time, at FACAdatabase.gov.

And it has information on every FACA committee in the government. And there's like 12 or 15 hundred of them. There's a lot of them.

And you can search by agency and see the different committees. And you can see the reports. And you can see who the members are. So you're all listed on that database.

And that -- get whatever information you might be interested in. And all kinds of different committees.

But, for our purposes, the membership balance plan for ACMUI includes healthcare professionals of diverse specialties who represent diagnostic and therapeutic applications of medicine, medical administration, and patient care advocacy.

And that's what's in the Charter. And so whenever we have vacancies, that's the template that we have to follow when we solicit for new members.

The terms are set at four years with a limit of two terms. Members are appointed by the Director of NMSS after consultation with the Commission.

And as you know, I think I saw on your

agenda that you had some ethics training yesterday. All members must comply with federal ethics laws and conflict of interest laws similar to what regular government employees have to do. Although I know there are some differences given the fact that this is not your full time job, so.

Subcommittees. According to the Charter there are no standing subcommittees for ACMUI. So, any subcommittee work you do, my understanding is that it's on an ad hoc basis.

One of the FACA rules is that subcommittees must report to the full committee. So the subcommittees don't necessarily provide their output or their deliverables to the decision maker.

They have to provide it to the full committee, which then would provide whatever they -- whatever output they wanted to the decision maker.

Meetings must be open to the public. There are some narrow Government and the Sunshine Act exceptions like personnel matters or internal process things. But for the most part any substantive discussions that you all have, have to be open to the public.

And then as I said earlier, I'm the Committee Management Officer, and I have to validate

an annual report to the General Service Administration. That then goes up to Congress so that they can see, you know, what the taxpayers are paying for.

And they do this on a government-wide basis. And we provide input on our three committees every year. And we upload it to this database.

And we have to consult with GSA to make sure that the information that we are providing is responsive to what they're looking for. And mostly that information is how much did we spend?

How many government employees, regular government employee FTE did we expend? So, we're looking at money. We're looking at FTE.

We're also looking at if you -- if the committee had contractor support of any kind, you know, that information we'd have to put in there as well.

We also have to make a recommendation as to whether or not the committee is planning to continue in the next fiscal year. You know, all those kinds of resources, information that, you know, decision makers in Congress when they're deciding how much money they're going to spend, they want to know that the money they are spending is being expended in

a reasonable way.

And so that's about all I've got. Again, it's been my pleasure to meet with you all. And I can take any questions that you might have.

CHAIRMAN PALESTRO: Any questions or comments from the Committee for Mr. Chazell?

(No response)

MR. BOLLOCK: Well then if the Committee doesn't have any questions for Russ, I can -- there's a couple of topics, some of them touch on FACA, some of them are just normal ACMUI process that I know Dr. Metter and Dr. Palestro can answer with no problem.

MR. CHAZELL: I can get out of your chair here Doug. Thanks again for your time.

MR. BOLLOCK: No, it's working now. Last chance to ask Russ a question before he leaves.

(No response)

MR. BOLLOCK: All right. So some of the questions or some things -- questions that have come up recently dealing with ACMUI subcommittees.

What is a -- and as Russ just said, subcommittees, there's no standing subcommittees. We've -- you've heard that from us before.

And their meetings are ad hoc. The meetings are -- but any full committee meetings have

to get on the public settings.

So, one of the questions is on subcommittee size and composition. The reason for the size restriction, that is a -- that is a FACA compliance concern.

If a subcommittee is greater than -- if you have 50 percent or greater of the full committee meeting and deliberating, then it has to be done in a public setting. So that's why we keep the subcommittees at a -- when we have a full committee of 13, the subcommittees can be up to six members.

So right now with a full committee, we can have six members. Yes?

VICE CHAIRMAN METTER: So if you have an open seat for our committee, does that make it less?

MR. BOLLOCK: Yes. And that has happened about a year or two ago. I know we had -- I think we were down to ll or 10. So we had to get subcommittees down to five or -- I don't know if we ever had to go to four.

But I know we had to cut that.

VICE CHAIRMAN METTER: So my question is, so let's say right now we have a full committee. And let's say there are a couple of our members are not -- the position is not filled.

What about our subcommittee? Let's say if we have to have a meeting on the -- before?

MR. BOLLOCK: Yeah. If it gets to the point where members rotate off and there's a subcommittee formed and they're working on something and they're at six, and we have -- then the DFO or one of the alternates would have to count, would make a determination that we have to cut the subcommittee down.

We would inform -- inform you. And we'd have to remove a member from the subcommittee. So that is a possibility.

VICE CHAIRMAN METTER: Okay. Thank you.

CHAIRMAN PALESTRO: Okay, before we go on, I just want to clarify that. It was my understanding, correct me if I'm wrong, that for example we have 13 members, full committee. We have six members on the subcommittee.

If two individuals who are not on the subcommittee rotate off, we're not required to remove someone from the subcommittee, are we?

MR. BOLLOCK: No, we are. Because that's -- because then that would be greater than 50 percent of the new full comm -- the full committee.

CHAIRMAN PALESTRO: I didn't think we had

to. This came up before. I just want to double check. I want to be clear about that.

MR. BOLLOCK: Sophie, you can correct me if I'm wrong. But they will --

MS. HOLIDAY: Okay. So generally speaking what Doug is saying is correct.

I think what you may specifically be thinking of, because very rarely do we actually have a subcommittee that has more than five individuals, but Dr. Ron Ennis' subcommittee that reports out every year on the medical events. You know, that -- we've had discussions with the subcommittee.

You heard during Russ' presentation that we don't have standing subcommittees. So while his subcommittee reports every year, it's titled a subcommittee.

It's not necessarily a subcommittee in terms of pushing forward an action or a recommendation. That subcommittee was pushing out information, a review of the annual reported fiscally -- fiscal year reported medical events.

So, for example, for that particular subcommittee that had six members, we didn't have to reduce the subcommittee membership for that. Other subcommittees, for instance, Yttrium-90 or comments

on other licensing guidance, training and experience, those we would have, and are expected to reduce the number of subcommittee members.

Because the idea is that when you are presenting the subcommittee's report to the full committee, because it has to be a product of the full committee, the full committee takes a vote.

If you have six members on that subcommittee, and say you only have ten members on the committee, and six members on that subcommittee are approving a certain motion, we support this. And you only have four remaining members on the committee that say we're against this, well by default the subcommittee is the majority. So the motion would carry.

So that's the reason why we have membership less than 50 percent of the current number of members on the committee.

MR. BOLLOCK: Right. And so it's -- and Sophie, thanks for bringing up Dr. Ennis' subcommittee. Because that -- that's normally what they do by practice.

But yesterday I think you were -- you had other things going. Yeah. They actually gave a recommendation because they did a review and gave a

recommendation to staff to do an information notice based on an analysis -- a three and a half year analysis. And not just going over the events and sharing information.

So that would be --

VICE CHAIRMAN METTER: Can you explain how that might be involved?

MR. BOLLOCK: So, if a subcommittee has -- if the subcommittee is doing work coll -- well Sop -- some of the examples Sophie was giving was the, you know, the subcommittee had six members and even with the changing. What the subcommittee did was sharing information.

But when a subcommittee is deliberating and the full committee -- for something the full committee to vote on and then give action to advise the NRC, you have follow -- right, you have to follow the under 50 percent requirements.

MS. HOLIDAY: Well, I wasn't here for that presentation.

MR. BOLLOCK: Right.

MS. HOLIDAY: But was there an actual product that came out of Dr. Ennis' subcommittee? Or was it after the subcommittee's presentation a recommendation or a motion was put forth by the

committee?

MR. BOLLOCK: They recommended that we do an information notice giving examples of -- or what they were -- yeah, what they thought were the, I guess, best practices that could help prevent events.

MS. DIMMICK: So, just to clarify, a motion wasn't actually made to do that. That was a recommendation the committee had. But we don't have a motion on the record to make -- to do the information notice.

There wasn't a motion made for the staff to develop an information notice to move forward the subcommittee's recommendations for the time out procedure or other best practices.

So we didn't actually have a motion for that yesterday. Just it was -- it will be reflected -- or it's going to be seen unless we do that before we convene today, it's just a recommendation that the committee would have that it made in the meeting.

It's not a formal recommendation.

MR. BOLLOCK: Right. So, because of -- we have to be careful with what -- with what we do to not violate FACA requirements, right. With what the subcommittee's work does.

And that's why generally we should -- or general practice with a rare exception if they're not going to have some sort of recommendation, would be less then -- no more than 50 percent of the members can be on the subcommittee.

