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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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WEDNESDAY,

SEPTEMBER 11, 2019

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The meeting was convened in room T-2D30 of Two White Flint North, 11555 Rockville Pike, Rockville, Maryland, at 8:30 a.m., Christopher J. Palestro, M.D., 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

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

ZOUBIR OUHIB, Member

A. ROBERT SCHLEIPMAN, Ph.D., Member

MICHAEL SHEETZ, Member

MEGAN L. SHOBER, Member

HARVEY WOLKOV, M.D., Member

NRC STAFF PRESENT:

ANDREA KOCK, Director, Division of Material Safety, State, and Tribal Programs

CHRIS EINBERG, DFO, NMSS/MSEB

MARYANN AYOADE, NMSS/MSEB

LISA DIMMICK, Team Lead, NMSS/MSEB

TOMAS HERRERA, NMSS/MSST

VINCE HOLAHAN, PhD, NMSS/MSST

DONNA-BETH HOWE, PhD, NMSS/MSEB

IAN IRVIN, OGC

KELLEE JAMERSON, ACMUI Coordinator, NMSS/MSEB

SARAH LOPAS, NMSS/MSEB

TIM MOSSMAN, NMSS/SMPB

KATIE TAPP, PhD, NMSS/MSEB

IRENE WU, NMSS/MSEB

MEMBERS OF THE PUBLIC PRESENT:

ASHLEY COCKERHAM, Mercurie Consulting

LELAND COGLIANI, *Unaffiliated*

MIGUEL de la GUARDIA, *Unaffiliated*

MATT DENNIS, CRD Associates/Lucerno Dynamics

CAITLIN KUBLER, Society of Nuclear Medicine and Molecular Imaging

RONALD LATTANZE, Lucerno Dynamics

CAROL MARCUS, *Unaffiliated*

RICHARD MARTIN, American Association of

Physicists in Medicine

MICHAEL PETERS, American College of Radiology

JOE RUBIN, *Unaffiliated*

NAN WISE-SILVERMAN, National Nuclear Security Administration (NNSA)

MALIKA TAALBI, NNSA

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

P R O C E E D I N G S

8:34 a.m.

CHAIRMAN PALESTRO: Good morning. I'd like to call Day 2 of the 2019 fall meeting of the ACMUI to order. Before beginning with the formal agenda, I would just like to take a moment to recall that today is in fact September 11, which marks the 18th anniversary of 9/11. And I would ask that we begin with a brief moment of silence.

(Moment of silence.)

Thank you. The first topic on today's agenda is reducing radioactive materials, and it'll be given or be presented by Ms. Taalbi from the NNSA.

MS. TAALBI: All right, good morning, everybody. Thank you very much for the invitation from the Committee and to the Chairman to giving this presentation. We are happy to be here, and hopefully I can answer questions that you may have that prompted you to ask for this presentation. And we'll be happy to follow up afterwards as well. I'll be here through the break.

My colleague Nan Silverman-Wise is here as well, and you can certainly direct any questions to any of our office members after the meeting as well. So please keep us in mind.

So, my name is Malika Taalbi. I'm a Foreign Affairs Specialist in the Office of Radiological Security. As you may know, NNSA is the semi-autonomous agency within the Department of Energy. I thought I'd make a couple of distinctions of where our office officially sits to start off this presentation. So, allow me to go through a little bit of the acronym mission jargon.

But in NNSA, my office is within the Office of Defense Nuclear Nonproliferation. DNN's mission is to work globally to prevent state and non-state actors from developing nuclear weapons or acquiring weapons usable as nuclear or radiological materials, equipment, technology, or expertise.

So that brings me to these. Okay, so this brings me to our office mission here. So, the Office of Radiological Security's mission is to enhance global security by preventing high activity radioactive materials from being used in acts of terrorism. If you can go two slides. Next slide, please. Go and skip back and so. So, one thing, yeah, right there, this is great.

So first I want to kind of talk about what the scope of our office actually is, and then I'll explain how we actually approach that mission. So,

the radioactive sources that we look at, first of all, when our program started, you may be familiar with us as the Global Threat Reduction Initiative, or GTRI.

In 2015, DNN did a reorganization, and the scope of the radioactive material protection and security work moved from GTRI and was split up into different offices. So our office, the Office of Radiological Security, the mission, the scope is still the same, it's just now part of a new office since 2015. The materials we started with are those covered under the IAEA's code of conduct and under 10 CFR Part 37.

But then from that, we did a further risk analysis and also a materials study to look at how much would it actually take of those materials to contaminate a square kilometer to the point where you may have to relocate or evacuate the area. So the basis for that is what we do.

We look at the risk, we look at the likelihood. That includes what are the opportunities to procure this material commercially in quantities exceeding a Category 2 amount of material. We also look at the half-life and the power to contaminate.

So primarily, the four isotopes of concern that we have as part of our office mission activities are cobalt-60, cesium-137, iridium-192, and

americium-241. And as you all are well familiar, these are the applications that are, that where they actually use those materials in the high enough activity thresholds. So nuclear medicine isotopes, brachytherapy devices, radiography cameras that are under that threshold.

Those are not materials that we look at from a security perspective, because they do not meet the thresholds that our office has set up based on our risk analysis. So that's kind of the first kind of scope question. Sure, please.

(Off-microphone comment.)

MS. TAALBI: Right, so because of the risk analysis, so, they're listed on here as an example of what the applications are, but the actual devices that we protect, the devices that are in use in the United States, the vast majority of which do not hit that threshold for us.

MEMBER ENNIS: Because they don't have the activity levels.

MS. TAALBI: They don't have the activity level, right. So we at one point in the program did work to secure the high dose rate brachytherapy devices, partly due to the consolidation looking at all of the devices together, right. But we don't do that anymore,

so based on our material risk analysis.

Can you go back one slide, please. So looking at, setting our office scope, these are the three strategies that we use in order to accomplish that mission. So our first strategy is protect. This is the physical security work that we do. If we are -- actually, I should start by saying we are a purely voluntary program.

So if a site chooses to go above and beyond their Part 37 requirements, our office works with those sites in order to provide physical security enhancements. We work with local law enforcement, the state regulators, NRC in order to protect the materials that are used for the entitled purposes.

If the site no longer wants to use this material, we have a program both in the United States and we work with our foreign partners to remove and dispose of the disused radioactive sources. So in the United States, this program is called the Offsite Source Recovery Project, and we've been recovering sources through this program and in conjunction with CRCPD and the SCATR program for quite some time.

And then our newest component of this office mission is what we call our reduce mission or our alternative technology portfolio. So I manage,

I started on the domestic side, and then I moved to international. I now manage our international alternative technology portfolio. And my colleague, Lance Garrison, who could not be here today, is the domestic manager for our alternative technology work.

So, the mission is to reduce the reliance on radioactive sources by promoting the adoption and development of non-radioisotopic alternative technologies.

So, we use the term alternative technologies, some of you may have seen this in different working groups or materials. What does this actually mean? So the definition that we use and that has been put forth in the U.S. government interagency documents are that alternative technologies are those which do not contain radioactive materials that perform an equivalent or better function as a comparable device.

It's an important distinction because we're not talking about, you know, we've actually had the question, and I don't think this was ironic, somebody was like, well, what about wind energy, right? That's not the equivalent thing, you're not going to be able to treat patients, you're not going to be able to irradiate blood with, you know, a solar or wind generator.

So this technology is not, here you go, okay, this technology is not necessarily non-radioactive. The alternative technologies may admit to ionizing radiation like the X-rays or like the linear accelerators for radiotherapy, or they may not.

One of the questions I know we've been talking about with our FDA colleagues is on UV pathogen reduction. And the companies' claims and the blood community's interest in using this as an alternative for blood irradiation. So, it's an important distinction, but in general, again, we're focusing on those major applications and what machines are in use that have the ability to serve the technical and operational needs of that community.

These machines, for the most part, are all widely commercially available and have been for some time. The -- next slide, please. The examples, just this is our standard slide, very familiar audience here. Looking at blood and research as X-ray irradiators and UV pathogen reduction, basically linear accelerators for cancer treatment, and then industrial e-beam for industrial sterilization. Next slide.

So, in general, why we are looking at this and what some of the questions are. We understand the

decision to use alternative technologies has many considerations and factors to balance. Again, the purpose of this is a, it's a voluntary program. So, we have been working closely with our interagency colleagues and with operators and industry and academia and professional groups.

And ultimately, what we believe the point is here is that the decision to use these has different equities, they have different stakeholders who have different interests. And there are a lot of pros and cons that a stakeholder will have to consider. These are some of the benefits that we have seen and that we have discussed with sites that are making this transition.

They see a benefit about being able to reduce the need for security procedures, the restrictions and the costs that come with management of those systems. Of course, from our office equity perspective, being able to use this alternative technology, it removes the material from the site. And so by removing material, you're eliminating the security risk that that material could pose.

For some, for sites, the liability is an important consideration for them. And looking at this end-of-life disposition is also an important factor.

If you're able to use an alternative technology, it removes the need that you're going to have to, you know, work with our Offsite Source Recovery Program. You're going to have to pay the self-ship, you're going to have to work with the manufacturer. End-of-life disposition is a big challenge, especially for these high activity sources.

One benefit that some sites see as well is the ability to have a steady device through-put, especially when it comes to blood irradiation. We know that as the machines get older, there is a tipping point, especially if you're a high through-put facility where your cesium decay may just be problematic for you if you're irradiating blood 24/7.

In addition, especially in the radiotherapy sector, there is a potential for expanded capabilities or technical performance. That point is more so applicable to our foreign partners than it is to the United States licensees. For the most part in the United States, we're not using the very basic, very old cobalt-60 teletherapy units that we find in some of the developing countries. So this is a benefit that some sites overseas especially are excited about.

And then, you know, depending on what kind of device you get, there's always the potential to

consider upgrades as the technology advances, which may be easier to do on the alternative technology machines. Next slide.

These are some of the bigger questions as well that could potentially make a site go one way or the other. Won't go through all of these, I'm happy to go back to this discussion. But the big ones here are site management administration preference.

That tends to be a driving factor I'm sure in what kind of devices a facility is allowed to purchase. Whether or not you have the budget for a new machine. Research standards, operating protocols. Timeline can be a big question if you're being driven as a site to replace a machine or to move a building, you may be motivated to get a certain technology over the other.

And cost and reliability of course are the fundamental components for the sites on whether or not they can choose to use these machines, and this is a decision for them to make. Next slide.

So the political foundation, before I get into the scope of what our office really does to support this mission, I want to spend some time talking about how did this evolve. This issue has gotten a lot of attention in the last couple of years, but this has

been in discussion, and I think this has been a growing topic really since 2005.

So, in 2005 the Energy Policy Act called for the National Academy of Sciences to do a report looking at radiation source replacement options. I know that this committee looked at the same issue in 2009. And so from the recommendation of the National Academy of Sciences, they called for the U.S. government to adopt policies that provide incentives to facilitate the introduction.

The other important interagency discussion that has been happening that was also called for by the Energy Policy Act is the Task Force on Radiation Source Protection and Security. So, the NRC chairs this task force, and it has experts from 14 different federal agencies and one state organization.

So, in 2010, 2014, and 2018, there were recommendations by this task force partly based on the National Academy of Sciences report that the U.S. government consider options to incentivize alternatives and lead by example.

And so primarily these programs are, the actual recommendation language is on the slide, but I want to highlight it's voluntary, it's prioritized, and it's incentivized. The big issue here, and this

was echoed in the National Academy of Sciences report, is that information about using an alternative may not be available to all licensees. They may not have the awareness that the technology exists.

But even if they do have the awareness, there are barriers that can also exist in order for them to be able to use this. One of these barriers is being able to remove the source. And so, this is why our disposition angle of our office mission is so important. We tie that very closely with everything that we do in alternative technologies.

The other aspect of this is the financial barrier to being able to procure new equipment, especially if you would want to replace your machine before the end of its useful life. If you have a plan for this in your capital operating budget, you'll probably not be able to come up with the funds, or you're going to have a hard time convincing your CEO that it's worth spending the money on this.

And so where our program wants to come in, as per this recommendation, is to be able to incentivize this replacement if it's something that you are choosing to do. Next slide.

Other aspects of the political foundation here. So there's been a number of working groups, one

of which is the, it was under the White House National Science and Technology Council. We published a report in December of 2016 on a best practices guide for federal agencies looking at alternative technologies, both for the agencies that are actually users of these devices, and for those who work with operators in the United States primarily on this equipment.

And then the other components of our political foundation here is the National Defense Authorization Act for FY 2019. So this was passed and signed and included a provision to meet the goal to eliminate the use of blood irradiation devices in the U.S. that rely on cesium or chloride by December 31, 2027.

It's a voluntary program, and it calls out our office's activity, which I'll talk about, the Cesium Irradiator Replacement Project. And this program is voluntary for owners of blood irradiation devices. It allows for the U.S. to pay up to 50% of the replacement of these machines, to pay up to 100% of the cost of removing and disposing.

And again, that component for us is part of our office mission, it's something that we want to support regardless. But we do feel it's important those two pieces are tied.

And then in addition, that this call replaces devices with X-ray or other devices, as approved by the FDA, that provide significant threat reduction. So this NDA I think has been important, and we've heard a lot of feedback from the states that this has been a motivating factor for sites who want to look at this technology. Next slide.

From my perspective, on the international side of things, one of the things we want to call out is that this is a growing political and global momentum as well. So in 2016 at the Nuclear Security Summit, there was a joint statement on the security of radioactive sources.

This included a component on alternative technologies, and it was signed by the U.S. and 26 other countries and Interpol. Since then we've had additional countries subscribe to this information circular, the IAEA as well.

And there've been a number of non-governmental organizations, think tanks, academic community reporting on this, calling for similar actions, one of which was a letter signed by 35 Nobel Laureate signatories in the run-up to the 2016 Nuclear Security Summit. In addition, there have been reports from the World Institute for Nuclear Security, the

Stanley Foundation, Nuclear Threat Initiative, and Center for Nonproliferation Studies, among others. Next slide.

So, what is it that our office is actually doing? These are the four strategies that we are approaching to try to promote the adoption and development of these technologies. So the first is policy engagement. It's looking at policies that will incentivize a long-term transition and make it easier for those who choose to use this technology in the future.

We also are looking at device replacements. So these are the actual incentives that we're talking about, about being able to remove the barriers to adopting this technology. We are heavily focused on outreach and education. We recognize that our office has a security mission.

And this is the expertise that we're coming from. We are not a cancer organization, we're not a blood organization. And so for us, it's vitally important that we take the time to attend professional society meetings, conferences, talk to sites, and get that feedback to understand what is actually going to be feasible and what do users want to see in their respective industry areas.

And then finally, the other aspect of our office is research, and this is how, this is one of the other important components that we're using to try to approach alternative technologies. One of the points on the research side of things is that for those that say it's not going to work for them for a variety of reasons or it's not going to meet their technical needs, it's important for us that we help to, we understand what those concerns may be.

We have a research and development sister office. Department of Energy has an extensive national laboratory network. And so, you know, if somebody says it's not going to work for me, that's totally fine, but I don't want to stop there, I want to know why. Because maybe there is an aspect of a technical study or there's a component of the device that needs some development.

You know, we want to make sure that this is not a short-term, nearsighted activity, and this is something that could positively impact the industry and both the security mission and also the respective (coughing) areas in the future. And so if there's something that can help that happen, then that's an activity our office wants to support.

So, in that vein, we then collaborated

heavily with our research and development offices, like I mentioned. We've also worked with sites across the United States. We've worked with different laboratory technical centers to find comparison studies.

We're looking at feasibility cost conversion. You know, being able to fund, if a site, like if a research site, for example, wants to get an X-ray research irradiator, but they need to finish up their studies, you know, that is a time that we are helping that site to accommodate. They don't have to immediately switch. And so that aspect I would just want to make sure to call out as being a very important component of what we do. Next slide.

So I'll go fast. The Cesium Irradiator Replacement Project actually, Nan, what's the updated number?

MS. SILVERMAN-WISE: A hundred and eight.

MS. TAALBI: A hundred and eight. So, we had 108 replacements to date. Additional replacements in the pipeline are 173 irradiators. Next slide.

Okay, so the Cesium Irradiator Replacement Project, I talk about some of this with the NDA example. We provide a financial incentive toward the purchase price of an X-ray. This is payable upon both procurement of the X-ray machine and the disposition

of the cesium. So, both activities need to happen before the sites get the incentive.

The sites are responsible to register the device with our Offsite Source Recovery Project and go through the coordination of the device delivery installation and the aspects of removal. Irradiator replacement is trending, so at this point, about 30% of the U.S. cesium irradiator inventory is currently being replaced through this program.

And there a number of major initiatives, the American Red Cross, University of California system, the New York City -- New York City just in general. Atlanta, Georgia. And this is at this point, the percentage of irradiators that are expected to be replaced and removed in these focused initiative areas. So we've had a lot of progress, and I think there's definitely more to come in the United States.

These are just some examples of the outreach and education activities that we talked about. We've held a number of workshops, both in the United States and overseas. We also attend industry conferences, meet directly with source users. And we have some public informational materials that we are happy to share.

All right, talk about the research and

studies. Policy and industry landscape is another important component of this to understand what devices might be coming out in the near future and how is technology developing, the way that may impact this area.

And then internationally, one thing I'll mention here is that we also have an international working group on this issue. So we have an annual meeting, it's co-chaired by the United States, France, and Germany. And at our last meeting, this was the fifth annual meeting, we had over 60 participants from 26 countries.

And I will stop there. Hopefully I can answer a couple more questions. These contacts I mentioned. I'm the International Portfolio Manager, my colleague Lance is the domestic manager. I'm happy to answer questions. Or come find me after.

CHAIRMAN PALESTRO: Thank you very much for that excellent presentation, very thorough. Any questions, comments from the committee?

MEMBER ENNIS: A few. So first, since you do the international, could you reflect for a minute on the relative risks of what's going on in the international world versus the risk that we have in the United States without any changes? Just basically

current state of affairs.

MS. TAALBI: It's a good question. So I think in general, the basis of both is that we do see the risk, we do know that the risk is out there. We know that there's an interest and demonstrated attempts at being able to look at radiation as a weapon and to -- there's a risk, there's a risk. I'll just put it like that.

And so I would say that there's a basis between the two. We are working, one of the questions relative to the United States versus the overseas environment is that the United States is a very, obviously a key player at the IAEA, and the international norms for being able to secure this material are, we play a key component in this, like, we're a heavy leader.

And so I guess I will defer the, because I think you're asking a more specific question than I can probably answer at this point. Unless that's --

MEMBER ENNIS: No, not really. No, it's just, I guess the underlying question, if you will, is it seems to me the risk is so much greater internationally with third, you know, like a lot of unstable countries and a lot of sources that, from what

I understand, no one can track because of governmental. And whereas here it seems like, don't want to give us any bad luck, but things are site-secured. And I'm wondering is the focus between the two appropriately balanced for the risk?

MS. TAALBI: Okay, yeah, okay, I understand what you're asking. So yes, you know, I think from our office's perspective, the United States component is we have a domestic program and an international program. So one of the things I think to consider is the amount of material that's available in the United States relative to other countries.

I mentioned on the CIRP slide, right, so at this point approximately 30% of the U.S. cesium irradiator inventory is being replaced through CIRP. We've done over 100 devices so far. Most countries don't have, like most regions don't have that much material. So I think there is a balance between the awareness of the state and non-state actors, the lone wolf scenario, and what is successful. So there's probably other offices that can speak to that concern better than I, but I think that's that.

MEMBER ENNIS: So the thought just went out of my head. But okay, so I'd appreciate that you seem to be emphasizing really only Category 1 sources.

But other people in the room might remember this better, but in the last year, I saw some legislation, regulatory proposals that were, wanted to change the way even Category 3 sources were tracked that would have added a regulatory burden.

And again, you know, Category 3 sources. I don't know if that came from your office, are you familiar with this legislation?

MS. TAALBI: I'm familiar with the legislation.

MEMBER ENNIS: Okay.

MS. TAALBI: It did come from our office, so it's one of the things that, you know, our NRC colleagues in the room. We are a voluntary organization, we're not the regulators. And so proposals to change the regulations for Category 3 materials, we have an interest in that, but we're not a driving factor by any means.

And for us, the driving factor of where that level is goes back to that risk analysis and scope evaluation I talked about. So I think for us, where we see that security threshold risk is a slightly different question than whether or not the regulations need to be changed for Category 3. So I would defer that question to my two colleagues.

MEMBER ENNIS: I do remember if I might.

MS. TAALBI: Yeah.

MEMBER ENNIS: So obviously, all this is about risk benefit analysis, including economic, as you alluded to. But there's one issue that really kind of concerns me particularly that I'm not sure has made it into that analysis, and that has to do with the effect it'll have on an industry and its interests in developing new products over time in an environment that is trying to basically remove it from the global scene.

So if one has a view that radioactive materials have intrinsic properties that nothing can really replace realistically, and development of that will help humanity, it would be, from my perspective, it would be a shame to completely eliminate that for a theoretical risk, as opposed to an emphasis more on securing those sites.

And how does one analyze the theoretical deprivation of future advances in science that could be applied to humanity? How do you factor that into an analysis about whether this a good program?

MS. TAALBI: Sure, and I, you know, I agree, right. I don't think we're going to see radioactive material disappearing any time in the near

long-term, you know, general human future, right. And that's, for us, that's why it's important that the alternative technology piece is that a component of our office mission, right.

