UNITED STATES

NUCLEAR REGULATORY COMMISSION

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MEETING WITH THE ADVISORY COMMITTEE ON THE MEDICAL USES

OF ISOTOPES (ACMUI)

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TUESDAY,

APRIL 8, 2025

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The Commission met in the Commissioners' Hearing Room, at 10:00 a.m. EDT, David A. Wright, Chairman, presiding.

COMMISSION MEMBERS:

DAVID A. WRIGHT, Chairman

ANNIE CAPUTO, Commissioner

CHRISTOPHER T. HANSON, Commissioner

BRADLEY R. CROWELL, Commissioner

MATTHEW J. MARZANO, Commissioner

ALSO PRESENT:

CARRIE M. SAFFORD, Secretary of the Commission

BROOKE P. CLARK, General Counsel

ACMUI MEMBERS:

HOSSEIN JADVAR, Chair

RICHARD GREEN

MICHAEL FOLKERT

RICHARD HARVEY

ZOUBIR OUHIB

JOHN ANGLE, Consultant

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

9:57 a.m.

CHAIRMAN WRIGHT: Let's do it. All right. Good morning again everyone. I call this meeting to order.

In today's public meeting of the Nuclear Regulatory Commission, we will have an opportunity to hear from the Advisory Committee on the Medical Uses of Isotopes on the medical related topics of regulatory interest.

We will first have members of the committee provide their perspectives and views on the medical use of radioactive material, and as is our custom, we'll hold questions from the Commission to the end of the presentations.

Before we start though, let me ask my colleagues if they have any comments they'd like to make before we start. Anyone?

(No response.)

CHAIRMAN WRIGHT: Okay. With that, we'll begin then. This morning we are joined by Dr. Hossein Jadvar, who serves as the Chair of ACMUI and nuclear medicine physician of the committee.

Dr. Jadvar, the floor is yours.

DR. JADVAR: Thank you, Chairman Wright, Commissioners Caputo, Crowell, Hanson, and Marzano. Good morning, and thank you for taking time to meet with us, the ACMUI panel.

Before I start my report, I just want to express my gratitude in working with such a distinguished panel and also extend my sincere

thanks to the NRC staff for their expertise and support.

With that, I start my presentation. Can I have the next slide?

So, I'm going to give an overview of the ACMUI activities over the past year, and then Mr. Richard Green, who is the nuclear pharmacist and also the ACMUI Vice Chair, will give a presentation on the growth in radiopharmaceutical therapy. Next slide, please.

Then Dr. Michael Folkert, who is the radiation oncologist on the panel, will give the ACMUI review of training and experience for emerging medical technologies. And then, this is followed by a statement from the ACMUI's patients' right advocate, which I will read. Next slide, please.

These are the overview of the ACMUI. I will go over the ACMUI role, the membership, the topics that we covered over 24/25, and the current subcommittees and what we are going to do in the future. Next slide, please.

ACMUI advises the U.S. NRC staff on policy and technical issues that arise in the regulation of the medical use of radioactive material in diagnosis and therapy.

We also comment on changes to NRC regulations and guidance, evaluate certain non-routine uses of radioactive material, provide technical assistance in licensing, inspection, and enforcement cases, and we'll bring key issues to attention of the Commission for appropriate action. Next slide, please.

We have 13 members on the ACMUI panel. The nuclear

medicine physician and Chair is myself, the nuclear pharmacist and Vice Chair is Mr. Richard Green, the nuclear cardiologist is Dr. Andrew Einstein.

The brachytherapy radiation oncologist is Dr. Michael Folkert, the Gamma stereotactic radiosurgery radiation oncologist is Dr. Harvey Wolkov. The diagnostic radiologist, who recently joined us, is Dr. Joanna Fair, the FDA representative is Dr. Michael O'Hara. Next slide, please.

The nuclear medicine medical physicist is Ms. Melissa Martin, the radiation therapy medical physicist is Mr. Zoubir Ouhib. The patients' right advocate is Mr. Josh Mailman, the agreement state representative is Ms. Megan Shober.