CHAIRMAN PALESTRO: Any other comments or questions on that Dr. Metter?

VICE CHAIRMAN METTER: I'm sorry. But I'm still confused. So let's use Sophie's scenario. Let's say the radiation oncologist and the administrator positions do not get filled.

But let's say a committee of six presented their final report. Then could -- that means that the ACMUI could not vote on it?

MR. BOLLOCK: We would have -- no. We would have to take a member off the subcommittee.

VICE CHAIRMAN METTER: So you would take that person off the subcommittee. Okay.

MR. BOLLOCK: Right.

VICE CHAIRMAN METTER: That doesn't make -- because that position would probably be the same. I'm just --

MR. BOLLOCK: Well, if -- okay, if you're talking time frames, the subcommittee did all the work yesterday. And then today two members drop off.

The work was already done. Following FACA and everything is fine. Right? There's no issues.

VICE CHAIRMAN METTER: But then who can -- let's say --

MR. BOLLOCK: But going forward, if they say there's further actions of that subcommittee, that subcommittee would -- and going forward now that the membership of the full committee dropped, they would --

VICE CHAIRMAN METTER: Um-hum. Right.

MR. BOLLOCK: And we have done, I know we have done this where we would have at least one member of that subcommittee if they were going to do further work, would then have to.

VICE CHAIRMAN METTER: But the -- let's say the subcommittee presented their report, then let's say a member has to then drop off. But then it will still go to the full committee with a person maybe being on a biased side.

I'm just wondering how the logistics -- you know what I mean on that. So, I'm just wondering what would happen there.

Thank you Sophie for the explanation.

MR. BOLLOCK: Yeah. A lot of the reason

it's for -- as Sophie said and the rules, or like Russ had presented under the Sunshine Act, which is the deliberations of what the federal government is considering, is done in the public setting.

All right, so that's the main reason why the membership has to be less. It's multiple reasons. Like Sophie said, was the reason of you could have that on -- that bias.

But it's also if you have -- we can't -- if you have deliberation of greater than 50 percent of the committee, that has to be done in a public setting. Because that is considered now enough for a quorum of the committee.

And it has to be done in a -- under the Sunshine Act has to be done in a public setting.

VICE CHAIRMAN METTER: Okay.

CHAIRMAN PALESTRO: You know, in listening to this I think it can potentially become a slippery slope with some of these committees, subcommittees trying to figure out in some cases what's simply reporting and where action is or maybe required.

So, I think the -- I think the simplest way to approach it is to ensure that when we're forming the subcommittees, that there's always well

under 50 percent.

So if we have a 13-member committee, if we have a five-member subcommittee, probably very unlikely that we're going to have to reduce that number.

MR. BOLLOCK: Right. And you know, there will be -- understanding there will be times when you will want a sixth member.

And if after that members drop off and you have to drop back down to five, the DFO will inform you. And that will be done.

So there -- but yeah, I mean, that's a -- that could be a practice that the committee decides in forming subcommittees. You don't have to.

But again, it can run into that tricky issue where there are members -- the full committee drops in membership. And then the subcommittee would then have to change its numbers.

CHAIRMAN PALESTRO: Thank you. I'm sorry, Mr. Ouhib?

MEMBER OUHIB: Yeah. I think that might be part of the -- what the responsibility of the chair of that particular committee or subcommittee or whatever, to prior to presenting anything if there's any action item or something, perhaps to evaluate

where are we on the count?

And should we propose that action, because it might not qualify?

MR. BOLLOCK: We're still looking at, it's the DF -- it's my responsibility to keep track of that. Yeah. And so it's not -- it's not the subcommittee's responsibility to keep track of that.

I mean, like in your practice, right? You're all team players. You work in team environments. You back each other up.

So, any, you know, if you recognize it and bring it up, that's much appreciated. But that ultimate responsibility does fall on the Designated Federal Officer.

MS. HOLIDAY: Doug, if I can clarify something. You stated that -- can you guys hear me? Okay.

In the FACA rule which Russ gave a citation to in his slides, the rule -- the final rule that was published in 2001. It's actually silent on the number of members that can be on a subcommittee or a percentage.

This is more so an agency practice, because we want there to be, I don't know if the work is impartiality, or -- but we want to make sure that

there's fair representation in terms of if there's five members on a subcommittee that whatever motion passes from the subcommittee that when it comes to the full committee for a vote that it's not, you know, like majority passes.

So, that is not a FACA requirement. That is an agency best practice that we are applying to this FACA committee.

As Doug said, it is the DFO's responsibility. The chair keeps in mind, but it is our job to make sure that we keep under that number. Because that is our agency's best practice. And should be the best practice for the subcommittee.

MR. BOLLOCK: Right. And so another -- just what a subcommittee of -- we have 13 members on the committee, a subcommittee made of five members.

Public -- we have a public teleconference on that subcommittee's report that five have been voted on. We have nine members that are able to participate.

We have a quorum that is considered a quorum for the full committee to give a vote on. We try to avoid that for the reasons that Sophie just spoke on.

But that can happen. And we would be

well within the FACA regulations.

CHAIRMAN PALESTRO: Any other comments or questions before we proceed?

(No response)

CHAIRMAN PALESTRO: Okay.

MR. BOLLOCK: So, one of the other questions that comes to us, in the make up and work distribution and the NRC staff resource for subcommittees.

So this is something, the staff resource, I can speak to the NRC resource. We will provide a resource to subcommittees to help provide information, give clarifying questions, guidance as far as just how our regulations work and what we are doing.

The staff resource is not a member of the -- is not a member of the subcommittee. They're not deliberating with the subcommittee.

They are just there as a resource to provide information and provide clarification. That's the purpose.

And they are assigned essentially by the -- there's a lot of factors. And what Lisa and I determined in assigning, whether it's something that they've already been working on, are familiar with.

Whether it's -- sometimes it's just the work distribution within our medical team. But as far as the subcommittee itself, the make up and the work distribution, that is up to -- I couldn't to the -- I'd leave that to the committee to just deliberate or consider for what you think a good make up is.

You can ask, you know, for a makeup of the subcommittee. And then the work distribution of the subcommittee.

I can just share. I know we've, you know, we have working groups, right. Most of my staff members are right now leading some working group, one working group or another.

They've got working group members. They distribute the work as they see appropriate. Sometimes it's best just to split it up, you know, equal amongst the different staff.

But, in the end someone has to write a report. Just much like subcommittees, someone has to give a presentation and write a report.

Who does that? I mean, that's up to the subcommittee -- that's up to the subcommittee chair to make that decision.

But that's just how we do it. I don't know. I mean, I can -- I think we have some time,

but I'll leave that to you all to discuss if that's something you want to discuss.

And again, with the member make up for who makes up the subcommittee. You know, we have -- we don't have any say in that.

But -- and just from my observation over four and a half year, I think the committee has done a good job putting the appropriate representation from the different representatives on the committee and the subcommittees to give it balance. Balance work with the right appropriate knowledge.

And so that's just my -- given my observation there. That's just something that the -- I'll leave it to Dr. Palestro if you would like to discuss that topic further.

CHAIRMAN PALESTRO: No. I agree. I think it's really up -- distribution work is up to the subcommittee, but in particular, the subcommittee chair.

MR. BOLLOCK: Okay. One of the other topics that have come up, and this is just kind of a logistical thing, about an active subcommittee.

So, when Dr. Palestro took over, we had a number of subcommittees. You know, and what makes it an active committee that's still working?

And what makes it, you know, what -- at what point is the subcommittee done with the work? I think sometimes in the past we'll have said, okay you know, maybe there's a comment that the work is done.

But usually once a subcommittee has completed their -- either their work and provided a report voted on by the full committee.

Or they've, you know, reviewed an NRC document that we've asked you to review. Such as, you know, the more recent SECY papers.

And once that's been completed, the subcommittee is essentially -- we just kind of let it go. And there's nothing formally done.

We could make it just by practice. We could make a statement that this committee's work is complete. And that it's no longer a subcommittee, it's just essentially disbanded.

And I can leave that -- again, I can give some opinions on that. Or I can leave that to the discretion of the ACMUI and the ACMUI chair.

If you have any thoughts Dr. Palestro?

CHAIRMAN PALESTRO: Yeah. I do. And I talked to Dr. Metter who's anxious to express her thoughts. So, I will defer to her.

VICE CHAIRMAN METTER: Thank you Dr.

Palestro. I would like to have like a formal closing. Because sometimes when you're chair of the committee and it goes to the NRC staff, I don't know where I am then.

And you know, so if there is a formal closure and maybe a site somewhere on the -- your site that you have these are the closed -- these committees have been closed. These are the current active committees.