So if you look at the bigger picture mission, it's just to prevent materials from use in acts of terrorism. And so if you want to use the device, use the device. We're not going to tell anybody that they shouldn't be doing that. We will work with you to help secure that material, you know, above and beyond what regulations call for if you want.

I don't think that, at least based on our discussions, I don't think that we see necessarily a lack of interest in development. If anything, I think, on the converse, there's been an interest in development in the other space. Like V-ray, for example, moving from using the cobalt-60. And I don't think there's any shortage of Gamma Knifes and interest in development of those, right.

So I think it depends on what industry and application, and that's where I'm hoping the, you know, I think by participating in these meetings and really just calling out for those health communities the idea that there could be this security nexus is something that factors in, but it's not a driving factor that

they're doing.

We're just kind of, you know, saying hi, don't forget about us. But really, their technical means in interest in developing, that's what's driving the industry, so.

CHAIRMAN PALESTRO: Any other questions?

MS. KOCK: I just wanted to clarify your question about Category 3 materials on those regulatory proposals. And there is a paper before the Commission right now, it was sent up, I believe, in August of 2017, looking at Category 3 sources and whether we should, for example, require more tracking. That's before the Commission; they have not voted. The staff's recommendation was not to require additional tracking, so we'll see what the Commission says.

And I'll also point you to a letter that was signed by our EDO in response to a recent GAO report on Category 3 sources. GAO is recommending that we take additional regulatory actions. And one of the things that our EDO said in that letter back to GAO is that we do need to consider holistically the risk of Category 3 sources, including the benefit that they provide to society through things like medical uses.

And so when we look at whether regulatory action is needed, we take that into consideration.

So if you're interested, we can get you all the, the ML number for that letter, but that was mentioned in our response to GAO just agreeing with their recommendations.

CHAIRMAN PALESTRO: Mr. Ouhib.

MEMBER OUHIB: Yes, just to follow up with what Dr. Ennis was saying, that it seems like this program will definitely favor that route. So like, so people will be looking. Because there is some incentive in all that. So, people who are like on the 50-50, but well, here's something that maybe we need to. So, it will eventually discourage further work and research and so on in that.

And I was looking at your list of individual organization and all that you have started the conversation with, but I have not seen any professional organization, such as ASTRO, ESTRO, ACR and so on and so forth, you know, these organization to have the discussion and see where they see things, how they view things regarding this program.

MS. TAALBI: Absolutely. So, the list, I should clarify, the list that we have on that site is not comprehensive by any means. So, we've been part of a DHS-led critical infrastructure advisory working group for the last several years. That includes an

extensive number of industry participants, including APM, HPS, ASTRO has been involved in some of our outreach events as well. There have been a number of organizations, and I'm happy to get more details on that to you after.

So, I will say we're definitely very widespread. We're attending the American Association of Blood Banks conference, for example, in October. We're going to a lot of events and talking to a lot of people. So, you know, that being said, there are obviously more people that we could talk to and more groups, and we're always open to that.

So, we're trying our best to make sure that we're getting feedback from as many places as possible. So that, to your second point.

On the first point, as far as favoring one or the other, I mean, I think that's part of the purpose of an incentive, right, we want to incentivize the alternative. But at the same time, you know, if you're truly on the fence, if you really don't care one way or the other, that's where I think the incentive will make a difference.

If you really are struggling favoring cesium, and we have seen this, right, we're working with the University of California system to replace

the irradiators that they have. And not all their irradiators are being replaced. The Board of Regents asked the universities to justify whether or not they wanted to continue using the cesium that they had, or if they wanted to switch.

And there were applications for which the Regents agree that it didn't need to, they didn't need to switch, they didn't want to. So, I think in areas where the research is still needed, you're not, we're not going to see that go away. And again, it's about being able to provide a balanced approach. It's about full information.

And that full information aspect, I will admit, is more of a driving factor I think overseas than it is in the United States. United States, it's a little bit more about the barriers to being able to remove your source. It can be quite costly to do that on a personal, on a site, individual level. So that's a big barrier for some. And being able to get funding to get a new machine is also a barrier.

Internationally, we have sites that literally don't know that X-ray irradiators are even available. They're using their cobalt-60 teletherapy units to irradiate blood. So that, in that case, it's more about just understanding what is on the market

and what's available to you as an operator.

MEMBER OUHIB: Just to follow up, have you thought about some sort of incentive for the other side to have -- to make safer devices and things like that, such that so we don't deprive that factor of, you know, in the research.

MS. TAALBI: Absolutely, so that's definitely a component of our office's program. So, our physical security protection program. We also have what we call our in-device delay. So, we work directly with the vendors to put, to improve the delay and prevention capability and make the device more tamper-resistant.

And so, for the most part, these IDD, these in-device delay kits, are, they're factory now from the vendor. So, we're working with these manufacturers to try to do that so that that's not a disincentive for users who want that. And there are some conversations as well about how do you expand the dialogue on this in an industry space.

You know, we have Energy Star, but we don't necessarily have like a security star program, right. So are there ways that we can make it clear that the security mission is being fulfilled one way or the other. So, I definitely acknowledge your point, and

know that that, that is still, that's a focus area of office as well. Yeah.

CHAIRMAN PALESTRO: Thank you very much. In the interest of time, we're already running behind. I'm going to move on, we're going to move on to the ACMUI's Institutional Memory Subcommittee report, which will be presented by Dr. Schleipman.

MEMBER SCHLEIPMAN: I'd like to present here today the Institutional Memory Subcommittee's evaluation.

So, our verbatim charge was to improve the ACMUI's institutional memory and provide possible recommendations or methods of tracking and/or retrieving ACMUI documents. The members include Drs. Ronald Ennis and Michael O'Hara, Ms. Megan Shober and Ms. Laura Weil. The NRC staff resource is Ms. Kellee Jamerson. And we also had, because of the historical nature of this, some assistance from Sophie Holiday.

So, at the last meeting we held in April, a lot of members discussed some difficulties in recalling or accessing our past deliberations and discussions. Thankfully, the staff members filled in the gaps. But because of rotating staff assignments and ACMUI turnover, this contributes to a loss of continuity and institutional memory.

As a federal advisory committee, our open sessions are transcribed and documented for member and public review. These transcripts do reflect our comments and proposals at the open sessions but perhaps do not capture all decisionmaking comments and rationales. For example, yesterday's last, the presentation was a recommendation to amend the report to include a rationale for why a decision was made or a recommendation was made.

Also, at that April meeting, the open action list showed just a number of issues without any clear documentation of why certain items remained open. At that time, staff members could chime in and say, well, this is why this is happening, this is not happening. But it wasn't clear to everybody who was at the meeting. Certainly, as we also saw yesterday, that open action item list has been considerably improved and refined.

So, the first thing we looked at were online tools. The staff recently enhanced the, relatively recently enhanced the webpage, which you all have access to. And additionally, the NRC website provides a number of links to regulatory processes, some background information on rulemaking, the authorizing and governing statutes. And there's also the NRC

ethics links to the Office of Government Ethics we heard from yesterday.

And then the webpage itself, and I'm going to preface my remarks that these are as reviewed in July of this year, contains and presents the ACMUI charter, the recently revised bylaws. There is an ACMUI history page with historical membership lists from 1988-2017, acknowledged as incomprehensive.

There's a current membership page for the committee, and then a number of meetings and related documents for the agenda, meeting handouts, slides, summary reports, open meeting transcripts. And also, ACMUI recommendations and actions from 2017-2018.

There's also an ACMUI subcommittee reports page covering 2002-2019. And a subcommittee file of shorter duration, which has the name, the charge, subcommittee members, including staff resource, and the status of those subcommittees.

So, I think if you look at those two together, that provides a record of our makeup, the dates of formation and deactivation of subcommittees, then their actual output, whether as draft or final reports.

So, I asked the staff how often is this updated, and the resource person said, well, at least

this has been happening before 2010 when they came there. Updates are posted by the ACMUI Coordinator. And the posting frequency varies, and generally subject to when we provide the documents that they're asking for. And then the subcommittee reports are posted after a report is finalized and received.

So, I looked at it this morning, and there's certainly more than has been there when I looked at this last in July. So, they're regularly updating this.

So, the last question that came up was great, there's a website, but I like to search for things, and how easy or difficult is that. And in general, the quality of the search engine and database are what drives that functionality. There are varied options to add this. I'm not an IT person, but I could say that the website main page does provide a Google custom search box directly linked to and available from the ACMUI webpage.

And the search box does not easily discriminate all acronyms. You're in an acronym-heavy industry I guess, or site, so if you put in, you entered AO to look for abnormal occurrence, you may not get those documents, you may get instead annotated outline documents.

And secondly, the retrieved documents are Commission-wide, not specific to ACMUI or even medically related documents. So, a good note to remember is that if you add ACMUI to your search category, you will receive and generate a list of ACMUI documents. As an example, if you, on the left, if you look at just typing in 90Y for yttrium-90 documents, you'll receive literally thousands of documents which have nothing to do with ACMUI.

But if you limit the search to ACMUI and 90Y, then you specifically get subcommittee reports and so forth. So, it's a very easy way to retrieve those documents.

The next thing we looked at was, and discussed, was new member orientation. If you go back to the NRC website, there's a new employee's portal but that doesn't apply to special government employees, though there is a section for major ethics rules affecting SGEs.

The other way new members are oriented, though, it hadn't happened uniformly in my experience in the past, but this was certainly distributed to people now, is a guide NUREG/BR-0309, and that's essentially serving on the Advisory Committee on the Medical Use of Isotopes members. Did everyone receive

that? Right, I don't think so.

So, this was last updated in 2004, so essentially, it's a 15-year-old document that not everyone is aware of. I think I heard that it's being revised. So, we thought possibly a less formal ACMUI-specific onboarding guide or current backgrounder could be provided to new members.

Alternatively, that sort of information could be added to a revised guide so that new members would have some idea of what we're actually looking at and discussing.

The more substantive suggestion, I think, was that a practice space change might be incorporated in subcommittee reports. And essentially, it's slightly formalizing what's already done, and that is that the subcommittee would review sort of the available materials regarding previous deliberations relating to that charge and provide a summary, in a few paragraphs hopefully, of deliberate references to past related ACMUI documents.

And this would be part of that record, so that the next report would say this page or so is what happened in the past. And you can more easily trace then the relevant historical documents and provide some continuity and a reference point for new deliberations.

On a somewhat ancillary track, we wondered what other resources were available to members. For example, does the Commission have a SharePoint sort of shared file application, Enterprise Dropbox, or local area network? And you know, staff said, sure, we have a LAN, we have a local area network. But if you wanted to be a part of that, this would require significant additional training and also some onerous security monitoring of your personal computers.

And when that was presented in the past to members, they said they quite understandably said no thank you. So currently there's no LAN available to us without going through some additional security and training.

So, in summary, the ACMUI's institutional memory is by necessity diminished by the turnover of our own members, as well as the transfer and occasional reassignment of staff. The NRC website seems to be, when used with ACMUI-focused searches, a robust and accessible source of documents. I'd like to congratulate the staff on keeping that up to date and putting that together, I'm sure it's a task.

The webpage does provide archived reports in systematic fashion.

Our only recommendations were to enhance

the onboarding process for new members with this updated new member guide, which could incorporate maybe some perennial topics and background information, or that could be done separately.

And then with the probable requirements for staff assistance, augment committee reports with a brief summary of previous deliberations and referencing the related NRC documents.

So, I'm happy to entertain any questions or discussion.

CHAIRMAN PALESTRO: Thank you, Dr. Schleipman. Questions or comments from the other members of the subcommittee? Questions or comments from the ACMUI?

I have a couple of questions, Dr. Schleipman, and also perhaps direct them to Mr. Einberg as well. Apparently, the list, if I understood your presentation correctly, of past ACMUI members is incomplete, is that correct?

MEMBER SCHLEIPMAN: At the time I reviewed it in July.

MR. EINBERG: Chris Einberg here. Can you clarify how far back or was it incomplete or what aspects of it were incomplete?

MEMBER SCHLEIPMAN: It didn't have all the

members.

MR. EINBERG: Of the current members, or?

MEMBER SCHLEIPMAN: No, past.

MR. EINBERG: Past members. We can take a look at it and see if we can augment that based on historical knowledge.

CHAIRMAN PALESTRO: And I would, get back to this at the end. I have a couple of other items, but I think I would add that as a recommendation to your report, that that list be updated.

My second comment is from the way you presented it, it doesn't sound like there's a standardized approach to -- standardized approach to posting information in documents? It's not done -- is it done on a regular basis?

MEMBER SCHLEIPMAN: It is.

CHAIRMAN PALESTRO: It is regular.

MEMBER SCHLEIPMAN: Yes, it's done after our meetings and updated regularly.

CHAIRMAN PALESTRO: Okay, that takes care of that. Then my last comment, my last question really is I'm intrigued by your suggestion about a new member guide, developing a new member guide. Mr. Einberg, what does that entail? Can that be done by the ACMUI ourselves, or?

MR. EINBERG: Well, that's an interesting thought. So right now, we do have, as Dr. Schleipman pointed out, we do have a branch position serving on the Advisory Committee on the Medical use of Isotopes a member's guide. And so, as he pointed out, that hasn't been updated in quite a while.

That, Kellee has been has tasked, Ms. Jamerson has been tasked to update that by December. What I would suggest, perhaps, is that she take the initial draft in updating that guide and circulate it to the members. And you're welcome to comment, and we could augment it and make changes based on your comments.

CHAIRMAN PALESTRO: All right.

MR. EINBERG: Or if you want to have the subcommittee to the take the guide and make revisions to the guide or a different document, then that's fine as well.

CHAIRMAN PALESTRO: No, I think rather than having two simultaneous, ongoing efforts, since there's work already underway, once Kellee and the group get finished with their revisions and updates, to turn it over to the subcommittee for review and comment. I think that would be, that's probably a better way and a more efficient way to do it.

And I would just add that, and of course this is just a suggestion, that in that guide, that you consider including a report template. Because I know when I did my first subcommittee report, I really wasn't familiar with the template, and had to go around and look at other reports and so forth. The pertinent information, the members, the staff, all of that. So I think it makes it a lot easier.

MEMBER SCHLEIPMAN: Rather than through osmosis or trying to figure it out, yes.

CHAIRMAN PALESTRO: Yeah, so that I think is important. In terms of the subcommittee, Ms. Weil is no longer on the committee. I think it's important to have someone who is new, because they are probably the ones most adept at identifying what's needed, what's lacking. And so therefore, I'm going to ask Dr. Wolkov to join that committee as a member, and I would ask that you remember the rest of subcommittee stay as is, with you as Chair.

MEMBER SCHLEIPMAN: Sounds great, thank you.

CHAIRMAN PALESTRO: So Mr. Einberg, can I make a motion regarding the, recommend that that list be updated, that member list?

MR. EINBERG: The, yes, make a motion to

do that.

CHAIRMAN PALESTRO: That the report be amended that an additional recommendation be added to your subcommittee report that the ACMUI member list be updated and completed. Second?

MEMBER SCHLEIPMAN: Second.

CHAIRMAN PALESTRO: Any further discussion? Yes, Dr. Dilsizian.

MEMBER DILSIZIAN: So, I find very interesting, so just two questions. How far back does the webpage go as far as years, where it's all electronic and you can find these documents? And then that I'm asking is because we've had a lot of discussions here about T&E --

CHAIRMAN PALESTRO: Can I finish with the vote on this and then --

MEMBER DILSIZIAN: Oh, yeah, absolutely, oh, yeah.

CHAIRMAN PALESTRO: Just I don't want to --

MEMBER DILSIZIAN: No, I want --

CHAIRMAN PALESTRO: And then I'll turn it back over to you. Any further discussion on the motion to add the additional recommendation? All in favor? Any opposed? Thank you. Dr. Dilsizian, please.

MEMBER DILSIZIAN: Thanks. So, two questions, how far back does the webpage for a search engine for all of us? And that particularly I guess I'm asking because we've struggled with T&E, how the decision was made for the hours, 80 versus 700. Because that's critical, because we don't have any idea how those hours came about, and we haven't been able to address it, so.

MEMBER SCHLEIPMAN: So, when I reviewed it in July, I found subcommittee reports from 2002-2019.

MEMBER DILSIZIAN: 2002. And how do we retrieve information before it, I guess, if we were to?

MEMBER SCHLEIPMAN: You go right to the webpage, this is the webpage. You can just type in ACMUI NRC and you'll get the webpage. And then the only, these various sessions, membership page, meetings and related documents, recommendations.

MEMBER DILSIZIAN: And that's 2002 and on, right?

MEMBER SCHLEIPMAN: Yes.

MEMBER DILSIZIAN: And anything before that, what do we do?

MEMBER SCHLEIPMAN: I think there may be some, I'd have to -- maybe we could log on. I'm not

sure, but I think you could just go to NRC to the main --

MR. EINBERG: Yeah, so, this is Chris Einberg. So, we do have an agency document management system, and it's a publicly available system. And there's a search engine there. If there are additional documents, then they would be in the ADAMS system.

CHAIRMAN PALESTRO: Dr. Metter.

VICE CHAIR METTER: I agree with Dr. Dilsizian as far as how to search these webpages. And perhaps in that new member template, you could also just add the links. Also, how to get to NMED and what things are available for us and how we should, we are able to log in. And I think that will be very helpful to new members. And current members.

MEMBER SCHLEIPMAN: Okay.

VICE CHAIR METTER: Yes. No, as Mr. Green just said, you know, and how to work with getting your travel through CONCUR and essential meeting items such as that, and hotel.

CHAIRMAN PALESTRO: Any other comments or questions? Comments or questions from anyone in the room? Comments or questions from the bridge line?

MR. EINBERG: Kellee, is the bridge line open? Just a moment.

CHAIRMAN PALESTRO: Okay.

MR. EINBERG: It is open. Any comments on the bridge line?

CHAIRMAN PALESTRO: Hearing none, can we have a motion to approve the amended report of the institutional --

VICE CHAIR METTER: I motion to approve the amended report.

CHAIRMAN PALESTRO: Second?

MEMBER GREEN: Second.

CHAIRMAN PALESTRO: Any further discussion? All in favor? Any opposed? Thank you.

Next item on the agenda is the open forum. Mr. Sheetz, I know you had approached me.

MEMBER SHEETZ: I would like to follow up on one of the recommendations made by the Infiltration Subcommittee yesterday where conversation results in permanent functional damage to be reported as a type of patient intervention for requirement in Part 35. And there were comments made by the staff that the passage you mentioned could not be captured in the current definition in 35.2 for patient intervention.

So, I guess I would ask for some guidance from the staff on what the options are for this recommendation to actually happen should -- is it true

of the current definition in 35.2 for patient intervention which states, Actions of the patient, intentional or unintentional, cannot capture passive, you know, intervention or passive acts.

If not, then we would be looking at rulemaking, and so do we pursue rulemaking to include that in the definition of patient intervention? Or do we pursue rulemaking in the medical criteria similar to the requirement that's already there for permanent functional, you know, damage to be reported. And so, I'm looking for, to follow up so we're not hanging there for guidance from staff on what approach would be best.

MR. EINBERG: Yeah, so after our meeting yesterday, again, we had, the staff discussed this, the issue a little bit. And then we think that there may be some latitude in guidance space, rather than going to rulemaking. We've asked our Office of General Counsel to investigate that. And when we can report out next week on that.

MEMBER SHEETZ: That's great, thank you very much.

MEMBER ENNIS: So, are we all, NRC staff and ACMUI, on the same page that the type of passive patient interaction ought to be considered intervention?

MR. EINBERG: I wouldn't, again, I don't want to make any determination on that aspect. The question that we posed to the Office of General Counsel is whether we have latitude to make changes for, you know, patient intervention, in guidance space. We want to, we're not saying this is or is not. But do we have latitude to redefine it in guidance space.

MEMBER ENNIS: Okay, so, because this is not what we've discussed with this committee already. For a while the late Frank Costello, our wonderful colleague, was really the leader in that. And I still feel like maybe we're talking a different language with the same words. And what patient intervention means in the doctor's head still might be exactly the same.

So, do we need to have some committee to further articulate what the ACMUI thinks patient intervention means in a little bit more detail, or is that already understood and it's just a lawyer question?

MR. EINBERG: Yeah.

MS. DIMMICK: So, if I could, Lisa Dimmick, team leader. So, I was actually going to bring this issue up today just for clarity, because we do have a patient intervention report from 2015 that provided recommendations on patient intervention. And Kellee

is trying to get to those on the screen for reference.

And then subsequently what occurred was the recommendations of this report were rolled up under the 2017 medical event patient safety culture recommendations as an addendum to that. And so where probably staff needs clarity on the ACMUI's position or recommendation with regard to patient intervention.

So, I think it merits further discussion or perhaps a subcommittee. Because we were going to ask for clarity, so when we issued the memo to close all of those action items in August, one of the ones that we had identified that we needed some clarity were, concerned patient intervention.

And now with the subcommittee recommending the passive patient intervention to be considered as part of a medical event reporting with regard to extravasations, I think there is, clarity is needed from the ACMUI. We can still evaluate latitude and guidance that we have here, but I think we need clarity on what the ACMUI would like to recommend to staff concerning patient intervention.

CHAIRMAN PALESTRO: Any other comments or questions?