The healthcare administrator is Ms. Rebecca Allen, and the radiation safety officer is Dr. Richard Harvey. Next slide, please.

We also continue to benefit from the expertise and advice of the, our consultant interventional radiologist, Dr. John Angle. Next slide, please.

The ACMUI provided the subcommittee's evaluation of recent Y-90 microsphere medical events, after NRC staff identified a sudden increase in reported events involving unexpected gastrointestinal deposition.

The ACMUI Subcommittee on Generic Process Checklist, provided a recommendation that licensees should develop a process checklist that is specific to their practice and processes, to minimize medical events.

The subcommittee provided an example of this checklist and recommended that the staff determine the best method to inform

licensees of this recommendation.

The ACMUI Subcommittee on Interventional Radiologist, recommended that the Commission consider including an interventional radiologist on the ACMUI to provide insight and recommendations regarding yttrium-90 microspheres given the increased use in this area.

Finally, the ACMUI Subcommittee on Training and Experience Requirements, provided recommendations for consideration in the emerging medical technologies rulemaking. Next slide, please.

The ACMUI reviewed and commented on the NRC staff's draft regulatory basis document for financial assurance requirements for disposition of Category 1 to 3 byproduct material radioactive sealed sources rulemaking.

The ACMUI reviewed and commented on the NRC staff's draft proposal rule and associated draft implementation guidance for reporting nuclear medicine injection extravasations as medical events.

The ACMUI reviewed and commented on the interim staff guidance on implementation of training and experience. Next slide, please.

The ACMUI subcommittee on bylaws provided recommended changes to the ACMUI bylaws to update conflict of interest procedures and ensure the bylaws were updated with the new FACA requirements.

The ACMUI also reviewed three emerging medical technology licensing guidance documents that the staff developed in 2024.

These were the Akesis Galaxy RTi Unit, which is a gamma stereotactic radiosurgery unit that includes moving sources and tables; Y-90

microspheres, which is a new Y-90 microsphere device that includes properties that allow them to be seen on the fluoroscopy; and, Liberty Vision Y-90 episcleral brachytherapy source.

For all these reviews, the ACMUI agreed with the NRC staff's recommendation that they should be licensed under 10 CFR 35.1000, and generally agreed with the draft guidance, but provided medical insights and recommendations for each draft guidance. Next slide, please.

An ACMUI member provided review of seven published articles describing error reduction methodologies to avoid prescription error.

Finally, the ACMUI reviewed historic medical events where it noted that medical events are relatively low, but noted an increase in medical events related to 10 CFR 35.300 and yttrium-90 microspheres licensed under 10 CFR 35.1000.

This evaluation was an initiation point for the generic process checklist report that I described earlier. Next slide, please.

In addition to the ACMUI presentations, NRC staff also provides presentations. At every meeting, the NRC staff provides an overview of updates by the medical radiation safety team, where they provide ongoing rulemaking and guidance development processes and schedules, overview of activities at the NRC that may impact the medical industry, such as teams' initiatives to look for efficiencies in licensing and oversight, and updates to ACMUI policies and procedures.

The staff also provides a presentation giving an overview of all the past years' medical events with a special presentation this year on yttrium-90 microsphere medical events, following their evaluation of these

events.

The staff provided a status update on patient release guidance. They informed the ACMUI that significant changes are being made to the guidance based on feedback from the industry.

These changes include the addition of many more examples, which will help the industry quickly release the majority of patients. However, the staff is trying to maintain flexibility to provide licensees guidance for unique patient situations.

Michael King of the NRC staff, provided an overview of the ADVANCE Act in the fall of last year. The medical team also continues to provide the ACMUI any updates related to the ongoing rulemaking and guidance development efforts, as well as discuss medical issues of interest with the ACMUI. Next slide, please.

The NRC provided an overview of their plans to develop guidance to address patient waste concerns following release. The NRC also leads a yearly discussion to discuss the ACMUI reporting structure.

Finally, the staff provides required training to the ACMUI. This year, the staff provided an expanded ethics training to cover more specific topics for apparent conflicts of interest. Next slide, please.

