UNITED STATES

NUCLEAR REGULATORY COMMISSION

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PUBLIC MEETING ON THE DISCUSSION OF MEDICAL USES OF RADIOACTIVE MATERIALS

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TUESDAY,

JANUARY 28, 2020

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ROCKVILLE, MARYLAND

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The Commission met in the Commissioners' Hearing Room at the Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, at 9:00 a.m., Kristine L. Svinicki, Chairman, presiding.

COMMISSION MEMBERS:

KRISTINE L. SVINICKI, Chairman

JEFF BARAN, Commissioner

ANNIE CAPUTO, Commissioner

DAVID A. WRIGHT, Commissioner

ALSO PRESENT:

ANNETTE VIETTI-COOK, Secretary of the Commission

MARIAN ZOBLER, General Counsel

NRC STAFF:

STEVEN WEST, Deputy Executive Director for Materials,

Waste, Research, State, Tribal, Compliance,

Administration, and Human Capital Programs

KEVIN WILLIAMS, Deputy Director, Division of Materials

Safety, Security, State, and Tribal Programs (MSST),

Office of Nuclear Materials Safety and Safeguards (NMSS)

LISA DIMMICK, Team Leader of the Medical Radiation

Safety Team, MSST, NMSS

KATHERINE TAPP, PhD, Medical Radiation Safety Team,

MSST, NMSS

DONNA JANDA, Chief, Medical and Licensing Assistance

Branch, Division of Nuclear Materials Safety, Region I

EXTERNAL STAKEHOLDER PANEL:

MURRAY SHELDON, MD, Associate Director for Technology and Innovation, Center for Devices and Radiological Health, U.S. Food and Drug Administration

TERRY DERSTINE, Chair, Organization of Agreement States

THOMAS EICHLER, MD, President, American Society for Radiation Oncology

VASKEN DILSIZIAN, MD, President, Society of Nuclear Medicine and Molecular Imaging

JOSH A. MAILMAN, President, NorCal CarciNET Community

P R O C E E D I N G S

9:01 a.m.

CHAIRMAN SVINICKI: Well, good morning, everyone and welcome. I call the Commission's meeting to order this morning.

The Commission is convening in a public session to hear an update on the NRC's program for medical uses of radioactive materials, a status of recent activities related to the licensing and oversight of medical uses of radioactive materials, to hear the views of stakeholders on recent NRC initiatives and to discuss or hear suggestions regarding transformation and innovation opportunities regarding the Agency's work on this very diverse and important set of topics.

I look forward to the discussion. In preparation I discovered there were a lot of really interesting things in this area, and I do look forward to hearing from the external panel.

Our meeting will consist of two panels today. The first panel we will hear from the NRC Staff. They're seated at the table, and I'll turn it over to them momentarily.

And then after a very short break we will have a panel of external perspectives provided to us. Both panels will be followed by Q&A from members of the Commission.

But before I do turn it over to Mr. Steve West, on behalf of the Office of the Executive Director for Operations, do any of my colleagues want to offer any preparatory?

I think we were discussing in the back how interesting the topics are today, so I think we just want to dive right in with that. I will turn it over to you, Steve, to lead the Staff's presentation. Thank you.

MR. WEST: Thank you, Kevin. Radioactive materials, next slide please.

Today's panel will cover the following topics. Kevin Williams, the Deputy Director of the Division of Materials Safety Security State and Tribal Programs in the Office of

Nuclear Material Safety and Safeguards, will provide the status of the NRC Staff activities in the medical program.

Lisa Dimmick, the Medical Radiation Safety team leader will discuss innovation opportunities and initiatives in the medical program.

Dr. Katie Tapp, a medical physicist on the Medical Radiation Safety team, will cover the staff efforts to prepare for the review of emerging medical technologies.

And Donna Janda, the Branch Chief for the Medical and Licensee Assisting Branch in Region I, will provide the regional perspective on licensing and inspection of medical uses of radioactive materials.

I'll get us started with an overview of the NRC's program of medical uses of radioactive materials.

And next slide please. This slide shows the objectives of the NRC's medical use policy statement, which guides the work of the medical team staff and others here at the NRC.

The NRC regulates the medical uses of radioactive materials to protect the radiation safety of workers, the public and patients, all while minimizing intrusion into the practice of medicine.

Next slide please. According to the Society of Nuclear Medicine and Molecular Imaging, more than 20 million Americans, myself included, benefit each year from nuclear medicine procedures used to diagnose and treat a wide variety of diseases and other ailments.

Broadly speaking, the medical uses regulated by the NRC fall into two categories. Diagnostic and therapeutic.

Diagnostic uses usually involve small amounts of radioactive from imaging organ systems and functions, medical fields that use radioactive materials for diagnostic purposes, include nuclear medicine, nuclear cardiology, endocrinology and diagnostic radiology.

Next slide please. On the other hand, therapeutic uses of byproduct material usually involve larger amounts of radioactively to treat cancers and other alignments.

Each year there are approximately 150,000 therapeutic procedures performed using radioactive materials. Some examples of therapeutic uses include radiopharmaceutical therapy, teletheraphy, brachytherapy and gamma stereotactic radiosurgery.

Fields of medicine using therapeutic byproduct material include nuclear medicine, endocrinology, radiation oncology and interventional radiology.

With this wide range of medical uses, the NRC strives to maintain a 21st century workforce that can keep up with the evolving medical landscape.

We accomplish this by using the Agency's strategic workforce planning to keep our staff skills current and reflective of the wide range of medical modalities and uses. And by continuing to use expertise from the Regions, the Agreement States, the Advisory Committee on Medical Uses of Isotopes and other medical consultants.

I will now turn the presentation over the Kevin. Next slide please.

MR. WILLIAMS: Thank you, Steve. Good morning, Chairman, Commissioners. Let me start off with some recent activities in the NRC's medical program that involved a great deal of coordination and communication.

Next slide. The NRC Staff routinely engages with stakeholders to better inform our activities in order to ensure an effectively medical program at the NRC.

This list highlights some of the staff's recent activities that involve stakeholder outreach. In addition to these activities, the medical team is developing licensing guidance for several emerging technologies and working on rulemaking activities for Part 35.

Before I go into greater detail on each of these activities, I want to briefly discuss our ongoing coordination with the Organization of Agreement States, OAS, our Advisory

Committee on the Medical Use of Isotopes, ACMUI, and the U.S. Food and Drug Administration, FDA.

Thirty-eight Agreement States regulate approximately 91 percent of the U.S. Medical Licensees. And the Staff values the close coordination with the Agreement States in carrying out the radiation safety regulatory programs.

To achieve this coordination, the medical team works closely with OAS during activities such as rulemaking and a development of licensing guidance.

Coordination with the ACMUI is another vital part of the NRC's medical program. Through ACMUIs work on several topical subcommittees per year, the ACMUI advises the NRC on medical policy and technical issues.

And the Staff relies on the ACMUI's medical expertise to inform our decision making. The medical team also works with the FDA to coordinate our respective regulatory programs for medical devices, drugs and biological products containing radioactive material.

Examples of this work include updating the 2002 NRC FDA memorandum of understanding, conducting a workshop to share regulatory information and planning for an upcoming joint public information that will solicit stakeholder input on the Agency's continued coordination.

Next slide. One recent activity that involved a great deal of input from external stakeholders was the staff evaluation of training and experience requirements for radiopharmaceuticals. Over 250 comments were received from physicians, medical professional societies, patient groups and industry groups.

The Staff's regulatory decision making was strengthened by their consideration of their wide range of opinions on their training and experience requirements. The Staff's evaluation also included input from several individual Agreement States, OAS, the Conference of

Radiation Control Program Directors and ACMUI.

Lisa Dimmick will further discus the Staff's evaluation of training and experience for radiopharmaceuticals during her presentation.

Next slide. Another area of extensive stakeholder outreach relates to patient release. The Staff published a patient brochure, patient release brochure, last May to support radiation safety conversations between patients and their healthcare provider.

With regards to updating guidance for patient release, the Staff is taking a phased approach. Phase 1 focuses on updating the patient release instructions and considers an input from a wide spectrum of stakeholders, including the public, patients, patients' groups, physicians, professional societies, licensees, ACMUI and OAS.

The revised guidance incorporating the Phase 1 changes will be issued this spring. Phase 2 began last fall and will update dosimetric equations, methodologies and tables used to calculate dose to members of the public.

Next slide. An important part of the NRC's outreach is to communicate operational experience relating to preventing medical events through issuance of Generic Communications.

This slide shows four Information Notices that were issued last year. Three were associated with the use of specific radionuclides and one summarized the ACMUIs and Staff's evaluation of recent medical events. And strategies to reduce or prevent all types of medical events.

Next slide. On a related note, the medical team worked with the Office of Nuclear Regulatory Research to evaluate the abnormal occurrence, AO threshold, for medical events.

As part of this evaluation, the medical team reviewed the 55 medical event AOs

that occurred over the past five years. And found that only eight of these events had the potential for causing harm. More significant than acute radiation skin complications.

Based on a complete evaluation, the Staff concluded that the medical event AO criteria may capture events that are not significant from the standpoint of public health and safety, and recommended to the Commission that the AO criteria for medical events be revised.

This recommendation aligns with the ACMUI and Agreement States position on this topic.

Next slide. The last activity that I wanted to highlight is related to extravasations involving radiopharmaceuticals. Generally, an extravasation is the inadvertent injection of a medical fluid into tissue surrounding the vein or in artery.

An ACMUI subcommittee concluded that extravasation is a practice of medicine issue and not an item that needs to be regulated by the NRC. And that extravasation should not be considered a medical event unless there is an unattended permanent functional damage.

Considering ACMUI's recommendation and the interest from external stakeholders, the NRC Staff has begun an independent evaluation of whether extravasation of a radiopharmaceutical should be considered a medical event.

Additionally, the further consolidated appropriations act will require the Staff to provide a separate report to congress on this matter, this spring.

This concludes my presentation and I will turn it over to Lisa Dimmick. Next slide.

MS. DIMMICK: Thank you, Kevin. Good morning, Chairman and Commissioners.

As you've heard so far, the medical team has been very busy, and we've been looking for ways to improve our processes and look at them through a different lens.

Next slide. The first example is the Staff's evaluation of the training and experience. In response to stakeholder concerns regarding unnecessary regulatory burden of the NRC's training and experience requirements for radiopharmaceuticals requiring a writing directive, the Commission directed the staff to evaluate whether requirements could be tailored for difference categories of radiopharmaceuticals.

The Staff recently provided the Commission with SECY-20-0005, “Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material”. Which is dated January 13th, 2020 and was made publicly available on January 17th.

SECY-20-0005 documents the staff's evaluation and potential options for revising the training and experience, or T&E requirements. While the Staff does not recommend tailoring the T&E requirements, the Staff did use the evaluation as an opportunity to determine whether broader changes to the T&E regulatory framework could better prepare the Agency for the expected advancements in nuclear medicine.

The current T&E requirements are prescriptive. They set out a specific number of trainings hours, training topics and case work requirements that physicians must complete to become an authorized user for broad categories of radiopharmaceuticals.

Licensees must submit detailed information of their physicians training and experience. And the NRC and Agreement States must review and approval training and experience in order to grant authorized user status to a physician.

In a series of internal brainstorming sessions, the Staff considered how the existing regulatory framework could be changed to increase medical community involvement in determining the training and experience requirements. And in credentialing authorized users.

Next slide. During those brainstorming sessions, the Staff debated several variables related to determining T&E requirements and the overall regulatory framework for T&E.

The Staff then developed several options for revising the requirements. And later we published those options in a *Federal Register* notice for public comment.

The Staff's options fell under two general approaches. The first approach would maintain the current regulatory framework of prescriptive T&E and NRC and Agreement State review and approval for T&E of authorized users.

The second approach would be more performance-based. Authorized user credentialing responsibility would shift the medical community while the NRC and Agreement States would continue to focus regulation of medical Licensees on the safe and secured use of radiopharmaceuticals with varying levels of oversight of training and experience.

With the exception of maintaining the status quo, all of the options were transformative in that they involved relatively significant changes to the current regulatory paradigm.

The Staff evaluated their options through the lens of whether they were aligned with the Medical Policy Statement and the NRC's Principles of Good Regulation. The Staff also heavily weighed input from the medical community, the ACMUI and the agreement statements.

Next slide. The Staff's paper provides a balanced view of these options as our goal was to fully inform the Commission's policy decision.

The option that the Staff recommended for Commission consideration, is one that shifts more responsibility for credentialing authorized users to the medical community, while the NRC and Agreement States maintain oversight of T&E through recognition of medical specialty boards that demonstrate their training programs meet certain high-level performance-based radiation safety competency requirements.

This would be a significant change in the current T&E paradigm because recognized specialty boards would credential authorized users. The NRC and Agreement States

would no longer review and approve training and experience for authorized users. And authorized users would no longer be listed on the medical user license.

This transformative approach for T&E could better prepared the national materials program for the expected growth of nuclear medicine and the potential for increased radiopharmaceutical use in different fields of medicine.

Next slide. Another area that we are looking to transform is our process for reviewing emerging medical technologies.

With the growth in medical applications of radioisotopes and advancements in medical technologies, it's anticipated that an increased number of emerging medical technologies will be licensed by the NRC. And many of these technologies may not fit under the current regulatory framework.

As a result, we've looked at our current review process, which takes about 14 months to complete, and decided to improve our internal process to gain efficiencies.

With our new process, instead of individual working groups reviewing each medical technology, we would have the licensing guidance developed by a medical team individual with support from a sealed source and devise reviewer or other technical staff as necessary.

We would then have a standing committee, which we would review and comment on the draft licensing guidance documents. The standing committee would include representatives from the Regions, Agreement States, the Office of General Council.

The standing committee would provide oversight to this process, provide more flexibility and agility by prioritizing reviews and shifting resources as necessary. And introduce better consistency across all 35.1000 guidance documents.

This new process does not change the step where we get comments from the

Regions, Agreement States and the ACMUI, as this is an integral part of our guidance development.

We estimate that this new process will result in a six month time savings and better utilized resources across the national materials program. We have socialized this new process with the Agreement States, and they view it as a good streamlined alternative to what has been done in the past, while maintaining comprehensive review and input across the national materials program.

This concludes my presentation, now I'll turn it over to Dr. Tapp.

DR. TAPP: Thanks, Lisa. Good morning, Chairman and Commissioners. In recent years we have seen an increased use of emerging medical technologies, so I'm going to discuss the efforts by the Staff to prepare for these reviews.

Next slide please. The NRC amended 10 CFR Part 35 in April of 2002 to add Subpart K. Which is also known as 35.1000.

This regulation was added to allow for efficient licensing of expected new medical users that are not specifically addressed in other subparts.

The addition of 35.1000 was forward thinking because it provides for flexible regulatory framework for emerging medical technologies, which allows us to conduct licensing process in an efficient and consistent manner avoiding delays in patient care.

Since 2002 we have used 35.1000 to license over ten emerging medical technologies. Without 35.1000, each of these technologies would have required rulemaking, which would have likely significantly delayed patient care.

Next slide please. Applications for new emerging medical technologies are evaluated by the NRC on a case-by-case basis. The significant number of new medical technologies fit into Subparts D through H.

However, if the emerging medical technology is not addressed in these parts, the Staff will develop the specific licensing conditions that are considered necessary for the medical uses of these materials for 35.1000. These specific licensing conditions are listed in licensing guidance documents which are posted on the NRC's medical uses licensee toolkit website.

The first 10 CFR 35.1000 licensing guidance was issued in 2002 for Yttrium-90 microsphere brachytherapy. If the emerging technology is addressed in Subparts D through H, there still may be a unique radiation safety aspect of the new technology that Staff may have to assess and provide additional information for licensees in Regional and Agreement State awareness. This information is also posted on our website.

Next slide please. The earlier we learn of emerging medical technologies the better we can predict our workload and ensure that we have the right regulatory infrastructure and workforce in place. Staff works closely with these stakeholders listed on this slide, who may become aware of the technology before us.

The Staff also continues to work closely with these stakeholders in the development of the 35.1000 licensing conditions and guidance.

Next slide please. Now I'd like to switch gears and discuss some of the emerging medical technologies. First are the Yttrium-90 microspheres. These are manual brachytherapy sources used for permanent implantation therapy.

However, they could not be licensed under the traditional 10 CFR Part 35 subpart for manual brachytherapy because of their unique properties. Such as their small size, the large number of microspheres used per administration and the route of administration.