MR. EINBERG: So Lisa, just to be clear then you were suggesting that the subcommittee

readdress this issue.

MS. DIMMICK: Or a, it might need to be a new subcommittee, because previous, not all of the members that were on the patient intervention subcommittee are still members, or they've rotated off. So it might be something to consider, just to clarify what the ACMUI recommends with regard to patient intervention and what that means.

MEMBER DILSIZIAN: To refresh our memory, I think I was part of that committee. Could you bring up the conclusion? I mean, because I think most of the members here were not part of that discussion.

MS. DIMMICK: Correct.

MEMBER DILSIZIAN: So, it would be nice to know before we create a new subcommittee and rediscuss this what were the conclusions. I think I was the Chair then.

MS. DIMMICK: Yeah. There was, you know, in the 2017 medical event reports a medical event patient safety culture report has an addendum.

(Pause.)

MR. EINBERG: Kellee, can you scroll up to the summary, and let's take a look at that real quick.

MEMBER DILSIZIAN: I think in the previous presentation, if you have the slides, we had a very

nice summary about the passive intervention if you have the slides from my presentation where it made the case about all the medicine and the difference between, you know, patients that goes -- I mean, I'm not sure which report this is but --

MR. EINBERG: Can you find me the presentation from the meeting in 2017?

MEMBER DILSIZIAN: I think so, yes.

MR. EINBERG: On patient intervention.

MS. JAMERSON: Yes, we apologize for the delays. Our monitor isn't working, so we have to look in that middle screen to see everything. This monitor is blank, so I apologize for being slow.

MEMBER DILSIZIAN: Yes, the slides will be easiest. You can just go on, and you can see the thought process.

(Pause.)

MEMBER DILSIZIAN: So, we really thought that this issue is really practice of medicine and it's really not, as I said, if you go to the previous slide, we were really making a distinction between an event and an error, and passive intervention falls into unintentional outcome on the left-hand side. So we've had great discussions. I mean, we can revisit this if you'd like, but this was covered several times in

this meeting in subsequent meetings. But if you'd like to revisit it, we'll be happy to.

CHAIRMAN PALESTRO: What would be the rationale for revisiting it?

MEMBER DILSIZIAN: Well, they were asking. I'm just --

CHAIRMAN PALESTRO: Mr. Sheetz?

MEMBER SHEETZ: So, you're addressing physiological or anatomical variations, you know, as being part of practicing medicine. You can't control that, and there's variations within a patient. Variation causes medical criteria to not be reported, and I agree with that. But I made a point yesterday where I think the type of passive patient intervention, the example was during halfway through a particular treatment when the patient has a myocardial infarction and the treatment is terminated and the patient can't complete the treatment and has to go for medical care. And so that, I feel, also is a type of passive patient intervention. It should not be reported as a medical event. There's no advantage to that.

And so, this is the type of, you know, acute medical condition change or something of the patient that occurs, which I don't think it's captured in your wording right there of that subcommittee. So maybe

we do need to look at this as a committee and some agreement that all these type of things that may occur with a patient that are completely out of the control of the licensee, you know, do we really want them to be reported as a medical event if that particular change in physiology or anatomy or acute condition of patient causes the medical event criteria to be exceeded?

CHAIRMAN PALESTRO: I'd like to get some input from the rest of the Committee before making a decision about reconstituting a subcommittee. Dr. Ennis?

MEMBER ENNIS: I agree with Mr. Sheetz. This seems to be a lack of clarity, and perhaps there's a lack of clarity about this. We've been dancing around it for a while, and it's clearly not totally resolved. Certainly, the example put out here, I think it's probably the most basic end-of-life course that's not a medical event, but, technically, by the language, it's pretty clear it is. So I think we got to further clarify our position and advise the NRC.

CHAIRMAN PALESTRO: Dr. Metter?

VICE CHAIR METTER: I also concur. As we talked about the new emerging rate of pharmaceuticals and more complex therapies, along with duration time, I think these patients are generally, many of them may

not be as well as others, you know, or our procedure with the larger volume and more complex therapies can result in other unintended issues that come out acutely with these patients. And so I think that is actually something that we should look at.

CHAIRMAN PALESTRO: Dr. Dilsizian?

MEMBER DILSIZIAN: I actually not only completely agree, but I will go one step further. I will say it would be intuitive for most physicians who are taking care of patients who has an intermediate complications with a bronchospasm, heart attack, goes to the emergency room where the therapy is stopped would not even think about reporting it to the NRC as an intervention or medical event. I mean, it just doesn't make sense for any physician who is taking care of patients, in the middle of the treatment something happens and acutely transferred to emergency room or CCU, would think that this would be a medical event. I can tell you that I suspect most physicians are not reporting it, and I support that because it isn't, in my opinion, a medical event, but that should be documented.

CHAIRMAN PALESTRO: Mr. Ouhib?

MEMBER OUHIB: Yes. I think the other factor is that that could very well be a discouraging

factor for some physician not to perform a certain procedure knowing that this particular patient has some issues and all that. You know, like, well, if I don't finish this procedure, then I could end up with a medical event that I'll have to deal with, report it, and all that. Granted, people look at medical event as a bad thing. It's not necessarily a bad thing. However, it's still out there, and I think that that's very critical. And so, therefore, the patient might not benefit off something that could potentially be very helpful.

CHAIRMAN PALESTRO: And so the objective of this committee would be to what? To define patient intervention?

MEMBER DILSIZIAN: No, no, to exclude that if there's a medical event that happens during a procedure where it interrupts the therapy, that would not be a medical event. That would be passive intervention. That's, I think, what you're saying.

MEMBER SHEETZ: Yes, I think it would be to completely define passive patient intervention and what that would capture. It may be challenging. It may be something we think of later. But I think it needs more clarity right now.

CHAIRMAN PALESTRO: Mr. Einberg, Ms.

Dimmick, comments?

MS. DIMMICK: That could be an approach to take to just provide clarity on the ACMUI's recommendation because this was what was rolled into the medical event safety -- if you could, scroll down. So, there were some changes with regard to, well, it was just clarity on what staff, what action for staff to take with regard to patient intervention. So, the 2015 recommendation is there and then a clarification on a policy change. Because this was rolled into that medical event safety culture report that described high-impact and low-impact events and things like that which were not accepted by staff, it presents a challenge to roll the patient intervention for reporting in those categories. So that's, in part, why I think it's an opportunity to relook at the ACMUI's recommendation with regard to patient intervention and medical event reporting in light of the extrapolation subcommittee's findings or recommendations.

CHAIRMAN PALESTRO: Passive patient intervention. Is that too limiting, the word passive?

MS. DIMMICK: Our current definition for patient intervention is --

MEMBER SHEETZ: It states active.

MS. DIMMICK: It says action, so it's, what

does actions mean? Can actions be involuntary or voluntary? And then we describe it to be unintentional or intentional by the patient. So, in this case, what his actions, how can that be interpreted. So that's what we would need to evaluate.

And then we don't exclude involuntary motion in the definition. We go on to give examples of things like dislodging of a source or an applicator. So, it implies that it was intended to be actionable items on the part of the patient, maybe not involuntary actions.

But, again, it's how the language, how it's written, and is there flexibility and latitude in the current definition to include involuntary movement of the patient. So, we would need to evaluate that. You know, should there be a recommendation to clarify that patient intervention should include nonvoluntary actions on the part of the patient.

CHAIRMAN PALESTRO: I kind of think it should be left as patient intervention.

MEMBER SHEETZ: I agree.

CHAIRMAN PALESTRO: If we define or we make a charge passive or active, then we're eliminating all sorts of things and it has to go back and be revisited. So I just, I suspect, no matter what we do, this will

come up from time to time, but I'd like to make it as comprehensive as I can.

So in light of that, I will form the subcommittee. I would ask that Drs. Dilsizian and Ennis be on that subcommittee. I would also ask that Mr. Sheetz be on that subcommittee and chair it, and I would ask --

MS. DIMMICK: Dr. Palestro?

CHAIRMAN PALESTRO: Yes?

MS. DIMMICK: I just wanted to make sure that you're aware that Mr. Bloom has been cleared and approved.

CHAIRMAN PALESTRO: Didn't know that.

MS. DIMMICK: So, I just wanted to make sure you're aware because I knew you were forming a subcommittee.

CHAIRMAN PALESTRO: Yes.

MR. BLOOM: I have a badge, but I don't think I've been cleared.

CHAIRMAN PALESTRO: I don't think you get a badge if you're not cleared.

MR. EINBERG: Mr. Bloom can serve on the committee pending verification that his security clearance has passed. We haven't been notified yet. He has a badge, but we want to verify that he's actually

been cleared.

CHAIRMAN PALESTRO: So, then his appointment to the subcommittee is pending. Can we do that?

MR. EINBERG: Yes.

CHAIRMAN PALESTRO: All right. Pending clearance. Mr. Bloom, you --

MR. BLOOM: Yes.

CHAIRMAN PALESTRO: -- that you be on that committee, that subcommittee. All right. And the specific charge, I want to be sure that it says exactly what you want to accomplish.

MEMBER DILSIZIAN: The word actions. Do I have to go and define the word actions?

CHAIRMAN PALESTRO: I'm sorry. I couldn't hear you.

MEMBER DILSIZIAN: To the knowledge of your patient interventions actions, we don't know what actions. I think to clarify it, passive, active medical events, et cetera, right? Maybe just --

MEMBER SHEETZ: The charge is for the committee to evaluate the definition of patient intervention, and then we can explore all the possible variabilities there.

CHAIRMAN PALESTRO: I would stop with

patient intervention, define patient intervention. And I would ask that you present your report at the next meeting, spring meeting.

MEMBER SHEETZ: Thank you.

CHAIRMAN PALESTRO: Yes?

MR. EINBERG: If I may add also, you know, pursuant to the discussions we had yesterday, to add some rationale as to why examples would be very useful for the staff.

CHAIRMAN PALESTRO: Thank you. All right. Any other items for the open forum?

MR. EINBERG: Oh, as far as a staff resource for the subcommittee --

CHAIRMAN PALESTRO: It originally -- oh, I'm sorry, yes, we didn't have one. We need one.

MR. EINBERG: Didn't we have one at the previous one? Maryann, you're waving your hand. Maryann will be the staff resource.

CHAIRMAN PALESTRO: Thank you.

DR. HOWE: It may be that we may also want to explore the concept of defining things that are not medical events on their own merit.

MR. EINBERG: Can you give us an example, Dr. Howe?

DR. HOWE: I am talking about patient

intervention. It may be just as easy for you to define a medical emergency as not a patient intervention. And so that will be something that we would be able to put on its own and we don't want to squish it into patient intervention. So I think you should look a little broader and you may come up with things that are just clearly not a medical event and you don't have to exclude them in patient intervention.

CHAIRMAN PALESTRO: All right. What do the members of the subcommittee think?

MEMBER ENNIS: Agreed. I just see the advantage of squeezing it in the patient intervention doesn't require rulemaking, whereas making a new category with the rulemaking, but we should probably consider all the options.

DR. HOWE: But you're also not sure that OGC will agree to --

MEMBER ENNIS: Right.

CHAIRMAN PALESTRO: Dr. Howe, can I ask you, I'm sorry because I couldn't hear you, if you could repeat that.

DR. HOWE: I think the subcommittee should also look at things that do not fit to define things that are not medical events on their own standing.

CHAIRMAN PALESTRO: To define events that

are not medical events?

DR. HOWE: Yes, at things that are not medical events on their own standing. They don't have to go into patient intervention.

CHAIRMAN PALESTRO: Define things that are not medical events and --

DR. HOWE: That stand alone.

CHAIRMAN PALESTRO: That stand on their own. So it's define patient intervention and events that are not medical events but stand on their own. Does that capture what you wanted to say, Dr. Howe? Thank you. Mr. Einberg?

MR. EINBERG: I'm not sure I'm clear as to what stands on their own mean.

DR. HOWE: You may not even have to go to patient intervention if you have a medical emergency.

MEMBER ENNIS: How about something that says define, look at the definition of patient intervention and other medical conditions that might arise --

CHAIRMAN PALESTRO: In the practice of medicine.

MEMBER ENNIS: -- in the practice of medicine that should, that should not be considered medical events.

MR. EINBERG: Can you please restate that?

MEMBER ENNIS: No, but maybe the transcription person can. No? So, again, so the charge would be look at the definition of patient intervention and the existence of other medical conditions whose existence should not be considered creating a medical event.

VICE CHAIR METTER: Can I just add, though, I mean, I think you can't get every little condition, so maybe consider general categories of events, you know, medical patient conditions that may not be considered medical, like Dr. Howe said, medical emergencies, disasters, or something like that.

MEMBER ENNIS: So categories of medical conditions?

VICE CHAIR METTER: General categories, rather than, because you can't define every little situation.

MEMBER ENNIS: Oh, yes, good.

CHAIRMAN PALESTRO: So let's try it again. Define patient intervention and categories, and general categories --

MEMBER ENNIS: Conditions.

CHAIRMAN PALESTRO: General categories of conditions that are not medical events?

MEMBER GREEN: Would that include something as simple as power failure? It's not a medical event, it's not my healthcare, I had a heart attack. The power went out. I can't continue my teletherapy.

MEMBER SHEETZ: Actually, I would like to include that because that currently is a medical event. The power was out, and you can't complete the treatment on the gamma knife. It's reportable as a medical event at no fault of the licensee. Does the Commission really want to have that reported to them as a power failure?

MS. DIMMICK: So in the evaluation -- so this is Lisa Dimmick. So in the evaluation, I mean, certainly, these are things that the subcommittee could flesh out and describe, depending on what the outcome of this initiative would be when the recommendation comes back to staff. If it, let's say, if it were not a rulemaking but might need to be clarified to licensees through a regulatory issue summary perhaps, that document would describe the situations. So that type of information that the subcommittee might consider or discuss would be valuable as part of your report, you know, how it works out, what you end up recommending. So you might describe many things in your subcommittee report, but your ultimate recommendation may not

include all of those specific items but would be part of your report.

CHAIRMAN PALESTRO: Dr. Schleipman?

MEMBER SCHLEIPMAN: I just have a suggestion of language. To clarify patient intervention and other general actions and circumstances that are exclusive of medical events.

MEMBER ENNIS: You're hired.

CHAIRMAN PALESTRO: All right. Anything else on this topic? Does anyone else have any open forum issues that they'd like to bring up? I have one, okay? A bit more mundane, less esoteric. A discussion that came up over the summer with the NRC regarding the ACMUI, the positions of chair and vice chair. There's nothing in the bylaws regarding term limits or, for example, whether or not the vice chair automatically succeeds or exceeds to the chair position. And I think, personally, that that's probably important to have it clarified one way or the other.

So we do have a bylaws committee that is already active. I'm just looking to see -- and so the bylaws committee has already done some very good work. I'm going to ask that subcommittee to continue with the following specific charges: number one, should

there be term limits for the chair and/or vice chair and, if so, how long? What should the length of each term be?

Charge number two, does the vice chair automatically become the chair? And I would ask that the subcommittee report on this at the spring meeting.

Bylaws committee is going to have to amend the membership because Ms. Weil, who is chair, is no longer on the ACMUI. She's rotated off, so I'm going to ask that, once again, Dr. O'Hara, Mr. Sheetz, Ms. Shober continue to serve on this subcommittee and I would add Dr. Wolkov and ask that he be chair of this committee.

The staff resource previously was Ms. Holiday. I don't know if she was going to continue. And if not --

MR. EINBERG: No, she will not continue. We will have Kellee Jamerson as the staff resource.

CHAIRMAN PALESTRO: Okay, all right. Any questions on that? Mr. Ouhib?

MEMBER OUHIB: Yes, there was one item that I saw made the news not too long ago, but it also has been a concern, actually, to me personally is the guidance on cremation of a patient containing radioactive material. And I would advise any one of

you to call your agencies and seek guidance, and you will be quite surprised.

At one point, I remember calling regarding a patient, and when you had to go, you know, to the state and the state would refer you to the EPA. The EPA turned around and says, well, it's the state, and then you go in a circle and you're trying to find resolution.

But I think this is something that we owe it to our patients because there are patients who feel like this is my last wish, this is my last hope. You know, if I'm going through these treatments, can I be cremated tomorrow or something like that? And I think we need some sort of a guidance on that.

CHAIRMAN PALESTRO: So are you suggesting that the ACMUI take this up?

MEMBER OUHIB: Yes, I feel --

CHAIRMAN PALESTRO: Wasn't there a discussion about this at the spring meeting; am I correct?

MEMBER OUHIB: I think there was a brief discussion.

MR. EINBERG: So the ACMUI provided comments on Reg Guide 8.39, and our discussion was they addressed patient cremation and, Kellee, I mean Katie,

do you have any additional insight on that?

DR. TAPP: I do. As Mr. Einberg just mentioned, Reg Guide 8.39 is in the process of being updated in two phases. In the first phase, Reg Guide 8.39, which is the patient release instructions and guidance, the first phase is updating to provide more instructions. It is including some instructions for cremation to give it to patients and for consideration of licensees before giving a treatment if the wish is for cremation. It is general right now.

The next phase is to update and provide a lot more methodology calculations and do a holistic update of Reg Guide 8.39. That is coming down in the future. That's going to be a longer process looking at the guidance in whole. I believe cremation will be looked at fuller at that point, but that's not to say that the ACMUI cannot take that up, as you mentioned. It is a mention right now. It has been in the news recently and we are working on it. I'm not saying that you guys can't work on it at the same time to provide guidance to help us in that update.

CHAIRMAN PALESTRO: Mr. Sheetz?

MEMBER SHEETZ: The subcommittee that reviewed 8.39, which I chaired, provided recommendations with respect to the postmortem

activities because there was a brand new section on that. We did provide directed comments on the content on what precautions need to be taken, and, with those revisions, we would be comfortable with that.

One of our recommendations was to come up with a dose-based model to provide guidance on when these precautions should be taken, how much activity needs to be in the body before you should take precautions for autopsy or viewing or not cremate. And so, until we come up with a dose-based model, the guidance is lacking. You know, we know what precautions to take, but we don't know when to take them.

And so, we're waiting for the phase two of the revision to this reg guide, assuming part of that will include a dose-based model not only for the precautions for the patient to the exposure to the public but for a model or maybe some research project will be done to come up with this model that would be accepted. So, I'm not sure if there is any more action that the ACMUI would need to take unless we would be charged to come up with this dose-based model.

CHAIRMAN PALESTRO: Mr. Ouhib, does that answer your question?

MEMBER OUHIB: I'm not certain, I have to

admit. I'm not sure. So I don't think it's just dose-based model but also isotope-based also. So there was --

MEMBER SHEETZ: That's what I mean. That's part of a dose-based model.

MEMBER OUHIB: You know, and I think that, and I think it's not just guidance for the AU and for the patient but maybe these cremation centers that don't know if a patient is walking in. Is there a questionnaire there for them for something like that to see if that particular patient has any radioactive material or not? I don't know that. I'm just throwing it out there.

CHAIRMAN PALESTRO: Mr. Sheetz?

MEMBER SHEETZ: That's why I said we need to come up with a dose-based model to predict what the exposure would likely be to a crematory operator, to a funeral director, to a pathologist doing autopsy. Until we know what the dose is, we can't provide guidance on what precautions to take. So, we're just not there yet. There's lots of precautions and you can say take all these precautions, but it may be excessive, or it may not be enough. So until we come up with a prediction on what the dose is going to be to someone for a certain postmortem activity, it's difficult to provide a

recommendation on what action to take.

CHAIRMAN PALESTRO: Mr. Ouhib?

MEMBER OUHIB: I think he --

CHAIRMAN PALESTRO: Oh, I'm sorry. Mr. Green.

MEMBER GREEN: To follow-up on Mr. Sheetz' comments, I agree. I think we need to get the dose-based model first, and then we can assist like we did with the nursing mothers document that was provided and released. We can provide a list not just by isotope but by drug. We have biological clearance that get a lot of it before the biology stops, and then it's physical decay at that point. So I think we can follow that model we did with the nursing mothers guidelines once we have a dose-based model that we can work towards.

CHAIRMAN PALESTRO: Dr. Schleipman?

MEMBER SCHLEIPMAN: I would just say I agree with all this. I think it's premature to do that until the Commission has got that second part of their methodology distributed to us.

MR. EINBERG: So, Dr. Tapp, if you go in the time line or the completion of phase two, as I recall, it's in 2020, but maybe you know the exact or --

DR. TAPP: As of right now, it's still 2020. We're currently in contract acquisitions to help the research projects that are going to be all based here.

CHAIRMAN PALESTRO: Mr. Ouhib?

MEMBER OUHIB: I guess, in the meantime, what do we do? I mean, 2020, that could potentially be delayed. Are we going to just let things happen?

CHAIRMAN PALESTRO: Mr. Sheetz?

MEMBER SHEETZ: Our recommendation from the subcommittee at the current time, upon becoming notified they're aware of a patient who has been administered a certain amount of radioactive material that is deceased, they contact the institution and the radiation safety officer, and the radiation safety evaluate the retained activity and advise on the precautions to take. So, I would bump it to my profession to take charge.

CHAIRMAN PALESTRO: Mr. Ouhib, anything?

MEMBER OUHIB: Perhaps wait and see at this point? I'm not sure.