I think that would be very helpful for not only us, but the public too. To see, you know, this committee maybe they would keep more -- keep tabs on what's going on there.

I think it would be helpful to know what are the committees that are still doing work and the committees that are no longer -- or have completed their charge.

CHAIRMAN PALESTRO: Well, I certainly agree that formally closing the committee at the end of their work should be done. And that's the end of -- or the subcommittee, excuse me. And that's the end of the subcommittee.

In terms of maintaining a list of the subcommittees, I would argue that we should maintain a list only of the active subcommittees. Because

then the list will go on forever.

You know, they can certainly be archived and kept for historical purposes. They may want to be revisited sometimes.

But, in terms of our day to day or our meeting to meeting work, it would be -- and I'll address that in my session later on, but it would be extremely useful to have the list of the active committees as well as their membership.

MR. BOLLOCK: So, I can -- we have some -- I mean, we do have some options. Right? And one of the things we keep, you know, Sophie and this week Lisa shared the -- our tracking list of the recommendations.

That's one place that we can keep that active list. So when we go every meeting, you'll see that a committee was formed.

And then we'll try -- you know, we'll write when it's the formal closing of it. Whenever the report is done, you can formally close it.

And then it would close that and take that off the list. But it would be on that. That's one way to do it.

I can -- I don't know if any of my staff, formally asking my coordinator who would handle most

of these things if she has any thoughts? Sophie, do you have any opinions on this? What you think would be best?

MS. HOLIDAY: I have tons of opinions.

MR. BOLLOCK: We'd like to hear them.

MS. HOLIDAY: So, I recognize over the last several years a lot of the feedback that we've received from the committee as well as our meeting attendees, and stakeholders, and staff, is that, you know, more information should be shared, historical information.

That's another reason why we have posted a summarized past recommendations, so that we can keep that historical knowledge. I don't see anything wrong with posting subcommittees, whether they be active or past subcommittees.

But what the past practice has been, is that when a subcommittee is given a charge, and their charge is usually to review something and provide recommendations on something. After that subcommittee has presented its recommendations to the full committee, and the full committee takes its vote, either they endorse or they don't endorse, and that product is turned over to the staff, generally speaking that is when the subcommittee's work is done.

So that is when we have considered a subcommittee to have completed its charge. And that it can be closed.

I will also note with respect to the old business or the recommendations and action charts, where we have listed on there, subcommittees that have been formed, a couple of years ago, there was a request from the committee to remove those types of items from the recommendation action charts.

That once a subcommittee had been formed, we no longer had to keep it on the list. Especially if that subcommittee's work had already been completed.

Again, this information is posted on the website now. Because we post all of the ACMUI's recommendations. So for historical purposes, those are listed.

So, my personal recommendation is that the staff would post a list of the ACMUI subcommittees. We could have a section that says active subcommittees. And there could be a section at the bottom that says past subcommittees or something like that.

All of the subcommittee reports are available on the ACMUI subcommittee reports' web

page. We can have the link that goes directly to the subcommittee reports web page.

Additionally, I still believe that once subcommittees' report has been presented to the full committee, and the full committee has taken a vote, that therefore closes the subcommittee's actions.

For some of my older members on the committee, not by age, by tenure, you will recall that sometimes after a subcommittee has completed its work, there have been motions from the committee to reestablish -- reestablish a subcommittee based on some product that the NRC staff is working on.

For example, patient release. That was a subcommittee that was formed and was sunsetted. And then we reestablished it. The Yttrium-90 microspheres ACMUI subcommittee did its work. Was closed. Reestablished.

So we always have those options. So in my opinion, once you have completed your charge, that handing over of your subcommittee's report which then is voted on and becomes a final report of the committee, is the actual action of closing the subcommittee.

I don't think that you need to actually have a let's make a motion to close a subcommittee.

In itself voting on the subcommittee's product is closing the subcommittee.

CHAIRMAN PALESTRO: Yeah. I don't have a strong opinion about that. But, in going through some of these subcommittees, there are several older subcommittees that are still being carried on the books.

The members of which have long since rotated off. So, somewhere there should be a process whether we formally state that this concludes the subcommittee's work and the subcommittee is formally disbanded at this point.

Just so it's a matter of record and we don't carry these subcommittees further. And if they have to be reestablished, they be reestablished. That's all. So, I -- and that's --

MS. HOLIDAY: Yes. I don't disagree with that. Perhaps, you know, when the subcommittee turns over its report to the full committee, while it doesn't have to be captured as a formal motion on our chart, because keep in mind, that chart is where you get the 85 percent from.

It's, you know, now that we have voted and approved your report, the subcommittee has completed its work and maybe sunsetted. Perhaps

those are the verbiage that you want to use.

As far as old subcommittees, the only old subcommittee that I think that still exists is the Medical Events subcommittee. And training experience, I don't consider that old, because that's fairly in its infancy.

But, we update those as needed.

CHAIRMAN PALESTRO: Okay. So you had a list and can just go over in a telephone conference with the group.

MS. HOLIDAY: Sure. Okay.

CHAIRMAN PALESTRO: Mr. Ouhib?

MEMBER OUHIB: Yeah. I just have a general question probably that was addressed in the past. And forgive me for that if that was done.

This is for Mr. Bollock. Was there any consideration at any point to actually have a nursing representation within the ACMUI?

MR. BOLLOCK: Just for clarification, you mean a represent -- like another ACMUI member? Like say, 14th member who's a nurse, an RN?

MEMBER OUHIB: Correct. Yeah. Because I can't think of anybody else that spends more time than anybody with a patient. And we're talking about patient safety.

And I can think of some medical event that probably could have been prevented by nurses if there was this awareness and so on.

DR. HOWE: I -- this is Dr. Howe. I've been in the medical group since '87. And we have changed the formation of the ACMUI during that period.

And I do not believe we have ever had the consideration of adding a nurse to the committee. The ones -- the new people that we have added, we've added the FDA.

We've added the hospital administrator. We've added the patient advocate. And -- well, we had a diagnostic radiologist back in '86. We lost him. And then we added him back.

We lost one of our medical physicists. We added that back. But we -- in the previous to '87, we didn't have a hospital administrator.

We didn't have a patient advocate. And I don't -- no, we had a pharmacist. So that was not it. But there might be three people that we did not have.

But we've never had a consideration for adding a nurse.

MEMBER OUHIB: I mean, the only reason I bring it up is you look at, you know, the addition

safety committees and all that, that are all in there. And they have some input.

And they have some valuable information that, you know, they could take to the nursing basically.

CHAIRMAN PALESTRO: Dr. Metter?

VICE CHAIRMAN METTER: Thank you for that comment. I think as an authorized user, you're responsible for the supervision. And that would be part of your team.

Because I think if you start adding the team members, and you have to consider the nuclear pharmacist and technologist and all those other individuals. And, you know, and I see what you're saying.

But I think as an authorized user, you're still responsible for the supervision. So, that falls under the authorized user's purview.

CHAIRMAN PALESTRO: Any other comments or questions?

MS. HOLIDAY: I could also add, you guys may recall Dr. Suh's subcommittee for the perfection icon. At one point -- no, I'm sorry, I might be mixing up subcommittees here. So many subcommittees.

Oh, I think it is Dr. Suh's. So, there's

a recommendation that ancillary staff or nursing staff return to the console or stay there throughout the treatment.

And it was clarified during a public NRC meeting that NRC does not regulate nursing staff. In the past we've had conversations from the committee members about adding other specialties such as interventional radiologists.

And for those same reasons that's why some of those individuals aren't represented on this committee. Everybody's that sitting at this table, from your physicists to your physicians, to your radiation safety officer, to your pharmacist, all of you guys are authorized individuals under 10 CFR part 35.

Our agreement state regulators have equivalent regulations that also apply to you guys. Our patient's rights advocate, her job here is to make sure that whatever comes out from the committee and from the NRC keeps in mind how it impacts the patient.

Those are the individuals that I feel like should be represented on this committee. I didn't mean to leave you out Dr. O'Hara, and our FDA partner.

But these are the specialties that are necessary, are applicable in our regulations. So, in terms of adding a nursing staff member to the committee, I'm not sure how beneficial it would be to the committee.

Those are just my personal thoughts.

CHAIRMAN PALESTRO: Sophie, benefits aside, if the committee felt that adding nursing, or some other discipline if you will, would be useful and worthwhile, how would we go about making that recommendation?

What exactly goes on?

MS. HOLIDAY: Sure. So, as you guys heard from Russ, we have what we call a membership balance plan. Anytime that we want to change the number of members on the committee or the specialties or sub-specialties on the committee that has to go through Commission approval.