Therefore, Yttrium-90 microspheres brachytherapy is regulated by 35.1000. While Yttrium-90 microspheres brachytherapy has been around for decades, their use has been

limited to two types, TheraSpheres and SIR-Spheres. And the licensing guidance is limited to their use.

However, we are now aware of several new manufacturers that are in the developing other microspheres and microparticle devices. So Staff is preparing to do another revision of the licensing guidance to make it applicable to the other manufacturers.

Next slide please. Another area where we have seen an increase in new technologies in Gamma Stereotactic Radiosurgery, or GSR units. The original regulations in Subpart H have been developed for Leksell Gamma Knife. Which treats the brain using stationary sources, helmet collimators and a head frame.

However, newer units are significantly different than the original gamma knife units. For example, the Leksell Gamma Knife Perfexion and Icon illuminated helmets, use sources in moveable sectors and has a frameless treatment option for the Icon.

Therefore, these GSR units are licensed under 35.1000. The initial guidance for the Perfexion was published in 2007 and it was updated in 2016 to add the Icon.

In recent years, Staff has become aware of several new GSR units, including the GammaPod. Which we issued guidance for earlier this month. And for the Infinity, which we are in the process of developing 35.1000 licensing guidance for.

Similar to the Perfexion and Icon, both of these units have engineering changes that are not covered in Subpart H, like moveable sources and collimators. The GammaPod is also the first cobalt-60 GSR unit not to treat the head, but instead used for treatment of the breast.

We have also been made aware of several other GSR units, such as the Galaxy, Orbiter and Vertex. Which we may develop 35.1000 licensing guidance for in the future.

Next slide please. So as you can see, there are more GSR devices coming onto the market and more manufacturers entering the field in microparticles and microspheres.

With the anticipated growth, development of a performance-based regulation incorporating these modalities would allow for future GSR devices and microparticles to be licensed without further NRC and Agreement State review.

To respond to the evolving medical landscape and further streamline or licensing process, we are looking to update Part 35. We have begun an effort to primarily bring in the modalities currently licensed under 35.1000 to be licensed under other subparts of Part 35.

We have chartered a joint NRC, OAS working group to develop rulemaking plans and emerging medical technologies. The working group has regular meetings on this and plans to submit a rulemaking plan this summer.

Next slide please. Another emerging medical technology of interest is the Alpha DaRT. Or Diffuse Alpha Radiation Therapy. Which uses alpha particles to treat solid tumors.

The treatment is similar to other manual brachytherapies as it has small radioactive seeds that are implanted into the tumor. However, the Alpha DaRT seeds contain radium-224, which release gaseous, short lived alpha emitting daughter products into the tumor as it decays. It is these daughter products which travel inside the tumor to deliver the therapeutic dose.

In 2018, the State of Massachusetts granted the sealed source and device approval which enabled the manufacturers to begin clinical trials with this technology. The Staff has started its evaluation and is expected to begin development of the 35.1000 licensing guidance document this year.

We are hoping to be able to use the new emerging technology review process that Lisa just mentioned.

Next slide please. Another new technology we are currently reviewing is the

check-cap C Scan system. This new diagnostic technology uses an ingestible capsule containing byproduct material to stream for colorectal cancer using imaging.

The manufacturer states that this technology does not require as much preparation like you do for a colonoscopy. But instead, allows the patient to continue with their normally daily routine as the capsule travels through their gastrointestinal track to scan for polyps in the colon.

The Staff has just begun its review of this technology and has not yet made a determination whether it should fall under Subpart G or 35.1000. The Staff is closely evaluating training and experience and waste disposal considerations to help make this determination.

Next slide please. In addition to medical uses, our team also reviews the use of radioactive material in veterinary care. And we have begun seeing an increase in this area.

Historically, the most common veterinary procedures involving radioactive material have been with cats, who are treated with iodine-131 for hyperthyroidism or horses, and horses, who are treated Technetium-99m for imaging.

However, more recently, we reviewed requests for authorization for more types of veterinary uses. Including treatment for osteoarthritis in dogs using tin-177m and solid tumors in household pets using Yttrium-90 particles.

Next slide please. 10 CFR 35.75 provides the public dose limits and the requirements for release of human patients, not animal patients, containing byproduct material found in treatments.

In the case of veterinary uses, the release of animals must comply with the public dose limits set in 10 CFR Part 20. Our current guidance in NUREG-1556, Volume 7, is pretty specific to the treatment of cats using iodine-131.

And Staff, in its early stages of drafting a regulatory guidance to support the

development and review of the release of animals following other veterinary procedures using byproduct material.

This concludes my presentation and I'll turn it over to Donna Janda.

MS. JANDA: Thank you, Katie. Good morning, Chairman and Commissioners.

Regional Staff continue to serve an important role in support of the Agency's mission. By performing radioactive material safety and security inspections and licensing activities from medical facilities.

Today I'll be discussing how we implement the Part 35 rule changes and inspect patient release and medical events while maintaining effective coordination with licensees, Agreement States and headquarters.

Next slide. As you heard earlier, recent changes in Part 35 have been of interest among internal and external stakeholders.

Amendments to the rule that the Regions have been addressing during licensing and inspecting our facilities include the removal of the training and experience requirements to obtain a written attestation for an individual who is certified by an NRC recognized specialty board, an exemption of certain board-certified individuals from certain training and experience requirements.

In addition, the new Part 35 introduced the concept of the allowance for licensees to name Associate Radiation Safety Officers, or ARSOs on a medical license. ARSOs support the licensee's radiation safety officer with specific duties and tasks assigned to each ARSO as determined by the licensees needs in each ARSO's qualifications.

In general, licensees have not raised significant concerns to the Regions as they implement the regulatory changes and appear to be pleased with the new requirements.

Specifically regarding information required to be submitted for board certified individuals.

This decision has already saved resources for external stakeholders and for Regional licensing staff. However, licensees have noted challenges in the licensing process. Including the current inability to use the standard NRC 313A forms to document training and experience.

As an update to that, we have recently received the Office of Management and Budget approval on the updated forms. And these will be available on the public website shortly.

So that should help licensees have a quicker experience with getting that training and experience documented.

In addition, some confusion exists among licensees regarding the specific requirements involved in the naming of an Associate Radiation Safety Officer.

Specifically, Regional license reviewers have received several questions regarding whether or not licensees may name their own ARSO, they cannot, whether or not the ARSO can be named for only one site, and they are to be named by type of use and not site, and whether or not they can have more than one ARSO, which they can.

These types of issues were addressed with issuance of supplemental guidance for NUREG-1556, Volume 9, Revision 3. Which is accessible from our website, as shown on this slide.

Note that licensees appear to be pursuing the option of naming Associate Radiation Safety Officers. To date, the Regions have approximately 20 active licenses with the Associate Radiation Safety Officers named in licensed condition.

Next slide. Regional inspectors use various methods to assess if patient release is in accordance with regulations. The written directive, patient instructions and patient release criteria calculations are part of what are typically reviewed during an inspection.

For instructions, we want to see that the licensee has presented applicable restrictions to the patient, that the patient has signed their indication of understanding these restrictions and that they consent to abiding by the instructions.

Regarding patient release criteria, this includes whether they are released based on administrative activity, dose rate surveys or patient specific release criteria. If patients specific release criteria are used, we will evaluate how the licensee interviews patients to make sure they can meet their criteria, and that they use the appropriate occupancy factor.

Regulatory Guide 8.39 is a resource we use to make sure the licensee's criteria and instructions conform to guidance. Although several isotopes are not included in the appendix, such as lutetium-177, licensees can develop their own independent values for patient release.

In the case of lutetium-177, the dose rates are such that patients can generally be released after half a day at the hospital. A revision to our guidance is underway to further evaluate release criteria.

Next slide please. Medical events are defined Part 35 and include instances where doses over a certain threshold are incorrectly administered or other issues occur as described within the regulations. Licensees are to notify the NRC Operations Center no later than the next calendar day after discovery of the medical event.

Since the medical event may indicate potential problems in a medical facility’s use of radioactive materials, our prompt review of a reported event includes assessing the licensee’s applicable policies and procedures and the written directive related to the medical procedure that resulted in the event.

We also interview the staff involved in the treatment to help us construct a timeline and identify what went wrong. On the right side of this slide I am shown at a facility in

Puerto Rico at which we reviewed an event involving a patient overexposure to iridium-192 during a high dose-rate remote afterloader treatment.

In that case, we determined that the licensee had failed to develop or implement an adequate written procedure to provide high confidence that each administration was in accordance with the written directive.

We don't only react to reported medical events, but we also ask the licensees during inspections if they have had any medical events. We then independently verify licensee responses by reviewing treatments against written directives and ensure that licensees have a policy and/or procedure in place to identify medical events.

Multiple events are reported throughout the national materials program this past year involving administration of Y-90 microspheres.

In 2018, Idaho National Labs published the review of ten years of data on such treatments and found that an increasing trend in Y-90 events could simply be the result of an increasing number of microsphere treatments being performed. The majority of such events involve patients receiving less than their prescribed dose.

Next slide please. Much of the coordination with our Agreement States is led by our Regional State Agreement Officers as they regularly support the Agreement States with technical, process and regulatory advice, including advice on the revisions to Part 35.

Notably, the Agreement States have until January 14th, 2022 to implement changes in their own regulatory programs for compatibility with Part 35. And we stand ready to support them in those efforts.

In terms of coordination with headquarters, Regional technical Staff actively participate in working groups devoted to developing guidance for new devices, such as the GammaPod and Infini gamma stereotactic radiosurgery devices and for emerging technologies.

Regional expertise and directly licensing and inspecting medical and research and development applications make these types of projects ideal for cross-coordination between the Regions and the NMSS medical safety and events assessment branch.

This concludes my remarks. I will now turn it over to Steve for closing remarks.

MR. WEST: Thank you, Donna. And thank you to all of the Staff on the medical radiation safety team and NMSS, the Regions, OGC, and others across the national materials program who contributed to the work we discussed this morning. And who helped us prepare our presentation.

And finally, thank you to the Commission for an opportunity to brief you on our activities in the medical arena. And we now look forward to your comments and questions.

CHAIRMAN SVINICKI: Well, thank you very much, Steve, and to all the presenters. And again, thank you for that acknowledgment that the work you're presenting on today is supported by a lot of your colleagues here at the NRC. So we thank them all as well. Some of them are probably in the room, others are probably busy at their desks working on the things that you're here talking about today.

But, Steve, if you thought that perhaps we would get through this morning without making some acknowledgment of the fact that you have indicated, and I believe I have confirmed that you have announced to the broader world that you will be separating from federal service, I think retirement.

I hesitate to use that word because I see so few of you and your peers that actually end up kind of going and sitting and relaxing. You tend to have a lot of personal interest in other things that you and your family want to pursue together, so I'm confident it will be a very active retirement, if it is one.

But on behalf of the Commission, and I suspect others will weigh in before they

begin their questions, but on behalf of the Commission, and really just on behalf of, I think the Federal Government, thank you for your long public service, the many contributions that you've made here to the Nuclear Regulatory Commission.

And I won't say that we scheduled this just to make sure that Steve had to sit through one more Commission briefing. You and all NRC Staff are always so respectful by saying it's so great to be able to come and present to the Commission at these meetings.

I'm sure it's not your favoritest thing but thank you so much. And, again, you occupy and will be retiring from, that really, I'll just be honest, horrible title, which I'll read for everyone. Deputy Executive Director for Materials, Waste, Research, State, Tribal Compliance, Administration and Human Capital Programs.

And I believe only Kevin is up here with a title that rivals that a little bit with his division. So I think we could maybe be a little more transformational to figure out some umbrella term that could house all those terms.

But again, thank you very much for all you've done here. And there will be many other recognitions and acknowledgment as your departure approaches.

Another thing, which a lot of NRC Staff wish they could just kind of exit quietly, but they have to be subjected to all kinds of recognitions and roasting. I guess if they've done the wrong people wrong over the course of the years that have to listen to people tell stories about them and stuff like that. But thank you very much.

And I, you know, I want to say, I hope you feel good about what we're talking about today because I think as I was kind of looking at what's been happening in recent months on a lot of these very important topics I notice that I think quietly this area is joining in some of our innovative and transformational thinking.

And I hope that everyone, and the teams that they work with, are gratified

because on, you know, Lisa talked about the looking at our approach to the T&E and I, you know, the paper is interesting because it has this enclosure. Which I really enjoyed but found unique.

And it's like, we were so innovative that we came up with so many different possible approaches to the regulation here that some of them are just in an enclosure because they really weren't worthy of being pursued. But to me it isn't so much about where you land in an innovation or transform exercise its about how wide of a net did you cast.

And I was deeply impressed by really the stepping back and looking at, given the state of some of the medical practitioners, the modalities, the different things going on, were there other ways that we could try to look over the horizon and think about how the regulation could be very robust.

And continuing on, Katherine a bit, in talking about Part 35.1000 and not wanting to have over the course of time, and I learned this phrase from Chairman Steve Burns, but I know all lawyers learn this, I don't have any formal legal training, but this notion of the exception swallowing the rule, you know.

If everything kind of lands under the part of the rule that everything that doesn't fit in Subparts D through H. At some point you want to step back and look at Part 35 broadly in the review of the emerging medical technologies.

But I did note, also Katherine, in your presentation you said, that significant number of new nuclear, new medical technologies still fit into those subparts. And then you kind of, at the end of your presentation you talked again about how, I think it was the Yttrium-90 microspheres she said, now we've got a lot of kind of brachytherapy that could fit more traditionally but then we look at engineering changes.

We look at maybe the way that the technology is applied to the patient and then it doesn't quite fit. And it ends up back again in the exceptions.

But what I take from your presentation is this broader look at updating Part 35, is going to look at that. And you don't want to have everything fall into the everything else category.

But that being said, you also, as Lisa was emphasizing, as things are so emerging in this technology and this area of medical practice, you want to be able to have it be kind of robust. And I don't know if either of you would like to talk about how you have to kind of balance those two things. Katherine, do you want to start?

DR. TAPP: Sure. It is a balance, as you mentioned. And the first thing we do with all emerging technologies is we compare, rule-by-rule, every regulation in that subpart to see if it fits.

And if something is a safety aspect that does not fit, obviously we have to move it into 1000 to do the licensing conditions. So it really is a safety focus.

The other aspect is, if it does fit but we notice there's something that might be missed by a Regional or Agreement State license reviewer because they're not doing as deep of review when they first come out, that's when we'll issue a memo just to alert them as guidance.

There's something that's unique about this that fits, there's a regulation covering that, but we want you to be aware just to make sure you know it's there and something to be looking for.

CHAIRMAN SVINICKI: Thank you. And, Lisa, do you want to talk a little bit about how you did such a broad canvassing for various options for approaches on the T&E look?

MS. DIMMICK: Sure. We were trying to, in the approach, not already have decided what the outcome was going to be. So we stayed --

CHAIRMAN SVINICKI: That's refreshing.

(Laughter.)

MS. DIMMICK: So we stayed very open to really thinking outside the box. I think we started with, if we did not have the Part 35 T&E regulations and we were crafting them from the beginning, what would they look like.

So we went through a number of exercises trying to think in those terms as well that if we were to create new regulations from scratch, how would we frame them. So I think that's why we were able to stay in that mind set.

And along the process, we would often get, so where do you think you're landing, so where do you think you're landing with regard to your recommendation. And the team that was working on this was like, we're not there yet, we're really trying to be very thorough and consider a spectrum of activities.

We looked to the international front on how do other countries regulate training and experience over physicians or something similar to this.

We evaluated the medical event reporting. Impacts maybe that training and experience may or may not have in that area.

And then we just really evaluated the tasking and what could we do if we were to do a limited scope authorized user. How would that really look.

So, we identified that the medical field is expanding, it's changing. We're hearing a lot of radiopharmaceuticals therapies coming down the pike. They're not routinely administered yet, they're undergoing FDA clinical trials.

But they will be in the future. So we wanted to identify, are our regulations inclusive of these new technologies that might be coming down the pike.

So if we have an opportunity to look at training and experience, how might we prepare ourselves for the future of nuclear medicine. And that was really how we continued in our process.

CHAIRMAN SVINICKI: Well, thank you. And again, hearing those responses, I want to emphasize that it is important that we do have kind of a .1000 or a process where we can take something genuinely and sincerely new. To modify a rule is, of course, not a quick process and so that needs to exist.