CHAIRMAN PALESTRO: That's what I'm concurring to do. I'm not going to take any action at the moment. I think there's a strong enough consensus, and it sounds logical to me, that we need

to wait. I think that, you know, all of our time, our staff and so forth, is precious, it's limited, and to embark on a subcommittee to go through this exercise and then maybe have to completely throw all of that work out or revise it after draft guidance is available to look at I think is a mistake.

MEMBER OUHIB: If I might just ask if we could just get some sort of an update by the spring meeting where you're at on that.

CHAIRMAN PALESTRO: Mr. Einberg?

MR. EINBERG: Yes, absolutely.

CHAIRMAN PALESTRO: That can be added to the agenda. Sure. Any other items for the open forum?

MS. JAMERSON: Just one clarification. For the bylaws subcommittee, the existing membership include Dr. Schleipman, Ms. Shober, and Mr. Sheetz, so did you want to add Dr. O'Hara or did you want --

CHAIRMAN PALESTRO: I'd like Dr. O'Hara to be added to that committee.

MS. JAMERSON: Okay.

CHAIRMAN PALESTRO: Okay. I thought he was on it. That's my mistake.

MS. JAMERSON: Okay.

CHAIRMAN PALESTRO: And Dr. Schleipman will not be on that subcommittee for the obvious reason

if he's the vice chair.

MS. JAMERSON: Got you. Okay. Thank you.

CHAIRMAN PALESTRO: No offense intended, Dr. Schleipman.

(Laughter.)

MEMBER SCHLEIPMAN: None taken.

CHAIRMAN PALESTRO: All right. Next item on the agenda is ACMUI external communications. And for those of you who are new to the committee, my predecessor, as chair of the ACMUI, Phil Alderson, had instituted or had developed an effort to extend communications between the committee in various external organizations, such as the American College of Radiology, the Society of Nuclear Medicine and Molecular Imaging, and so forth and so on, and that was probably about four years ago.

Dr. Metter and I, with the support and assistance of the staff, have run this session at the annual meeting of the Society of Nuclear Medicine and Molecular Imaging for the past three years. And the first year, we didn't have particularly good attendance. Second year, we had much better attendance and it was well attended. This is the third year that we've run it, and the attendance was really very poor.

And so, I'm bringing this up for discussion. We've never had a subcommittee for this. I don't intend to form one now. But the request proposals for sessions at the annual meeting probably will be due sometime in October or perhaps early November, so it's something that the ACMUI needs to think about.

One of the problems I think we had this year was the topics that were selected that we presented, and they were selected in conjunction with the Society of Nuclear Medicine. They would not have been topics that I thought would have appealed to the clinical individuals, the clinicians in the group. I think these would have appealed more to physicists, radiation safety officers, and so forth. And, in fact, some of this information may have been covered. There was a joint meeting with the FDA and NRC participants at the same meeting.

So we began with a brief introduction. Then we had the ACMUI recommendations for the Germanium Gallium Generator, the ACMUI recommendations for the Molybdenum/Technetium, it's not really Molybdenum/Technetium, the RADX generator for Technetium. And then, finally, I think the one topic that was clearly a hot topic and has been presented

for a couple of years, an update on the discussion, the ongoing discussions about training and experience.

So, I'm just putting this out for discussion. I will be off this committee in 10 - 12 days, whatever it is. So regardless of what my own personal beliefs are, I'm not going to be able to recommend anything. So, Dr. Metter, you've been onboard for all three sessions and the one we did at the ACR. I'd be curious to hear your thoughts on this.

VICE CHAIR METTER: I think, for that upcoming meeting, I think we should continue because I think it's very important for the outreach that the NRC has to the stakeholders in the community that this continue on. And I think perhaps being more clinically-oriented which would actually be regarding training and experience. And I think the issue of patient intervention would be actually very interesting to the community because they need to know what is involved and what is not involved in a medical event.

So I think there are topics now that would be very useful to our nuclear medicine community on what we're doing, and we can get input from them, too, at that time. I'd like to continue with that.

CHAIRMAN PALESTRO: Other members of the Committee? Dr. Dilsizian?

MEMBER DILSIZIAN: You know, I've been attending these, you know, some-odd meetings for over 25 years, and I remember only a few times that I attended such regulatory meetings and the ones that I attended were the ones that was combined FDA/NRC type of meetings because I was curious, as an investigator, what the FDA's decisions were. Also, I wanted to know what the regulatory answers of the NRC was.

If you feel that the attendance is low, I would encourage that you combine it with FDA type of lectures so that, you know, people who would come in for one or the other, and you can kind of enlarge your audience.

CHAIRMAN PALESTRO: I believe there was a combined session at the past meeting. Is Ms. Ayoade here?

MS. AYOADE: I'm here.

CHAIRMAN PALESTRO: Oh, I'm sorry. Am I correct on that?

MS. AYOADE: For the --

CHAIRMAN PALESTRO: And did you present --

MS. AYOADE: The last meeting that you guys just had, that was with you, Said, Dr. Metter, there was no FDA representative, but the one before where

I wasn't present, the first one that you all did, there was an FDA representative there.

CHAIRMAN PALESTRO: No, no, was there another session, I guess that's my question, was there another session at this past June's meeting that included both FDA and NRC representatives?

MS. AYOADE: No, no.

CHAIRMAN PALESTRO: No? Okay. I thought there was.

MR. EINBERG: Dr. Palestro, I'm not sure. I know that Dr. Daibes has presented with the FDA, and I'm not sure if it was this last meeting, but at the SNMMI meetings and it's been very well attended.

CHAIRMAN PALESTRO: Dr. O'Hara?

MEMBER O'HARA: The Center for Devices and Radiological Health looks at these kinds of things as very important. So if a session is going to be at any one of the radiological societies and you want FDA involvement, that's very easy to do. You can just, I can be the contact for that, and either I'll do it or somebody within our organization will do it. So we look upon it as outreach for where we get our message out to folks that are using medical devices or using radioactive drugs.

CHAIRMAN PALESTRO: Dr. Ennis? I'm

sorry.

MEMBER ENNIS: Just in terms of ASTRO, I mean, we've been very happy and have had a number of sessions, usually jointly, FDA with NRC representatives. What we found most effective is having it in sessions of people within the society are focused on policy issues. So always at the annual meeting, there's a couple of subgroup meetings of people involved in the health policy areas, public relations areas, and those people are particularly interested in these topics and have really enjoyed the interactions with staff. I believe staff has felt the same.

This year, we have another pressing issue which is totally dominating the discussions of those groups, so we're actually not having any. But it's been an important feature of the meeting for a couple of years.

CHAIRMAN PALESTRO: Any other comments, questions?

MEMBER OUHIB: Ms. Ayoade and I actually have done a session for the American Brachytherapy Society, and we've been asked by the ABM to do a session at the next annual meeting, which would be 2020, on the Part 35. So I think there has been an interest because there seems to be still a lot of questions from

people out there regarding the rules and things like that.

CHAIRMAN PALESTRO: Mr. Sheetz?

MEMBER SHEETZ: Ms. Holiday and I provided a joint presentation at the Health Physics annual meeting this past year on the functions and operations of the ACMUI and also the recent subcommittees that were formed on different topics. It was just a very small meeting with a small group, the Health Physics Society. I think it's important outreach for the professional societies to hear the functions of the ACMUI.

MS. KUBLER: Hi, good afternoon or good morning. Caitlin Kubler with the Society of Nuclear Medicine and Molecular Imaging. I think that combined idea with FDA is a great idea. I would also recommend the one year that you did have higher attendance was when you made a SAM session, and people always want CME and they're always looking to get involved there.

Also, just reaching out to the program chair and making sure there's no conflicting very popular sessions at the same time. That's something that, as a staff person, I can help and make sure that we don't have that conflict because, you know, if you have very popular emerging topics, you know, it's hard

to compete with that. Thank you.

CHAIRMAN PALESTRO: Cait, you will continue to be the contact person?

MS. KUBLER: Yes, yes.

CHAIRMAN PALESTRO: Okay, all right. Any other comments, discussion on this? All right. Dr. Metter, just to let you know that this has been, when we've run it over the past couple of years, it's been in conjunction with the General Clinical Nuclear Medicine Council, and we'll continue to support it, just so you know. All right?

All right. That concludes this session. We will take a brief break and resume at 10:45. Thank you.

(Whereupon, the above-entitled matter went off the record at 10:22 a.m. and resumed at 10:46 a.m.)

CHAIRMAN PALESTRO: The next topic on this morning's session is the NRC regulatory process and other tools, and it will be presented by Mr. Irvin.

MR. IRVIN: Good afternoon, everyone. My name is Ian Irvin. I'm with the Office of General Counsel, the General Counsel for Policy and Rulemaking Support, the Rulemaking Materials Division. I know that's a mouthful. I have to frequently look it up myself. But it's the RMR Division, and I help support

the staff in a lot of reviews of the documents and helping them out with legal questions. Ms. Kellee Jamerson is going to help me out with the last part of the presentation, so let's get going.

So our objective today is regulatory tools the NRC may use to accomplish its regulatory objectives, identify when a change to the NRC regulations is required or may be the best means to accomplish an objective, understand the primary steps of the rulemaking process, and to understand the other regulatory tools available to accomplish the NRC's objectives.

So, basically, there's two types or two fundamental types of regulatory tools: rules, which is what I deal with with the staff, and orders. There's another OGC division that deals with orders. I do sometimes help the staff with that, but there is another group that is a point of contact for that.

Rules is a rule statement of general or particular applicability and future effect designed to implement, interpret, or prescribe the law. The easiest example I can think of is your 10 CFR Part 35s, which I think everyone has in front of them, at least the one part. There is a second part which I don't advise you carry around because your backpack becomes

very, very heavy.

Orders. Orders are final disposition of an agency matter other than rulemaking. So a licensing is a kind of order and is defined as giving someone the permission or approval to do something.

So here's a quick list of the regulatory tools. Everything in green is going to be a rule or rulemaking. Everything in blue is an order or order type. And then we do have the option of those things in red of not doing anything and relying on other actors to do something. An example of that would be your agreement state program where you might have an issue come up in an agreement state where we've discontinued our regulatory program. We would turn that over to the agreement state to handle. We would take no action.

Another example is sometimes there's criminal penalties for some of the things that we do, and the Department of Justice helps us out with those criminal cases. That's not something that we would do.

So the forms of laws of statutes. Part of me wanted to pull up Schoolhouse Rock. I am just barely old enough to remember that. The I'm just a bill, sitting here on Capitol Hill little skit and song. But the basis of the law is always the Constitution,

and I have my handy dandy pocket Constitution with me. I will say frequently we forget about these things. There's a couple of times where I had to invoke, you know, what statute or what rule is that, and it's like it's actually in the Constitution. So there is that.

Statutes which are adopted by Congress. There is a NUREG that has a list of all the statutes that are applicable to the NRC, and that's NUREG-0980. You can find it on the public website. It is three volumes. I like to show and tell, so I did bring my version of 0980.

The first volume is actually this one. This is a lot of the substantive statutes that deal with what the NRC is regulating, things like the Atomic Energy Act, the Uranium Mill Tailings Radiation Control Act, Low Level Waste Policy Act, things like that. That's the substantive rule. You can find that in Volume 1.

I think of Volume 2 is more the procedural rules, the Administrative Procedures Act -- yes, that's the right one -- the Administrative Procedures Act, things like that. I think those are more procedural, which we're going to go over here later in this presentation. I think that's more in Volume 2.

I honestly have never opened Volume 3.

I think a lot of it is our international program. We do have an office of International Program Affairs, and we do have a group in OGC, our legal counsel, that deals more with the international, so I don't usually touch that. You can see that I've never broken the spine. It looks brand-spanking new.

So why choose a regulation? So a statute may require a rulemaking. So at various times Congress has passed things like the EPA Act of 2005 or the Uranium Mill Tailings Radiation Control Act of 1978 and directs the NRC to engage in rulemaking. So we've got our marching orders from Congress that we've got to do something, and so we do it.

Rulemaking is required to change 10 CFR, and we'll go over a little later of some of the reasons why to do that and how to do that.

To avoid the possibility of a significant adverse consequence or adverse public reaction that may be inherent in a reactionary approach to regulatory oversight and then a case-by-case review in regulatory action is too time and resource-intensive and it fails to provide regulatory certainty and transparency in decision-making. So one of the things the NRC could always do instead of doing rulemaking is to engage in a case-by-case determination where someone comes in

with an application, we look at it holistically without any reliance on the regulations. But to do that for every licensee would just be so time-consuming. We just don't have the resources. There are issues that are just going to be the same for a whole host of licensees, so why would we engage in that same review time and time and time again, hundreds, if not thousands, of times, when we could just make a rule and just do it once?

So, there's various rulemaking pathways. Here we have four different pathways, and the first is an advanced notice of proposed rulemaking and we follow that by the proposed rule and the final rule. And so the advanced notice of proposed rulemaking is a particularly, we use that for particularly important, complex, or controversial rulemakings where we think public engagement is going to be important to better inform what we do. Advanced notice of proposed rulemaking is not required by law, but we do frequently engage in that so we can just get stakeholder feedback.

Now, that will be followed, if we are changing the 10 CFR, it will be followed by a proposed rule which will go out for notice and comment, which the public can submit comments. We'll review them and consider them. We do something called bin them. So

binning is basically if two people have similar comments, we're not going to send out a response to each individual. They're the same, so we're just going to send out one response to the same substantive comment. And then we'll issue the final rule.

Like I said, that advanced notice of proposed rulemaking is not required by law, so, frequently, we also do just a proposed rule with a notice of comment and then we follow that by the final rule.

There are two exceptions to that. They're rarely used, but we have seen them. A direct final rule. A direct final rule is a proposed rule, is a rule where notice of comment is unnecessary because the Agency determined that the rule relates to routine or uncontroversial matters. The Agency provides its basis for its determination in the Federal Register notice that goes out with the direct final rule. Frequently, I see this for, I think twice a year we have a corrections FRN where we just have misspellings or an address or a phone number has changed or an email address has changed or an office has changed its name. So instead of having the public comment on an email address change, we just go ahead and do that.

If there is a substantive adverse comment made during that process, we're no longer in the direct

final rule process. We actually kick back to bullet two then. We actually then consider that direct final rule a proposed rule, respond to the comments, and then go forward with the final rule.

An interim final rule, it's a special exemption in the Administrative Procedure Act. That's when notice of comment opportunity is either impractical, unnecessary, or contrary to public interest. And if the NRC was to engage in that, we'll have to describe one of those three in the Federal Register notice that goes out with that interim final rule, but that is a super high bar to meet. And I don't have any experience of where we've used the interim final rule. The only instance that I think could possibly come to mind is possibly the post 9/11 orders that we issued about 16 or 17 years ago for safety sake.

So like I said before, the Atomic Energy Act is more of our substantive rulemaking. We do have a lot of procedural statutes that we, at the NRC, have to engage in. I've mentioned the Administrative Procedure Act. That provides what we have to do to engage in rulemaking, for example that notice of comment rulemaking for proposed rules.

Some of the other statutes that we have to find, the Federal Register Act, we have to publish

any proposed rules or final rules in the Federal Register. That's a daily report that's issued by the Office of Federal Register.

One thing that I'll mention here, and I overheard it in part of the conversation before this session, it also requires that our rules be published in 10 CFR. 10 CFR is updated at the first of the year, so January 1st is when we update the rules. And I know there's an applicable rule that actually got updated in Part 35 that happened in mid January. So this latest edition of 10 CFR, it's actually not captured fully because it's relying on what was in 10 CFR Part 35 on December 31st, 2018. But what they did is they did include the new language rule that became applicable in January, mid January, in this version of the CFR.

So it's a little bit more confusing. The language is there. They just didn't publish it like they normally do. And just real quickly, I turned to 35.40. It has the rule that was in place at the end of 2018 and then it provided what the amendments were in mid January, so you could follow that and not rely on the old rule. I have gotten, I made that mistake once in interacting with Chris's branch. I relied on the old rule, and I think it was, as Dr. Howe was like,

hey, you're actually looking at the wrong thing.

So that's the Federal Register Act. The Paperwork Reduction Act is basically when we require licensees to save or submit information to the NRC. We have to get something an Office of Management and Budget Clearance where we have to justify them submitting that information. So you may hear that thrown around. I think it was thrown around a couple of times yesterday. If we were to request new information from licensees, you actually have to go to OMB to get that cleared with them.

The Congressional Review Act. Certain rules have to go through Congress to sort of get a vote of non-approval. A lot of NRC rules do not get Congressional Review Act, but some do.

The National Environmental Policy Act, that provides that we have to issue a report, an environmental report, on what our action, as the NRC, will do on the environment. And then the government in the Sunshine Act. That basically provides that a lot of our meetings have to be publicly available, that we can't meet in secret and do things outside the public purview.

So, in essence, this is actually the Office of Management and Budget's rulemaking map. And I know

that I'm looking at the screen and the words are just way too small to even read. I'm looking at my note page. I can barely read the words. In my desk, I had to, like, zoom it up to like 300 percent to actually read what this OMB rulemaking says.

I'll mention that some of these steps we don't have to do at the NRC because we are an independent agency, specifically step four and step eight. Those steps have to be taken by other Executive Branch agencies. But we, as an independent agency, don't have to do that.

But you can see it can be quite intensive what we do here at NRC for rulemaking. I just don't want that to deter you either. If we need to make some changes to 10 CFR, we just got to do that and we'll go through this process.

We do have some internal guidance of procedure to help us with the rulemaking. In your 10 CFRs that are around you, Part 2, Subpart H, has the rulemaking procedure in the CFR. We also have Management Directive 6.3. That's publicly available. That's the rulemaking process. That recently got changed this summer, so, if you haven't taken a look at that management directive since June, it has been changed.

And then early Commission involvement in rulemakings. Most rulemakings require the submission of a rulemaking plan to the Commission so that they can approve of going forward with the rulemaking. And that's one of the things that's probably not captured in this OMB rulemaking map. Some of the things that that rulemaking plan, it's going to have an estimated schedule, the background, the scope of the rulemaking, the priority of the rulemaking. We have something called the common prioritization of rulemaking, so we're going to say this is a very high priority, this is a very low priority. The resources involved. It doesn't impact Part 35, per se, but we have back-fit provisions that apply to certain types of licensees, like Part 50 licensees here at the NRC, which are mostly reactors.

And so an overview of our typical Part 35 rulemaking processing. We usually engage in early public and ACMUI input. I think this is somewhat similar to that advanced notice of proposed rulemaking with the early public input and also going out to you. We submit a rulemaking plan for the Commission to review and approve, and then the staff drafts a regulatory basis of proposed rule and guidance. Sometimes that regulatory basis does go out before the

rest of it and we receive public comments on the regulatory basis. Sometimes it all goes out together and we receive comments on everything.

The ACMUI, agreement states, and the Organization of Agreement States will review draft proposed rules and, from those comments, we'll make changes to the pertinent documents. And then, after those changes, we'll send it up to the Commission for their review and vote. And then if they vote go ahead, go for it, we'll publish it in the Federal Register, we'll receive notice or comments on the proposed rule. I will take a look at those proposed rule, make those changes, or we'll take a look at those comments, bin them, respond to them, make the pertinent changes to the 10 CFR, the guidance, and then we'll send back a draft final rule package back to you guys, the agreement states, the Organization of Agreement States, make further changes, and then send it up to the Commission for their final review and vote. If they vote yes again, then we finally publish it, we send it to the Office of Federal Register for inclusion in the CFR and publication in the Federal Register.

So I'll say the time varies greatly on these rulemakings. The scope and complexity of the rule, priority of the rulemaking, the degree of controversy.

If something is very controversial politically or even with the industry it might take longer. The amount of public input. Of course, if we have more public comments on something, it takes us longer to respond to those public comments. And also we might require more changes.

Any recommendations from you. There might be, sometimes the Commission doesn't necessarily vote yes or no. Sometimes they vote yes, but do this on top of that or make these changes. So we'll have to make those directional policy changes from the Commission. And, of course, agency resources or congressional action may also implicate the time line for a rulemaking.

For minor or routine rules, it might be one year. But for more complex or controversial rules, it may take several years or a few years. There are rulemakings that I've been working on that have been around for five - six years. I've only been here at the NRC for four years, so they predate me. I just inherited them.

So mostly I've talked about changes to the 10 CFR, the procedure to do that. We do have some non-legally-binding rules, so our guidance, our NUREG series, you're familiar with 15.56. That's guidance.

We do have regulatory guidance, as well. Regulatory Guide 8.39, that's being updated. We also have generic communications, like regulatory issue summaries, RISAs, or information notices.

We also have policy statements. They're issued by the Commission. The one you're probably familiar with is the medical use policy statement.

The total time for these changes vary. I'll mention that there has been some recent changes in these non-legally-binding rules. The big change was before 2015 the D.C. Circuit Court, in a case called, and I'm probably getting into way too much detail, but it was a case called Paralyzed Veterans required that all guidance policy statements had to go through notice of comment rulemaking, which did not square away with the Administrative Procedure Act.

The Supreme Court in 2015 in a case called Perez v. Mortgage Bankers Association said, look, the plain language of the Administrative Procedure Act says that guidance policy statements don't have to go through notice of comment rulemaking. So they don't have to go through notice of comment rulemaking.

Frequently, the NRC staff does engage in that because we like that stakeholder input. A lot of corrections are caught. Input from you guys on the

final rule or the guidance is very much appreciated. And so although it's not a legal requirement, we frequently do use that to get input and make a better document.