So, if this is a recommendation that comes from the committee, staff will, like everything, have to evaluate the committee's recommendations. We would have to write a paper to the Commission.

And the Commission would have to render its official decision. Because that is changing the

total number for this committee.

Currently our charter, your charter is for 13 members based on specific specialties identified.

CHAIRMAN PALESTRO: Dr. Schleipman?

MEMBER SCHLEIPMAN: I would just say that short of adding nursing to the table, we could certainly still -- that would not preclude seeking their input, counsel and so forth.

There's the American Nurses Association. There's an OR Nurse Association. And there are topics that are germane to nurses and around radiation.

I think we can certainly still canvas and solicit their opinions.

CHAIRMAN PALESTRO: Any other comments or questions on that? Does anyone want to make a motion to recommend that a nurse be appointed to the committee before we move on?

(No response)

CHAIRMAN PALESTRO: All right. Thank you. Back to you Mr. Bollock.

MEMBER OUHIB: Oh, I'm sorry. I make a motion. This is Zoubir. Sorry, this is Zoubir. I'll make a motion to add a nurse to the committee.

CHAIRMAN PALESTRO: Thanks. Is there a second?

(No response)

CHAIRMAN PALESTRO: All right. Then I guess the motion dies without a second. Am I correct?

MR. BOLLOCK: Correct.

CHAIRMAN PALESTRO: I'm sorry, Ms. Weil?

MEMBER WEIL: I'm not sure that, you know, the issue that Zoubir raises, is an interesting one. And perhaps at some point in one of the meetings going forward we'd like to set aside some time to discuss the composition of this committee.

And determine if there are any disciplines or constituencies that are not included. And whether or not we should consider expanding or changing the membership.

It wouldn't involve a charter revision, which is no small thing. But perhaps it bears discussion rather than just a simple motion on a particular person and, you know, group of people.

CHAIRMAN PALESTRO: I think that's an excellent suggestion. No, I do. I think it makes a lot of sense.

I think it also gives us an opportunity to review the current membership and decide whether

or not it's appropriate as is. Whether you want to add or perhaps subtract.

So, I would ask if we could add that to the agenda for the spring meeting.

MS. HOLIDAY: Dr. Palestro, this is Sophie.

CHAIRMAN PALESTRO: I'm sorry.

MS. HOLIDAY: Maybe what I would suggest is, as the committees were every year prior, someone from the team gives a presentation to the ACMUI, the annual presentation to discuss the composition of the ACMUI.

How often we meet here at headquarters. If the frequency of the meetings, things like that. Perhaps that would be the time where we add additional time and you can discuss it in that setting.

Because that's something that goes along with that. Are you happy with who you report to? Are you happy with how the committee composition is?

That would be, in my opinion, the appropriate. Another place that the committee could discuss is, many of you, though my newer members don't know, but every year we -- or every two years we do the biannual evaluation.

And that -- there's a section on that

form that says provide your comments about ways to improve. Or there's also another question about do you think that the current membership is satisfactory, should there be changes?

That's another opportunity where you can provide that input. And that input is directly included in the staff's paper.

MR. BOLLOCK: Right. And this is Doug Bollock. That paper's the -- the next one will be next -- is due next fall.

So we'll be soliciting ACMUI member input probably early 20 -- yeah, early 2019, spring 2019. And it -- so for us to make a change to the committee membership, you know, go up, add another position that would take NRC Commission approval.

They would have to do that. And you know, it is possible as Dr. Howe said, you know, in her time here the membership numbers and positions have changed.

They've, you know, some of have gone away and then come back. And others have been added. So, it is, you know, it can happen.

And actually some of the discussion and what Dr. Schleipman had spoken about brings one of the other topics that was brought up, the stakeholder

outreach and input. Formal -- both formal and informal.

I think, you know, seeking or getting the nurses or other -- or the nuclear medic -- techs. Or any of the team members input, their organizational input.

I think that's the perfect example of stakeholder, you know, informal stakeholder input from you. You know, the ACMUI members bringing it to us is just, you know, points that your staff or your team and constituents have shared with you.

Or formally when we are seeking output say for, you know, we just discussed the team outreach. If things may affect them or if you think they may have some input they can, you know, provide formal input there either individually or through any of their professional organizations.

So, that is another topic. You know, that's an example of some informal or formal input that came through.

And I do -- I know we've had discussions. Dr. Alderson brought this up with the -- and it's been continuing on with Dr. Palestro and Dr. Metter and our stakeholder input.

As ACMUI members going and presenting at

ACR, SMMI, ASTRO, among others. You know, we, the NRC staff, we encourage that. And you know, we try to participate where we can.

And I know Sophie has said this to you members throughout the years, both in these meetings and individually. You know, we encourage you all as ACMUI members to bring that informal input that you receive from your constituents.

And to, you know, to help with the decision making. And to help with you being -- bringing your professional opinions and helping with your objectivity and you know, the issues that are covered here.

Is there any -- and I'll open it back up. Is there anything else specifically that --

CHAIRMAN PALESTRO: Yeah. I just wanted to go back again. I'm sorry Sophie, if you would clarify for me again, the time when you thought it would make sense to discuss considering whether or not the committee should be revised, the membership.

MS. HOLIDAY: Sure. So, based on what Ms. Weil suggested further discussions, in the springtime is when the NRC gives its presentation to the committee. I think I call it the annual review of the ACMUI or something along those lines.

And we talk about the frequency of the meetings, the number of members on the committee and the positions. At that time, you know, when I open up for comments and discussions from the committee, that could be the opportunity to bring it up if you would like to discuss it further.

CHAIRMAN PALESTRO: Ms. Weil?

MEMBER WEIL: Yeah. That makes some sense. It fits.

CHAIRMAN PALESTRO: Could I then ask that staff somewhere make a little note to remind us about that for the spring meeting at the time of that presentation?

MS. HOLIDAY: Absolutely.

CHAIRMAN PALESTRO: Thank you. I appreciate that. Mr. Bollock?

MR. BOLLOCK: Okay. Any other discussion on stakeholder input? Formal/informal? Comments, thoughts? Dr. Metter?

VICE CHAIRMAN METTER: Can you just go through the process again of like when you have the -- for the training experience she had a stakeholder initial outreach, but it was limited.

And can you kind of go through that, what the rules were? Because you had some -- a time frame

on some.

MR. BOLLOCK: Sure. Yeah.

VICE CHAIRMAN METTER: And you had certain goods you needed to address.

MR. BOLLOCK: So the -- it was because of time constraints we didn't -- so when we sol -- when the NRC solicits input from the general public, it typically requires if we're asking specific questions of the public, say please give us information on this.

It can require an OMB clearance, because they have to do a review of the burden that we're asking of people providing us information. There is another means sometimes if it's something that falls under our current regulations, we could put out a Federal Register notice and ask the questions.

But without, you know, verifying that we have to -- we have verified that we're not violating the burden of course on OMB to put out a Federal Register notice.

Because of that, to not violate OMB you can solicit input from up to nine non-federal entities. And that's what limited who we can go out to.

So, for the T&E example, we went out to

nine non-federal entities. And then we also reached out to a number of federal entities who have license and uses of the radiopharmaceuticals.

VICE CHAIRMAN METTER: So you just have a limit on the nine non-federal. The others are up to you all?

Or is there a total limit?

MR. BOLLOCK: It's just it's not a -- it's not considered a burden if it's other federal entities. We can seek input from other federal entities.

VICE CHAIRMAN METTER: Okay. So that number is open. So there's just a limit on the num -- nine non-federal.

MR. BOLLOCK: Right. We cannot go ten. We can't go to ten or more. We can't solicit -- we can't ask ten or more entities outside of -- in the general public to give us information.

We can't request information.

VICE CHAIRMAN METTER: But the other number is, it could be whatever you think would be adequate to solicit what the greater diversity of opinions?

MR. BOLLOCK: Well, the other number was just other federal entities. So for instance we

reached out to Army hospitals and -- right? So that -- it's a burden -- it's a burden issue that limits the numbers.

But it's not considered a burden if it's a federal entity. It's not considered a burden for us to ask another federal entity.

CHAIRMAN PALESTRO: Ms. Weil?

MEMBER WEIL: Just to clarify. This is in the preliminary outreach? Not for --

MR. BOLLOCK: That's what limited our preliminary outreach. Because we hadn't had -- because now we get into the time constraints.

We didn't have the time to verify if we could get a burden review to do an OMB clearance. If we needed to get that verification whether we needed an OMB clearance to put out the questions.

MEMBER WEIL: But the expanded outreach is not limited by nine non-federal?

MR. BOLLOCK: No.