What I was commenting more on is that you'd like to have your regulations. At least have swim lanes for the general types of technologies that we're talking about.

And I see the updating of Part 35 is going to look at those swim lanes. And then complemented by the general lane through which other things go if they don't fit into one of the narrow lanes.

But again, I hope that as things, the Staff has an opportunity, as they did on the T&E requirements, to back up and go through that exercise. I hope they found it as gratifying as I found to read about it.

And as a decision maker, I'll just end with this, I've read the paper, I have not formed any view on your recommendation or the other options that you looked at. But I am always reminded in this subject matter area that I approach it with some level of humility.

I'm human being so I'm just, I'm trying to kind of invest my decision making with the best insights that I can have. So knowing that the Staff looked broadly is something very helpful as a decision maker to know that you cast a wide net because you are more expert in the area.

But this area I approach with humility I guess for two reasons. One is its complexity and it is dynamic. But the other is, of course, the fact that this area of our regulation can have such a direct subject, could have such a direct impact on individual, you know, Americans, their families.

And so, not that there is an importance in all of the applications of nuclear

materials that we regulate, but there's something about the directness on human beings of this work that makes it something. That I always kind of approach it that way.

I'm sure we'll hear some perspectives from the next panel about, so it's awkward since we haven't heard that yet, but I think the Staff has awareness of the materials provided in advance, as do I. And I know that they'll be, I think probably some hunger in patients that maybe we could make a bit more dramatic changes.

But I think it's going to be hard because it's not, we're not just covering any particular one case, we've really got to have something very broad and it is interesting.

I've stepped back and challenged myself to say, is there a point in time in which the fit of the mission of the Nuclear Regulatory Commission, with these materials, doesn't fit so well and they're becoming more biologically based or there's just, medicine is changing so much and it's we think that nuclear power has changed a lot. In 40 or 50 years medicine has changed a lot more than power production. At least by my assessment.

So, the notion that Congress at some point may want to look at the division of responsibilities. I respect that, but right now I think we can separate out the radiological part of it and address it.

I hope that, I know this Commission will always be sensitive to hearing perspectives that feel that maybe that's becoming an imperfect fit, but I don't think it's happening today. I hope future commissions will stay sensitive to just wanting to make sure that patients that need care are getting the best care, but also have access to these important new technologies.

And I'm going to give my last few seconds to Steve because I didn't give you a chance to react to my big public statement about your service here.

MR. WEST: That was unexpected, but I certainly appreciate it, your very

generous comment. It's been my pleasure to work at the NRC, to serve the public.

And to answer the one question you kind of fit into your comments, I do appreciate what I heard today and what we're doing as an agency, as a public servant, an employee of the NRC and as an aging American that expects to be using some of these technologies.

And I really can't think of a better subject for my last Commission meeting to be sitting at the table. Because it gave me an opportunity to hear about all the good work that's being done at the national materials program led by our Staff here at the NRC.

And some of the things you're hearing about today where we're transforming innovating things, trying to keep these technologies moving and available to the public is very gratifying. Very, I'm sure you'll feel the same way.

But I really appreciate learning more about it. And I think I'll be using some of those, so, thank you very much.

CHAIRMAN SVINICKI: Okay, thank you. And with that, I will turn it over to Commissioner Baran.

COMMISSIONER BARAN: Thanks. I'd like to start with some follow-up questions about the Staff's rulemaking recommendation on training and experience requirements.

As Staff discussed earlier, a physician can become an authorized user either by being certified by a medical specialty board recognized by NRC or by completing 700 hours of training and experience.

And the Staff has, was discussed earlier, is proposing essentially to drop the alternate pathway of 700 hours while potentially expanding the number of recognized specialty boards. Do we have a sense of how many additional medical specialty boards would want to develop a certification process, have any expressed interest to us?

MS. DIMMICK: So, Lisa Dimmick, I'll respond to that. So, we do not have an idea of how many new medical specialty boards might be interested to use, that would come in under the revised specialty board criteria.

We know there are physician groups or types of physicians that are interested, but in and of themselves they're not a board requesting to become recognized as a specialty board.

COMMISSIONER BARAN: Well, as I'm thinking through the various options, and I agree with the Chairman, I thought the Staff did a very good job laying out a bunch of different options, it seems like for the recommended option this is pretty key. Because if NRC didn't end up recognizing any additional medical specialty boards, maybe because they weren't interested, but still dropped the alternate pathway, couldn't that make it hard to become an authorized user than under the current framework?

Because there would be just the medical specialty board route, not the 700 hours. And if you don't add any additional boards to that route then it's actually narrower.

MS. DIMMICK: So, currently with the alternate pathway, we looked at who uses the alternate pathway. And we identified in our initial assessment that physicians using the alternate pathways are many, are ones that are waiting or are board-eligible so they have not yet taken the board examination but they intend to take the specialty board examination. Or they might be a foreign trained physician who is using the alternative pathway.

So we had identified through, in our assessment, that through the ANPR, the Advance Notice of Proposed Rulemaking, that these were things that we would further vet. And I identify how, the scope of that issue.

And we needed the medical community involvement for that as well.

COMMISSIONER BARAN: Okay. Under the Staff's proposal NRC would no

longer review and sign off on the training and experience of authorized users and authorized users would no longer be listed on the license. And that would eliminate about 2,500 license amendments each year.

It's not clear to me though that the current practice is the only possible method of confirming that the training experience requirements are met for an authorized user. We don't use that approach, for example, for reactor operators. They aren't listed on the license.

Why do we do it this way for authorized users?

Is there a reason that the authorized users need to be listed on the facilities license, even if we stick with a 700 hour alternate pathway, couldn't we have a system where a licensee, a facility licensee kept a list of physicians that met the T&E requirements in that list and supported documentation would be inspectable by NRC?

MS. DIMMICK: So, Lisa Dimmick. To answer that question, authorized users, by their definition in Part 35, are a physician or a dentist or a podiatrist, depending on where they fit, under which modality.

But they're a physician who is listed on a Commission or Agreement State license. So the regulations for the definitions of an authorized user include that they are listed on a Commission license.

COMMISSIONER BARAN: Is there some reason for that though?

I mean, again, if we were talking about changing the rule, is there some reason not to depart from that?

Because if I think about the different options available, one option would actually to be to keep the current structure of the specialty medical boards, the three of them, and the 700 hours, but not verify them the same way if what we're doing now is super labor intensive and different than what we do in other areas of NRC's jurisdiction. Do you see what I mean?

Is there some reason, either historically or practically, why listing folks individually on the license is really critical?

And I ask that as a genuine question. Maybe there is and I just don't know what it is.

MS. DIMMICK: Again, with the way the regulation is written with regard to identifying that an authorized user is listed on the license, the historical part of Part 35 of how that was included, they had historically been listed on the listed.

COMMISSIONER BARAN: I see John Lubinski standing up, and I'm interested to hear him chime in --

MS. DIMMICK: Yes.

COMMISSIONER BARAN: -- but I just would kind of point out, when I read the paper, and you did a great job laying out all the options and pros and cons, so many of the benefits of the recommended approach flowed from moving away from the license amendment approach.

But that actually seems like kind of a separate issue. You can move away from the license amendment approach and not drop the alternate pathway. That's why I'm kind of asking about this, trying to figure out, is this really just actually another option you could have in the option paper.

MR. LUBINSKI: Thank you, John Lubinski, Director of Nuclear Material Safety and Safeguards.

If I could add to Lisa's comments. Distinguishing between being listed on the license and doing the review, I think the more important part where Lisa was getting to is, today it requires the NRC to do the specific evaluation of the individual against the alternate pathway. So it's the evaluation that's being done.

Whether or not they end up being listed on the license or not, it's the issue of

whether or not NRC does the evaluation and is the person, for lack of a better term, the competent authority to do the evaluation of that user and whether they met the 700 hours or not. And that would be for the NRC reviewer or the Agreement State.

It's very efficient from the standpoint of that prescriptive nature that allows us to do it in a very efficient way, even though we're doing so many authorized users a year. The concept you're talking about, I think, really starts to align with either the current option that the Staff is recommended or some variation of it where another group does that evaluation.

And I this space we would say, some medical board that was approved by the NRC that we found that they had the appropriate authorization to do that.

In interpreting your question, I would say you're leaning more towards having an authorized user or the licensee themselves continue to identify additional authorized users where we could do that. That could be a next level down from the recommended option that's discussed with a medical board.

Instead having licensees authorize their own medical, own authorized users without going through an NRC review, we would review their programs. And that was an option that came out during the brainstorming session, to allow licensees, authorized users, to then subsequently review additional authorized users.

COMMISSIONER BARAN: Well, and I want to turn to another issue. I want to ask about patient release too.

But that was also another option that was identified, having it more turned over to the licensee. I could see some distinctions between what I'm talking about that, but again, thanks for the additional context.

On patient release, NRC's current regulation requires authorized users to provide post-treatment instructions to a patient before the treatment and early enough to give the

patient adequate time to make any necessary arrangements for isolation.

But the Staff notes in a paper that came up, I think last year, that the dominate factor in determining internal and external doses to members of the public is based on the behavior of the patient after release.

In other words, if a patient follows the doctor's instructions, their family members and members of the public should be able avoid a dose higher than the regulator limit of 500 millirem. But if the patient doesn't follow the instructions, a family member or someone else could get a dose higher than the regulatory limit.

That's a lot of responsibility to place on patients. And obviously the patients themselves are not subject to any NRC requirements so we have no control over their behavior.

Again, kind of looking at it from a high level, does it make sense for NRC to rely on patients following a doctor's instruction to protect members of the public from doses of radiation?

Would it make more sense to think about requiring inpatient care in circumstances where family members or members of the public could get a dose higher than the regulatory limit if a doctor's instructions weren't followed?

MS. DIMMICK: So, Lisa Dimmick. We believe the regulation is adequate to protect public health and safety.

The regulation to radiation exposure we believe can be safely controlled with the current regulation use of calculations to assess exposures to the general public for release of the patient as well as the patient instructions.

What we're doing, we're enhancing those instructions through issuance of the brochure that we developed specifically for the patient and then also with the update to our guidance document to enhance the instructions before, during, and after the patient care.

COMMISSIONER BARAN: Taking step back, I appreciate the importance of the instructions and I obviously am not dismissing the importance of the physicians providing the advice and the instructions to patients.

But I guess what I'm trying to get at is a little bit of a higher-level question of in the end, we're really relying on the patient following those instructions to protect members of the public, and their family members could be kids, from doses that would exceed the regulatory limit.

Does that make sense? The Staff's review found that family members of patients treated with iodine-131 on an outpatient basis received doses between 4 millirem in 1330 millirem.

So, many of the family members are receiving doses much lower than the regulatory limit of 500 millirem but some are receiving doses much higher.

The highest dose of 1330 millirem was to the child of a patient and the NRC Staff noted in the paper that whether the patient is a child or a parent, close contact for extended periods may be unavoidable. That's particularly true for families with limited means who may be living in small spaces.

What are we doing to address those situations? If it's not practical to avoid close contact with a family member at home, especially a child, the outpatient approach seems problematic.

MS. DIMMICK: So, again, the regulation is a performance-based regulation in the sense that the physician or the licensee needs to determine or assess whether or not they have confidence that the patient will be able to follow the instructions.

So, in that sense, that should be factored in the release decision of that patient. The outpatient therapy aspect is the performance-based, for the rule.

The current regulations don't preclude hospitalization so if a physician feels that

the patient cannot meet the criteria or they have a post-treatment living condition that they could potentially exceed, a member of the public could receive more than the 500 millirem, then they should not be releasing them from their control.

COMMISSIONER BARAN: Let me just ask one quick one. I don't know how quick it is but I'll just ask one more question.

The 500 millirem regulatory limit for patient release is 5 times higher than the general dose limit of 100 millirem to members of the public from other sources of radiation. What's the basis for that differential?

Why is there a higher limit in this case than for all other types of sources? Have ICRP or NCRP supported a 500 millirem dose limit for members of the public in the context of patients treated with iodine-131?

MS. DIMMICK: So, ICRP and NCRP have in their documents, their standards, a 100 millirem public dose limit. However, they also describe or provide for a different limit for the family members or caregivers of the patient.

So, for NCRP that's 500 millirem and for ICRP they use some conditional constraints so it could be higher than 100 millirem.

So, with that said, again, with our regulations in a situation where a patient could exceed 100 millirem, they are to be provided written instructions on how to keep their exposures as low as reasonably achievable.

So, that's a control that we have in our regulations to further ensure that patients will keep exposures ALARA with those written instructions.

So, we're not completely dissimilar from ICRP or NCRP in that regard because they have separate limits for the public, family caregivers, and then also women and children. Whereas, our patient release limits are for all members of the public, to include the family

members.

COMMISSIONER BARAN: Thank you.

CHAIRMAN SVINICKI: Thank you, Commissioner. Commissioner Caputo?

COMMISSIONER CAPUTO: Good morning, I would just like to add my congratulations to Steve. It's a distinguished career, there are I think two main ways to approach retirement and that is, gee, what am I going to do, or, gee, what am I not going to do.

Considering your distinguished career, I'm sure you're in that second category and I encourage you to embrace it on behalf of the rest of us, who will be here plugging on after your departure.

MR. WEST: Thank you.

COMMISSIONER CAPUTO: Kevin, I think I'd like to start with you and maybe Lisa.

There was a recent assessment done on safe use of Yttrium-90 -- maybe Dr. Tapp as well -- which included a trend analysis for Yttrium-90 medical events for a ten-year period. And this resulted in development of an Information Notice.

Can you just help me understand how do you make a decision whether to conduct this kind of a trend analysis, how many events do you look for, is there a process for discerning what triggers this kind of analysis.

And then once you have that analysis, what's the framework for making a decision to issue an Information Notice?

MR. WILLIAMS: So, I do think that question is better answered by Dr. Tapp.

COMMISSIONER CAPUTO: Sure.

DR. TAPP: Thanks, Kevin. We do have a process to trend medical events. The NRC Staff evaluates medical events on an annual basis, as well as the ACMUI does their

own separate analysis on an annual basis.

With that trending, we look at past events and look at the number going up. For Information Notices, that's a little bit more when we notice something that we believe should be spread, something occurred that we believe could be prevented and maybe not other individuals aware of.

So, we presented four Information Notices at the MBIG event where there was a patient that was contaminated. That was something new that we've never seen before and was significant so we issued an Information Notice on that one to shed awareness to other licensees to be aware.

But the Yttrium-90 Information Notice, that was found and recommended from our ACMUI trending review. So, when they reviewed they noticed system events of a similar nature and they recommended we issue this so other licensees were aware and could consider things to prevent those type of events.

COMMISSIONER CAPUTO: So, with that Information Notice out there, as I understand it I think it's fairly recent, how long until you'll have a sense for whether or not that Information Notice actually addresses the situation and improves the safety?

Are you tracking that? Do we have metrics? We're sort of monitoring?

DR. TAPP: We do not have quantitative metrics but again, we will continue to look on an annual basis and track the events as well as we attend society meetings and discuss it with the manufacturers when we see events.

COMMISSIONER CAPUTO: Okay, so it's adequate to just continue tracking it through the normal approach at this time.

So, this may be Lisa again, with regards to emerging medical technologies, is there anything we can do to improve transparency for applicants on the status of their review?

Maybe is it feasible to give them a time estimate for their review?

Is it possible to maybe have some schedule and milestones like we do in other parts of the Agency for licensing reviews?

MS. DIMMICK: So, as we're developing or implementing our new process we can be aware of the milestones and metrics for developing the guidance. So, that's something that we can consider or include in developing our process, or our new process, for reviewing emerging medical technologies.

Typically, the technologies are either already just approved by the FDA or still undergoing a review by the FDA as well.

And so there will be alignment or we try to time things so that we are ready at the same time the FDA is with their approval of a new technology.

COMMISSIONER CAPUTO: Okay, good, that rolls right into my next question.

Given the new process and Dr. Tapp mentioned the evolving medical landscape and increasing applications for emerging technologies, how much of an increase are we seeing here? And how do you monitor that?

Is it enough to sort of watch the progress of new technologies through the FDA? Does that give us enough time, like you said, to actually stay on track? Or are we going to face some challenges if there's some sort of steep ramp?

DR. TAPP: I think the first question you said is how much of an increase and right now we're keeping an eye on about 15 medical devices and then several radiopharmaceuticals. That is a large increase from the past.

COMMISSIONER CAPUTO: That's a faster pace than we've seen in the past?