So some other tools that are available to us. There's a specific exemption in 35.19 which basically says that you got to follow the rules but there are certain exceptions to it. An applicant or the Commission on its own initiative may exempt you from our regulations if we believe that there won't be a danger to life or property or the common defense and security. And these are usually used to address unique circumstances. Specifically, for Part 35, we had the 35 1000 licensing. It's used when a modality is not specifically addressed in Part 35, and it codifies the process by which the NRC may license new and emerging technologies without having to go through that process of developing, first developing generic regulatory requirements. You can see how long it takes. A lot of the data and information probably extends that time frame out. So we do have that 35 1000 process to use, and that's a lot shorter. It usually takes approximately one year to do.

So I'm going to turn this over to Kellee who will take it from here.

MS. JAMERSON: Thank you, Ian. So, I'll be covering, with respect to ACMUI recommendations, how the staff receives your recommendations and what actions may prompt receiving those recommendations.

So, the ACMUI is generally provided draft documents, which may include SECY papers, such as the T&E SECY paper, the draft SECY paper, which you're reviewing right now, rule text, NUREG-1556 licensing guidance, Part 35.1000 licensing guidance, and regulatory guides.

And so, based on an evaluation of these types of documents, the ACMUI could provide recommendations, and we would -- which would result in changes to the said document.

So, examples of this include the Part 35 Rulemaking, and these are subcommittees that provided recommendations on these items, Reg Guide 8.39 Subcommittee, the Yttirum-90 Microspheres Brachytherapy Licensing Guidance Subcommittee.

And timing for these changes varies depending on, as Ian mentioned, the scope and complexity of the rules, the time it takes for the Commission to review the SECY paper and provide their vote.

Licensing guidance revisions, as Dr. Tapp mentioned yesterday, could at a minimum be six months

for minor revisions or it could take longer.

In other cases, the ACMUI is given a topic to provide recommendations on, without having a draft document, staff-generated document to review, such as the extravasations policy issue that the subcommittee was formed for that.

So, based on evaluation of those recommendations, the staff must determine the more appropriate regulatory tool and path forward.

So, in taking your recommendations, the subcommittees' recommendations for that, the staff will evaluate whether to change the regulations or develop new guidance or change or develop a statement of policy. Examples, as I mentioned, for this would be the Extravasations Subcommittee and the Nursing Mothers Guidelines Subcommittee.

So, Scenario 1, this was just an instance where the Abnormal Occurrence Criteria Subcommittee, around the 2015 time frame, which predates my involvement with the ACMUI, but at that time, the staff reviewed the report and agreed with some of the ACMUI's recommendations.

And so, this was considered and discussed in the staff's SECY paper to the Commission. And so, we made -- if those proposed changes had been accepted

by the Commission, it would have resulted in the Agency's policy on abnormal occurrence criteria. So, that's just an example of how the recommendations are incorporated.

Scenario 2 is the Nursing Mothers Guidelines Report. So, amongst many things, the report included the breast feeding interruption values. And while the ACMUI didn't specifically suggest that these values be included in Reg Guide 8.39, the staff suggested that we take that approach, to include those in the draft Reg Guide.

So, the draft Reg Guide Revision 1 included many of the values from that report and was issued for public comment back in July. It's still out for public comment and the time frame for that, expected to be issued in April of 2020.

So, I'll turn it back over to Ian for a summary.

MR. IRVIN: Yes. So, in conclusion, just basically, we have two fundamental tools that we use here at the NRC, rules and orders. Rules is the one that we are most familiar with here.

Rules may be legally binding, and that's through the regulations, through the 10 CFR, or non-legally binding through guidance or policy. Which

tool is appropriate to accomplish a regulatory objective depends on many factors, timing, scope of the regulatory objective, the available resources.

And I want to make it clear that you all should continue to make all recommendations that you deem appropriate. Don't let any of that OMB long slide deter you from making your recommendations. That's for me and the staff to deal with on our end.

And the NRC will continue to act on your recommendations, as appropriate, to use what we believe the best regulatory tools for achieving that objective.

So, I'll turn it back over to Dr. Palestro.

CHAIRMAN PALESTRO: Thank you very much. Comments, questions? Dr. Ennis?

MEMBER ENNIS: I suggest, in the Onboarding document that we're going to have, this presentation be included in the onboarding information for new ACMUI members.

CHAIRMAN PALESTRO: Okay. We'll take that as a suggestion as opposed to a formal motion and a vote.

MEMBER ENNIS: Okay, thank you.

CHAIRMAN PALESTRO: Any other comments or questions? Dr. Jadvar?

DR. JADVAR: The last comment you say that

NRC will continue to act on ACMUI recommendations, as appropriate. Define as appropriate?

MR. IRVIN: So, there might be recommendations from the ACMUI that we may feel that there might be a better regulatory tool to put forward or that there was no recommendation, so we decide on one.

I know that Kellee earlier talked about the Nursing Mother Guidelines. I think there was no suggestion of where that goes and so, we as the staff decided, let's put this in the update to Reg Guide 8.39, chose that as the best regulatory tool. Hopefully that answers your question.

DR. JADVAR: So, does that -- do you give that feedback to the ACMUI before this is done? Or, so there is no feedback, do you just -- a decision is made by staff, or do you go back to ACMUI with your suggestions or what you think that has to be done?

MR. EINBERG: So, let me try to address that. So, the ACMUI advises the NRC staff and make recommendations to the NRC staff. We evaluate those recommendations and we make a determination whether to accept those or not accept those.

And then, when we have -- hopefully, and we try to do a better job at this, when we go through

the open items to address the recommendations, we give you the rationale as to why we have closed or did not accept any of your --

DR. JADVAR: Okay. So --

MR. EINBERG: -- and we also document that in a formal memo. For instance, I just sent out a formal memo documenting how we closed numerous of the open items, going back to 2007.

DR. JADVAR: Okay. Thank you.

CHAIRMAN PALESTRO: Any other comments or questions? Comments, questions from anyone in the room? Anyone on the bridge line? All right. Thank you very much.

MR. IRVIN: Thank you.

CHAIRMAN PALESTRO: All right. Next presentation is the Status of Emerging Technologies Licensed Under 10 CFR 35.1000. Mr. Sheetz will present this.

MEMBER SHEETZ: Thank you, Dr. Palestro. So, I'm going to cover the current status of the emerging technologies licensed under 10 CFR 35.1000.

Topics I'd like to cover are the types of medical use that are captured under the Part 35.1000. I hope to also provide an overview of the status of the existing technologies licensed under 35.1000. I'm

going to identify some new emerging technologies that will likely be licensed under Part 1000.

And I will also identify some other emerging uses of radioactive material that would traditionally be covered under 35.300, but due to the type of administration and proposed use may present some unique radiation safety issues or problems. And I'll try to answer any questions.

So, with respect to the emerging medical technologies category, Part 1000 is developed following the rule change in 2002 for the use of byproduct materials not specifically addressed in other parts of 10 CFR 35, and it permits new modalities to be added by license amendment or application.

Typically, a working group from the NRC and OAS develops the licensing guidance document that will become license condition for the new use of the radioactive material. The guidance document will also address specific radiation safety aspects for the use.

It will establish training and experience requirements for the AU, ANP, and other involved personnel, as applicable. Also identify what, if any, sections in the current Part 35 are applicable. And it will also define the required components for indirect medical events.

Licensing guides developed under 35.1000 have some flexibility to be changed, just as we've already heard, to address unforeseen issues that arise or changes in use. And so, it does not need to go through the rulemaking process again, which was just addressed, which can take some length of time.

So, I'd like to cover now the current modalities or items that are in Part 1000. First is the Novoste Beta-Cath Intravascular Brachytherapy System. It's a handheld device, with a jacketed Strontium-90 sealed source train for the use of treatment of coronary in-stent restenosis.

It's manufactured by Best Vascular and contains up to 24 millicurie sources, source trains hydraulically pushed out to the end of the delivery catheter that's been positioned in the treatment zone of the coronary vessel and dwells there for a predetermined amount of time to deliver the prescribed dose.

This is performed by a team of an interventional cardiologist, a radiation oncologist, and a medical physicist.

The device was widely used in the early 2000s at several hundred sites in the U.S. However, with the introduction of drug eluting stents, the use

of IVB has waned.

The original guidance was issued in 2006 and was actually the first licensing guidance document in 10 CFR 35.1000.

The use of the device is seeing a slight resurgence for the treatment of recurrent in-stent restenosis with drug-eluting stents, where several studies have shown the effectiveness for this patient population. There are currently approximately 35 sites in the U.S. using the device for this indication.

And my comment is, it will be interesting to see if the use of the device continues to expand with the logistical challenges of coordinating the cardiologist, authorized user, and medical physicist team.

Another device, the I-125 Iotrex Liquid Brachytherapy Source and GliaSite Radiation Therapy System is a device used for the treatment of recurrent glioblastomas. Original guidance issued in 2006. Consists of an inflatable balloon catheter that's placed in the resection cavity at the time the of the tumor debulking surgery, to deliver a low dose rate treatment from the infusion of an I-125 solution.

The device was originally developed by Proxima Therapeutics, who was purchased by Cytyc

Corporation. IsoRay purchased the licensing rights for GliaSite in 2011. Studies showed only a modest survival benefit. The device is no longer available as of 2016.

Radioactive seed localization is a technique that uses a low activity I-125 seed guided excision of small non-palpable lesions, primarily in the breast.

The seed is implanted in the patient by a radiologist and removed during excision of the lesion by a surgeon. And the seed is then extracted or recovered from the tissue by a pathologist or pathology assistant.

The technique was developed in the early 2000s and gradually became popular due to the benefits over the standard wire localization technique. Initial licensing guidance was developed in 2006 and since it used the same radioactive seed as that for brachytherapy, many of the requirements were patterned after those for manual brachytherapy.

Strict compliance with these requirements made it burdensome and difficult for licensees to implement the RSL program, such as the training and experience requirements for the radiologist, requirement for a written directive. And it's

interesting to note that RSL is the only non-therapy procedure in Part 1000.

In response to a request from the user community, the NRC formed a working group and revised the license guidance in 2016 to make it more relevant to how the procedure is performed.

There are currently three manufacturers of the packaged seed and needles and it's widely performed by many licensees throughout the country. At my institution, the University of Pittsburgh Medical Center, we implant over 1,000 seeds per year.

The NeoVista Epi-Rad90 Strontium-90 Ophthalmic System is a small handheld device used for the treatment of age-related macular degeneration. The device is different from the Strontium-90 superficial applicators licensed under 35.400.

Clinical trials for use of the device started in 2007 with approximately 20 centers in the U.S. The original guidance was issued in 2009. Results of the clinical trials were insufficient to justify extended routine use of radiation therapy for the treatment of AMD, despite an acceptable efficacy and safety profile. The manufacturer is no longer in business and the device is no longer available.

TheraSphere and SIR-Spheres Y-90

Microspheres are used for the selective intra-arterial radiotherapy of liver cancers. The radioactive microspheres are delivered through an infusion system, which is approved by the FDA as a medical device.

TheraSphere was first used in the U.S. in 2000 and is approved by the FDA through a humanitarian device exemption for the treatment of hepatocellular carcinoma or primary liver cancer. SIR-Sphere was first used in the U.S. in 2002 and is approved by the FDA for the treatment of colorectal metastases to the liver.

The initial licensing guidance was issued in 2002, which has been revised nine times, mostly to address the topics of AU training and experience pathways, required components of the written directive, medical event reporting criteria. And draft Revision 10 is out for public comment and currently being reviewed.

There were over 15,000 patient treatment using Y-90 microspheres in 2018, somewhat evenly divided between the two manufacturers, each approximating 50 percent. It's estimated that there are currently approximately 400 to 500 licensees approved for Y-90 microspheres.

It's interesting to note that this modality

also accounts for the largest number of medical events reported annually, but it still represents a small fraction compared to the total number of treatments.

The Leksell Gamma Knife Perfexion and Icon are gamma stereotactic radiosurgery devices for treatment of brain lesions, using 192 Cobalt-60 sources at 30 curies each.

The original Leksell Gamma Knife was first licensed in the U.S. in 1987. This device had 201 Cobalt-60 sources in a hemispherical configuration and used helmets for collimation to focus the beam of radiation to the target lesion.

Subsequent models of the gamma knife, Models B, C, and 4C, were developed, which improved on the source configuration, automatic patient positioning, and source reloading. These units are regulated under the authority of 35.600.

The Perfexion Gamma Knife was developed with movable source sectors and internal collimation, so it differs significantly from the previous gamma knife devices and, therefore, was regulated under Part 35.1000 in 2007.

The guidance was revised in 2016 to cover the new model, Icon Gamma Knife, which is the same as the Perfexion device, but it has a cone-beam CT imaging

and patient motion management system, which allows for thermoplastic mask patient fixation as opposed to a stereotactic frame.

The guidance was revised again just this year to change the physical presence requirements for the AU and ANP, to be essentially the same as that for HDR.

There are currently a total of 107 Icon and Perfexion units in the U.S. and there's 13 Model C or 4C units in the U.S. There were 18,000 gamma knife patient treatments reported in the U.S. in 2018. And this only represents 85 percent of the site service numbers, probably closer to 20,000.

The ViewRay is a Cobalt-60 teletherapy device, uses a magnetic resonance imaging to guide the radiation therapy, using three 15,000 curie sources. The device can be used for treatment of both the head and the body.

Guidance was issued in 2013, for which the, I believe the five sites that have the device. The company developed a Linac or linear accelerator version to replace the Cobalt-60 in 2017. The company no longer offers a Cobalt-60 based unit in the U.S.

There are currently two sites that have the Cobalt-60 system, with one scheduled to convert

to the Linac sometime later this year and the other site is using it as a research device.

Recently, there have been two radionuclide generator systems added to Part 35.1000. The one is a Germanium-68/Gallium-68 pharmaceutical grade generator for the production of Gallium-68, which is a 68-minute half-life positron emitter, which makes it optimal for tagging to different traces of molecules for diagnostic imaging studies, primarily for the detection of malignant tumors.

The initial licensing guidance was issued in 2017, which was specific to the generator manufacture Eckert and Ziegler. The guidance was revised just this year to be more generic, so to be applicable to other generator manufacturers coming on the market.

The other is the NorthStar RadioGenix Molybdenum-99/Technetium-99 Generator System, which is used to produce sodium pertechnetate that is used for making FDA-approved diagnostic radiopharmaceuticals. The generator has FDA approval and has been used in thousands of diagnostic patient doses.

What makes this generator different from the conventional moly/tech generators is that it used non-uranium based targets for production of the

Moly-99. Initial guidance was just issued last year.

The newest device for Part 1000 is the GammaPod, a device for the stereotactic treatment of breast cancer, which is undergoing licensing guidance development as we speak.

There was a comprehensive presentation on this device yesterday by Dr. Wolkov, so I'm not going to go into much detail on it. Essentially, the device has 25 180 curie Cobalt-60 sources and a rotating source body and collimator system to deliver a focused beam of radiation to the treatment site.

There are currently two sites in the U.S. that have this device and a third is scheduled to be installed sometime this year.

Now, I'd like to cover some technologies that are coming on the line, that probably will get licensed under Part 1000. This is certainly not an all-inclusive list, I'm sure there are some that I am not aware of, but these are the ones that I found.

The RGS Vertex 360 Radiosurgery Device is manufactured by Merrick and Radiosurgery. It is designed for the treatment of tumors in the brain using a stereotactic train.

It contains 30 Cobalt-60 sources of 200 curies each located in a 60-degree hemispherical

sector. Again, beam shaping is performed by rotating source, body, and collimators. This is marketed as a more affordable alternative to the Leksell Gamma Knife. I believe there are currently two devices in the U.S., not one as I state in my slide here.

There's also another rotary gamma knife system for the treatment of brain lesions, called the MASEP-Infini, which is manufactured in China. It has 25 Cobalt-60 sources distributed in a spiral node. The device is also marketed as a more affordable alternative to the Leksell Gamma Knife. I believe there are currently three of these devices in the U.S.

The Rotating Gamma System RGS Orbiter, also manufactured by American Radiosurgery, is the first gamma knife type device that can treat tumors of both the head, as well as in the body. The device contains 42 Cobalt-60 sources, 230 curies each, in a 50-degree circular configuration.

The source, body, and collimator system rotate within a C-arm gantry. The patient is fixed to the treatment table with an immobilization device to avoid any patient movement during treatment for the whole body. In the case of skull treatment, the patient head is immobilized via standard stereotactic head frame.

The device is currently pending FDA approval and there are no operational units in the United States.

Alpha DaRT, where the DaRT stands for Diffuse Alpha-emitters Radiation Therapy, is a new type of brachytherapy wire or seed that contains Radium-224, half-life 3.6 days, which then decays into Radon-220, a noble gas with a half-life of 56 seconds, which diffuses uniformly into the surrounding tissue to develop a high LET radiation dose from the alpha emissions from the radon daughters.

It's intended to treat solid tumors and has an effective therapeutic diameter of five to seven millimeters around the source and resulting in minimal radiation dose to surrounding healthy tissue. Activity per seed or source is approximately five microcuries.

The source has a sealed source and device registration for manual brachytherapy and the source applicator has an investigational device exemption approval from the FDA. Use of Alpha DaRT is still considered research, most of which has occurred in Israel. It can be used as both permanent or temporary implants.

The device obviously presents lots of

licensing challenges, should it be regulated under 35.400 or 35.1000? While the sources are being implanted in the tumor, some of the radon daughters will migrate via blood to other organs.

They are not sealed sources, so precautions need to be taken with respect to the spread of contamination. Unique criteria need to be developed for the written directive and medical events.

There's also a similar brachytherapy device, I don't have a slide for it, it's P-32 Microparticles called OncoSil. And essentially, it's silicon microspheres with P-32. It's used for the infusion and treatment of pancreatic cancer right now. Again, it's another research and development product.

Switching gears to some new types of radiopharmaceutical therapies that traditionally would have been and they'll still be considered under 35.1000.

There are a number of new targeted therapies being developed for the treatment of different cancers. Many of these involve a new field called theranostics, where trace amounts of molecules tied to a radionuclide for diagnostic imaging studies, such as Gallium-68, to evaluate the uptake and then, if determined appropriate, tied to a different radionuclide for the therapy, such as with

Lutetium-177, Y-190, or Iodine-131.

Two currently approved agents are the Lutetium-177 Lutathera for the treatment of neuroendocrine tumors and Iodine-131 Azedra for the treatment of adrenal gland tumors or pheochromocytomas or paragangliomas.

Both of these involve the infusion of high activities in relatively larger volumes over an extended period of time. The infusion is performed either with a syringe pump or with an IV drip, pushing the mixture out of the glass vial, so it requires a good understanding of what I call the plumbing for the infusion process.

The Lutathera involves four different administrations, 200 millicuries each, separated by two months. And the standard treatment for the Azedra is two 500 millicurie treatments separated by three months. So, it's not just a once and done treatment.

There are also a number of agents currently in clinical trials, such as the Y-90 DOTATOC for neuroendocrine tumors.

Lutetium-177 PSMA-617 for prostate cancer. This one will probably result in the largest number of patient therapies, once it becomes approved. It will essentially be seven to ten times more patients

than what we're currently predicting for Lutetium-177 Lutathera, so it's going to really open up a large patient population base for this type of therapy.

Iodine-131 Iomab-B for acute myeloid leukemia. There are also a number of other studies that are going to be targeted therapies using alpha-emitters, such as with Actinium-234 Thorium-227. So, again, while these targeted therapies will probably fall under 35.300, they'll present some new challenging radiation safety issues.

Another device currently pending FDA approval is the RefleXion BgRT. It's a new device that combines a PET/CT scanner with a linear accelerator to biologically guide the radiotherapy, even for tumors that are moving.

So, it uses a real-time tracking and the PET/CT imaging device to focus the external beam of radiation. It's intended for advance stage cancers with multiple tumors, so it can treat multiple tumors at one time as the device rotates. It's currently pending FDA approval.

The reason for presenting this is that it may present some challenges in who will be the AU for the PET imaging component, as radiation oncologists do not meet the training and experience requirements,

the 35.200. So, it may present some challenging as far as how we would license or how an institution would license that.

And in conclusion, I think the process for licensing emerging technologies relatively quickly and without going through a rulemaking is a huge advantage of this Part 1000. I'm a fan of Part 1000.

It's also able to be revised, as different applications or issues arise. And so, again, not having to go through the rulemaking process, I know much time and effort is required in developing licensing guidance, by both the NRC and the Agreement States, and lots of the, some of the devices I pointed out never make it and go away, so I'm not sure what the answer is on how to select at what point in time you do the licensing guidance.

Also, I think it would be helpful if Part 1000 had a compatibility level of C and not D. This would provide for standardization across the country, because right now, with compatibility level D, Part 1000 licensing guidance is not required to be adopted by the Agreement States.

And so, there can be situations where licensing guidance comes out and then, an Agreement State may do something totally different or require

something more or require something less. So, from the licensee community, that was what we're seeing, standardization of that.

And then, the other is the new targeted radiopharmaceutical therapies will probably present some unique challenges in radiation safety. And I think as we saw with the increased use of the Y-90 microspheres, which, again, involves lots of plumbing with the device, we may see some issues or problems in the administration of the targeted therapies where we have high activities and large volumes.