The ACMUI has formed a subcommittee to evaluate and provide recommendations, if any, to ensure NRC licensing and oversight of medical use of byproduct materials aligned with the NRC's mission statement that was established on January 24, 2025. This subcommittee plans to present findings later this year.

The ACMUI also has some standing subcommittees to

evaluate and provide recommendations on the staff products in their arenas, in their areas.

This includes the NRC Mission and Medical Use Licensing and Oversight, Patient Release Subcommittee, Training and Experience for All Modalities Subcommittee, Medical Event Reporting and Extravasation Subcommittee, Yttrium-90 GI Deposition Medical Events, Emerging Medical -- next slide please, Emerging Medical Technologies and Rubidium-82 Generator Subcommittee, and the membership of an interventional radiologist. Next slide, please.

The ACMUI will continue to provide advice and technical assistance, comment on NRC regulations and guidance, evaluate uses of radioactive material, and bring key issues to the attention of the Commission.

And, with that next slide, these are my acronyms. And, that's the conclusion of my presentation. Thank you so much.

CHAIRMAN WRIGHT: Thank you for your presentation, Dr. Jadvar.

Next, we'll hear from Mr. Richard Green, who is the Vice Chair and nuclear pharmacist on the committee.

MR. GREEN: All right. Commissioners Crowell, Caputo, Hanson, and Marzano, thank you. Again, good morning.

Thank you for the opportunity to speak with you today. As a nuclear pharmacist representative on the ACMUI, my presentation today was prepared by myself, given my area of expertise, to share on the projected growth of therapeutic radiopharmaceuticals as this relates to my

work reviewed by the ACMU -- as this relates to work reviewed by the ACMUI.

But, this presentation is not an official production or presentation endorsed by the ACMUI. Next slide, please.

Today we'll start with a quick look backwards at the history of FDA-approved therapeutic radiopharmaceuticals. Essentially, what therapeutic radiopharmaceuticals are available today and when where they added to the Physician's Armamentarium.

Next, we'll look at the projected growth of radiopharmaceutical therapies, what new radioisotopes might be utilized. We'll then look at clinical trials currently underway to get a glimpse of what might receive FDA approval.

We'll conclude with some possible new challenges that may be faced by the NRC and licensees. Next slide, please.

For this slide, I've grouped the FDA-approved history of therapeutic radiopharmaceuticals into five-year brackets.

In 1951, the FDA approved the first therapeutic radiopharmaceutical, iodine-131 sodium iodide, for the treatment of hyperthyroidism and thyroid carcinoma.

This was a prototype theranostic, a term we hear all about today, with smaller doses administered for diagnosis and then larger doses administered for therapy, or both diagnostic and therapeutic nuclides attached to the same chemical entity used for diagnosis and therapy respectively.

It was six years later in 1957, that P-32 sodium phosphate,

was FDA-approved for the treatment of polycythemia vera. And then, 17 years after that, that the other variant of P-32, chromic phosphate, was FDA-approved for intracavitary installation for the treatment of pleural effusions.

It was then 19 years later when strontium-89 chloride was FDA-approved for bone pain palliation. Then, the pace seems to begin to pick up a little quicker, with Quadramet in 1997, also for bone pain palliation.

In 2002, Zevalin, and then 2003, Bexxar were approved by the FDA, both indicated for treating non-Hodgkin's lymphoma.

A decade long gap exists until 2013, when Xofigo was FDA-approved for the treatment of patients with castration resistant prostate cancer, who had symptomatic bone metastases and no known visceral metastatic disease.

2018, Lutathera was approved by the FDA to treat, this is a tongue twister, gastroenteropancreatic neuroendocrine tumors that are positive for the hormone receptor somatostatin. That same year Azedra was FDA-approved to treat patients with iobenguane-positive, unresectable, locally-advanced, or metastatic pheochromocytomas or paragangliomas.

The newest rate pharmaceutical therapy was approved in 2022, is Pluvicto, indicated for the treatment of adult patients with prostate-specific membrane antigen, PMSA-positive metastatic castration resistant prostate cancer that had been treated with antigen receptor pathway inhibition, and are considered appropriate to delay chemotherapy.