DR. TAPP: That is a faster pace. One thing, though, is we don't expect them all to come out at the same time. Medical is a complex landscape and sometimes it's hard to

predict what is going to make it into the market.

With the FDA, there is some limitations with their ability to tell us about a device that's coming to them at the beginning. So, we have changed our workings with the FDA and they are alerting the manufacturer about our process and about the 35.1000 reviews.

But they cannot tell us themselves about a new device so they are recommending them to contact us or be able to talk to us, but because of their restrictions they cannot tell us about devices.

COMMISSIONER CAPUTO: Okay, so that sounds like it's probably in the vein of business proprietary.

Given that we're working on an MOU with the FDA, is there room to address that in our MOU to be able to have those communications directly?

MR. WILLIAMS: So, one of the things that we've been doing is we recognized that's a challenge for us so we've been working or partnering with FDA to figure out how best to share information.

Most recently, we were going to have a public meeting where we talk with external stakeholders, make them aware of the challenges that are there.

But we're also looking at forming a Working Group with FDA to figure out how best do we share information so that we stay ahead of these things?

And we can do that under the existing MOU. We don't need to revise it for that.

COMMISSIONER CAPUTO: Looks like you got a lifeline.

DR. SHELDON: Hi, I'm Dr. Murray Sheldon, I'm from the FDA Center for Devices and Radiological Health and I'll be speaking on the next panel. But to address this particular issue there are some things that I do want to be sure that you are aware of.

First of all, of course it's been understood when a manufacturer comes to us to

review any of their products, that remains confidential. And so we cannot be reporting to you those issues.

But we've also had very similar problems with patient access to innovative new medical devices because, in general, patient access also requires coverage and reimbursement generally by either private payers or CMS.

And so in order to deal with some of those issues, we've actually created a program with CMS that enables us to look at the data that's being developed in parallel simultaneously.

It's called our Parallel Review Program, which also began with an MOU and has been currently in place since 2016. I run that out of my innovation group. So, I wanted to make you aware of that, that there are ways to do that, but I also wanted to make you aware of one additional factor.

There's a new pathway, at least in the Devices Center, called the new breakthrough devices program. And with that, these are for very specific life-threatening or irreversibly debilitating conditions for which there's an unmet need for which we really want to move a product to patients as quickly as possible.

We may approve that product to go onto the market with greater uncertainty that we might otherwise have in the pre-market and capture the residual data in the post-market, generally with registries or with other methodologies from the real world.

When we release these products with greater uncertainty, this makes it much more difficult for payers to be able to provide coverage and reimbursement.

So, we've again worked with CMS and a few private payers and recently CMS has instituted a program to allow new technology add-on payments for any medical device that carries an FDA breakthrough designation.

COMMISSIONER CAPUTO: Thank you.

DR. SHELDON: So, I just wanted to be sure that you understood that there are very close similarities.

COMMISSIONER CAPUTO: Thank you. I have one last question maybe for Steven, Kevin, and Lisa, maybe the whole panel.

Just a very broad question, you have taken a situation where you're addressing evolving technologies, new technologies perhaps, an increased pace of reviews. This isn't dissimilar from what we are also seeing in the area of advanced reactors.

Is there anything in the nature of how you have approached this or the way that you have developed processes that there might be insights to share with the advanced reactors group and see if there's some cross-pollination in terms of how to approach this situation?

MR. WILLIAMS: So, I think right now we're in the infancy stage of it but we've looked at our program, looked at our processes to see how we can streamline and what can we learn from it.

And I think we need a little more runtime in order to be able to share what we've looked at effectively or what worked for us.

We do recognize that some of the things that we've done in the 35.1000 area has paid big dividends for us in terms of being able to pick a technology or take a modality and be able to move that forward.

But I think right now we're analyzing and evaluating how can we streamline our processes?

MR. WEST: I know we're running out of time but I agree with Kevin, although I'll take a step further and say we should be sharing both ways.

Thanks for the question, it was a great question, but I think there is things we

could be learning, even at an early stage, from this program into theirs and theirs into this one. So, thanks for that.

COMMISSIONER CAPUTO: Thank you.

CHAIRMAN SVINICKI: Thank you, Commissioner. Next we'll hear from Commissioner Wright.

COMMISSIONER WRIGHT: Thank you so much and thank you for your presentations. You covered a broad range of stuff. This is really a fun meeting for me, I really enjoy this a lot.

I really appreciate also the preparation and all that you put into it. And Steve, congratulations on your retirement, you're a very kind soul, you've been very helpful to me and to my staff.

You're observant and you'll speak when you need to speak but I've noticed that you're just a genuinely nice man, and I appreciate the way that you've handled yourself at the Commission in the time I've been able to interact with you.

I wish you the best and I also hope that you don't need any of this stuff.

MR. WEST: Thank you very much, I really appreciate that.

COMMISSIONER WRIGHT: So, you know I'm a colon cancer survivor myself and I'm kind of a testament to the power of innovation and to new technology in this field.

And everything I've heard, not just in the area of colon cancer, is just very impressive. I've been in the colon cancer part and I knew about the photo pill and I wished that I could have done it. But by the way Chairman, I'm a good company man and I had my colonoscopy on Martin Luther King Day so that I could be back at work the next day. But I wanted to ask you about the pill real quick.

It's not something that's going to be used for everybody in every situation

because if you're a Crohn's or if you're some other area where you might have a blockage, that's not going to be something they can use.

Is that right?

DR. TAPP: Yes, that's not something that we look at, per se, for the radiation safety aspect but the manufacturer is marketing specifically to a certain section of patients.

When I look at their website, they market towards people who could normally receive a colonoscopy but don't want to because of the prep for colonoscopy.

COMMISSIONER WRIGHT: I hear that. I want to get into the patient release area. Commissioner Baran brought up a couple of things and I'm going to set the table just a little bit, just because of concerns in other areas.

For example, to stay in the area of colonoscopies. So, when the Affordable Care Act was passed many years back, there was a loophole that was missed. In private pay insurance you would go in and have a colonoscopy.

It was a preventative procedure and you're co-paid and you're out. If they found polyps, no big deal, you're done.

If you were on Medicare and you went in, up until I think they just fixed it maybe at the end of the year, I think. If you went in as a Medicare patient and you went under thinking you were preventative and you woke up and they found polyps, it became a diagnostic and it charged you maybe $200 a polyp.

So, you were waking up with an $800 bill, something like that, so it was actually discouraging people from going to get a colonoscopy. Doing just the opposite of what you really wanted it to do.

So, I want to focus a little bit on the insurance part and that's where I'm coming from. In patient release, are these therapies that we're talking about usually insurance-covered?

Would that be the case or no?

MS. DIMMICK: The iodine therapy is a traditional therapy, it would be covered by insurance, the cost of the therapy.

COMMISSIONER WRIGHT: So, if we were to change our regulations to require, say, in-hospital treatment so the patient had to stay in the hospital, would this be something where an unintended consequence would be maybe the insurance company is not covering something?

Because right now it's a doctor's choice, it would be if a doctor is working with a patient and says I think you'd probably be better off, you've got somebody driving you home so you're going to expose them, or you're at home and you've got too many people there.

I can understand that being a decision between a doctor and a patient. If we change that, are we causing a problem potentially that might need some other solution before something like that even was considered?

MS. DIMMICK: So, it's difficult to speculate if we changed our regulatory requirement such that the patient could not be released, if that would then -- then what that would do for an insurance company, if an insurance company would pay or not pay for that hospitalization, that's information we don't have.

COMMISSIONER WRIGHT: Would that be something we would want to know maybe? I'm just asking the question. I'm thinking just as open as I can, and transparent about it.

And quite honestly, the next panel can address it too when it gets to my turn to question.

MS. DIMMICK: Our current requirements do not preclude hospitalization.

Again, if the physician isn't confident the patient can meet the release

instructions or comply with them, then the patient should not be released outside of their control.

DR. TAPP: If I can add, during the evaluation that we did, we had physicians comment to us that if a patient needed to stay in a hospital, they could work with insurances and they get covered.

Insurance is a very complex world, it may not happen in every situation but doctors did know to deal with insurance and in medical need they could get insurance to cover hospital stays after radioiodine surgeries, radioiodine treatments.

COMMISSIONER WRIGHT: Hopefully. Thank you for that, I know it's probably not something that you expected but I was like, the minute you make it mandatory then we may cause some problems, and I just wanted to see to make sure we think through some of that stuff.

Katie, and I guess maybe Lisa too, maybe you might want to -- maybe even you. So, over the past year and a half, I've had the pleasure to go to several medical licensees and talk with different interest groups and stuff in the medical community.

And one of the things I've heard several times, especially as it relates to the GammaPods, the Gamma Knife and all that, is that doctors, some of them, a brain surgeon in particular, feel like the requirement for a physical presence encroaches on their ability to practice medicine.

Because these patients are sick and the ones that they're wanting to see are as sick or sicker so they feel like they're being taken away from their ability to practice medicine with their other patients while they have to be there to watch this procedure.

I'd like to get your thoughts about this and I was curious as to whether there are any plans to re-look at the requirements for the physical presence when you update Part 35.

DR. TAPP: When we look at the advanced rule, we will look at physical

presence. I should note that when we do 35.1000 reviews for the new Gamma stereotactic radiosurgery units, we do look at physical presence because of the new engineering safety features.

The last three GSR units that we have licensing guidance for, the Icon Perfection and GammaPod, we did modify the physical presence requirement.

In the regulation it requires you authorize user to be present during the duration of the treatment, now it can be the authorized user to be the initiation and then another physician can come and be there instead of the authorized user for the duration of treatment.

The reason that we have a physician present is due to the high dose rates in the gamma stereotactic units using a source because it can't be turned off like an external beam.

And if there's a medical need to assess, you have to look at patient dose versus medical need, that is a decision by the physician sometimes so that's why the physical presence requirement is still there with the new systems.

COMMISSIONER WRIGHT: Okay, and I just have a minute or so left, and I'm not going to take it to ask any more questions.

But I do want to make sure that I let you know and anybody who's listening that where I've been going and the people that have been coming to see me and drop by some periodicals and things like that, they have nothing but amazing things to say about what's happening in NMSS.

And I shared that with John Lubinski the other day, I shared it with Margie as well, and I wanted to share it with you.

So, congratulations on what you're doing and how you're approaching the transformation and innovation and just looking at things. It's being noticed not just inside the building but outside as well.

CHAIRMAN SVINICKI: I know we're hard up against the break, which is always keenly desired by everybody in the room, but I feel I want to ask one question so I'll allow anyone to ask a quick one question after I do this.

But just as a point of clarification, given the division between our regulation in that we are not the regulatory agency for the practice of medicine on these techniques broadly, is it a correct statement that to structure our regulations to say this radiopharmaceutical in this application must always be inpatient, would that be outside the bounds of a decision?

No matter the radiological dose, it just has to be inpatient? My understanding is that would be immediately subject to challenges outside our regulatory scope.

Can someone verbally answer that?

MS. DIMMICK: I'll answer that. Yes, I believe that would be outside the scope of our swim lane.

CHAIRMAN SVINICKI: Okay, and I think that Dr. Tapp kind of said that in terms of looking at the radiological aspects of these treatments and radiopharmaceuticals.

But speaking of swim lanes, which is my term of the day, we have a swim lane here so there are things that are definitely outside that swim lane. Does anyone else want to -- yes?

COMMISSIONER BARAN: Well, just a follow-up on that. It would be a different question if the standard were if a patient release had the potential to dose people, members of the public or family members at a certain level, that would require inpatient treatment.

Because then we're dealing with a radiological issue.

CHAIRMAN SVINICKI: Yes, I agree with that. Thank you for making that distinction. Okay, anyone?

COMMISSIONER CAPUTO: I guess I'd just like to sort of follow up to both of

those questions with just the statement that it really is a balance here because if the release criteria are more extreme, might that also serve as a disincentive for some people to actually seek the treatment that they may need medically because of the situation that that would provide in terms of aftercare?

MS. DIMMICK: So, we believe that the current regulation adequately balances patient safety, public safety, and patient treatment to help medical treatment for patients. In our regulations our current requirements adequately balance those things.

COMMISSIONER CAPUTO: Thank you.

COMMISSIONER WRIGHT: And I want to thank the last two comments because that's where I was going with the Affordable Care Act thing with not being able to come in because the diagnostic would cause that issue with a patient.

I'm not coming in because it's going to cost me money. So, thank you for your question and for your answer.

CHAIRMAN SVINICKI: Okay, thank you all and we will take a break now until 10.35 a.m. Thank you.

(Whereupon, the above-entitled matter went off the record at 10:28 a.m. and resumed at 10:37 a.m.)

CHAIRMAN SVINICKI: Thank you, everyone, for taking your seats and I think we will shortly be joined by one additional presenter on this panel but in the order of recognition I was going to say he's not going until the second half of this panel so we will go ahead and start again.

Now we will hear a set of perspectives on some of the topics that we just discussed with the NRC Staff but potentially other topics that the presenters will raise. And we will begin the presentations on this panel.

I'll just go in order that we've published them here on the notice, the Public Notice, but we'll begin with Dr. Murray Sheldon, who gave us a little bit of a teaser about topics generally.

But he is from the U.S. Food and Drug Administration, he's the Associate Director for Technology and Innovation of the Center for Devices and Radiological Health.

So, Dr. Sheldon, please proceed.

DR. SHELDON: I thank you very much for inviting me here, it's been a pleasure to come here. I wanted to preface my remarks by letting folks know that I am not a subject-matter expert in any radioisotope pharmaceuticals nor radiation-emitting devices.

My background is that of a cardiac surgeon/medical device developer, but I have run several innovation programs at the Center for Devices and I will tell you about what we're doing and hopefully it might be helpful to you.

Next slide. What we do at the FDA relates to a mission which is to promote and protect public health, but our vision states that patients in the United States shall have access to high-quality, safe, and effective medical products of public health importance.

First in the world, we don't say that because it's a competition but it is an aspirational goal and it's measurable.

However, we have found that in the past ten years or maybe a little bit longer, U.S. patients don't always have timely access to life-saving and supporting medical devices.

And one of the big drivers for this has been the cost and time to bring these devices to patients and medical manufacturers, and venture capitalists who support them have often taken their products outside of the United States. And we felt this was a considerable problem and we wanted to do something about it.

Next slide. To demonstrate some of the issues, of course, in 2008 you can see

when the peak began to drop. With the recession the startup communities diminished quite a bit but unfortunately, even until 2012, 2013 it did not recover.

Next slide. Josh Makower from the Stanford Biodesign published his report in 2010 about the same issue.

Next slide, that when a company either took the product to the United States or to outside the United States -- oh, go back one, yes, perfect -- there was a significant gap of sometimes as long as ten years but often usually three to four years, and often $10 million to $12 million to bring a device through the U.S. regulatory systems as opposed to those outside the United States. And this was a critical driver.

As a matter of fact, some of the newest innovations in cardiac care for percutaneous heart valves, the United States was the 46th country in the world to approve those valves, and that had a lot of personal consequences to people.

We really needed to do something about that so our Center Director -- next slide -- understood about the issues and needed to do a few things about it, and I'm going to mention some of the activities that we've done.

This is a very, very brief overview but one of the approaches, he created a position that I'm currently in, the Associate Directorship for Innovation. And we ran an entrepreneurs and residents program, the first one was in 2011.

It was time-limited, six months, we brought in outside stakeholders, often critics, and matched them up with our staff in order to really have them share a lot of information, have them thinking about things in a different way.

And the goal was really to create transformational change if we could. One of the first things they did was to create a different pathway altogether called the Expedited Access Pathway.

That eventually led to the breakthrough devices program. We did this actually through a pilot so we would encourage a lot of pilots in these areas to understand things better.

Next slide. In 2011 the National Venture Capital Association put out their report of what are the reasons that venture capitalists would take their money outside the United States.

And 70 percent of them included these areas, regulatory challenges, reimbursement challenges, and clinical trial cost, as I mentioned before.

Next slide. So, the following year we set up a second entrepreneurs residents program to deal with these three issues and we really spent most of the time developing problem statements.

We would refrain from putting out solutions too early. As a matter of fact, we had a fine of a dollar for anybody who suggested a solution before the problem statement was really well understood.

But it was incredibly important to go down to the drivers to really understand if we made a change to A, would it affect the problem that we're trying to solve? And sometimes it wouldn't and, of course, we needed to recognize the unintended consequences.