Thank you.

CHAIRMAN PALESTRO: Thank you very much, Mr. Sheetz. Questions, comments? Dr. Metter?

VICE CHAIR METTER: That was very thorough and very up-to-date, and thank you very much for the presentation, it's very informative.

MEMBER SHEETZ: Thank you.

CHAIRMAN PALESTRO: Dr. O'Hara?

MEMBER O'HARA: Yes, just a comment for clarity. The things like the Beta-Cath, for example, while it is a radiation emitting device, it's not directly regulated by the Division of Radiological Health at the CDRH. It's regulated by the Cardiology Department in CDRH, with a consult from Radiological

Health.

Many of these devices have that particular problem, where another group regulates it. But many of, most of them have been reviewed by our Division of Radiological Health.

And one of the things that people don't know is the slide that you had on generators, while the generator is a medical device, it's not regulated as a medical device.

As a matter of fact, it's not even regulated by CDRH. It's actually regulated as an isotope reduction mechanism by CDER. Again, there's a consult from CDRH. So, there's a lot of talk, back talk going back and forth. But they're all reviewed.

CHAIRMAN PALESTRO: Any other comments, questions? Comments or questions from anybody in the room? Dr. Tapp?

DR. TAPP: I just had a question on the standardization. Was that just a recommendation from you to the group or is that a recommendation from the ACMUI?

MEMBER SHEETZ: That was just a personal recommendation or comment from me.

DR. TAPP: Okay.

CHAIRMAN PALESTRO: Dr. Ennis?

MEMBER ENNIS: Maybe we want to turn that into an ACMUI recommendation, either now or at some point.

CHAIRMAN PALESTRO: Okay. Any other comment? Ms. Shober? Dr. Jadvar?

DR. JADVAR: Should Radium-223 be included in your list? I mean, some people think Radium-223 Dichloride and Sodium Fluoride PET, for example, as a theranostic pair. One finds where the metastases are and then, basically, based on stain mechanism, radium goes there. So, they think of Sodium Fluoride PET and Radium-223 Dichloride as a theranostic pair.

MEMBER SHEETZ: Yes, it would, but I was just covering or addressing the new modalities coming --

DR. JADVAR: Oh, okay.

MEMBER SHEETZ: -- down the pipe. Radium-223 is already approved and under --

DR. JADVAR: But you have currently approved, that's also approved. It's under the same list.

MEMBER SHEETZ: Yes, I -- very good point. Thank you.

DR. JADVAR: Yes.

MEMBER GREEN: May be a nuance in a

definition that's being used for theranostics, but I typically use that as the same molecule with different nuclides for imaging versus therapy. I-131 is a classic example, sodium iodide is the first theranostic --

DR. JADVAR: That's right.

MEMBER GREEN: -- from the 40s. Your description of sodium fluoride and radium dichloride is not the same molecule.

DR. JADVAR: It's not.

MEMBER GREEN: It goes to the same sites.

DR. JADVAR: Exactly, but people are expanding that a little bit now.

MEMBER SHEETZ: Thank you for the point.

MEMBER GREEN: Sure.

CHAIRMAN PALESTRO: Any other comments or questions? From anyone in the room? Anyone on the bridge line? All right. Thank you again, Mr. Sheetz. Next presentation is U.S. Pharmacopeia General Chapter 825. Mr. Richard Green will present this.

MEMBER GREEN: Thank you, Dr. Palestro. Before I start, I need to provide a disclaimer. I am a volunteer member of the USP expert panel that wrote this chapter, appointed in 2007 and serving since then, and there are eight nuclear pharmacists and I am one

of the eight that wrote the chapter. This presentation is my opinions, it does not endorse or represent the views of the USP.

So, first of all, if you are not familiar with the USP, it is a nonprofit organization, it's non-governmental, that sets safeguards for the public health and safety by developing standards for medicines, dietary supplements, and food ingredients, the vial of saline we're all used to using and all the drugs we say has USP as part of the name.

It's incorporated by the Pure Food and Drug Act of 1906 and it's compendial under federal law. So, these standards are enforceable and recognized and incorporated into laws and regulations.

Who enforces the regulations depends on who you are. As a pharmacist, I'm very used to having the Board of Pharmacy paying a knock on my door on an annual basis for a social call to see how we're doing with their regulations.

The FDA can enforce these standards directly, as we saw I think most recently in the New England Compounding Center, when they knocked on their door and said, people are dying with non-sterile intrathecal injections, stop what you're doing. It was arguable that the Massachusetts Board of Pharmacy

wasn't doing their part, the FDA stepped in.

For healthcare institutions, we're most likely to see the regulator being the Centers for Medicaid and Medicare Services. There's always strings attached with federal money. If you're going to get Medicare payments for Medicare patients, you've got to meet the conditions of participation.

And you can be inspected by CMS directly or you can belong to what I call a club, a deemed organization that can do the inspection for CMS. And that could be AOA, DNV, Joint Commission, or other deemed organizations.

So, it is a federally enforceable standard. You're not going to have the feds come out and regulate you, but someone else, a surrogate, will.

And so, this public standard was made official, made public on June 1 of this year. I've got my well-loved and dog-eared copy. If you don't have a copy, you're welcome to go get one, a free download at the USP website. They'll ask you for your name and your email address and let you pick whichever of the four chapters that are coming official this December.

So, it becomes enforceable December 1. There's always a six-month interval between when it

becomes public in its final form and there's the expectation for compliance. So, December 1 is when licensees may be inspected for compliance.

And so, this is a heads-up to the medical practitioners here on the committee of what this chapter is and also to the staff, because it may affect some licensees and what they are amending or having to deal with in their departments.

There are 14 subsections within the chapter, briefly going to go through just a few of them.

Introduction is the first part. This chapter is intended to provide uniform minimum standards for the preparation, compounding, dispensing, and repackaging of sterile and non-sterile radiopharmaceuticals for both human and animal use that occur as part of a state-licensed practice, either the practice of medicine or the practice of pharmacy.

So, in the title of the chapter, there are four verbs. There's preparation, compounding, dispensing, and repackaging. Those are separate functions, separate activities. And there is a glossary with 75 defined terms, which I highly refer people to go read the definitions.

And so, very rarely do I as a pharmacist do any compounding. I'm taking a commercial kit for

preparation of Compound X, I'm adding pertechnetate to it, and I'm preparing it. It's using a cake mix, everything's there except the isotope.

There are occasions where I may be compounding, where I'm making something that does not exist commercially and I'm putting raw pieces together, cooking from scratch, if you will.

So, the terms are separate and they mean different things. But it applies to all types of radiation, whether it's a gamma, a photon, a positron, or a therapeutic particle. Doesn't matter what type of radioactive decay, if it's radioactive, it's in this chapter.

And this chapter, although it applies to drugs, this is in the pharmacopeia, it also applies to the sterile intravascular radioactive devices, or hepatic brachytherapy devices, SIR-Spheres, TheraSpheres that Mr. Sheetz just mentioned. So, they're also explicitly inside this chapter.

Briefly, what the chapter does not apply to is the administration of a radiopharmaceutical to a patient. So, that's the practice of medicine, that's taking, it could be a prepared patient-ready unit dose that's received from an outside vendor and the nuclear medicine technologist is going to take that and ready

it for administration.

Assay it or change the needle. Patient showed up early, I want to express off some excess activity to adjust the activity to what it should be at this time of day, dilute it. Put on a three-way stopcock or change the needle for a needleless cannula. Put in a saline flush. All those are examples of patient administration and that's outside the chapter. Okay?

Because we asked for a chapter for radiopharmaceuticals, because we felt we were not well-served under the current 797, where we were given six small paragraphs of 38 pages and we were just a square peg in a round hole, this chapter is explicitly on radiopharmaceuticals and it only covers radiopharmaceuticals.

So, any adjunct pharmaceutical that's not radioactive used in nuclear medicine, so the pharm stress agents, adenosine, dobutamine, dipyridamole, regadenoson, are not inside the chapter. Sincalide for contracting gallbladder, not inside the chapter. Esmolol, morphine, phenobarb, all those regular drugs are not here.

If they're oral, they're under 795, non-sterile chapter. If they're a sterile intravenous

drug, they're under 797. I'll refer you to those chapters for what the standards say for the handling of those drugs.

Who does -- what practice settings do the chapter apply to? Well, it applies to all state-licensed nuclear pharmacies. I'll raise my hand, that would be me. It applies to federal nuclear facilities. That would be a VA or a Naval institution or an Army base.

Or to any other healthcare facility, including, but not limited to, nuclear medicine departments in hospitals, in clinics, nuclear cardiology centers, either fixed-site or mobile, and any other specialty clinics, I think endocrinology might be one of those. So, anywhere.

What individuals does this chapter apply to? It applies to two classes of individuals who are named on the RAM license, authorized nuclear pharmacists, ANPs, and authorized user physicians, or AUs.

In addition to those individuals, it also applies to any individuals working under the supervision of those RAM licensed individuals. That's including, but not limited to, student pharmacists, nuclear pharmacy technicians, nuclear medicine

technologists and student technologists, as well as physician residents and trainees.

So, I think it's been all-encompassing. Who does the chapter cover? Anybody who touches a radiopharmaceutical anywhere in any type of facility for animal or human use. I think it's very clear.

In the chapter, there are described three different environmental settings where radiopharmaceuticals are sterile, radiopharmaceuticals are prepared.

And starting with the least restrictive would be the Hot Lab. The Hot Lab is ambient air, there's no purification, no HEPA filtration, no pressure gradients. This room would qualify as a Hot Lab. And in that environment, only immediate-use can be performed. And I'll go into that just a bit more. But that would be immediate-use in a Hot Lab.

The next level up of environmental control would be a Segregated Radiopharmaceutical Processing Area, or SRPA. That's a space of dedicated use that has limited access, gloving and garbing requirements.

It has located within it an ISO Class 5 Primary Engineering Control, or a hood. Don't confuse this with an exhaust hood, it is not an iodine or a xenon exhaust hood, it is a HEPA-filtered Primary

Engineering Control, makes sterile air that flows, typically vertical laminar flow air to the work environment.

So, there's a PEC, a hood, Primary Engineering Control, located in a SEC, Secondary Engineering Control, which is the room. There's a box in the room.

And I'll show a chart on the next slide that describes the beyond-use date available in these different environments.

The last, highest restricted level of environment is a Clean Room Suite. That infers that there's two rooms adjacent to each other. And this is what we operate within a nuclear pharmacy, where there is a anteroom with purified air, HEPA filtration in the ceiling, where we doff street clothes and don garb, low-linting garb, to go in and prepare drugs. And there's pressure gradients and air changes per hour.

And we go into the buffer room, where we do the sterile drug prep, where the ISO 5 Primary Engineering Controls or hoods are located.

This is an excerpt of Table 7, Table 7 is much larger than this, but it describes three basic levels.

So, immediate-use, again, on the

countertop, ambient air, has no hood, no specific room requirements, but has a beyond-use date of one hour. So, if you're going to -- I'll get into it in a minute.

The next level is the SRPA, which would extend a beyond-use date up to 12 hours. And then, in this example, a Clean Room Suite with an anteroom -- did I do that? All right, sorry. I'll keep my fingers off the button.

A Clean Room Suite, again, depending on whether or not you've got ISO 7 or ISO 8 there, it can -- the 24-hour beyond-use date can go up to 96 hours. Again, this is just an excerpt of that table.

Briefly, I'll talk about immediate-use. This is where we think most nuclear medicine clinicians are going to be finding their clinical site to fall.

The chapter is not one-size-fits-all. I would encourage practitioners to do an introspective look at, what do we do here at this licensee? We do X and Y and Z, we do these processes and we perform these images on these patients. So, look at what you're doing and then, look what the chapter requires you to do to support those activities.

And so, the lowest level of engagement, of what you've got to do -- I always use example of the chapter's like an onion. You can cut the onion

in half and expose all the layers, all the concentric rings in that onion. Or if you just cut the onion shallowly, you're not exposing many layers, there's very little for you to do. So, it depends on what you do and how deep you cut that onion.

So, immediate-use is available to be performed in ambient air. It doesn't have a hood, doesn't have any particular qualifications for floors and ceilings and pressure gradients. But you cannot have a moly or germanium generator in a Hot Lab, unless it has an air quality measurement.

So, you can prepare kits. You can take a litholized vial of a commercial drug product, such as MAA or DTPA, and I can nuke that on the countertop and prepare a dose for a single patient to be used within one hour in ambient air.

And because we don't have any sterile controls involved in this process, there is a requirement in the chapter that you must be starting with a commercially manufactured drug product, something that's FDA approved. We don't use that language, but it's a sterile conventionally manufactured drug product that's approved with an NDA or an ANDA.

So, with a known starting material, you

can work in ambient air with no sterile controls to make a dose.

You can dispense products under an IND or RDRC protocol. Again, manipulations of unit dose are outside the chapter, so if I can express off that material, change a syringe, change a needle, dilute it.

But because we're working in ambient air, there is a one-hour, get it done and then, throw it out requirement. And that clock starts when we first breach the containment system. So, I open that syringe or pierce the needle into the septum of a drug vial to aspirate drug out into that vial is when the clock starts.

If you're making a kit in ambient air, you may do so, but again, within that one hour, you have to purge and discard everything that you've made and what you made it from, because you're working in ambient air.

There's a defined term, dose pooling, in the chapter. This is where you may have a unit dose calibrated for 8:00, let's just say it's a bone scan with medronate, and the patient's a no-show. Smart technologists save that, it may be useful later.

You may have a patient with an 11:00

no-show. If the physician comes and says, hey, I've got time on the camera, can you accommodate a patient at 1:00 p.m.? If those two syringes have not expired, you may pool them, so many go into one, so you can accommodate a patient for a 1:00 administration.

Again, it's for one patient, you can add those two together, measure it, express off what you don't need --

MEMBER DILSIZIAN: So, this is without a technetium generator, right? These are all --

MEMBER GREEN: Correct.

MEMBER DILSIZIAN: -- pre-prepared, ordered, unit doses that you're mixing?

MEMBER GREEN: Correct.

MEMBER DILSIZIAN: But you don't have a technetium generator there to milk and --

MEMBER GREEN: Correct.

MEMBER DILSIZIAN: Okay.

MEMBER GREEN: Okay. There is a requirement, if you're making a kit, of a small contingent of hand hygiene and garbing. If you have a sink, wash your hands. If you don't have a sink, use an alcohol-based hand run and rub your hands according to the length of time in your institutional policies. But you do want to decrease the bioburden.

There are separate sections for unique activities, such as radiolabeling blood cells for a GI bleed or a MUGA. UltraTag is a brand name, you can also do it the in vivo method with pyrophosphate. There is a separate section for radiolabeling of leukocytes, either with Indium-111 oxyquinoline or Technetium exametazime.

You can -- separate section for compounding from scratch, taking a non-sterile ingredient and making it a sterile drug.

And there's a separate section on direct infusion systems. So, a Rubidium-82/Strontium Generator is a direct infusion system. Or a Medrad Intego Infusion Cart of F-18 FDG is another example of a direct infusion system. I believe, Michael, your syringe infusion pump for injectable imaging with Technetium would also fall in that category.

So, as I said, the licensee should look at what they do in this clinical site. What type of drugs, what type of procedures, what type of processes do we do here? And then, evaluate, to continue doing those activities as currently performed, what does the chapter require me to do? What do I have to do to support those practices?

And then, make that decision, do I continue

to do those practices or do I modify the offering that we're doing in this clinical site or look to other providers to provide material that we're not receiving currently?

I had a thought, but I just lost it. All right.

I know there are many clinical sites today that have a very nice marketing job. There's a vendor that made a USP 797 hood. It's a little tiny hood that goes behind a little tiny L-block.

And that hood is a very functional device, but to have that hood on the counter requires you to have a dedicated space and an SRPA with requirements, and media fill challenges on the individuals and glove fingertip testing and surface sampling every month and viable air sampling every six months.

So, people need to look at, okay, this is what I do, this is what I have, what do I want to continue? Again, it goes back to that onion analogy of what you're doing and how deep you're cutting.

So, RAM licenses today are probably been in effect and been held by licensees for many years. 797 became effective in 2004. But the Sterile Compounding Chapter 797 was primarily focused by regulators at the hospital pharmacy level and they

didn't typically go down into the basement to check out nuclear medicine or to labor and delivery for their use of oxytocin.

Well, now we have a separate chapter that is just radioactive drugs and that only involves one hospital department, that's nuclear medicine. So, it's very likely that nuclear medicine departments will get a knock on the door from a regulatory body. The Joint Commission, CMS, Board of Pharmacy will visit the centralized pharmacies.

Pharmacies have been living the dream since '04. This may be new to hospital departments. So, they'll need to perform that internal assessment, modify activities, modify their procedures, perhaps even remodel if they want to continue doing the activities that they're currently doing.

So, just a heads-up to the community, to members on the committee, to staff, that the chapter's available. If you haven't got a copy, I recommend you get one.

It becomes enforceable December 1 of this year and there may be RAM licensees that are seeking amendments to put in equipment or to change their activities or they may just decide to, it wouldn't require an amendment, but to look for a contractor

provider for some of the things that they were currently doing.

But just wanted to make everyone aware, I think what a once-in-a-lifetime event is. So, congratulations, we're all here.

(Laughter.)

CHAIRMAN PALESTRO: Thank you. Comments or questions? Dr. Jadvar?

DR. JADVAR: So, when this chapter became official in June 1, 2019, how was this communicated to the nuclear medicine clinics around the country? I personally didn't know about this and I'm not sure if my colleagues know about it.

Tomorrow, we have a Radiation Safety Committee meeting, where everybody shows up. I'm going to bring this up and let them know to kind of follow your advice. But has this been communicated to people? Are --

MEMBER GREEN: It has and --

DR. JADVAR: -- and how?

MEMBER GREEN: -- it's been multi-factorial. I can tell you that the SNMMI is very aware of it, their committee on radiopharmaceuticals.

DR. JADVAR: We have sections of it --

MEMBER GREEN: The largest group that

started at the recent SNMMI meeting in Anaheim, California, there were two CE sessions on it.

I can tell you that I've spoken in live, VOICE credit CE sessions at least five times this year. I've got one more this month. I've conducted eight live webinars and I've got four more on the calendar. Mr. Sheetz suffered through one of them and is here today, so it wasn't too bad.

So, we're trying to get the word out. Nuc med departments have been subject to 797 since '04. That was revised in '08. But this is a spotlight that's just on one department, so they're likely to get a guest, an inspector.

DR. JADVAR: Okay.

CHAIRMAN PALESTRO: Yes, Ms. Kubler?

MS. KUBLER: Hi, Caitlin Kubler again with the Society of Nuclear Medicine. Just to reiterate, the Society has done many efforts on this. We've published the new announcement to all members.

We actually will be announcing next week a separate drop-down menu from our government relations tab on our website, so that there's an easy link to the USP FAQ.

We had a conference call with USP directly a couple of weeks ago to talk about those changes and

to figure out ways that we could communicate this broadly to members. We did an Uptake article, that was published July/August, which explains many of the provisions that Mr. Green mentioned in a lot more detail.

So, on the Society's side, we are doing a broad outreach to members to make sure that people are aware of the new changes that will be enforceable December 1. Thank you.

CHAIRMAN PALESTRO: Okay, thank you.

MEMBER GREEN: Caitlin, could we --

CHAIRMAN PALESTRO: Dr. Dilsizian?

MEMBER DILSIZIAN: We are on top of this, my nuclear medicine technologist is actually little bit anxious and nervous. And let me ask you some questions, how you came about to changes?

So, for institutions like University of Maryland, where we have a generator, where we use it for on-call convenience for GI bleeding studies, et cetera, HIDA, it seems like these new regulations are pushing all of us to go to unit doses, because it seems like there's some limitations for using tech generators to radiolabel and use it at night time. So, that's, at least, that's what I'm told.

In your discussion, you're making a real

distinction between Hot Lab, not to include technetium generators. So, what is it that -- why such strict regulations, that we're all going to go to, ultimately, unit doses?

MEMBER GREEN: Thank you for the question. I'd have to push back a little bit. I think there may be a misconception.

MEMBER DILSIZIAN: Yes.

MEMBER GREEN: So, you're -- a department may possess a germanium or a gallium/moly generator, back that up, moly/technetium generator --

MEMBER DILSIZIAN: Yes.

MEMBER GREEN: -- in ambient air in an SRPA. So, you'd have to have a defined flooring, it cannot be the one-foot square tiles where you can grow crud between each seem of these square tiles.

So, a little bit of improvement, but you can have, without a clean room, you can have a generator in a department that can be eluted for daily use, for afterhours emergency use. It does not require the use of a hood, a Primary Engineering Control.

So, you can elute the generator, perform the NRC required moly breakthrough, and then, you could aspirate the pertechnetate from the elution vial, nuke a HIDA kit for a gallbladder study, perform quality

control testing of the radiopharmaceutical, and then, draw and administer a single patient within one hour and then, discard everything.

MEMBER DILSIZIAN: So, that's what we've been doing.

MEMBER GREEN: Yes, and that --

MEMBER DILSIZIAN: I guess I want to know --

MEMBER GREEN: That's still --

MEMBER DILSIZIAN: -- what's changed since --

MEMBER GREEN: That --

MEMBER DILSIZIAN: -- the new regulation?

MEMBER GREEN: That may still be done.