MEMBER WEIL: Okay.

MR. BOLLOCK: We've had time to define -- right. We've had time to verify that what we're doing is all this. All well and good.

MS. DIMMICK: So if I could just add, so for the outreach that we're seeking to do, we'll be

doing a general solicitation for that information through a Federal Register notice.

And once we provide a general solicitation in the Federal Register, then we're not bound by the number of stakeholders we can reach out to, provided we're asking the same kind of information that's in the general solicitation.

MR. BOLLOCK: Okay. Any other questions on?

(No response)

MR. BOLLOCK: All right. And then the last top -- specific topic that we've been asked to address. And this, I know it came up on Wednesday and the T&E subcommittee was asking it.

So how does it work for the ACMUI, NRC staff, NRC management with say reviewing a report or documentation? And I think there were some comments from the subcommittee.

They actually saw the concurrence blocks on our SECY paper. And it just brought the question, okay, what is the process?

And so I can just walk the committee through the process for say, you know, for our -- the training experience SECY paper we just sent up to the Commission.

So, how the process works, typically staff will write -- staff will draft the paper. And then it goes through a management review.

And the medical teams, one of the medical team members typically write it. And then it goes to the medical team leader.

Lisa will review it and concur. And then I'll review it and concur. And then our division management, right now Dan Collins or Sabrina Atack, will review and concur.

And then it will go out to -- because a lot of what we do involves licensing inspection, it affects the regions. So we'll send it out to the regions for their review.

We send it to the agreement states for their review. And then -- and that's the same time we send it to the ACMUI for your review.

And then after it comes back and we've addressed the comments from all three of those -- of, you know our regions are the NRC. Address the agreement state comments and the ACMUI comments, then it goes back through -- it goes to our Office of the General Counsel.

And then it goes to our office director. And then it could possibly go to our Executive

Director for Operations for signature.

So there's still further, our lawyers get to look at it. Our senior managers get to look -- and then our senior managers get to look at it before it goes to the Commission.

For those SECY papers, because ACMUI you are our advisor, external advisor, your report, your unfettered comments go with those SECY papers to the Commission. They see exactly what you say, your exact thoughts, your being the committee's, exact thoughts on whatever that paper is.

We also have a section where we include a synopsis of what the agreement states, their comments on those papers. You also -- the ACMUI also gets a synopsis.

But you're -- just the Commission has asked for they want this -- the ACMUI's unfettered opinion. So we also send that as well.

So, that's the process for say a paper that's reviewed. For the 35-1000 guidance that's reviewed, that goes a similar start. Typically though the work is done at a working group level.

So, my staff -- one of my staff typically, or maybe in a regional staff, will co-chair along with an agreement state representative, will co-chair

the working group.

That product goes to Lisa and I. It goes to division management just for review. It goes out to all the agreement states. It does to ACMUI>

And then it comes back. It goes to the Office of General Counsel. And then goes just back to our division for final approval.

CHAIRMAN PALESTRO: Could you repeat that back to us Dr. Metter?

(Laughter)

VICE CHAIRMAN METTER: It's a long process.

CHAIRMAN PALESTRO: Any other comments or questions?

(No response)

MR. BOLLOCK: Those are the specific topics that have come up in discussions we've had over the past couple of months that I believe the committee or subcommittee members wanted me to address. Are there anything else now that we're about four minutes over?

They like me as the DFO or just the NRC, any questions for us? Or me, any you'd like to address?

(No response)

CHAIRMAN PALESTRO: Thank you.

MR. BOLLOCK: I think that was enough. All right.

CHAIRMAN PALESTRO: All right. The next item on the agenda is sort of continuing along with the same theme. The ACMUI subcommittees, subcommittee membership and the ACMUI Chair.

As I indicated when I was -- when we were talking before, when Mr. Bollock was talking, that I would like for a list of the subcommittees and their members to be available for the ACMUI, along with the staff liaison.

Or is it staff resource? What's the appropriate term? I'm sorry?

MS. HOLIDAY: The term is synonymous. Don't worry.

CHAIRMAN PALESTRO: I'm a creature of habit. I like to see consistency. So, whatever you prefer.

MR. BOLLOCK: So for my last three weeks, it will be staff resource.

(Laughter)

CHAIRMAN PALESTRO: All right. Fine. So, what I'd like to see for the committee is, as I said, the list of the subcommittees and their members,

along with their term expiration. As well as the staff resource.

And I would -- I know that it will be on the website. But I would appreciate it if it could be mailed, email excuse me, to the committee members just after each meeting or something, twice a year.

And on the reports of the subcommittees, I think that the staff liaison's name should appear on all of the reports as well as on the slide presentation. So that everybody knows who they are.

And so that they also are acknowledged for the time and effort that they put into it. We do it most of the time. I don't know that we do it consistently.

Ms. Weil?

MEMBER WEIL: In addition to the name -- the chair and the names of the subcommittee members, it would be interesting to have the actual charge of the subcommittee listed.

CHAIRMAN PALESTRO: Absolutely correct. Thank you. Yeah, because it seems over time the charge shifts. And it's not what it originally was.

So, I think that's an excellent point. I apologize for that oversight.

All right. So, next --

MS. HOLIDAY: Dr. Palestro?

CHAIRMAN PALESTRO: Yes, ma'am?

MS. HOLIDAY: Procedurally, is this a motion from the ACMUI?

CHAIRMAN PALESTRO: Does it require a motion?

MS. HOLIDAY: Do you want to keep it on the record? Then it should come forth as a motion.

CHAIRMAN PALESTRO: All right. So the motion is that -- the motion is the following: that the members of the ACMUI be provided at least twice yearly a list of the subcommittees along with the specific charge or charges for the subcommittee, its members and their date of termination on the committee, the subcommittee, as well as the staff liaison member. Staff liaison, excuse me.

MR. BOLLOCK: Staff resource.

CHAIRMAN PALESTRO: Staff resource. It's been a long day Mr. Bollock. I'm sorry.

MR. BOLLOCK: Yeah. It's been a long month.

CHAIRMAN PALESTRO: Ms. Weil?

MEMBER WEIL: The date of termination might be problematic. Because if you're finishing your first term, it's not known whether you're going

to continue on for another term.

CHAIRMAN PALESTRO: But I would still have it.

MEMBER WEIL: Okay.

CHAIRMAN PALESTRO: All right, I mean, I think even if it is your first term, then your subcommittee chair should be aware of the fact that you may not be there.

MEMBER WEIL: Okay.

CHAIRMAN PALESTRO: It's just something to have a guide. Because I don't -- that information I don't think is readily available to us on a routine basis.

And I'd rather have that then have nothing.

MR. BOLLOCK: Yeah. And we have that information.

CHAIRMAN PALESTRO: Mr. Green?

MEMBER GREEN: Or it would be simple enough to indicate the year of termination followed by a parenthesis (1), first term or (2), second term.

MS. HOLIDAY: There is a contact sheet that normally is provided to the committee ahead of the meeting that lists all of the contact information, including first or second term and start date.

That was not provided for this meeting. But you will get it shortly after this meeting concludes.

If I can also ask, I think I heard you say, but it was not mentioned during this motion, that you're also requesting that we create a web page or listing for subcommittees?

CHAIRMAN PALESTRO: No.

MS. HOLIDAY: Is that also included in this motion?

CHAIRMAN PALESTRO: No. Not at all.

MS. HOLIDAY: So this is just information to the committee membership about members' terms and contact information?

CHAIRMAN PALESTRO: Yeah. It's information to the committee about the subcommittees' membership, charge, and the members and when their terms are up.

MR. BOLLOCK: And the staff resource.

(Laughter)

MS. HOLIDAY: But I thought earlier in our discussion we said something about listing something on the website for active subcommittees and --

CHAIRMAN PALESTRO: I thought it was

already on the website?

MS. HOLIDAY: Subcommittee reports are posted on the website. Subcommittees and their membership are not.

CHAIRMAN PALESTRO: All right. Then we will -- I will amend the motion to include all of the information that you're going to email us, staff is going to email us, to be maintained on the website.

MS. HOLIDAY: If I may suggest, I think I heard the motion to be, that the NRC staff will provide the committee membership, just the committee membership, with the information regarding the member's terms and their contact information, and which subcommittees they're on or the membership of the subcommittees.

The second part of that motion is that the NRC staff will create a web page that will list active subcommittees and sunsetted subcommittees. I believe that's the motion?

CHAIRMAN PALESTRO: Correct.

MS. HOLIDAY: Thank you.

CHAIRMAN PALESTRO: Is there a second?

UNKNOWN: Second.

CHAIRMAN PALESTRO: Any discussion?