Next slide. So, for these three challenges we started the clinical trials program in our Office of Device Evaluation and we instituted a new early feasibility program, adaptive trials, Bayesian design and we brought in patients to get patient perspectives on what they were doing.

We also set up a payer communication taskforce, which is the taskforce that I run. I mentioned the Parallel Review Program, we have multiple programs with payers as well so we interact with folks outside of our expertise and work with them directly to address the specific issue of patient access to innovative medical devices.

And we also try to balance the pre-market with the post-market data evaluation.

We're currently in the process of developing a national program called NEST, the National Evaluation System for Health Technology, that enables us to try to capture in real time patient experience with the use of medical devices in the real world.

Most clinical trials on which most medical devices had been approved are based on randomized clinical trials with a lot of inclusion and exclusion criteria that just did not reflect what we would eventually see once a product was listed for open use.

And so by doing this sort of approach, first of all we get a broader knowledge and we're able to get some of these products onto the market a lot sooner, which is helpful to patients.

Next slide. And we maintain our practices with continuous innovation. We believe that the definition of innovation is that change is the only constant. We know things will change and the only way to help create that change in the right direction is to be a part of that change.

My group with innovation focuses on both internal and external. Our internal innovation is mostly to be able to enable our staff to learn the challenges that medical device developers face.

We have an incredibly brilliant staff as you do here. Most of our staff our Ph.D.s, engineers, and other types of scientists but they often have not actually developed medical devices themselves, nor have they practiced medicine.

So, to give them that kind of exposure we send them to accelerators and incubators, and we also send them to meet with payers so they understand those challenges. And we've also worked with public-private partnerships.

We believe this is a great opportunity to work in one particular area where there's been a lack of innovation, the kidney space.

A public-private partnership between the FDA and American Society of Nephrology, it's called the Kidney Health Initiative, and recently KidneyX with HHS and the American Society of Nephrology, has been developed to bring innovative products for renal replacement therapy.

Thank you very much for allowing me this opportunity to be here and to present this information.

CHAIRMAN SVINICKI: Thank you very much, Dr. Sheldon, I'm sure Members of the Commission all have questions so we'll keep all of our questions until all presentations are heard.

The next presentation will come from Mr. Terry Derstine, who is the Chair of the Organization of Agreement States. Please proceed.

MR. DERSTINE: Hello, my name is Terry Derstine, current Chair of the Organization of Agreement States and the Radiation Protection Program, Manager for Pennsylvania Department of Environmental Protection.

Thank you for this opportunity to share and discuss some emerging issues regarding the regulation of the medical uses of radioactive material.

Recently, I have witnessed firsthand the development of two emerging challenges concerning the licensing and inspection of radioactive material used in medicine. The first is a perceptible increase in -- this is my term -- high-dose systemic liquid radiation therapy.

And the other item I'd like to discuss is the next generation of technitium-99m generators. Perhaps most pressing due to its patient-facing nature is the increasing use of high-dose systemic liquid radiation therapy.

This cancer treatment consists of a radioactive substance delivered intravenously, common over the span of several hours. The most concerning therapies are

MIBG and Iomab-B. Typically, these therapies use radioactive iodine-131.

Now, the radioisotope iodine-131 is used every day in nuclear medicine departments worldwide primarily for the treatment of hyperthyroidism and thyroid cancer, and is typically delivered in the form of a capsule.

Lower doses of liquid radioactive material have also been a longstanding staple of nuclear medicine primarily for diagnostic studies.

As nuclear medicine staff are therefore familiar in handling these lower doses of isotopes, it is quite common for facilities that perform some of these newer radiation therapies to task the experienced technicians with delivering the high-dose treatment.

Without proper respect for the differences between these types of treatments, complacency may develop. Understandably, there are unique safety concerns for high-dose therapies compared to the typical uses of radioisotopes.

Most pressing among these is the risk of contamination. The duration of one high-dose systemic liquid radiation therapy infusion can last several hours. Over such a length of time, the risk of contamination spills because much more serious.

Furthermore, after the infusion, the radiation emitted from the patient in excreta can provide some challenges, especially when using radioactive iodine. Again, this greatly increases the risk of external contamination.

Another pressing concern with high-dose therapy is the detection of contamination. Due to the large amounts of radioactive material in the patient's body, the background radiation becomes very high, thus hindering the effectiveness of hand-held radiation detectors.

This makes detection of any small leaks of radioactive material especially difficult, compounding the possible danger of mismanagement.

And based on the number of reported events where treatment of high-dose systemic liquid radiation resulted in contamination and even radiation-induced skin injuries, new safety procedures should be emphasized for each treatment.

Facilities should strongly consider developing training and procedures to specifically address this challenge, such as development of patient-specific decontamination procedures, proactively looking for contamination on linens, gowns, chucks, carts, and flooring and the use of beta radiation measurement devices in order to detect contamination.

There are also several other concepts that regulators may want to discuss with licensees, development of fluid management procedure and employee familiarity with the infusion system that would limit potential spills of radioactive material.

The establishment of a multidisciplinary committee to review and update associated policies while conducting periodic drills on responding to a patient contamination incident would also ensure appropriate measures are taken to preserve the safety of both patients and healthcare professionals.

This list is by no means complete, but simply by addressing the differences in developing some basic procedures specifically for high-dose systemic liquid radiation therapy all staff will be reminded of the pitfalls associated with it and the potential for complacency can be staved.

I would also like to discuss the next generation of technitium-99m generator systems. The decay product of molybdenum-99, technitium-99m is used in about 80 percent of all nuclear medicine procedures.

The United States, with over 40,000 patients imaged per day uses about 50 percent of the world's supply of technitium-99m. And although nuclear medicine is not growing rapidly, it is still considered a pillar of modern medical diagnostics.

For decades the U.S. supply of molybdenum-99 has relied on solely on aging nuclear reactors that are located outside of the United States. In part due to their age, these uranium-fueled reactors have experienced an increased frequent of unplanned outages in recent years.

Some of these outages have caused critical global molybdenum-99 supply shortages, resulting in delays in patient treatment.

The next generation of technitium-99m generators have been designed to create a redundant, reliable, commercial molybdenum-99 supply produced domestically and without reliance on highly enriched uranium.

Even though the technitium-99m produced in these newer-generation generators is interchangeable with the technitium-99m produced with current generators, these next-generation generators are proving to be vastly different, relying less on human interaction and incorporating automation in the production of technitium-99m.

The molybdenum in this system is not derived from the fission of uranium and requires different processes to isolate and concentrate the technitium-99m different than existing generators.

These newer devices are designed as closed-system to contain, move, and shield all molybdenum-99 during a computer-driven process of isolating technitium-99m, a significant change from the current technitium-99m generators.

Currently, there is only one manufacturer with FDA approval to provide the next-generation system, but this one system and the increased complexity associated with it has created the need for licensing guidance.

This guidance will provide applicants with acceptable means of satisfying requirements for a license as well as helping regulators understand and regulate the associated

complexities.

And there appear to be three more U.S.-based commercial technetium-99m generating systems in development.

Each one may be just as unique and different from the others, requiring the continued partnership of the U.S. Nuclear Regulatory Commission, the Organization of Agreement States, and the Conference of Radiation Control Program Directors to ensure the safe use of these next-generation of technitium-99m generators.

These developments prove that the role of radiation in medicine is developing just as quickly as any other time during my career. It is imperative that we provide rational, effective guidance to those on the forefront of radioactive medicine.

Thank you.

CHAIRMAN SVINICKI: Thank you very much. Next on the panel, we will hear from Dr. Thomas Eichler, who is speaking today in the capacity of current President of the American Society for Radiation Oncology.

Dr. Eichler, please proceed.

DR. EICHLER: Good morning, everybody, thank you for inviting me here today.

As duly noted, I am Dr. Thomas Eichler, I'm a board-certified radiation oncologist at the Virginia Commonwealth University Massey Cancer Center in Richmond, Virginia, and also the President of the American Society for Radiation Oncology, or ASTRO.

ASTRO is the largest radiation oncology professional society in the world with over 10,000 members, who specialized in treating patients with a variety of radiation therapy techniques. And on behalf of ASTRO we thank you for your commitment to stakeholder engagement and appreciate the opportunity to collaborate with the NRC.

If I can begin by commenting on the Staff's recent recommendations regarding training and experience for radiopharmaceuticals, the proposal gives us cause for concern.

We continue to believe that there is no need to pursue additional rulemaking insofar as current regulations are appropriate and protect the safety of patients, the public, and practitioners.

If, however, the Commission ultimately decides to proceed with rulemaking, we believe the board recognition criteria must ensure that existing requirements are maintained and that any criteria for additional boards is equivalent to existing requirements.

Let's focus now on transformation and innovation opportunities from the perspective of the medical community and begin by highlighting a 2017 Advisory Committee on the Medical Uses of Isotopes, or ACMUI report, entitled, “Medical Event Reporting and Impact on Medical Licensee Patient Safety Culture”.

In its report, the ACMUI made two important observations. First, the NRC's medical event reporting criteria are set at conservative levels, including events that rarely cause patient harm.

When compared to other criteria set by the Joint Commission, the Food and Drug Administration, and the centers for Medicare and Medicaid services. This lack of consistency in definitions leads to varying levels of response to a patient safety event and causes confusion in the medical community.

Second, despite the recognition that the medical events rarely cause patient harm, a licensee is required to notify the NRC no later than the next calendar day after discovery.

After the notification, an inspection occurs looking for violations as the cause of the event.

In other words, the NRC's conservative medical event reporting requirements

are inconsistent with other regulatory agency requirements as well as current radiation oncology processes of care, and do not encourage a culture of safety.

Based on these observations as well as the need to consider other ways medical events could be evaluated, the ACMI made the following recommendations.

First, the NRC should establish a program allowing a medical use licensee to evaluate medical events as described in current regulations with an approved patient safety program.

The ACMUI describes an approved patient safety program as one or more of the following: a safety program that reports medical events to a patient safety organization, or PSO, which has medical expertise and medical use as defined in Part 35, a safety program evaluated by a CMS-approved accrediting organization, or a safety program which is established as part of accreditation by a professional organization for medical use as defined in Part 35.

Number two, NRC licensees within an NRC-approved patient safety program will continue to report medical events as required but that the NRC not include these events in the event notification report, or if this is not possible, posting them anonymously.

In addition, the NRC should not conduct a reactor inspection unless the event results in or will result in death, unintended permanent harm, or unintended significant temporary harm for which medical intervention is required.

Instead, the licensee will write a detailed report describing the event and corrective action taken, which will remain available at the next NRC inspection. The NRC will then develop inspection procedures to support a test of this program.

Third, the NRC should test this program with various medical practice sizes and locations, evaluating the medical event reports with the ACMUI.

And finally, after completion of the test year, the NRC should consider opening the program to all NRC medical use licensees who request approval of their patient safety program and to Agreement States who request to implement the program with their medical licensees.

ASTRO supports the recommendations offered by the ACMUI to promote a culture of safety for medical licensees.

These progressive recommendations align with ASTRO's commitment to improving quality and safety in radiation oncology and support the NRC's Safety Culture Policy Statement while at the same time maintaining the NRC's regulatory authority to protect patients during the medical use of byproduct materials.

We believe that both Astro's Accreditation Program for Excellence, or APex, and the Radiation Oncology Incident Learning System, or ROILS, fulfil both the spirit and the requirements set forth by the ACMUI.

APex was launched in 2015 with the mission to objectively assess and accredit radiation oncology practices by systematically reviewing the policies, procedures, personnel, and equipment to ensure the delivery of safe, high-quality patient care.

APex standards are centered on five fundamentals: process of care, the radiation oncology team, safety, quality improvement and assurance, and patient-centered care.

This is a multi-step process that begins with a thorough program self-assessment, document upload of policies and procedures, a robust medical record review, and finally, a site visit by a trained APex accreditation team.

Over 150 facilities have been accredited to date. The culture of safety standards specifically requires the cultivation of a facility environment in which all team members participate in assuring safety, capitalizing on opportunities to improve safety, and does not take

reprisals upon staff that report safety concerns.

Learning from these patient safety events and unsafe conditions, therefore, becomes ingrained in the process of care. We believe that the most effective ways for facilities to take action on a patient safety event is to take ownership of the corrective actions in a non-punitive environment.

We are pleased that the ACMUI has embraced this approach to safety, especially with regards to medical event reporting.

The Radiation Oncology Incident Learning System, or ROILS on the other hand, is a data collection tool devoted to reporting patient safety events from enrolled facilities, and then suggesting process improvement by sharing learning in a non-punitive environment.

ROILS is part of the Agency for Healthcare Quality and Research, or AHRQ, approved PSO, with over 500 facilities enrolled and more than 12,000 events reported, approximately 300 of which involve radioactive materials.

Approximately 44 percent of the reported events sort of classified by users as, quote, operational/process improvement, close quote, which is defined as a non-safety-event.

This suggests that practices are utilizing the system for more comprehensive quality improvement.

An additional 12 percent of events are classified as therapeutic radiation incidents where the radiation dose is not delivered as intended, with or without harm, with the majority of those having a less than 5 percent dose deviation.

The culture of safety in medicine as a whole has shifted from one of blame to one focused on learning, which has led to an increase in reporting. ROILS participants not only identify patient safety events and near-misses, but also generate interventions to prevent a recurrence and share relevant safety risks and solutions with others.

Analyzing safety events that were caught before reaching the patient and addressing those faulty processes is a critical aspect of incident learning in medicine.

It is ASTRO's belief that the current NRC medical event reporting approach does not focus sufficiently on learning and that the ACMUI recommendations holds greater promise for process improvement.

In conclusion, we believe that the NRC could play a greater role in improving the safety culture in radiation therapy by implemented the ACMUI's recommendations. Thanks very much.

CHAIRMAN SVINICKI: Thank you, Dr. Eichler.

Next we'll hear from Dr. Dilsizian, who, while no stranger to the NRC through his terms of service on the Advisory Committee on the Medical Uses of Isotopes, presents to us today in the capacity as President of the Society of Nuclear Medicine and Molecular Imaging.

Dr. Dilsizian, please proceed.

DR. DILSIZIAN: Chairman Svinicki, Commissioners, I appreciate the opportunity to speak on behalf of the Society of Nuclear Medicine and Molecular Imaging.

It's really an honor to be the president of such a large organization, established since 1954. It's a multidisciplinary organization, physicists, radiochemists, technologists, and the purpose of my presentation today is multifold.

One is the current pathways of obtaining AU status and the T&E recommendations.

If I could have the next slide, please? The current pathways for certification is one of the medical specialty boards recognized by the NRC or an Agreement State, which is the ABNM, ABR, and American Board of Osteopathic Radiology.

The second option is completion of 200 hours of classroom training and 500

hours of supervised work experience. In ACGME, which is Accreditation Council of Graduate Medical Education, declares the programs and those include nuclear medicine, diagnostic radiology with 16-month nuclear medicine and nuclear radiology pathway, or radiation oncology.

And the third, a previous identification of as an authorized user or an NRC or Agreement State license of permit.

Next slide, please. We thank the NRC for the opportunity to provide feedback on the T&E requirements. Our main objective is to emphasize patient and public safety while ensuring access to quality of care.

The NRC Advisory Board, of which I am a Member selected by you, rather knowledgeable and selective-knowledge experienced group of physicists, physicians, scientists, healthcare providers, patient advocates, have reviewed this topic.

And they've recommended that there is no authorized user shortage in their revised report of July 2018 and strongly supported maintaining the current AU pathways. Thus, there seems to be no clearly defined or compelling need to develop a new type of T&E pathway.

Next slide, please. Nonetheless, the SECY paper, the Commission paper summary, suggests that the NRC Staff expects growth in the field of nuclear medicine and uncertainties in the safety-related characteristics of emerging and future radiopharmaceuticals such as energy level dose, half-lives, and necessary protocols.

And therefore, a less prescriptive and more performance-based approach in regulating T&E would be beneficial because you could cover radiopharmaceuticals beyond those currently known or in use.

I just want to spend a little bit of time about the word prescriptive. It seems like we're talking about this a lot these days. I just want to emphasize that everything we do in medicine, the entire medical and surgical training, is prescriptive.

We are required to have a number of CNE hours or grand rounds, we are required to have a certain number of months of training in radiology and nuclear medicine, different aspects of rotations.

We are required to do a number of years before we sit on the boards, we are required to do a number of procedures of cardiac catheterization, cardiography.