MEMBER DILSIZIAN: Oh, okay.

MEMBER GREEN: There's no --

MEMBER DILSIZIAN: Because there seems to be a lot of anxiety at night time that we have to order, that's why I wanted to clarify.

MEMBER GREEN: Yes.

MEMBER DILSIZIAN: And I'm not a radiopharmacist, but there seems to be a lot of anxiety by nuclear medicine technologists that just this rule is so, I guess, restricting --

MEMBER GREEN: No, it's --

MEMBER DILSIZIAN: -- to use the technetium generator.

MEMBER GREEN: -- really no different than has been in effect since 2004.

MEMBER DILSIZIAN: Okay, that's good to know.

MEMBER GREEN: Now, we're helping nuclear medicine departments, they may have received in the past a sterile vial of pertechnetate, because they don't have the generator --

MEMBER DILSIZIAN: Yes.

MEMBER GREEN: -- and they can make after hours kits on-call. If they do that going forward, if they aspirate some of the vial to make a HIDA kit, well, then, the whole vial has to be tossed --

MEMBER DILSIZIAN: Yes, because --

MEMBER GREEN: -- because they're working --

MEMBER DILSIZIAN: -- the one-hour --

MEMBER GREEN: -- in ambient air.

MEMBER DILSIZIAN: -- the one-hour rule.

MEMBER GREEN: So, what we can do is, we can provide pertechnetate in syringes. If you wanted 100 millicuries every night at midnight, we might give you two syringes of 50, so you could access the first

syringe, make that HIDA kit, take care of that patient, emergent patient need, and have an untouched 50 millicurie syringe for a subsequent patient, should they appear in the department. So, there's things we can do to help out.

MEMBER DILSIZIAN: Okay.

MEMBER GREEN: But you still can have a generator, if you wish to do so.

MEMBER DILSIZIAN: Okay, good.

MEMBER GREEN: If you wish to make a Myoview kit for all nine of your patients that day, then that would require a Clean Room Suite with a hood and media fill and glove fingertip testing and air sampling and pressure gradients and the whole shebang. Again, it's the onion.

CHAIRMAN PALESTRO: Mr. Green, in terms of your example of the generator, you use the generator for on-call coverage and we elute it to prepare a HIDA kit. Well, a half hour or two hours later, you get a request for a lung scan. That means we have to re-elute the generator. Am I correct, because I have punctured that --

MEMBER GREEN: Not necessarily. If your facility is equipped with a laminar flow hood, a primary engineering control --

CHAIRMAN PALESTRO: If it's not?

MEMBER GREEN: If it was, then you could take the elution vial and place it in the hood, and now that elution can be retained for up to 12 hours to make that first patient kit, and then two hours later, another kit, but because you don't have a hood, then that entire elution would have a one-hour time frame on it.

CHAIRMAN PALESTRO: Any other comments or questions? Anybody in the room? Anyone on the bridge line? All right, thank you, Mr. Green.

Next item on today's agenda, the ACMUI membership composition and balance, and it will be presented by Ms. Lisa Dimmick.

MS. DIMMICK: So I'm the last to talk before the close and end of the meeting, so I don't know if this is a good place to be or not. Anyway, so I'm Lisa Dimmick, the Medical Radiation Safety Team Leader.

By way of background, the ACMUI's role is to provide advice on policy and technical issues that arise in regulating the medical use of radioactive materials for diagnosis and therapy, to comment on changes to NRC's regulations and guidance, to evaluate certain non-routine uses of radioactive material, and

to provide technical assistance when requested, and to bring key issues to the attention of the Commission for appropriate action.

So the ACMUI, the current committee is a 13-member committee. You all are appointed as special government employees. Your terms are set at four years with a limit of two terms. That's just for information.

So, the other thing to note by way of background is that the ACMUI is a federal advisory committee, and under the Federal Advisory Committee Act or FACA, one of the requirements for the FACA committees is to maintain a membership balance plan, so as part of the biannual renewal of your charter or the ACMUI's charter, the membership needs should be assessed.

The ACMUI's charter next renews in March of 2020, so if there is an opportunity to evaluate membership, there's an opportunity now to consider membership. Consider it now or think about it for the next time the charter renews, but I'm just bringing it, again bringing this just for awareness.

So, the membership balance plan for the ACMUI includes healthcare professionals of diverse specialties who represent diagnostic and therapeutic applications of medicine, medical administration, and

patient care advocacy.

So, as I mentioned, as you are aware, it's a 13-member committee and with very diverse backgrounds, and that is by design so that there is, we encompass the diversity of topics and issues faced by the NRC. All of the members have expertise in their respective areas.

So when we were, just as we, on the medical team, evaluate medical events and other emerging medical technologies and things like that, we are mindful of the various issues that we're confronted and things that we'll be passing along to the ACMUI for your evaluation and consideration.

So just for reference, the last time the membership composition was changed was back in 2009. At that time was when the Commission did approve the expansion of the ACMUI by one position to include a diagnostic radiologist.

Before that was approved by the Commission, just for awareness, there was a -- the committee was supported by a diagnostic radiologist as a guest member to the committee, I think to identify if there was benefit and value to having a diagnostic radiologist support the committee in the regular dialogue and discussions that were before you.

So here is an opportunity, as I had mentioned, that the charter does renew every two years, so the next charter expires March 2020 and would renew. Is there a consideration for support or representation by an interventional radiologist?

And the reason why I'm asking that or as something for the committee to consider is that we have several emerging medical technologies that require the skills of an interventional radiologist.

We're all aware of microsphere brachytherapy. There are currently two vendors on the market with two new vendors coming down the pipe. I don't know if that's going to expand the market or use, or if they're going to share with what's currently the 15,000 procedures that were done in 2018 as Mike Sheetz had mentioned.

So that's one area that we are, I think, Yttrium-90 is here, or microsphere brachytherapy has been around for a long time and it appears that it's a growing field.

The other thing is the other technology that Mike Sheetz mentioned, the Oncosil, which is the P-32 for pancreatic cancer. I believe the intended user for that treatment will also be an interventional radiologist.

There could be other techniques and technologies that are being developed that would require image guidance placement of the material like Oncosil and like the microsphere for -- or the Yttrium-90.

And then also that we're very aware that with microspheres, that of all of the modalities, it is the microspheres that would have the highest number of medical events, and please be aware that there's maybe a lot of reasons for that. There's a number of inherent risks already associated with this particular treatment, and many of them are beyond control of the clinicians, but they trigger the medical event reporting notification.

So, you know, we are mindful that we have a lot of events in this area, but there are also inherent risks associated with this treatment that are part of why, and why we have so many, maybe many medical events compared to the other modalities, but for the period, for a two-year period, there were 71 medical events for, involving Yttrium-90 microspheres.

So, I just wanted to offer up that, you know, for this duration, for the ACMUI to think about its membership, is it represented for uses? Should there be consideration for other representation on the

committee? Maybe there is another clinician that should be represented on the committee, so that's something the committee should think about, and I'll just end there.

CHAIRMAN PALESTRO: Comments or questions from the committee? Dr. Schleipman?

MEMBER SCHLEIPMAN: I think with Y-90 proposals and so forth, you probably heard from interventional radiologists and perhaps also the T&E for authorized users.

MS. DIMMICK: Right.

MEMBER SCHLEIPMAN: I'm wondering to what extent have they or other clinician groups as stakeholders reached out for this particular issue?

MS. DIMMICK: So, the interventional radiologists have not reached out for this position or for this, have not reached out for this presentation, and I do know that it may have been discussed in the past by the ACMUI, not formally as an agenda topic, but maybe in discussions in trying to search for the minutes for discussion to bring that forth.

I believe when the interventional, I'm sorry, the diagnostic radiologist position was added in 2009, there was some discussion that the support for that position were the cross-cutting technologies

between, in diagnostic for PET/CT and other things, the benefit of having the diagnostic radiologists because they were doing dual roles in their respective departments, in the department, but also the diagnostic radiologists have knowledge and skills with Yttrium-90. So that was discussed as part of the support to add the interventional, the diagnostic radiologist back in 2009, and that was 10 years ago that that position was added.

CHAIRMAN PALESTRO: Other comments or thoughts on this matter? Dr. Jadvar?

DR. JADVAR: I think generally that's a good idea. Interventional radiology, as you know, is becoming actually its own kind of residency. You know, right now, you can actually -- I think it occurred last year or two years ago, very recently that now you can actually apply as a resident physician directly into intervention radiology.

So as in the old days when it was just radiology and eventually it kind of became therapeutic radiology, it's changed its name to radiation oncology and also diagnostic radiology.

Now we're having a third, you know. Then, of course, we had nuclear medicine. Then there's another branch that is developing recently as, you know,

a separate entity, interventional radiology.

And I think as time goes on, they're going to be more involved with these procedures, using these targeting drugs to various places in the body, and I think it's a good idea.

CHAIRMAN PALESTRO: Dr. Metter?

VICE CHAIR METTER: And I'm sure you've also probably reached out to SIR, the Society of Interventional Radiologists?

MS. DIMMICK: No, no outreach was done for this.

VICE CHAIR METTER: Okay.

MS. DIMMICK: This was just doing our, just evaluating the various uses, especially in the emerging medical technologies of the different modalities, there was no outreach to any of the professional societies.

CHAIRMAN PALESTRO: Dr. Metter, and I don't mean to put you on the spot, but you are the diagnostic radiology representative on this committee, and so my question to you would be what's your opinion on this? Do you feel that the Y-90 microspheres and so forth, this sort of therapy can be adequately addressed by the diagnostic radiology member, recognizing that they change from time to time?

VICE CHAIR METTER: I think that radiology

has actually expanded into many subspecialty areas, and I think vascular intervention is a very unique subspecialty within radiology, and like Dr. Jadvar mentioned, that they actually have their board certification, their own training pathway, so I think would be actually a very interesting approach to consider perhaps an individual.

First of all, I think we should probably reach out to the specialists themselves and maybe invite them at some point in time to our meetings and kind of, you know, get a feel of what's going on there.

But I think this is very important, particularly with the new, different, and more complex treatments, and particularly with the major medical events being the Y-90 microspheres, and maybe that can also be helpful, and they can educate their users on the issues that we're facing.

CHAIRMAN PALESTRO: Dr. Ennis?

MEMBER ENNIS: Just being not that familiar, someone not familiar with interventional radiologists and their training, especially as they're developing, and I agree with the analogy to how radiation oncology develops.

But it seems like at a high level, their exposure and involvement with radiation is just as a

guidance tool and not as -- and therefore, I wonder whether they have, would have the knowledge and expertise of radiation and all of the issues surrounding radiation that we are grappling with in a way that would be helpful, or would it be as though we had a surgeon on this committee, which again, maybe it would be useful, but it's a very different mindset than coming from a group of people who have been trained in radiation expertise and are bringing that to bear in medicine?

CHAIRMAN PALESTRO: Dr. Metter?

VICE CHAIR METTER: As I mentioned, the ABR has changed their format as far as the area of vascular interventional, and for example, in our residency program, the new pathway, there's a large number or percentage of our residents who are actually in that pathway.

And so these are new vascular interventionalists that will be coming out in the next 10 years, and so I think it's very important for them to be aware of the issues that we are facing with medical events regarding the administration of radionuclide therapy through vascular interventional techniques.

And they can also help provide the insight to, "Well, maybe this is where I see a major problem is," and that can be helpful for us in regard to patient

safety.

CHAIRMAN PALESTRO: Dr. Dilsizian?

MEMBER DILSIZIAN: I do want discussions, but I want to support Dr. Ennis in that in Maryland, for example, the interventional radiologist always does a procedure either with a radiation oncologist or nuclear medicine physician. So we deal with the radioactive component of it. They simply do the procedure.

And I think I echo that, but I'm not against the concept that if this subspecialty becomes mature and they do take over their own interventional procedures, that they would help someone out. Whether it's now or should we wait a few years until they develop, I think it would be worth it to discuss that.

CHAIRMAN PALESTRO: Dr. Jadvar?

DR. JADVAR: At our place, actually interventional radiology does the whole thing.

MEMBER DILSIZIAN: I see.

DR. JADVAR: Yeah, so there are mixed practices out there. They're an AU. They can do whatever they want, so they deal with the radioactive material. They also -- well, I mean, it's broad nuclear medicine to them, but they deal with all of the tubing and connections and all of that, and also, of course,

they deal with the fluoroscopy and all of that, yeah.

CHAIRMAN PALESTRO: Dr. Ennis?

MEMBER ENNIS: So I guess if we do entertain it, it might be a very good idea if we always stipulate that the person be an AU.

CHAIRMAN PALESTRO: Mr. Sheetz?

MEMBER SHEETZ: Yeah, at our institution, the nuclear medicine physicians were the authorized users and came over and pushed with the interventional radiologist doing the guidance and catheter placement, but now though, our interventional radiologists have completed the requisite training and they are the authorized users, and the fact our office used to do the treatment plans and calculate the dose and the vials to get. The Interventional radiologists have now even taken that over, so they're doing everything.

(Simultaneous speaking.)

MEMBER SHEETZ: So I would surely recommend that if we have an interventional radiologist on the committee, that they would have to be an AU.

MEMBER DILSIZIAN: I agree.

MEMBER SHEETZ: And both manufacturers.

CHAIRMAN PALESTRO: Mr. Green?

MEMBER GREEN: I'd just remind that Ms. Dimmick said that the charter is up for renewal in March

of 2020, but it's a two-year cycle, and in the past, a diagnostic radiologist was invited as a guest for a length of time. We might want to do a test drive.

MS. DIMMICK: Okay, sorry. I think the -- I'll have to review exactly how that transpired, but I think -- thanks. I didn't want to speak for you.

MR. PETERS: Yeah, believe it or not, I was around back then. So, yes, Mickey Guiberteau, who was the first official diagnostic radiologist on this committee, obviously had both expertise in Y-90 and in diagnostic radiology more generally, so the position was kind of modeled on his expertise.

He served as a non-voting for, I believe, about one and a half or two years until the Staff and the Commission decided to go ahead and make the position a formal voting position, so that's kind of the origins of that. Does that help? I don't know.

MS. COCKERHAM: This is Ashley Cockerham with Mercurie Consulting. So I was actually the individual who wrote the SECY paper to add the diagnostic radiologist position to the committee. And so when Dr. Guiberteau was the ABR representative, I believe we had him as a consultant to the committee, so it wasn't necessarily a guest.

I know that's the term that's kind of been

thrown around, but I think that's maybe the legal way to get it in there so he can be a consultant to the committee to advise and participate, but not be a voting member, and then the Staff can write a Commission paper to add that position if that's the direction that the group chooses to go.

MR. EINBERG: Okay, that is very helpful. Thank you.

CHAIRMAN PALESTRO: Dr. Jadvar?

DR. JADVAR: But again, if that's going to happen as a consultant, or observer, or whatever, I think it's important we have somebody who is kind of dual, does both things, you know, interventional who directly understands the use of radioactive material and does it clinically.

There are a few people like that out there. I know them and they are actually both nuclear medicine physicians, a dual boarded nuclear medicine physician plus interventional radiologist.

So we should really identify who these people are rather than just anyone in interventional radiology because not all of them are involved and they don't understand some of these things, so that's important to consider.

MS. COCKERHAM: This is Ashley Cockerham

again. To add to your point, that's actually exactly what the committee had done with radiation oncology. So there are two radiation oncologists here, one specifically for gamma knife and then one that was really focused on brachytherapy, so there is kind of a precedent for that, and that's something that the Staff and the ACMUI considered in the past as well.

DR. JADVAR: Okay, thank you.

CHAIRMAN PALESTRO: Any other comments or questions?

MR. PETERS: Sorry, one more question. If Staff and the committee decided to move forward with this idea, would there be any sort of open nomination period for the organizations involved in interventional radiology to be able to put forward names that you could choose from or would you go through a less formal sort of process? Just a question.

MR. EINBERG: That's an excellent question. We would have to take that under advisement, and I would most likely lean towards having an open nomination to get the best candidate for the position.

CHAIRMAN PALESTRO: How would the committee like to proceed? Would you like to form a subcommittee to pursue this further? Dr. Ennis?

MEMBER ENNIS: The only problem with a

subcommittee is we have a March deadline.

MS. DIMMICK: So I wouldn't -- I think part of it was just to illustrate that the charter renews every two years, so, and it still would involve a Commission paper to change the membership.

MEMBER ENNIS: Oh, okay.

MS. DIMMICK: So the -- so now would be an opportunity to think about it so that if there is a membership change, it could roll into, maybe not this March 2020, but the next review period.

MEMBER ENNIS: All right.

MS. DIMMICK: I mean, to make a change between now and March, in six months, that's a challenge.

MR. EINBERG: So I had a question for Ms. Cockerham. So, and for those who don't know Ms. Cockerham, Ms. Cockerham used to work for the NRC and she used to run the committee here. She was the ACMUI coordinator before Sophie and before Kellee, and so, and she did an excellent job, and so she has very much familiarity with what happened back many years ago, and so it's great that she's in the audience today to ask her questions.

So back when we brought in Dr. Guiberteau as a consultant, what was the process for adding him

as a consultant? Did we have to consult with the Commission for that or was that -- as I recall, it was a little bit more informal.

MS. COCKERHAM: Correct, I don't believe there was a consultation with the Commission, and I'll have to look back. It was too many years ago, but I believe it was a committee selection because essentially the ACMUI is saying, "Hey, there is additional expertise," because the committee always has the option to say, you know, "We would like to consult outside," so you go back to your professional societies or to your colleagues.

And I think it's just a little more formal for the ACMUI to say, "We would like a formal consultant for this particular knowledge base, to consult to them," so not necessarily something that the Staff has to go up to the Commission for.

MR. EINBERG: Okay, so was it an issue driven reason that the ACMUI selected or recommended having to consult the Committee?

MS. COCKERHAM: I'd have to go back and look. I remember the SECY paper, but I'm trying to remember if we just did like a memorandum or what kind of basis we put together. Donna-Beth was here as well.

DR. HOWE: I think I remember the ACMUI

meeting in which Dr. Eggli was the nuclear medicine physician, so he really could not represent the radiologists, and he asked the committee to consider getting a diagnostic radiologist, and I think that may have been the first piece and then there was an entire process after that.

MR. PETERS: I was just agreeing that Dr. Eggli, who was the nuc med representative at the time, did push it initially, so she was right. I was just agreeing loudly, sorry.

MR. EINBERG: You know, thank you for that. So one option that the committee here has is if there is an issue that requires a consultant, then we can address it at that time and bring on a consultant, and work with ABR to bring on a consultant or for you to put out a nomination, or you guys could make a recommendation to bring on a consultant right now because you feel that there is a need.

CHAIRMAN PALESTRO: Dr. Jadvar?

DR. JADVAR: Although I said it's a good idea, but, you know, the number of procedures that the interventional radiologists right now are involved using radioactive materials is rather limited, so maybe that increases in time.

For example, you know, there are

interventions using intra-arterial radioembolization with, you know, DOTA-TATE or something like that for, a Y-90 DOTA-TATE for local ablation of liver metastases or something like that. So these are emerging and increasing in time perhaps, but now right, this is it. This is basically what they're involved with.

So, I mean, I'm not on the committee, I guess, yet, but my suggestion is that it would be good to kind of look into this a little further. If there is a necessary situation, you can have a consultant, but have one standing right now as a member may not be necessarily the time right now.

Again, the limited scope of their work that is kind of combined at the moment, he's right. They're just using guidance and that's what they do, but anyway, I think it is good to look into it.

CHAIRMAN PALESTRO: Dr. Metter?

VICE CHAIR METTER: I agree. I think we should consider forming a subcommittee just to look at that before we reach out, and I think we need to understand what we're looking for and what that individual would be important to contribute to the committee.

CHAIRMAN PALESTRO: Right.

VICE CHAIR METTER: I think we should take

that approach first, and then from the subcommittee, review what the subcommittee had reviewed regarding the current needs, previous steps that were taken, and the issues of medical, I think, is very important, because with more complex agents, as I mentioned before, and longer procedure times, we should look at that, but I would recommend a subcommittee.

CHAIRMAN PALESTRO: All right, that's what I'm leaning toward after listening to the discussion. I think it's too premature at this point to recommend definitively even for a consultant.

So I think the better approach, the more prudent approach would be to begin with a subcommittee with at least, I'm going to say an initial or interim report at the March meeting. I don't know that it should be a final report. I'm not sure about that. I think this is something we should -- that's going to take some time.

And the charge for the subcommittee, I would suggest that it be to investigate the need for an interventional radiologist physician on the ACMUI, but that charge shouldn't be limited just to the need for, say, a full member. It could conceivably be a consultant or an invited member, whatever the term that's been used in the past.

In addition to that, it would, by forming the subcommittee, it would give them the opportunity to go back through our institutional memory and identify how Dr. Guiberteau and so forth, how his tenure on the ACMUI evolved and hopefully a rationale for why these things were done.

So is there any opposition to that? All right, so we need to create a subcommittee.

DR. TAPP: Dr. Palestro?

CHAIRMAN PALESTRO: Yes? I'm sorry, Dr. Tapp?

DR. TAPP: I have nothing to add. I was just going to make a recommendation I be the Staff resource, but --

CHAIRMAN PALESTRO: Oh, thank you. That's fine with me. All right, so we have the first member of the subcommittee staff, Dr. Tapp. All right, let's see, volunteers for the subcommittee? You really can't.