MEMBER OUHIB: Well, I had another

question. I'm not sure if we're moving.

Along with the charge, do we have an option for a sunset date on those reports? Subcommittee reports or not?

CHAIRMAN PALESTRO: I don't think I would put that into any of that detail. I mean, we can anticipate that subcommittees are going to conclude its work at such and such a time.

But it may or may not. And I think that's probably more important to the individual subcommittee then to the rest of the group.

I mean, I think we've already got a lot of information. And I don't want it to turn into a, you know, into a tome.

I want it to be something that's easily accessible to everyone. Particularly the Chair of the ACMUI. Which I'm Chair now.

And Dr. Metter who follows me. Because we're the ones ultimately responsible for putting these subcommittees together and making sure that they have sufficient membership.

And if we're going to have -- I think there's already a lot of information. And I would prefer not to add anything else. Unless people feel strongly about that.

Any other discussion?

(No response)

CHAIRMAN PALESTRO: All in favor?

(Show of hands)

CHAIRMAN PALESTRO: Any opposed?

(Show of hands)

CHAIRMAN PALESTRO: All right. It passed.

All right, so this is a list -- excuse me, this is a list. Next slide, please. No, actually this is the correct slide. I'm sorry.

The list of the ACMUI subcommittees that currently have. Are the annual review of medical events; training and experience for all modalities; the medical event reporting and impact on patient safety culture; medical event reporting for all modalities except the brachytherapy, which was combined with the former patient intervention subcommittee; and the patient release SECY paper review.

In addition we created a new subcommittee yesterday. So, I'd like to start with training and experience for all modalities.

The current members are Dr. Metter, Dr. Suh, Dr. Alderson who just rotated off the committee,

Ms. Weil, and Ms. Shober. And Dr. Suh rotates off the committee, I imagine in a few --

VICE CHAIRMAN METTER: And then Michael Sheetz.

CHAIRMAN PALESTRO: Mr. Sheetz is on now?

MEMBER SHEETZ: I'm on there also.

CHAIRMAN PALESTRO: Okay. So Dr. Suh rotates off the ACMUI in a couple of weeks. And Dr. Alderson already rotated off.

So, I would like to add Dr. Ennis to replace Dr. Suh. And Dr. Schleipman to replace Dr. Alderson.

And let's just make sure, I'll check with you Dr. Metter, that the charge of this committee is to periodically review the training and experience requirements currently in effect for all modalities, and make recommendations for changes as needed.

Is that correct?

VICE CHAIRMAN METTER: It is correct. Thank you.

CHAIRMAN PALESTRO: All right. And the staff -- the staff resource or staff liaison Mr. Bollock? The staff resource is Ms. Ayoade.

All right. Let's see, can we go back? I think I may have looked -- yeah, go back. Yeah.

The annual review, I'm sorry, I did this out of sequence. The annual review of the medical events includes Dr. Ennis who's chair, Dr. O'Hara, Dr. Suh, who's rotating off, Dr. Metter, Mr. Ouhib, and Mr. Sheetz.

Is that correct?

VICE CHAIRMAN METTER: Yeah.

CHAIRMAN PALESTRO: And the charge, the specific charge of this committee is to periodically review trends in medical events. And to formulate recommendations to reduce them.

And the staff?

MR. BOLLOCK: It's Dr. Howe.

CHAIRMAN PALESTRO: Dr. Howe.

MEMBER GREEN: Dr. Palestro, I'm not sure if this is a onetime consult, but I was asked and looked up the information on 35, part 200 for this subcommittee.

CHAIRMAN PALESTRO: For which subcommittee?

MEMBER GREEN: For the medical events. And that was presented yesterday.

CHAIRMAN PALESTRO: Were you -- I don't believe I added you to the committee.

VICE CHAIRMAN METTER: It's six to five.

CHAIRMAN PALESTRO: Let's see, Dr. Suh, one, two, three, four, five. So then Mr. Green, I will add you. And Dr. Suh is rotating off.

All right. Then there are several subcommittees that I believe are ready to be disbanded. That would be the next slide, please. Can we go back one? Okay.

Medical event reporting and impact on patient safety culture; the medical event reporting for all modalities except the brachytherapy combine -- which is combined with the former patient intervention subcommittee; the patient release SECY paper review; and the Y-90 microspheres.

These subcommittees have all completed their tasks. And as I said, on several of these subcommittees, the members have already rotated off.

Any questions about that?

(No response)

CHAIRMAN PALESTRO: Sophie, do we need a motion to -- no? Okay.

MS. HOLIDAY: Dr. Palestro, if I could go back just to the training and experience for all modalities subcommittee slide.

CHAIRMAN PALESTRO: Yes.

MS. HOLIDAY: I don't think you mentioned

Mr. Michael Sheetz. He was added to the subcommittee. So you currently just - you're fine with membership numbers.

But this is six individuals total. So we will now have Dr. Metter as the chair, Dr. Ennis to replace Dr. Suh, Dr. Schleipman, Ms. Laura Weil, Ms. Shober, and Mr. Sheetz.

CHAIRMAN PALESTRO: And that brings us to six total?

MS. HOLIDAY: Six total.

CHAIRMAN PALESTRO: Well, as you see as I'm going through this, I think I'm the best example as to why we should have a list of subcommittee members.

Because going back and forth in emails, and I obviously have not kept track of it the way I should.

But, thank you Ms. Holiday. All right. Next slide, please.

Additional subcommittees to be ended or sunsetted as you prefer. The physical presence requirements for the Leksell Gamma Knife Icon; the - - I guess that's the last, no I'm sorry, the Nursing Mothers Guidelines, which is on the next slide.

And that is it. Dr. Schleipman?

MEMBER SCHLEIPMAN: Your previous slide also had a Germanium Gallium 68 there.

CHAIRMAN PALESTRO: That is a mistake.

MEMBER SCHLEIPMAN: Okay.

CHAIRMAN PALESTRO: Okay?

MEMBER SCHLEIPMAN: Okay.

CHAIRMAN PALESTRO: So for the Gallium 68 -- or before we get to that, any discussion about those subcommittees?

As I say, they've all completed their charges. The reports have been submitted and accepted by the full ACMUI.

All right. Ms. Holiday, any? Okay. All right, so let's go to the Germanium 68, Gallium 68 licensing guidance.

Ms. Shober is chair, Mr. Sheetz, Dr. Metter, Dr. Martin, I'd like to have on that subcommittee. Staff?

MR. BOLLOCK: Dr. Daibes.

CHAIRMAN PALESTRO: Next slide. All right, I need to form a subcommittee to review and comment on the Regulatory Guide 8.39, the release of patients administered radioactive materials.

I would ask that Mr. Sheetz chair this committee.

MEMBER SHEETZ: I'd be glad to.

CHAIRMAN PALESTRO: Members, Ms. Shober, Dr. Dilsizian, Dr. Schleipman, and Dr. Martin. Staff?

MR. BOLLOCK: Dr. Daibes.

MS. HOLIDAY: Dr. Palestro?

CHAIRMAN PALESTRO: Yes, ma'am?

MS. HOLIDAY: May I also ask as since this is related to patient release, might you consider your patient's rights advocate?

Or is this because her -- keeping in mind that her term will be up next August.

(Laughter)

CHAIRMAN PALESTRO: Ms. Weil, would you agree to join the committee for the reminder of -- that subcommittee for the remainder of your time? Thank you.

And then the Yttrium-90 -- I'm sorry. Mr. Ouhib?

MEMBER OUHIB: Yeah. Just a comment on the release of patients administered radioactive material. Is there a representation on therapy and all that?

Has that been looked at? And brachytherapy?

CHAIRMAN PALESTRO: I'm sorry, you lost me.

MEMBER OUHIB: So, what are we talking about? What radioactive materials are we talking about? I just want to make sure that there's a representation within the --

CHAIRMAN PALESTRO: I believe this is the release of patients who have received unsealed sources. Is that correct?

MR. BOLLOCK: Correct. And it's all -- it's our guidance for all. Yeah, it's all

MEMBER OUHIB: All?

MR. BOLLOCK: Um-hum.

MEMBER OUHIB: That means if you have a prostate implant and the patient was released, that's one of them. Is that correct?

MR. BOLLOCK: Correct. It's -- yeah.

MEMBER OUHIB: Okay. I think my question, is there a good representation within that committee that can address all of those? That's all.

CHAIRMAN PALESTRO: Okay. Well, I'll ask the members of the subcommittee. Dr. Martin?

MEMBER MARTIN: Sure.

CHAIRMAN PALESTRO: All right. Acceptable to you Mr. Ouhib?

MEMBER OUHIB: Yes. Thank you.