And therefore, the idea that we have a prescribed 700 hours by experts to assure that physicians in training are properly trained is not unusual and it's not against the current medical practice.

So, as a matter of fact, in medical practice it's prescription plus certification.

So, I think that if the NRC is moving in the direction of perhaps the prescribed hours are not enough, that we should assure that the physicians are competent, I think that it's appropriate to request and additional certificational board examination, which is what medical practice does.

In addition, increasing involvement by the medical community in determining the appropriate safe criteria for radiopharmaceuticals and setting the associated T&E requirements could -- this is very important and I underline that, if I could have that slide -- help accommodate the increasing interest -- I like the word interest because I'm curious to know, interest is not need, I would be interested but that doesn't mean I need -- of non-nuclear medicine and non-radiation oncology physicians in using radiopharmaceuticals.

And the next sentence is very interesting. While the Staff considers stakeholder concerns -- that's an interesting term, isn't it? No data.

ACMUI reviewed this, I don't understand what the term concern stands for because there's no actual data to support that about patient access. The availability is to be sufficiently used in not drive -- this is very important -- the Staff's evaluation of T&E.

Next slide, please. And so the additional recommendations that NRC sets is to initiate a rulemaking to remove prescriptive T&E requirements, which I object to and I gave my recommendation, and to eliminate the need for NRC review and approval of use.

The Staff recommended the option with required physician is certified by NRC-recognized or Agreement-State-recognized medical specialty board.

Now, that's important because there are legitimate medical specialty boards, which is the American Board of Medical Subspecialties that currently exists.

And I guess I don't have clarification here whether any subspecialty can come up with their own board certification independent of the ABMS. That's important.

Are we going to expect any societies or any organizations to have their own certification or are you going to require the certification to be strictly under ABMS? I think that needs clarification.

The second bullet, as policy recommended rulemaking, the NRC would revise its board recognition criteria so that certification by specialty boards other than existing nuclear radiation oncology boards would be an acceptable T&E pathway for the use of radiopharmaceuticals.

The Staff's recommended rulemaking option would continue to protect public health and safety, better align the NRC's T&E requirements with the medical policy statement, and position the Agency for more effective and efficient regulatory decision-making with respect to the expected increase in the number of complexity emerging radiopharmaceuticals.

So, the recommended option would also alleviate regulatory burden for the NRC. I would think that the NRC should not be delegating their responsibility to others.

You are the experts, we are the experts, you should be defining what the training is. That's what keeps everything safe in my opinion. Even though it may seem like the

estimated cost savings is $2.4 million per year for your organization.

Next slide. So, other important views then to consider, one, who will be training the current oncology, urology, or other medical specialists?

And how do we ensure that the next generation of residents and fellows in these areas receive competency-based training? Who's training them?

If currently there are no, or perhaps only a handful of, authorized users in these medical specialties at the present time, how do we assure who's training who? And how are they going to be board certified?

Expansion of medical specialty training requires ACGME review committed discussion and approval in each of these medical specialties. NRC does not have jurisdiction to require changes in the current medical and surgical residency or fellowship training.

Bullet Three, nuclear medicine, radiation oncology and diagnostic radiology with 16-month pathways are the only ACGME-approved training programs that have specific goals and objectives pertaining to administration of radioactive material.

These have to be completed under the supervisional board certified physicians who also have been trained in this area.

Next slide, please. Other important things to consider, independent of the medical or surgical specialty board, the AU candidate must attest to the acquisition of 35.390 knowledge, topics, and skills by successfully completing a formal competency assessment with continued formal periodic competency reassessment.

That's important. Just because you take a course once doesn't mean you've captured it. We know that there has to be reassessments to maintain their limited-scope AU status.

Bullet two, given that this type of training is not part of standardized program

requirements in these medical and surgical subspecialty areas, the question arises as to which organization is best suited to actually ensure competency and safe administration of these from individuals who have sought this additional training.

Which subspecialty board would be most qualified to certify these medical specialty candidates as qualified and competent in radionuclear therapy?

American Board of Nuclear Medicine or the medical subspecialty boards without adequate mentors or educators to cover the current required NRC requirements?

Undoubtedly, organizations that have the most experience and expertise in these areas are nuclear medicine, diagnostic radiology, and radiation oncology.

Next slide, please. So, to switch topics to release of patients administered radioactive material, again, we thank the NRC for the opportunity to provide feedback on the patient release criteria. The Society submitted comments to this patient guide in June of 2017 and again in September 2019 following the current revision to provide licensees with more detailed instructions for their patients before and after they have been administered radioactive material.

The revision included a new section, death of a patient following radiopharmaceutical or implants administration, dosage of radiopharmaceuticals that require instructions and record when administered to patients who are breastfeeding an infant or child.

Next slide, please. SNMMI submitted specific comments related to radiation monitoring of family members, breastfeeding interruption limits and guidance for families and children.

SNMMI agrees that written and oral instructions must be provided to the patient far enough in advance of treatment without compromising patient care to ensure that the patient has sufficient time to determine whether or not he or she can actually comply with the instructions

to make whatever arrangements may be necessary for compliance.

I just want to emphasize that, at least in our practice in Maryland, we have so-called occupancy factor. We go through all these questionnaires and based on the occupancy factor, we determine whether to keep the patient there or not, independent of the dose.

We do take care of all the patient-related issues obviously and those would not be as far as insurance is concerned. If we determined that's necessary, insurance will pay for it.

And the last point I think we have to be all aware that all of this is good but I've been asking my patients where they get their information and often I would assume it would be the endocrinologist who is referring, and the most common answer is YouTube.

So, we have to move where the patients are these days and I've highlighted that in Bullet Three. We are keenly aware of the usage and impact of social media in education.

I think that those documents, long pages, is not the way we are educating our communities these days. Accordingly, the Society will be planning to develop a video clip that will be available on the SNMMI website.

We also learned that most people don't go to the website, they just Google it. So once you Google it, there will be YouTube, hopefully one of those will be SNMMI-based, that would educate the patients before and after the treatment.

Next slide. Regarding what's coming and what's exciting, the world is a huge, exponentially growing area. We are moving from diagnostic to therapeutics in the field and we are excited.

There are a number of new alpha- and beta-emitting targets that the FDA approved, such as Radium-223 therapy for metastatic breast cancer and other cancers of bone.

Other alpha emitters targeting a variety of receptors including PSMA, or prostate-specific membrane antigen, there's also already an FDA approved Lutetium-177,

somatostatin analog, which treats neuroendocrine tumors.

Lutetium-177 is also being labeled to PSMA for prostate cancer. Iodine-131 labeled antibodies for leukemia targeting, such as CD-33.

Other indications are currently in Phase 2 or 3 clinical trials, colorectal cancer, Non-Hodgkin's Lymphoma, and leukemia.

So, it's an exciting area, it is important to make sure as the field grows that we do administer this safely to patients.

And then the last slide is what are the potential barriers to patient access. I think that the addition of new diagnostic and therapeutic isotopes to a radioactive material license can be time-consuming.

And we do appreciate that the NRC is addressing that and facilitating that, although, we do also understand there's a state-to-state variability in that process.

Rulemaking related to generators can cause delays such as decommissioning, which you addressed with generators and isotope agent-specific training for targeted therapeutic dosing patient administration, we the Society have taken that burden.

We are having road shows, chapters, different areas of the state as well as a national meeting to make sure that currently practicing physicians are well educated, including the new residents. Thank you very much for your attention.

CHAIRMAN SVINICKI: Thank you for that presentation.

The final presentation on this panel will come from Mr. Josh Mailman, who will be addressing us in his capacity as the President of NorCal CarciNET Community.

Please proceed. Thank you very much.

MR. MAILMAN: Thank you.

That was fairly comprehensive. So, I can shorten what I'm doing a little bit and

that will be helpful.

Next slide, please.

I have a few disclosures. But, really, what I want to say is I have talked to a lot of patients and medical providers in preparation for this, and I want to thank them for their time.

I want to thank the Commission for having me here as well. But the views here that I talk about represent my own opinions.

Next slide, please.

So, at the end, I'm the actual end-user. I'm the one who gets all these things at the end of it. I was diagnosed with a rare pancreatic neuroendocrine tumor in 2007. I was able to find additional imaging therapies in Germany where I went for my first gallium-68 PET/CT in 2008. I was also treated there before we had any clinical trials here or any active current clinical trials on nuclear medicine therapy for neuroendocrine tumors. Subsequently, they've been approved, which I'll talk to in a second.

I helped Society in the gallium-68 Working Group, the Society of Nuclear Medicine, work on some INDs for gallium-68 that later got adopted as well. And I work with a bunch of really great organizations for both patients, for research, and for nuclear medicine therapists, practitioners around the world.

Next slide, please.

Just a quick background of NETS because many people don't know about them. They are considered a rare disease because the prevalence is under 200,000. They fall under the rare disease or orphan drug designation. There are about 20,000 new diagnoses a year. But, because of the prevalence, because we are living longer, and due to better therapies, it is the second-largest GI malignancy that is around, which is shown on that chart.

One of the things about neuroendocrine tumors is that we have these receptors,

somatostatin receptors, that make us the target child. While we've talked about diagnostic and therapeutics, the term "theranostics" or "theranostic," depending on where you're from has been used to describe this, the idea of using a diagnostic isotope to actually light up the tumor and, then, replacing that using the same targeting agent, but replacing that isotope with something that would cause a DNA break or do something to damage and kill the tumor, which is the idea behind theranostic.

So, next slide, please. We've been very fortunate in the neuroendocrine tumor space to have four approvals in the last four years, starting with NETSPOT, which was a Gallium-68 Dotatate; followed on by lutetium; Azedra, which I think was mentioned here as well, and also another indication for Gallium-68 Dotatoc in June, of neuroendocrine tumor patients.

This has led to an actual rapid adaptation of nuclear medicine in the neuroendocrine tumor field. There are over 600 locations that currently can offer a Gallium-68 NETSPOT. There are over 150 locations performing about 8,000 treatments for Lu-177 Dotatate in the United States last year.

Next slide, please. As was mentioned, there are many isotopes that are under consideration that will be new to the medical field. Although I will bring this up in a second, I will bring this up right now. You've talked about some coordination between the FDA and the NRC as far as new isotopes, and I would also ask you to bring that up to Homeland Security as well because many patients who are dosed end up going out of the country and come back and get caught.

Recently, I introduced the Homeland Security to the FDA, so they could work together, because they were unaware at Homeland how many patients were being dosed with Lu-177. As a patient who has been caught several times coming back into this country, it is a very exhausting pattern to go through because it is not recognized as an isotope in most of

Homeland Security's equipment and they are very unaware of these things. So, I would ask the Commission to work with that.

Next slide, please. So, look, patients are overjoyed with availability. It's something, you know, especially with the new diagnostics, with NETSPOT, it has allowed patient care. About one-third of the patients have a change in management that will significantly change their life arc.

But there's little understanding of the complexity of delivering nuclear medicine. My guess is this is consistent not only with just neuroendocrine tumor patients, but other patients as well.

Next slide, please. I want to echo Vasken's comments on this new options in the era of information. This is how patients communicate. Most everyone has talked on Facebook before they've actually talked to their doctor on what they have. This makes it hard when someone goes to Homeland, gets caught, but it also makes it hard when people get different release instructions, depending on where they are in the country, and then, they share them and wonder why one thing has one set of release instructions versus another set of release instructions.

And I'll get to this in a second, but one of the challenges, some places just cut and paste an I-131 release instruction for a neuroendocrine tumor patient. And some of them, as I list out here, have some really Draconian things for neuroendocrine tumor patients that are completely appropriate for an I-131 patient as well.

We've talked about a little bit of the challenge of getting it paid for, and that is a major concern, although it may not be of the Commission's purview.

Next slide, please. I believe there's three main areas, and actually, this is what for the most part this hearing or this meeting has been about.

Next slide, please. Patient release criteria. We did send in comments to the NRC regarding the patient release criteria. And one thing, although it was mentioned earlier that Lu-177 is not on the Table 1, it did make it on to the breastfeeding and other tables.

I would ask the Committee to think about making sure that, even if a release criteria is not needed because it falls below standards, that some mention of that be made in the document. Because what happens is these reference documents get used. When someone doesn't see it, they may do exactly what is done, which is copy and paste I-131 instructions for NET patients, and that is problematic.

Obviously, I've also talked to friends in the thyroid communities who would really like to also see more stringent release criteria or at least discussion of it, if it's required to be hospitalized, because they do not feel that, while you were able to get insurance coverage for most of your inpatient, but most of them are not able to get insurance coverage, this is sending many people home 10 minutes after having an I-131 treatment.

Next slide, please. While I'm not an expert in training and education standards, I would ask that the Committee consider making sure that -- first, we don't see in our community, in the neuroendocrine tumor patients, an issue with the shortage of Authorized Users. As a matter of fact, what we're finding is that they're gravitating towards centers of nuclear medicine competency. And so, in fact, many centers that have the drug available to them are not getting fully utilized because they're just going to where high-volume centers are to start out with.

We just want to make sure that, with any new rulemaking, that additional focus is on the therapies that are happening as well, because I think a lot of the training was really when there was much more in the imaging diagnostic and less about the therapeutics. And we are entering an age where PSMA and other therapies will start dominating the scene as well, and multiple isotopes, including the alpha isotopes, will change the safety profiles as well.

Next slide, please. Again, I want to thank the NRC for updating the guidance in 2017 and 2019. I was on many of the phone calls trying to understand what these extra burdens -- it looked like a clerical error for the issue of germanium and its breakthrough. And so, I want to thank the Commission for taking care of that and listening to both the SNMMI and other stakeholders, as well as the patient voice, in getting that out. And it's a testament that we have really over 700, 600 facilities that are able to do a gallium-68 scan.

And with that, I'll conclude my remarks. So, thank you very much.

CHAIRMAN SVINICKI: Well, thank you again to each of you.

And I realize that our meeting format required you to cover a tremendous amount of material in a short period of time, but I think you've set the table very well for the Commission's questions.

Let me kind of just dive in, since I'll begin here.

Dr. Eichler, you talked about a topic that we really didn't spend much time on with the NRC staff, and that was the medical event reporting criteria. I'm a longstanding member of this Commission and I'll confess that I've struggled generally with the criteria, where they're set, and as a result, the kinds of medical events that are reported. I acknowledge candidly -- and I think it's explicit often in the reporting -- that there is no anticipated patient harm from the preponderance of these events.

And therefore, as a human being, I can be certainly sensitive to the fact that, if I was told as a patient, or if it was my loved one, that this requires a medical event report, you're going to presume that it has some injurious effect on you or your loved one. So, the anxiety that that produces, I'm not insensitive to that.

That being said, looking at patient harm just singularly, I would struggle with that as well because, to the extent that the criteria require reporting of things where the procedural

outcome -- I'll say it this way, not the health effect, but the procedural outcome -- was not as intended, it often does indicate perhaps poor training or some calibration issue with the device or something else, something you would want to know about as a practitioner and correct. So that the two statements are true. While there's often not patient harm, there is something addressable having to do with the event.

So, again, I look continually at that, on the frequency that the Agency reevaluates those medical event criteria. I think it is always worthwhile for us to spend some time thinking about the conundrum that I've put forward there.

You've talked about other kinds of corrective action programs into which events, if they are procedural matters that need to be addressed, are corrected or training inadequacies. I know that the medical community itself has a lot of monitoring and looks at the lessons learned there.

But can you talk a little bit or do you have any advice for me in terms of striking the right balance, if it is, indeed, your view that we haven't struck the right balance right now in the criteria?

DR. EICHLER: Well, I think what we were talking about there with the patient safety organizations, there are a lot of those out there. I talked about one that we use, the ROILS system, with 12,000 events in there and 500 organizations already in there. And ROILS I think does a very good job of making the information available anonymously and publishing reports with regularity about how to fix these different issues that are coming into the registry.

So, I think maybe erring on the side of allowing a little more flexibility with involvement in PSOs, and without going off on a huge tangent here, a lot of the hospital systems, the bigger ones, have their own in-house PSOs. So, HCA, for instance, where I was for 15 years, they use a system called Radiation Right. And it's the same thing. There's a lot, you know, a

fair amount of paperwork involved and a fair amount of reporting, but, nevertheless, the whole thing is designed for patient safety.

So, I can't give you a direct answer in terms of what you should do, other than to maybe be a little more flexible in terms of using patient safety organizations as a tool.

CHAIRMAN SVINICKI: Dr. Dilsizian, did you want to weigh-in?