MEMBER ENNIS: I will be on it, but I can't chair it.

CHAIRMAN PALESTRO: Okay, that's fine. I think it should be radiation oncology because you do have, in some places at least, participating just like nuclear medicine. Dr. Dilsizian?

VICE CHAIR METTER: Can I be a member? Sophie said yes.

CHAIRMAN PALESTRO: You can be a member for the next 10 days, then you're off and you'll have to be invited back on.

PARTICIPANT: You have to wait for the chair to invite you.

PARTICIPANT: The sub chair has to invite you on.

MS. HOLIDAY: Correct, per the recent revision to the ACMUI bylaws, we said it's at the discretion of the subcommittee chair --

CHAIRMAN PALESTRO: Correct.

MS. HOLIDAY: -- if they want the knowledge and expertise as the ACMUI chair.

CHAIRMAN PALESTRO: So we will leave you off for the time being, Dr. Metter, and you can apply.

(Laughter.)

PARTICIPANT: Just for a couple of days until we have a chair.

(Laughter.)

CHAIRMAN PALESTRO: All right, so we have Dr. Ennis. We have Dr. Dilsizian agreed to be on the committee. Ms. Shober, are you willing to serve on the committee?

MEMBER SHOBER: Sure.

CHAIRMAN PALESTRO: Let me ask you, would you be willing to chair it?

MEMBER SHOBER: If you'd like.

CHAIRMAN PALESTRO: All right, thank you.

MEMBER ENNIS: I'd like to be invited.

MEMBER SHOBER: I heard that.

DR. JADVAR: I wish I could join, but --

CHAIRMAN PALESTRO: And I would ask, and again, I'm no longer going to be around, so I have no say, but Ms. Shober, I would ask that you would consider, once Dr. Jadvar is officially on board, that he too be included on that subcommittee. Any other comments?

MEMBER SHOBER: So right now, it's just three of us, is that --

CHAIRMAN PALESTRO: It's you, it's Dr. Ennis --

MEMBER SHOBER: Dr. Ennis and Dr. Dilsizian.

CHAIRMAN PALESTRO: -- and Dr. Dilsizian.

MEMBER SHOBER: Okay.

CHAIRMAN PALESTRO: Yes.

MEMBER SHOBER: I just wanted to make sure I wasn't missing --

CHAIRMAN PALESTRO: And then in 10 days,

if you should so choose, it will be Dr. Metter. All right, thank you.

All right, final item for this meeting's agenda is the administrative closing. Ms. Jamerson will present that.

MS. JAMERSON: Good afternoon. So for our administrative closing, prior to this meeting, I provided a Doodle poll to all of the members of the committee to schedule our tentative dates for the spring ACMUI meeting, and again, our spring meeting occurs in either March or April.

I had about eight responses. Of course, there are no set dates for when everyone is available, but the dates that received the most votes were March 24 through the 26, so with the meeting either being on the Tuesday or Wednesday or Wednesday or Thursday.

People were available for that, or with the second date receiving the most votes was April 21 through the 23. And so I did not hear back regarding availability from Dr. Dilsizian, Mr. Green, Dr. O'Hara, Dr. Wolkov, and Mr. Bloom if you had any input about your availability for those dates.

MEMBER GREEN: Both dates are good for me.

MS. JAMERSON: Okay.

MEMBER O'HARA: Whatever date you come up

with, I'll live with. I can't -- my FDA computer won't allow me to answer --

MS. JAMERSON: Understood.

MEMBER O'HARA: -- a Doodle poll.

MEMBER DILSIZIAN: In my case, at least for the April dates, I'm in Australia.

MS. JAMERSON: Okay.

CHAIRMAN PALESTRO: Ms. Jamerson, if I may ask --

MEMBER DILSIZIAN: And you are too.

DR. JADVAR: Yeah.

CHAIRMAN PALESTRO: If I may ask a question, when I started on this committee, which is now eight years ago, in fact, during the interview, Mr. Einberg and Mr. Lewis had said that the meetings are almost always held either at the beginning or the end of the week to minimize, either a Monday, Tuesday or a Thursday, Friday to minimize the amount of time that we have to take off from our other responsibilities, and over the past two years, I think, the meetings have tended to shift more towards a Tuesday, Wednesday or Wednesday, Thursday as opposed to Monday, Tuesday or Thursday, Friday.

And so my question is, is that just because of ACMUI member or staff availability or what? And

I think, and correct me if I'm wrong, but I think I'm speaking on behalf of the committee, that, for all of them, no longer me, but for all of the committee, it would be preferable for Monday, Tuesday or Thursday, Friday.

DR. JADVAR: Monday, Tuesday would be best because you can fly across the country on Sunday.

MS. JAMERSON: So, in response to that, I don't have the historical perspective. Maybe I can defer to Sophie for that on the scheduling of why the meetings are in the middle of the week.

MS. HOLIDAY: So, it is essentially what you said, Dr. Palestro. The staff generally offers up all of the available dates as long as they do not conflict with federal holidays, or Jewish holidays, or professional society meetings.

So the Tuesday, Wednesday or Wednesday, Thursday, those are the ones that end up being the ones that the ACMUI coordinator provides to the committee as the most viable dates. That's based on the input received from the ACMUI members. It's not necessarily Staff's desire to have it as such.

CHAIRMAN PALESTRO: Thank you.

MEMBER ENNIS: Just a little historical, so I think the move to Thursday, Friday was to

accommodate some of my needs, if I remember. Sophie, is that accurate? If we have a meeting on Friday, I end up being stuck here until Saturday night or Sunday morning because I can't travel when sundown happens.

So I think the committee was very nice to me in saying, "Okay, we won't do that to you." I can live with it if it needs to be, but I think that was the shift away from Friday.

Monday, Tuesday, I don't mind. Monday, Tuesday is totally fine with me. I don't mind the middle of the week either personally, but just a little historical background. I think that's how we moved away from the Thursday, Friday, and I do appreciate it, so.

CHAIRMAN PALESTRO: Dr. Wolkov?

MEMBER WOLKOV: I was just checking because there was another professional society around that time. It looks like there's no conflict for either date.

MS. JAMERSON: Either date, okay.

CHAIRMAN PALESTRO: Dr. Metter?

VICE CHAIR METTER: So could I just, since those dates are in the middle of the week for this suggestion, can we move it to Monday, Tuesday of the same time frame? Would that be a problem for people?

DR. JADVAR: In March?

VICE CHAIR METTER: In March and April.

DR. JADVAR: Like 9 and 10?

MS. JAMERSON: For the 23rd and 24th?

DR. JADVAR: 23rd?

VICE CHAIR METTER: Unlike --

MS. JAMERSON: You mean that same week or --

DR. JADVAR: I'm sorry.

VICE CHAIR METTER: That same week, but just move it to Monday.

DR. JADVAR: Yeah, that's right, yeah.

VICE CHAIR METTER: Would that be a problem with anyone? Because then you could fly in on Sunday again.

DR. JADVAR: Yeah, because I live in California. Basically, you need one day to get across.

MEMBER GREEN: It's not crucial. It's selfish on my part, but I'm here in D.C. for the American Pharmacists Association 20, 21, 22, and 23, so that has Monday for the professional meeting.

MS. JAMERSON: So that leaves you out, Mr. Green, for the 23rd?

MEMBER GREEN: I could do it.

MR. BLOOM: When did you say it started?

MEMBER GREEN: The pharmacy meeting is 20 through 23 here at National Harbor.

PARTICIPANT: Nice.

MEMBER GREEN: I could attend ACMUI on the 23rd if need be.

MR. BLOOM: When does it start on the 20th?

PARTICIPANT: It's on the 20th, right?

MR. BLOOM: No, when?

PARTICIPANT: I'm going to that meeting too.

MR. BLOOM: Is it in the afternoon?

MEMBER GREEN: It's the afternoon, yeah.

MR. BLOOM: Well, could you do the 19th and 20th and roll right into it?

MEMBER SHOBER: We were staying away from Thursdays and Fridays.

MR. BLOOM: Oh, you were, that's right.

VICE CHAIR METTER: So you could still do the 23rd of March?

MEMBER GREEN: I could, or the 24th through 26th.

PARTICIPANT: Was there a conflict in April?

MS. JAMERSON: So, we would need to select the preferable date, and then the second date would

be the alternate.

MEMBER SHOBER: It's going to depend on Commission availability.

MS. JAMERSON: Right, so the scheduling of the Commission meeting depends on their availability as well, so whether it's in March or April.

VICE CHAIR METTER: So could we move the April one to the 20th, like shift it again? Is that a problem for anyone, that Monday?

DR. JADVAR: So 20, 21 you're saying?

VICE CHAIR METTER: 20 to 22.

PARTICIPANT: 20 to 21.

VICE CHAIR METTER: Right, 20 to 21, or they can go -- yeah, 20 to 21, sorry.

DR. JADVAR: Again, I cannot be here. That week, I am in Australia.

MEMBER DILSIZIAN: I think we were together, right?

DR. JADVAR: Yeah.

MEMBER DILSIZIAN: Okay, so two of them.

DR. JADVAR: Yeah, two of us are, that week is an Australia meeting and we are going to be gone.

VICE CHAIR METTER: Would the following 27th and 28th be a problem for people?

DR. JADVAR: Not for me.

MEMBER GREEN: The 29th would be a problem for me.

VICE CHAIR METTER: Okay, so the 27th and 28th would still be -- would that work for most people? Who would it not work for?

MEMBER ENNIS: April what?

VICE CHAIR METTER: April 27 through 28. Who would it not work for if you're looking at your -- oh, you said it wouldn't. Oh, and you're chairing that meeting.

MEMBER SCHLEIPMAN: It's tough.

VICE CHAIR METTER: It is tough.

PARTICIPANT: The 20th actually does not work for me.

VICE CHAIR METTER: So do we have the first date then as March 23 to 24? So that will be the first choice.

MS. JAMERSON: So, our first choice, so we have a motion for our first choice for March 23rd through the 24th.

VICE CHAIR METTER: Yes, and then that would be the first choice.

MEMBER SHEETZ: What about April 6th and 7th?

MS. JAMERSON: Is there a consensus for

the first option, for March 23rd to 24th?

VICE CHAIR METTER: Yes, there was, anybody who couldn't make -- would vote against it? Anybody against that? So, it's nobody against, so it's unanimous for that date as number one, and then I wanted to know for April 6th to 7th?

MEMBER ENNIS: That's not ideal for me. Passover starts on the 8th, but I could do it, but it's a little difficult, so not ideal, but not impossible for me.

DR. JADVAR: And it's my birthday.

(Laughter.)

VICE CHAIR METTER: So, is there a motion to make April 6th and 7th the second choice? Do we have a motion?

MS. HOLIDAY: Dr. Metter, this is Sophie. Before you guys put that motion on the table, I recognize that one of your members is not present at the meeting today, Ms. Melissa Martin. I don't know if Ms. Martin provided her input or not, so I'd like for her to be considered as well.

MR. MARTIN: I'm Richard Martin from AAPM. We have our spring clinical meeting and there's a board meeting following it April 4 through 7, so it would also probably include the 8th for the board meeting,

which is maybe a problem for some of our people.

MS. JAMERSON: And so Ms. Martin did provide input to the Doodle poll indicating her availability for the first, well, the dates of March 24th through the 26th and also the 21st through 23rd.

DR. JADVAR: What about that 27th, 28th that Mr. Einberg mentioned?

MS. JAMERSON: For April?

DR. JADVAR: Yeah.

MR. EINBERG: Dr. Schleipman, can you do later that week?

MEMBER SCHLEIPMAN: Sorry?

MR. EINBERG: Can you do later if --

MEMBER SCHLEIPMAN: Oh, I can. I can Thursday and Friday, but Friday -- I can do the week before at any time. You mentioned, I think you mentioned the 6th and 7th, there's a physicist --

MR. EINBERG: The physicists, and I believe Melissa Martin will probably participate in that.

DR. JADVAR: Does it have to be in April? Can it be the 4th and 5th of May just a week later?

PARTICIPANT: Or can we pick two weeks in March? It seems like March is a little more flexible for people.

VICE CHAIR METTER: Yeah.

MR. EINBERG: Sophie, is there any opposition or any problem selecting two days in March?

MS. HOLIDAY: In March?

MR. EINBERG: Yes.

MS. HOLIDAY: No.

MR. EINBERG: Okay.

VICE CHAIR METTER: So it's possible?

MR. EINBERG: It is possible, yes.

PARTICIPANT: But you've got a week blocked off the 10th, 11th, and 12th.

MS. JAMERSON: So the 10th, 11th, and 12th will be the NRC's RIC meeting, so essentially that's out. The Marriott across the street will be booked and full.

DR. JADVAR: What about --

VICE CHAIR METTER: The 30th and 31st, March 30th and 31st?

DR. JADVAR: Yeah.

VICE CHAIR METTER: Would that work out? Would March 30th and 31st work out for people? Would it work out? Who would it not work out for? Okay, could I have a motion to move that March 30th and 31st be our second choice?

PARTICIPANT: So moved.

VICE CHAIR METTER: Second? Okay, Mr. Sheetz. Okay, all in favor? So would that be okay, Kellee, that we have our first choice as March 23rd and 24th and our second choice as March 30th and 31st?

MS. JAMERSON: Okay.

MEMBER ENNIS: When will we know the time of it?

MS. JAMERSON: For the Commission's availability?

MEMBER ENNIS: Yeah.

MS. JAMERSON: I'm not sure of the time frames. Sophie, can you clarify?

MS. HOLIDAY: So they usually do Commission agenda planning no greater than six months in advance. Shortly after this meeting concludes, Kellee will inform the Office of the Secretary of the ACMUI's proposed meeting dates, and we should know the Commission's tentative availability perhaps no later than end of October, November, but it depends on when they have the Commission and other things.

PARTICIPANT: Could you repeat the dates?

MS. HOLIDAY: So for now, I would recommend that the ACMUI hold both dates in your calendars, and then we'll discuss them after it's been confirmed.

PARTICIPANT: Could you just repeat the

dates again?

MS. JAMERSON: Okay, so to confirm, the first option, March 23rd and 24th, and second option, March 30th and 31st.

DR. JADVAR: Okay.

MS. JAMERSON: Thank you. So the last portion of the administrative closing, I'll go over all of the new recommendations or actions that have occurred during the course of this two-day meeting.

So first, and please correct me if I have miscaptured anything, Dr. Palestro amended the membership of the training and experience requirements subcommittee. The subcommittee membership now includes Dr. Schleipman as the chair, and it is at the discretion of the subcommittee to allow Dr. Metter to continue to serve on the subcommittee.

Second, the ACMUI endorsed the medical event subcommittee report as presented. The ACMUI endorsed the appropriateness of the medical event reporting subcommittee report and the recommendations provided therein.

The ACMUI endorsed the evaluation of the extravasations subcommittee report as amended to note that under future revisions to Part 35 rule makings, extravasations be captured as a type of passive patient

intervention and the definition of patient intervention.

The ACMUI endorsed the Xcision GammaPod licensing guidance subcommittee report as amended to include the rationale that one, the written directive should include dose and frequency, and two, replace the chemical physical formula to describe the sealed source and not the device.

Dr. Palestro endorsed -- excuse me. The ACMUI endorsed the institutional memory subcommittee report as amended to include the recommendation that a complete list of ACMUI members be updated and added to the web page, and the subcommittee membership was amended to add Dr. Wolkov.

Dr. Palestro formed a subcommittee to evaluate the definition of patient intervention and other actions and circumstances that are exclusive of medical events. The subcommittee membership includes Dr. Dilsizian, Dr. Ennis, Mr. Sheetz as chair, and Mr. Bloom pending verification of his clearance, and the NRC staff resource is Maryann Ayoade.

MR. EINBERG: So, Ms. Jamerson, for this table here, when the subcommittee, or when the full committee endorses the subcommittee reports, wouldn't that close the action item? Why is that showing open?

MS. JAMERSON: Yes, it will close it.

MR. EINBERG: Okay, so in all of these instances where there has been endorsement by the full committee, then those will be reflected to be closed?

MS. JAMERSON: Yes.

MR. EINBERG: Okay.

PARTICIPANT: Can you scroll down, please?

MS. JAMERSON: Dr. Palestro amended the charge of the current bylaws subcommittee to determine, one, if there should be term limits for the ACMUI chair and vice chair, and if so, how long should those term limits be, and two, should the ACMUI vice chair automatically become the ACMUI chair?

The subcommittee membership was amended to remove Dr. Schleipman and to add Dr. Wolkov, who will chair this subcommittee, and the NRC staff resource has also changed from Sophie to myself.

CHAIRMAN PALESTRO: I'm not sure that I amended the charge. This is really a new charge. The original charge had to do with the chair of the ACMUI sitting on subcommittees. This is a completely different charge.

MS. JAMERSON: Okay, so a new charge for the existing bylaw subcommittee.

MR. EINBERG: Again, Dr. Palestro charged

the current bylaw subcommittee to determine, and then so forth and so on.

MS. JAMERSON: Thank you. One that was not added to this, but Dr. Palestro formed a subcommittee to investigate the need for an interventional radiologist on the ACMUI and whether a non-voting consulting member or a full member, to include whether a non-voting consultant member or a full member should be added to the committee, and to produce an interim report at the spring meeting.

The staff resource is Dr. Tapp, and membership includes Dr. Ennis, Dr. Dilsizian, and Ms. Shober as chair, and to consider Dr. Jadvar once he's on board as a full member. And lastly --

VICE CHAIR METTER: And I would also like to be considered for that committee.

CHAIRMAN PALESTRO: Dr. Jadvar?

DR. JADVAR: Similar to this, can I be considered for the T&E committee when I'm clear, just is that possible?

CHAIRMAN PALESTRO: That will be up to the incoming chair, yeah.

MS. JAMERSON: And lastly, the ACMUI tentatively scheduled its spring 2020 meeting for March 23rd through the 24th, 2020, and the alternate date

is March 30th, 31st, 2020.

MEMBER GREEN: Can we ask that, I really appreciated having the roster of members of the committee, if we could have that revised when new staff come and personnel rotate off? Could that be revised, and could we also have an amendment to that with the emails, and names, and phone numbers of support staff as well?

MS. JAMERSON: Yes.

MEMBER GREEN: Thank you.

MR. EINBERG: Ms. Jamerson, can we also close some of the -- or at least one of the open items that's coming to mind, the open item that indicated that at this meeting, we would have NNSA make a presentation? I think that should exclude that action since they presented today.

MS. JAMERSON: Yes, I think I closed that yesterday when I did the -- I mean, yes, yesterday --

MR. EINBERG: Okay.

MS. JAMERSON: -- since that was one of the recommendations from the spring meeting.

MR. EINBERG: Okay.

MEMBER ENNIS: I think we usually, at the end, run through all of the open things and close what can be closed based on this past meeting. Isn't that

our normal procedure?

I thought our normal procedure is that we run through everything that was open when we started the meeting and close off all of the things that through the meeting we closed as part of this, but maybe I'm not remembering.

CHAIRMAN PALESTRO: No, I think you're correct, Dr. Ennis.

MR. EINBERG: So can we go through the open items that are still pending right now, then we close, or are you not prepared to do that?

MS. JAMERSON: From the spring?

MR. EINBERG: Well, that were open at today's meeting. For instance, the NNSA was a good example.

MS. HOLIDAY: Just for clarification, when Kellee did her old business presentation yesterday, she went through all of the open items and you guys, my assumption, I wasn't here, I'm sorry, is that you guys discussed which items should be closed and so on and so forth, so that's already been accomplished.

So for the purposes of the administrative closing presentation, that's when Kellee would go over your proposed meeting dates for the next meeting as well as the new items that have been brought up during

this meeting.

So when you come back for the spring 2020 meeting, the chart where you have already closed the items that were from your spring meeting will no longer be on the table.

MS. JAMERSON: So did you want to start from the spring meeting?

MEMBER ENNIS: Maybe we don't really need to do this. I apologize.

MS. JAMERSON: Okay, well, that concludes my portion. I will turn it back over to Dr. Palestro.

CHAIRMAN PALESTRO: All right, thank you, Ms. Jamerson. Any other items that need to be addressed? Dr. Ennis?

MEMBER ENNIS: One more --

CHAIRMAN PALESTRO: Yes.

MEMBER ENNIS: -- thanks to Dr. Palestro for his excellent leadership of our committee, and the best of luck going forward. I hope we run into each other.

CHAIRMAN PALESTRO: Thank you very much. Thank you.

(Applause.)

CHAIRMAN PALESTRO: Thank you. Mr. Einberg?

MR. EINBERG: Yeah, on behalf of the NRC, I wanted to thank you once again, but I also wanted to thank the entire committee here for all of the excellent presentations, the excellent discussion. I know there's a lot of work that goes on behind the scenes and leading up to a meeting, and a lot of subcommittee work, and I look forward for the T&E report coming out of here shortly.

But I also wanted to thank the NRC staff, and as Dr. Palestro pointed out, there's a lot of work that goes on behind the scenes here as well leading up to these meetings, and this was Kellee's first meeting flying mostly solo, and I think she did a great job running the meeting here and with very few hiccups, so thank you, Kellee, and thank you to the staff.

CHAIRMAN PALESTRO: Again, it has been a pleasure and an honor. Thank you all. The meeting is adjourned.

(Whereupon, the above-entitled matter went off the record at 1:07 p.m.)