CHAIRMAN PALESTRO: Right. No, thank you for bringing it to my attention.

Again, you know, if this points out nothing else, it certainly points out how to me, how difficult it is to try to put the subcommittees together and get the appropriate individuals. But maybe that's just my limitation.

Okay. For the regulatory guideline and the release, Mr. Sheetz is chair. The members are Ms. Shober, Dr. Dilsizian, Dr. Schleipman, Dr. Martin, and Ms. Weil.

Next is the Yttrium-90 microspheres. Which on the slide I have, is not slated to be formed until late 2019. But I believe that it's due earlier at this point.

Am I correct based on the discussions of this morning?

MR. BOLLOCK: Yes.

CHAIRMAN PALESTRO: So, we really should form that subcommittee now.

MR. BOLLOCK: Yeah. You can form the subcommittee to be standing by to review the document when staff's ready to provide it.

CHAIRMAN PALESTRO: Okay. All right.

Then for the subcommittee whose charge will be to review and make recommendations on the Yttrium-90 microspheres, and so it's going to be a regulatory guidance.

MR. BOLLOCK: Yes. This is 35-1000 licensing guidance.

CHAIRMAN PALESTRO: Okay. I'm going to ask Dr. O'Hara to chair this committee. Membership will be Dr. Dilsizian, Mr. Ouhib, Dr. Martin, and Dr. Schleipman.

MS. HOLIDAY: May I ask if a radiation oncologist will be on the committee? Or if your diagnostic radiologist would be on the subcommittee?

This is to provide comments on the staff's draft guidance, correct? AU Training.

CHAIRMAN PALESTRO: Then I'm going to ask that Dr. Metter also be a member of this committee.

VICE CHAIRMAN METTER: Delighted.

MS. HOLIDAY: Just to recap, I have Dr. O'Hara as the chair, Dr. Dilsizian, Mr. Ouhib, Ms. Martin, and Dr. Metter?

CHAIRMAN PALESTRO: And Dr. Schleipman.

MS. HOLIDAY: And Dr. Schleipman.

MEMBER OUHIB: So Ms. Holiday, were you requesting a radiation oncologist on that group? Is

that what you were asking?

MS. HOLIDAY: I was just asking the Chairman if he would like to consider adding a radiation oncologist. If he chose not to, that's perfectly fine.

CHAIRMAN PALESTRO: Yeah. And Ms. Holiday raised a good point. And my rationale for selecting the radiologist is that in the vast majority of cases, they are the individuals administering these agents, the microspheres.

And that's my rationale for that.

MEMBER OUHIB: That's debatable.

CHAIRMAN PALESTRO: Okay. Well, correct me if I'm wrong Ms. Holiday, but in this case the Chair has the final word?

MS. HOLIDAY: That is correct.

CHAIRMAN PALESTRO: Thank you.

(Laughter)

CHAIRMAN PALESTRO: Any other comments or questions? Mr. Bollock?

MR. BOLLOCK: And Dr. Palestro, if you may. I can speak to the Gallium/Germanium generator subcommittee like why, what the confusion was there.

So, and it brings back a point --

CHAIRMAN PALESTRO: I'm sorry, before we

get to that, staff?

MR. BOLLOCK: Staff will be Dr. Tapp.

CHAIRMAN PALESTRO: Thank you.

MR. BOLLOCK: Okay. And I know you all have your ethics training yesterday. Well, one of the members already used his ethics beforehand. So, Mr. Richard Green has recused himself from the Germanium/Gallium generator review.

So, we had to -- there was some -- so the subcommittee had to be formed. We originally thought the subcommittee would be formed with our nuclear pharmacist. Right? That makes sense.

Unfortunately he did recognize that it could be a conflict. Brought it to the NRC staff's attention. We made sure just to, in good conscience that it was the right thing to do to have him recuse himself.

And that's why we had to reform the committee. And there's some -- that's why the slides were off with what was supposed to be done.

So the new subcommittee will review the staff's draft guidance. And then present to the full committee.

And we'll be setting up, whenever the subcommittee is ready to present, we'll set up a

public teleconference in the next few months.

CHAIRMAN PALESTRO: Yes. I would hope to hold a telephone conference review rather than waiting until the spring. I don't think we need to wait that long.

Are you agreed Ms. Shober? You're chair.

MEMBER SHOBER: I agree.

CHAIRMAN PALESTRO: All right. Any other comments or questions?

(No response)

CHAIRMAN PALESTRO: All right. And I skipped around a little bit. I want to go back to the bylaws committee. Okay?

And we reviewed the bylaws a couple of years ago. But I would like to have them reviewed again.

The specific charge for this subcommittee is to review and update the bylaws as needed with specific attention to the role of the ACMUI Chair on the subcommittees.

The reason why I am raising this issue is because I was the chair of the subcommittee on training and experience. And I was informed that when I became Chair of the ACMUI that I had to give up that position.

And I originally understood that those were part of the rules and regulations. And it eventually came to be that it really wasn't rules and regulations, but more tradition with a good purpose obviously.

To ensure that the Chair of the entire committee doesn't exert undue influence. Or in colloquial terms, strong-arm the subcommittee.

(Laughter)

CHAIRMAN PALESTRO: Which, I guess is fine. I had a vested interested for those of you who have been on the committee of several years, know that I was chair and actively involved and had the pleasure of presenting to the Commission a couple of times on this topic.

And I don't have an answer as to what the role of the ACMUI Chair should or should not be. My own personal opinion is that it should be defined one way or another rather than left up to, well you really shouldn't, but you could.

But it's just I need rules for my life personally.

(Laughter)

CHAIRMAN PALESTRO: I may not like them. But I can live by the rules. And I just find it

difficult not to have that sort of guidance.

So, Ms. Weil is going to chair this subcommittee. Dr. Schleipman, I ask that you be on this committee. And I've got to find the -- oh, Ms. Shober, and Ms. Sheetz.

Ms. -- I'm sorry, I apologize Mr. Sheetz.

(Laughter)

MEMBER SHEETZ: Whatever. I was just looking behind me.

CHAIRMAN PALESTRO: And now a couple of comments for the subcommittee. Neither Dr. Metter nor I, are going to participate in any of the discussions.

Okay? I want it to be arm's length. This is really up to the subcommittee to form their opinion.

And so we're not going to participate in any of the discussions. Nor are we going to participate in any voting on your final recommendations.

And then finally, assuming that it doesn't -- that it's not a transgression of the rules and regulations, whatever decision you make will become effective the time I rotate off as Chair. All right.

I'd like it to be as much at arm's length as possible. I think it's -- at least to me it's important that that be formalized in one way or another.

Any comments or questions? Yes, Dr. Schleipman?

MEMBER SCHLEIPMAN: Oh, yeah. I do have a resource?

MR. BOLLOCK: The staff resource will be Sophie Holiday for now. That may change when I'm -- when we get an ACMUI coordinator. And it will be -- that will be the staff resource.

So for now Sophie Holiday.

CHAIRMAN PALESTRO: Any other comments or questions? Concerns?

(No response)

CHAIRMAN PALESTRO: Ms. Holiday, anything?

MS. DIMMICK: Since in this session we're discussing the subcommittees that are being formed during this meeting, if you just want to revisit the medical event report subcommittee that was formed yesterday. That committee, the members in there.

CHAIRMAN PALESTRO: I don't have the list of new --

MS. DIMMICK: Oh. So for the -- so the subcommittee on reporting medical event reports, Dr. Ennis is the chair. Ms. Weil, Dr. Martin, Ms. Shober, Mr. Ouhib, and Dr. Dilsizian.

CHAIRMAN PALESTRO: Staff?

MS. DIMMICK: And the staff resource is me, Lisa Dimmick.

CHAIRMAN PALESTRO: All right. Any other questions or comments on this topic?

(No response)

CHAIRMAN PALESTRO: All right. Then I'm going to turn this over, the meeting over to Ms. Dimmick for the final session the Administrative Closing.

MS. DIMMICK: Okay. I'm going to do the Administrative Close my way. And so -- and capture the items.

So, at the close of this meeting, we -- the Chairman, Chairman Palestro established five subcommittees or five new subcommittees.

And they are a medical event reports subcommittee; the regulatory guide 8.39 release of patients subcommittee; the Yttrium-90 microspheres licensing guidance subcommittee; the Germanium 68/Gallium 68 licensing guidance subcommittee; and a

bylaw's subcommittee.

Okay. Catching up to where the motions were. There was a -- the committee, a motion was made to approve the nursing mothers' guidelines report. That was seconded and approved unanimously or endorsed by the full committee, all in favor.