DR. DILSIZIAN: Yes. Thank you very much.

So, one of the things at ACMUI did, as you know, is in the spirit of safety culture. We're reported to you several times. And one of the, I think, kind of immediate solutions is that we always equate medical event equals to medical error. Now, as you know, there are medical events that are minor; there are medical events that are major; high impact versus low impact.

One of the recommendations we made was to consider, why is that important? It's because of the urgency of the reporting, the urgency to do it in 24 hours. So, that urgency of reporting will make everyone very nervous or may not report. That's the concern.

So, if we somehow divide it up into high impact versus low impact reporting, where the low impact one would be two weeks, just kind of give time to analyze the data, why it happened, I think it may go far. And I think also that can fit into the PSO --

DR. EICHLER: Yes, that's an interesting proposal. Okay.

DR. DILSIZIAN: Yes, yes.

DR. EICHLER: Yes.

CHAIRMAN SVINICKI: Thank you for that.

Dr. Sheldon, again, thank you so much for being here today. And although you wouldn't have a basis to know how relevant your remarks are to other aspects of what we regulate here on the advanced technologies or advanced reactor systems for power production, as an Agency, we do confront the same assertion that some investors are going outside the United

States for approval of new power production systems.

As just a personal perspective, I feel that those decisions about which country's regulatory system to enter I think has a lot to do with factors that are outside of our regulatory system. Sometimes it's where they would project their customer base might be to sell their reactor power systems.

But, that being said, it was noteworthy to me your slide 6 had a survey of what was causing venture capitalists and others to want to take their investment outside the United States. Regulatory challenges came in at, I think, 38 percent, which dominated the responses there. We've not, to my knowledge, done any kind of a similar survey among advanced reactor developers in the U.S., but we do certainly confront a view that our regulatory system is in some ways a very complicated kind of edifice to approach and enter and if you're not familiar with the system.

I would think that medical technology developers would already probably be pretty familiar with the FDA system. Maybe venture capitalists are not. Do you have any insights into, of that 38 percent that regulatory challenges causes people to take their systems outside the U.S. for investment or development, do you think there's a perception element to that or is that community pretty familiar with FDA regulatory processes, that it was really the process itself that was causing them to take their systems elsewhere for approval?

DR. SHELDON: Thank you for the question.

I don't think it was as much perception as it was actual reality. When we looked at it ourselves for innovative medical devices that required what we call a PMA, Premarket Approval, the time to approve a medical device was approximately 422 days in the U.S. in about 2010.

I mentioned in my initial remarks that, although I practiced cardiac surgery for

20 years, I also developed medical devices for about 10 years. And I actually produced/developed medical devices during those same 10 years that we described. I can tell you personally that I had one minimal interaction with FDA and all the rest of my work was in Europe for those 10 years, and these were for real reasons. And we knew that and we just went elsewhere because FDA was definitely a large barrier. FDA did not want to know that before with some of the other Center Directors, but the current Center Director, Jeff Shuren, recognized that and saw that it was correct and put in corrective action to change things.

Actually, one of the interesting parts about it is that 422 days is now down to a median time of 30 days. That's a long discussion to tell you how we got there. But, nonetheless, the perception hasn't changed as much that FDA remains a barrier. That has been changing, but changing very, very slowly. So, it's kind of like, if you lose a customer, it takes 10 times longer to get that customer back than to keep that customer. So, it was a real issue.

CHAIRMAN SVINICKI: Well, I thank you for that. And since it is part of a longer conversation, I'll be inquiring with the NRC staff after this meeting whether perhaps some of the FDA experts that were a part of that longer journey to get to those results could get in touch with some of our innovation leads here. I think we're entering well into year two of looking at lot of our Agency processes, and it sounds at least preliminarily like there may be some experiences that the NRC staff would welcome an opportunity to in a different setting talk to folks in the Center you lead and talk to them about that.

DR. SHELDON: I would be more than happy to introduce them.

CHAIRMAN SVINICKI: Thank you.

And just turning quickly to -- and I'm confident my colleagues will pursue this more thoroughly -- but there was discussion with the Staff panel about the recommendation that is currently laid before the Commission. I, like other members of the Commission, are still just

kind of trying to differentiate between the options that the Staff looked at and the recommendation they've made. But, as Commissioner Baran pointed out, of course, the elimination of the alternate pathway is a significant discriminator amongst these various options and things that the Staff looked at.

Would anyone who's kind of deep as a practitioner in the field, if that were eliminated, the Staff indicated that their assessment of practitioners using the alternate pathway were kind of two things: people who hadn't yet entered a Board certification process and perhaps medical practitioners who have been educated outside the United States.

I guess my first question is, is that generally an accurate description of people pursuing the alternate pathway? And then, what do you think would be the effect of eliminating the alternate pathway? In immediate terms, what would we observe in the two or three years after it were eliminated?

DR. DILSIZIAN: Is the question to me? I'm going to be fair. Even though I'm the President of the Society for Nuclear Medicine, I'm also a cardiologist. And so, if you were to say cardiologists cannot practice nuclear cardiology and I wouldn't have the alternative pathway, that I would only have to be a radiologist or a nuclear medicine physician, that would not be fair, I would think.

So that the alternate pathway that exists is because, currently, as you know, endocrinologists who are practicing therapy can, beyond their Board certification, fulfill that criteria and treat patients. It is true that the AU pathway of training is good and that some physicians don't pass their Boards or don't take their Boards, and there's a limit of, say, six years you will have to take it. And then, afterwards, you just have to take it again. So, during that period of six years, if that's their subspecialty, it will be nice that AU allows them to treat and not limit their practice by board certification. I think that it is a fair thing to have it there and to maintain

because, necessarily, board certification should not allow someone to practice -- as long as you're board-eligible, you should be able to continue practicing until you document that you can't pass the boards.

So, I support keeping it and, then, you know, I'd like to go beyond that. But it's not just the hours that you're spending, it's competency afterwards as well.

CHAIRMAN SVINICKI: Well, thank you for that, and that tees up a lot of interesting topics, which I will allow Commissioner Baran and others to pursue. Thank you.

COMMISSIONER BARAN: Your confidence is warranted. I will ask about this.

So, just following up Dr. Dilsizian on that -- and others can chime-in if you have thoughts about this -- you noted that there are currently three medical specialty boards recognized by NRC for the purpose of certifying Authorized Users. Do you have a sense of -- and this is a little bit of a variation of the question I asked the staff -- a sense of how likely it is that additional medical special boards would want to develop a certification process? And how challenging or straightforward would it be for them to do so?

DR. EICHLER: I was just going to say I think it's an extraordinary expense process to start that up.

COMMISSIONER BARAN: Okay.

DR. EICHLER: And it's hard for me to imagine that someone is going to want to take that on, to be perfectly honest. I can tell you right now that, if we were to take over certification of, say, all of radiation oncology, it wouldn't happen. The ABR already does it well. Why reinvent the wheel?

COMMISSIONER BARAN: Right. So, if the Staff or we were banking on the fact that there's going to be additional specialty boards that want to run in and fill this gap if the

alternate pathway goes away, we should really question whether that's a solid assumption?

DR. DILSIZIAN: I have no doubt that certain subspecialties are interested in training their physicians. As I pointed out in my presentation, they don't have the background to train, to educate, and it's going to take a long time.

I think that the quickest way for me is to maintain what's already worked as an Authorized User pathway and have the competency test being provided by experts who already know and provide the tests. That's a very simple thing. Why reinvent the wheel? You can do this, 20 different subspecialties -- urology, oncology, cardiology, et cetera -- or you have one that's an ABNM subspecialty and just say certification for all subspecialties, as long as they fulfill their AU criteria. So, that would be simple. You can monitor that much better and you can supervise that much better than having 20 different ones.

And again, the other question is, what are you going to consider a board? If I'm an organization and I'm going to create my own board, that's not under ABMS. Are you going to recognize that? So, it's a little bit complicated.

COMMISSIONER BARAN: Uh-hum. There's also this issue where the staff's approach addresses future physicians who could become Authorized Users through board certification, but there's the question of existing physicians who have been certified by a board already that doesn't currently have a radiation safety program. And the Staff says, well, they could do guidance on that.

Do you have a sense of or thoughts about how easy or hard it would be to address that situation where you've got someone who is board-certified, but before that board went ahead and had a radiation safety component? Maybe that's being too in the weeds, but it does seem like another -- it's easy to say, well, we do guidance for that, but I just don't know how tricky that's going to be to deal with.

DR. DILSIZIAN: Well, again, I think that if you have a training and experience guideline to say that, even if you're in practice now, retrospectively, we realize that there are new radioisotopes or radiopharmaceuticals that are being introduced. Now you want to be trained at this. There has to be an educational pathway where you would be certified on those isotopes only, no matter what subspecialty you are.

So, again, my recommendation would be to fulfill the 700 hours and, then, to take a certification exam, and that can apply to whether you're trained now or 20 years ago. It's a very clear pathway and it's a very simple pathway. There's no confusion in multiple directions on how you're going to approve different boards.

COMMISSIONER BARAN: Go ahead.

DR. EICHLER: Twenty-five years ago or 30 years ago when I trained, the only radioactive isotopes that people were using were iodine-131, phosphorus-32 in ovarian cancer, that sort of thing. And then, all of a sudden, this stuff called Metastron appeared, strontium-90, and then, it was Quadramet. And then, a few years later, it was something else. And now, you saw the list up there. It's an amazing list of isotopes that are coming out now. So, we didn't have any training in that. We had to go to courses and whatnot to learn how to use them. There was no 700 hours in terms of that back then. But, anyway, for historical purposes.

COMMISSIONER BARAN: Terry, I read the comments of OAS and CRCPD on this training and experience issue. And CRCPD argued strongly for sticking with the current approach while OAS seemed more supportive of making a change.

Given that there's a lot of overlap in the individuals involved in the two groups, can you talk a little bit about what accounts for kind of the divergent recommendations?

MR. DERSTINE: Probably the difference is the people that review the proposed changes and how vocal they are --

COMMISSIONER BARAN: I see.

MR. DERSTINE: -- and the states and which organization that they --

COMMISSIONER BARAN: So, OAS is just, for maybe obvious reasons, more focused on the effort that went into the actual review on their end of people leading the team?

MR. DERSTINE: That would probably be a safe assumption to say.

COMMISSIONER BARAN: I see.

MR. DERSTINE: But I can't speak for CRCPD and, then, how well they did it.

COMMISSIONER BARAN: I talked about it a little bit on the first panel. I could see another option. It seems like options are proliferating. But I could see another option of keeping the current structure of the three recognized medical specialty boards and a 700-hour alternative pathway, but thinking about moving away from listing Authorized Users on the license, the facilities licenses, and that could, then, maybe eliminate the processing of the 2500 license amendments each year, I think 90 percent of which are the Agreement States doing that.

Do any of you have thoughts about an approach like that, whether something like that would make sense?

DR. EICHLER: I think hospitals and insurance companies might be a little bit leery of that.

COMMISSIONER BARAN: Okay.

DR. EICHLER: I think they would want to know who's doing what and are they competent to do it, and that there's some sort of codification that they're listed somewhere. But I think insurance companies would be very nervous.

COMMISSIONER BARAN: Nervous about the NRC not actually signing off on the team you meant?

DR. EICHLER: I think they like having you guys sign off on that stuff.

COMMISSIONER BARAN: Okay. Do you have the same sense?

DR. DILSIZIAN: I really think that I want to emphasize that everything is safe, everything is done right I think needs your guidance and supervision. I don't think NRC should delegate this with other institutions.

COMMISSIONER BARAN: I wanted to just ask a brief question or two on patient release, because I agree with my colleagues this is a complex issue. It's not a black-and-white kind of issue. And there are a lot of factors you're trying to balance here. Commissioner Wright wisely asked about insurance as being one of those factors.

I visited Washington Hospital Center last January, and I think they do more iodine-131 treatments than any other facility, and they do most of those treatments on an inpatient basis. I had heard going in that insurance typically wouldn't cover that or it would be a challenge, but they said there that insurance hadn't been a problem for them. I think you maybe made a similar point.

What's your sense of whether insurance coverage is a barrier to treating patients with iodine-131 or another radiopharmaceutical on an inpatient basis?

DR. DILSIZIAN: Again, I think that, like everything else we do in medicine, preclearance, et cetera, advice, a lot of insurance companies will -- they're responsible and will listen to the recommendations of the physicians.

So, when I started in Maryland, I was given, when I first started with I-131, I was given the six forms to fill out. And as I was filling those out, I was telling the patients, "Just bear with me. This is required by NRC. I have to fill out all of these forms." I was letting them know that it's all detailed and everything was completed, and it takes about 30 minutes.

And then, later on, I learned, after I joined the NRC, that this was just the Maryland criteria. NRC doesn't require any forms, forms to fill out.

But it was very good in that, because if you don't treat a lot, it makes you go through every step, teaching, lecturing. So, I was recommending -- and again, I don't want the NRC to micromanage medicine, but you have to guide us. I mean, you have to go give us some forms. Why do we have that? Because if I miss something, my RSO will find it, and then, the Human Use Committee will discuss it and will let me know. So, again, it's a safety culture thing. It's the right thing. It's not punitive. It's just letting me know what needs to be done.

I think that if NRC does these kind of recommendations and some forms to say what needs to be done, occupancy factor, what questions you should ask, which patients should be admitted or not -- I don't want you to, again, tell us what to do, but just recommending what dose is recommended and levels. I think it would go far.

DR. EICHLER: So, I don't think you have to worry about the NRC micromanaging anything. The insurance companies already do that. Okay? And they will micromanage this.

I think the release issue is very interesting because it's isotope-dependent, it's patient-dependent, and it's clinician-dependent. You could have all the uniform instructions you want, everybody gets the same thing if they get -- throw in the isotope -- the same set of instructions. But you're going to understand those instructions better than the farmer who has an eighth grade education. But, believe it or not, the farmer is going to listen to you better and will have the fear of God struck in him by the clinician; whereas, you might say, "I don't feel bad. I don't need to do any of this stuff." So, it's very different for everybody.

MR. MAILMAN: But I don't think it's universal. I mean, we spent some time with ThyCa discussing this, and I think they do have challenges with thyroid patients who need to be admitted or aren't considered for admission because of insurance challenges as well. And I know, certainly with Lutathera, when a patient is determined to need hospitalization due to

something, it becomes a challenge as far as both insurance coverage for the hospitalization, but, even more so, it becomes an inpatient treatment versus an outpatient treatment, and the entire way that gets paid becomes complex and challenging. So, it has more complexity than I think we're giving it credit for.

DR. EICHLER: Yes, we could go down the rabbit hole on preauthorization here, which I'm not going to do because we're going to blow up the whole meeting. But it's a mess in radiation oncology; I'll tell you that right now. Most practices now have hired people specifically to do nothing but preauthorization, which is ridiculous.

COMMISSIONER BARAN: Thank you.

CHAIRMAN SVINICKI: On that sobering note, Commissioner Caputo.

(Laughter.)

COMMISSIONER CAPUTO: I guess I'm going to put my oar in the water on training and experience. I think, obviously, we've heard from three very qualified people today that everything should stay the way it is; that there is no limit to access, there are no problems with access.

But, obviously, OAS has got to have a basis for its position, support of what the Staff has recommended. Can you just give us a little more detail on what's behind where OAS came out, whether or not you're seeing some problems in terms of patient access, and whatnot, that you feel argues in favor of a revision?

MR. DERSTINE: Yes, well, that was some of the comments that we got, was that it might be limiting to patient access and stuff like that with the current position. So, they're the basis of the comments that were received.

COMMISSIONER CAPUTO: So, I know there were comments made earlier about stakeholder concerns and fairly dismissive of that, for a lack of a data. Is OAS gathering

data on sort of this access question, or do you believe the NRC Staff should gather data on this?

MR. DERSTINE: Well, all the people that are out there dealing with each licensee, each facility, are the perfect people to start gathering that data. So, yes, it probably would be a good OAS-NMP program to start maybe looking a little bit deeper into that.

COMMISSIONER CAPUTO: Okay. Thank you.

And because you've had a fairly easy ride yet today, I'll hit you with another question.

MR. DERSTINE: Oh-oh.

COMMISSIONER CAPUTO: On abnormal occurrence criteria, as has been stated several times today, there may be cause to revise those criteria because they may be capturing events that are not significant from the standpoint of public health and safety. Could you just elaborate a little more on OAS's position on that issue?

MR. DERSTINE: Well, I know for reporting reportable events, and everything, I know every Agreement State makes it a big deal to get out there and investigate. And it has to be reported, and it's up to the licensee to determine a reportable event and they have a timeframe, after they determine that it is a reportable event, to get it to us. Then, we have a timeframe to pump it on up through to the NRC. And then, we also have to get out there and investigate.

We learn a lot from reportable events. So, they are important for us, for a licensee to report it to us, and it gets the information out there to share with all the licensees throughout the country. And that's very important as well.

Yes, I would hate to take away some of the requirements for a reportable event. It's a great learning experience for everybody, even though I do see the other side. The facility does struggle. They don't want their name being out there. Everyone perceives it that a mistake happened, and that's not always the case.

COMMISSIONER CAPUTO: So, maybe what we are doing is room to draw a bit of a distinction. Abnormal occurrence for us means that it actually triggers reporting to Congress on each of these events. Is there room for sort of refining a breakdown between what actually warrants that level of reporting versus a more normal level of reporting and tracking? Is there a breakdown that sounds reasonable there?

MR. DERSTINE: Yes, that sounds like a decent proposal, yes.

COMMISSIONER CAPUTO: Okay. Mr. Mailman, you've also gotten off easy so far. And so, I have a fairly basic question for you. So, we have developed a brochure for patients: "What you should know about treatment with radioactive drugs". Are you familiar with it?

MR. MAILMAN: I have not reviewed it yet.

COMMISSIONER CAPUTO: Okay.

MR. MAILMAN: I just reviewed the actual guidelines themselves.

COMMISSIONER CAPUTO: Okay. All right. Well, I guess I'd be curious, once you have reviewed it, whether or not you think it hits the mark in terms of the level of education, the level of information that patients need in order to feel comfortable with the procedure and the ramifications.

MR. MAILMAN: I do think one of the challenges for any generic piece is that these isotopes are pretty specific in the energy and what kind of considerations you're going to have to do as well. And so, it is a challenging -- they also need to be developed at the isotope or therapy level as well.

COMMISSIONER BARAN: Okay.

DR. EICHLER: Commissioner, ASTRO would also love to see that brochure. We have a very extensive education arm that started off very broad with prostate cancer and

breast cancer. Now it's narrowed down to stereotactic radiosurgery and things like this. So, we would be very interested in seeing that.

COMMISSIONER CAPUTO: I'll just start with this.

(Laughter.)

DR. EICHLER: Okay.

COMMISSIONER CAPUTO: The color came out a little funky on the printer, but there you go.

DR. EICHLER: Thanks so much.

COMMISSIONER CAPUTO: And I'm sure you can find that on our website.

DR. EICHLER: Thank you very much.

COMMISSIONER CAPUTO: Because I'm sure I can get another one later.

So, Dr. Sheldon, I have a couple of questions for you. We've talked a little bit today about how our two agencies work together. So, just one kind of open question about, are there ways that you think we can maybe work smarter together? And considering that we are working on an MOU, are they all captured in that MOU? Are we making enough progress on bringing that MOU to completion, to really help each other as sister agencies to move forward?

DR. SHELDON: Well, of course, I'm not familiar with your MOUs and where you're working on that with FDA.

COMMISSIONER CAPUTO: Okay.

DR. SHELDON: That's not been an area that I've been. But what I would definitely recommend is, as the Chairman mentioned, have some follow-up afterwards. I know the people that do that type of work, and I think it would be really helpful for both of us to learn from each other lessons learned, et cetera. I've been involved with multiple activities outside of the FDA, with the NIH, with CMS, as I've mentioned, and others. And I'm never surprised by

what we learn from each other.

COMMISSIONER CAPUTO: Okay.

DR. SHELDON: So, I think it's a good idea.

COMMISSIONER CAPUTO: Well, thank you. I think there are probably two areas. One, just in terms of the nature of how we both operate in closely-related space with regard to medical isotopes, but, also, the broader issue in terms of your introspective analysis of how to respond to the need to make more timely decisions and the response to criticisms that this drives business decisions. We do receive a fair amount of that ourselves. So, I think, obviously, I wholeheartedly support what the Chairman discussed earlier because I think there's a lot of room there for us to sort of do our own introspective look and come up with, hopefully, some frank observations and room for improvement.

But one that you mentioned, in particular, that caught my eye was your entrepreneur-in-residence. Now, for us here, my immediate reaction to that is we would be quickly criticized for being cozy with industry in terms of either bringing an industry person to educate our staff or placing our staff in a company to learn.

So, given the fact that FDA would have the same need for ensuring independence and objectivity and ethical standards, how did you handle that sort of fox-in-the-henhouse criticism in terms of bringing your entrepreneur into residence?

DR. SHELDON: So, that's always a very big challenge. And it's very interesting, I'm relatively new to the FDA, about six or seven years, but I've already seen two or three, or maybe four, new Commissioners in that period of time. And every new Commissioner always gets grilled about the relationship between industry and the regulators.

And it's always seemed that the regulators and those who develop the products are, I guess, adversarial. What we've done, at least in the Center for Devices, is to recognize

that we're really on the same team, and the team that we're on is the team for the patients, the people that need the services. Once you put the patient in the middle, some of those things go away.

We sometimes like to even say that at least the Device Center is not fundamentally a regulatory organization. We're a public health organization and regulation is the process by which we improve public health.

So, if we focus on the patient, the user, why we're trying to do this, we must work with industry very, very closely. We must learn from them and work together. It's a challenge, but we also recognize that innovation flourishes at the borderline between different expertise. And innovation also means that change is the only constant.

We know that there are others who will criticize that, but, in the end, if the work that comes out benefits the user, which in our case the customer is the patient, and we improve public health, it tends to go away.

COMMISSIONER CAPUTO: Got you. Thank you.

CHAIRMAN SVINICKI: Thank you very much.

Commissioner Wright, please proceed, and thank you for your patience.

COMMISSIONER WRIGHT: I've just enjoyed listening to the questions and the dialog.

And to pick up real quick on the insurance and the preauthorization stuff, I agree with Mr. Mailman; I believe this is a lot more difficult in areas. And I hear you, Doctor, and I'm sure in some hospitals and some practices it's easier. But I have known personally of some other outcomes and I know that I'm sure that Mr. Mailman knows the same thing. So, I do think it's something that really needs to be looked at and considered as a whole, as part of the whole thing. But I really did enjoy that discussion. Thank you so much.

Dr. Sheldon, I really have enjoyed listening to you today because we're trying to transform here at the NRC, as you probably know. And it's helpful to hear that other agencies are going through the same thing possibly and probably. It's interesting for me to learn how the regulators are maybe approaching, in other agencies how you are approaching it.

It sounds like FDA's reforms to its licensing process would or might require the staff to change how they look at licensing and maybe to accept a little bit more risk, to include risk. Would that be fair?

DR. SHELDON: Yes, it would. Most of what we faced was an internal culture change process, because there are a lot of staff that have been at FDA for many, many years. And I would often hear, as I also hear from physicians routinely, "I've been doing it this way for 35 years and I'm not about to change now." And that is really counterproductive because, as Darwin has shown us, everything changes, and if you don't change, you become extinct.

COMMISSIONER WRIGHT: I'd be interested in hearing a little bit about how maybe they addressed making some of those changes or if some of the risks were perceived as being too high. How did you go about addressing it?

DR. SHELDON: We went about it in two or three ways. One, of course, was the entrepreneurs-in-residence program, where we actually allowed our staff to be interacting with those experts outside, often who were identified as the biggest critics.

That was always a funny challenge. My mentor in medical device development is Tom Fogarty. I don't know if anybody knows who Tom Fogarty is. He's probably the most impressive medical device developer in the world for cardiovascular devices; received a medal from President Obama just for that.

Tom is about 86-87 years old; in 2011, became an entrepreneur-in-residence. But he tells the story that, when he got the telephone call from Jeff Shuren, "Would you like to

come and help us?", it took him quite a while to pick up the phone after laughing so hard. He said, "Do you know who you're calling?" He said, you know, "You don't want me." And Jeff said, "Yes, we actually do. We think it's time to listen."

And really, it was all important because of the patients. When I hear Mr. Mailman's story of having to go to Germany and patients coming back from elsewhere, and we learn that we're the 46th country in the world to approve percutaneous heart valves, when the companies who built the percutaneous heart valves are all U.S. companies, we say, that's a problem and it must be addressed.

And so, we really needed to reach out. Of course, our staff resisted. And one of the things, as I mentioned, we went from 422 days as a median to 30. The staff resisted immediately. "So, you just want us to give up our standards and just rubberstamp everything that comes to us?" He said, "Absolutely not, but there are a lot of things that you can do."

One of the biggest things -- and I'll never forget this -- when Rob Califf became one of the new Commissioners, I interacted with him previously because he's a cardiologist. And he came by the office and he said, "Now that I'm here, tell me, what is it that you guys really do the best?" And without blinking an eye, I told him, "Rob, one of the things I've learned is we build great silos."

(Laughter.)

All silos, thick silos, no windows, no walls. And that's one of the things that we do the best. I don't think that's really so good.

And so, the first thing that we started to do was to break down the silos. We got out sledgehammers. We put in doors. We put in windows. And we told our review staff, "If you've got a problem with something that you're seeing, pick up the phone; call the sponsor, call the manufacture, and discuss it with them and try to figure out how you can work this out

today" not by buying a catapult and putting in all of your materials and shoving it over the wall, and it lands with a big thud with dust all over the place. And then, you look at it and we put it in the FDA catapult and send it back.

And the communication is very, very poor. Nobody understands what they're talking about. So, direct communication we found has been incredibly useful, and our staff kind of loves it. And they're all very excited to help to bring new, innovative products to patients. Now they're really engaged.

DR. EICHLER: Murray is absolutely right. Doctors as a rule don't like change. Just take an extreme example. If it takes me six weeks to treat something, and somebody comes along and says, "I have a way to do this in one day," the first thing you say is not "Wow, that's fantastic. That's great for the patient." It's, "What's that going to do to the coding? What's it going to do to reimbursement?" Because, I mean, there's a whole string of questions that pop up that shouldn't pop up at all.

DR. SHELDON: The only people who like change is our babies with wet diapers.

(Laughter.)

Change is very difficult to deal with, but it's mandatory. It will happen.

DR. EICHLER: Well, you either have to do it or it will be done to you.

DR. SHELDON: That's right.

COMMISSIONER WRIGHT: Exactly. So, I really appreciate the comments.

Again, earlier the Chairman was suggesting that we ought to have more dialog with FDA, and I think this is another area where we share a lot of the same kind of silos --

DR. SHELDON: Yes.

COMMISSIONER WRIGHT: -- that we're trying to break down. So, thank you

for your comments. I learned more about how you're doing it.

DR. SHELDON: More than happy to interact.

COMMISSIONER WRIGHT: Quickly, Mr. Derstine, I join Commissioner Caputo; it would really be good to get a little bit more data, if you all can pull that together, as to how you reached the position that OAS did. I was at the meeting when Mike Fuller from Virginia made the presentation, and it was like an "Oh, wow" moment there, and it has sparked a lot of discussion. So, if you have any comment, I would be glad to hear.

MR. DERSTINE: Thank you. I'll take that back to the OAS and even, yes, maybe on our next monthly call with the NRC-OAS-CRCPD, throw that out there.

COMMISSIONER WRIGHT: Fine.

MR. DERSTINE: And maybe we can brainstorm the best way to get that data.

COMMISSIONER WRIGHT: Okay. Thank you.

And for you two, you discussed earlier about social media a little bit and about providing useful information, and how to stop misinformation from getting around. And I think you're spot-on with that.

So, talk to me a little bit more about how you help patients and others navigate this to ensure that they're going to get accurate information. I mean, is there more that we need to do? And if you can be a little bit more specific, that would be great.

DR. EICHLER: Yes, that has become, obviously, a huge problem in the information age. Especially, social media has changed everything. There's a ton of stuff out there now that's completely inaccurate.

But how I would approach it with patients is I would direct them to specific websites. And we give everybody a piece of literature specific to their cancer and it lists the websites that we have already vetted. And then, we have an in-house one called

RTAnswers.org, which is spectacular. It's got two-minute videos, five-minute videos. It's got all kinds of information in there. So, I make sure they're directed to that.

But, again, it comes down to the patient. Not everybody has, believe it or not, not everybody has internet savvy, and you've got to sit and talk with those folks and make sure they understand in very plain terms what you're going to do to them and what the expectations are, what the chances of success are.

So, it's still a very individualized process. Social media and the internet are both a blessing and a curse. There are people that walk in the office sometimes with shopping bags full of books and want to discuss every little piece of information that's out there. So, you really kind of have to guide them to the right place, and over a period of time you get used to doing that. I think there's, from my own perspective, a fair amount of success in doing that.

DR. DILSIZIAN: So, I agree. I think, obviously, it's generational, right. The older patients are still going to be listening to you and not go to Facebook or YouTube. But the majority of the patients are in the new era of media through Facebook, through YouTube. And I agree that there's a lot of noise out there.

But I think at least that my experience is, I used to think -- I was pretty naive -- that that brochure that you handed them, I mean, that's what we used to do. We printed those up, give to the patient. You know, "Here's radiation safety instructions. Here's what you're going to read." And, you know, I thought that would fulfill it. Of course, it's not because some people don't read at all; they misplace it.

And I'm looking at my kids; I mean, their education of high-level physics and quantum physics is on media. I mean, they're just getting a lot of good information.

So, I agree with you, how do we guide them? Again, first, to make the tape, the video clip, and the next thing is to guide them. So, I think that we're going to be targeting not

just the SNMMI website, but the endocrinologists, patient advocacy. So, the same clip has to be everywhere that the patient may have access. Otherwise, it would be naive for us to think that they're going to come to our site only. So, it's just a matter of being clever and saying, where do patients get their information, and target those sites.

MR. MAILMAN: And also, make them patient-relative, relatable information. Because, I mean, I was looking at the back page. The back page is actually the one that I was making large comments on. That's really generic, sleep alone. Okay. I look at that. That's why people, then, go get their own apartment for a week to stay away from their family, which might be interesting for I-131, really not interesting for Lu-177. But just like that you can really lose people.

So, this has to be relatable to the experience they're going through. You have to be multi-modality, in different channels, whether it's YouTube, whether it's Twitter. There have to be ways to have information that's accessible to patients in a language they understand, because, otherwise, they just make stuff up.

It's one of the things I do when I'm on the road shows with the SNMMI as well. Even docs make stuff up when they don't know things, and we've got to stop making stuff up and really have good, credible, easy-to-understand information that can be accessed in a multitude of ways.

DR. EICHLER: So, as a major cancer therapeutical "doubty," we commission surveys every couple of years to find out what are patients hearing; what do they want to know; what are we not doing well, and try to change to accommodate the patient population.

Even with these brochures that I mentioned that went out, the videos that went out, they had been edited again and again and again to get it to the right level of education for the patients. So, it's an ongoing effort.

MR. MAILMAN: And another thing that I do is patient communication education because, for the most part, when we leave your office, we're going to forget 85 percent of what you told us, and that 15 percent that we actually retain, we're going to get half of it wrong.

So, it's a repetition. There are studies that are done about this. And it really is having the material ready when someone needs it, when they can absorb it, and then, retesting it because, in fact, even if you think they have it, they don't.

DR. EICHLER: So, I encourage people to bring someone with them and tell them at the outset, "You're only going to remember 50 percent of what I say. Your job is to remember the other 50 percent."

COMMISSIONER WRIGHT: Yes, yes. And with that, on the brochure, any feedback -- I appreciate Commissioner Caputo giving it to you -- and any feedback you can give us would be very helpful. So, thank you.

Thank you.

CHAIRMAN SVINICKI: All right. Well, thank you again to our panelists.

Again, it's interesting because we do have on a routine frequency a meeting of our Commission with the Advisory Committee on the Medical Uses of Isotopes. And I'll just candidly admit that, when this meeting was proposed, not by me, but by my colleagues, I wasn't sure that there wasn't a redundancy there, but I observe that we had a very different dialog today on different topics. And maybe some of it, we got to see the cross-connections and we got to just kind of view it all from standing back a little further. I found it very valuable. I thank my colleagues for proposing the meeting.

And I want to thank all of you for being here today, and for the NRC staff for their hard work and their presentation.

With that, we are adjourned. Thank you.

(Whereupon, the above-entitled matter went off the record at 12:17 p.m.)