That report was then also appended with a motion made to add language to the report to indicate that the radiopharmaceuticals identified in that report were as of this date. And that included known radiopharmaceuticals as the date of that report.

So that motion was seconded and unanimously approved to add that language to the nursing mothers' guideline report.

A motion was made to approve the Gamma Knife physical presence requirements licensing guidance. It was seconded and approved unanimously by the full committee.

The ACMUI requested a few administrative items of staff. One being for staff to provide a list of all the ACMUI members and the categories that they represent along with their contact information so that all committee members had that access, that information available to them.

The committee also requested that the NRC staff provide a copy of the AARM agency action review meeting slide on Yttrium-90, as well as the business line meeting slides that -- where we presented a report of Yttrium-90 as well, to the ACMUI for the medical event reporting -- for the medical event subcommittee.

We'll provide it to the full committee. But, there were specific committees that requested that information.

We also -- a request was for NRC to consider if it could draft an information notice on best practices for certain medical events that were described in the medical events subcommittee report.

And last, the April -- the spring meeting, the dates that -- our first choice are April 15 and 16. And the second choice dates as the alternate are April 3 and 4.

And I believe that's all the action items that the committee voted to approve and/or subcommittees that were appointed and additional action items.

CHAIRMAN PALESTRO: Thank you. Any other business? Questions, comments? Anybody have anything they'd like to say before we adjourn?

MS. DIMMICK: Sophie has a question. Did I --

MS. HOLIDAY: The -- I have a question regarding one of the items that you just said Lisa, regarding the medical event subcommittee's recommendation for the information notice.

Was that formally a motion made by the committee? Because as I understand, that was a recommendation from the subcommittee.

But it did not come forth as a motion from the committee. Am I correct?

MS. DIMMICK: That's what I have in my notes.

MS. HOLIDAY: That it came from the committee?

MS. DIMMICK: No. It did not come -- that the subcommittee commented on it for NRC to consider an information notice.

But there was not a formal motion made for NRC to develop an information notice on best practices.

MS. HOLIDAY: Okay. Then I will have to ask if there is a motion from the committee?

CHAIRMAN PALESTRO: Is there a motion?

MEMBER SUH: I make a motion.

CHAIRMAN PALESTRO: Second?

UNKNOWN: Second.

CHAIRMAN PALESTRO: Any discussion?

(No response)

CHAIRMAN PALESTRO: All in favor?

(Show of hands)

CHAIRMAN PALESTRO: Any opposed?

(Show of hands)

MS. HOLIDAY: Okay. Thank you. And then I'm also going to follow up on the items that Lisa said. Just like you, I need order. So, for the subcommittees, I'd just like to go over the membership.

So as I have noted, Dr. Palestro amended the training and experience for all modality subcommittee membership to now include Dr. Metter as the chair, Dr. Ennis, Dr. Schleipman, Ms. Weil, Ms. Shober, and Mr. Sheetz.

Are there any questions and comments on that?

(No response)

MS. HOLIDAY: Okay. Then I have the second item. Dr. Palestro created the Germanium/Gallium 68 licensing guidance subcommittee to include Ms. Shober as the chair, Dr. Metter, Ms.

Sheetz, and Ms. Martin.

The staff resource is Dr. Said Daibes. And this subcommittee will plan to have a -- or the ACMUI will plan to have a public teleconference in the near future to be determined at a later date.

Are there any questions and comments on that?

(No response)

MS. HOLIDAY: Then the next subcommittee that I have is the regulatory guide 8.39 release of patients administered radioactive materials. I have Mr. Sheetz as the chair, Ms. Shober, Dr. Dilsizian, Dr. Schleipman, Ms. Martin, and Ms. Weil.

Dr. Daibes is NRC staff resource. Are there any questions and comments on that?

(No response)

MS. HOLIDAY: Okay. And then I have the Yttrium-90 microspheres brachytherapy licensing guidance subcommittee. Dr. O'Hara will be the chair, Dr. Dilsizian, Mr. Ouhib, Ms. Martin, Dr. Metter and Dr. Schleipman.

NRC staff resource is Dr. Katie Tapp. Are there any questions or comments on that?

(No response)

MS. HOLIDAY: Okay. And then I have the

ACMUI bylaw subcommittee. The charge of that subcommittee is to review and update the bylaws as needed with specific attention to the role of ACMUI Chair and his or her participation on subcommittees.

This subcommittee will be chaired by Ms. Weil. Additional members are Dr. Schleipman, Ms. Shober, and Mr. Sheets.

NRC staff resource is myself. Are there any questions or comments about that?

CHAIRMAN PALESTRO: Yes. I just want to -- I'm sorry. I just want to add that the review of the bylaws isn't limited just to the role of the ACMUI Chair.

But I want to make sure that that's covered as part of your review. So feel free to make any other recommendations for change as you see fit.

MS. HOLIDAY: Okay. And then I believe the last subcommittee that I have noticed is the subcommittee that was formed yesterday for the medical events subcommittee. Medical event reporting subcommittee.

The chair will be Dr. Ennis. Additional members are Ms. Weil, Ms. Martin, Mr. Ouhib, and Dr. Dilsizian.

NRC staff resource is Dr. Donna Beth

Howe. No? Is --

MS. DIMMICK: She's another committee.

MS. HOLIDAY: Ms. Lisa Dimmick.

MS. DIMMICK: Yes.

CHAIRMAN PALESTRO: It's not the medical event reporting committee, because that's already in existence. I don't --

MS. DIMMICK: It's the committee that's going to look at the medical event, the information in medical event reports.

MS. HOLIDAY: Okay.

MS. DIMMICK: Okay.

VICE CHAIRMAN METTER: Excuse me Sophie, I think -- can you go over that list again of the members for that last committee?

MS. HOLIDAY: Sure. I have Dr. Ennis as the chair, Ms. Laura Weil, Ms. Melissa Martin, Mr. Zoubir Ouhib, and Dr. Vasken Dilsizian.

MEMBER SHOBER: And Megan Shober.

MS. HOLIDAY: And Megan Shober.

VICE CHAIRMAN METTER: And Megan Shober, yes.

MS. HOLIDAY: With NRC staff resource as Ms. Lisa Dimmick. Okay. Are there any further questions or comments on that?

MS. DIMMICK: Not on that Sophie. I did have two items I did not mention. So, for the administrative close that I've omitted, I'll add those now.

So, a motion was made to provide a list of all the subcommittees, their members, the expiration of the member's terms, and as well as the charge for each subcommittee to provide a list of that information to all of the members.

And in addition, it was to create a web page that included the current subcommittee information as well as sunsetted committees on the NRC web page.

So that motion was seconded and approved by all committee members. So that will be another recommendation that will appear on the 2018 recommendation chart.

The other thing I wanted to note, at the request of the committee that in the spring we will be doing the annual review of the committee meetings and memberships.

And at that time we'll remind the ACMUI members that we're going to hold that session in that spring meeting so the committee can be prepared to talk about changes to membership.

I think that is all that I have on my notes.

MS. HOLIDAY: And I have one final item. Is that the ACMUI tentatively planned to hold its spring 2019 meeting with the first choice being April 15 and 16. With the backup date of April 3 and 4.

MS. DIMMICK: Yes.

MS. HOLIDAY: Thank you.

MS. DIMMICK: I did.

MS. HOLIDAY: Sorry.

CHAIRMAN PALESTRO: All right. Any other business?

(No response)

CHAIRMAN PALESTRO: We're adjourned. Thank you all. I'm sorry, Mr. Bollock?

MR. BOLLOCK: I was just -- it's a privilege being on the committee. I was just going to introduce Chris Einberg is going to be my replacement.

Many of you members remember Chris when he was in this role four and a half years ago before I took it over. And Chris is taking it back when I depart.

So I know Chris has gone around and introduced himself to many of the new members. But,

for everyone's awareness, that's in person there is Chris.

MR. EINBERG: Yeah. Thanks Doug. You know, so four and a half years ago Doug took over. And I'd like to thank Doug for his excellent service, for serving as the ACMUI Coordinator or the Branch Chief for the Source -- or the Medical Safety Events Assessment Branch.

And so I think he's done a great job. I know many of you from when I was here. I hired many of you or I was in the interview process with many of you.

So, I look forward to working with all of you again. And getting to know the new staff here.

So, we'll be working together. And so all the best. Thanks.

MR. BOLLOCK: Thanks Chris.

CHAIRMAN PALESTRO: Anything else?

MR. BOLLOCK: No. Close the meeting.

CHAIRMAN PALESTRO: All right. Thank you. The meeting is adjourned.

(Whereupon, the above-entitled matter went off the record at 2:46 p.m.)