It was just last night that I saw my first ever in my life, direct to the consumer, advertising on TV for a radiopharmaceutical, for

Pluvicto.

The FDA modified its indication just on March 28, to allow it to be used earlier in the patient's treatment pathway, effectively opening it up to use in many times more patients than it was previously.

In the 74 years since the first therapeutic radiopharmaceutical was FDA-approved, there have been a total of 11 drugs approved.

But, not all of these FDA-approved radiopharmaceuticals therapies have remained on the market. None were withdrawn because of lack of efficacy or because of patient harm.

Those that are gone have died an economic death. They've fallen out of favor or been replaced by newer, better agents. Next slide, please.

Okay. In 2003, the first of these therapeutic agents was withdrawn from the market, Bexxar, the same year it was approved. Followed by the withdrawal of both P-32 agents in 2009.

Zevalin was withdrawn in 2020, followed shortly thereafter by Quadramet in 2021, and Azedra in 2024. So, although we have had 11 FDA-approved therapies approved, only five of these remain on the market currently.

But, as we'll soon shortly discuss, this very slow rate of therapeutic rate of pharmaceuticals development and approval will be accelerating markedly. Next slide, please.

One way we could evaluate the increasing interest in theranostics, is to look at the change over time of published studies via

PubMed.

Here you can see the dramatic increase in published studies with a search term theranostic between 2014 and 2024. Quite an increase in growth over the last 10 years. Next slide, please.

Another way to assess the projected growth of theranostics, is to look at a published projection of the growth of theranostics from an economic standpoint.

The global market for theranostics is anticipated to move from 111 billion in 2024, to a projected 185 billion in 2029, just five years away.

It is estimated that the market for U.S. radiopharmaceuticals is 50 percent of the world value. This is a projected, compounded annual growth rate of 10.8 percent.

The traditional pharmaceutical industry has discovered the radiopharmaceutical market, as evidenced by all of the high-dollar acquisitions in recent years.

It is hard to keep track of all the plant investments and acquisitions that have been made public. Next slide, please.

The pace of approved therapeutic radiopharmaceuticals will be dramatically changing soon. It is estimated there are currently 38 companies conducting 45 clinical trial programs.

You can see the companies listed on this most outer ring of this chart. This graphic does a great job of graphically representing the degree of commercial interest in therapeutic radiopharmaceuticals.

If we start in the center of the circle, there are the two most

recently approved therapeutic radiopharmaceuticals, Pluvicto and Lutathera. In the dark blue band, just beyond that central circle, is the Phase III band, where there are eight agents.

And then, moving outward, the next two light blue concentric bands represent Phases II and Phase I, which have 28 agents. As you can see, there are numerous agents in the outermost ring, the preclinical stage.

All of the commercial firms are identified in the outside circle. Overall, there are 275 clinical trials underway with theranostic therapeutic radiopharmaceuticals.

This graphic goes on to identify these investigational therapeutic agents as to their type, whether they're small molecule, antibodies, peptides, and identifies the radionuclides involved.

This graphic supports the projection that there will be more than a 10 percent compounded annual growth rate. There's lots of things coming. Next slide, please.

There are several radioisotopes that will be new to nuclear medicine utilized in some of these investigational new drugs, and perhaps to be approved radiopharmaceuticals.

We'll run through these in order of their atomic number, starting with scandium-47, that can be produced in reactors or cyclotrons.

This 3.35-day beta-emitting radioisotope, can be paired up with either scandium-43 or scandium-44g, both of which are PET-emitters. In addition, scandium-47 itself, has a 159-keV gamma emission that is imageable via SPECT.

Copper-67 can be produced using photo nuclear reaction, and is a 61.8-day, hour half-life beta-emitting radioisotope. It can be paired with copper-64, a PET emitter. Copper 67 itself also has two SPECT-imageable photons.

Terbium-161 can be produced in a reactor, and is a 6.96-day half-life beta-emitting radioisotope. Dosimetry analysis has revealed that terbium-161 has a 1.4-fold higher energy deposition to established tumors, compared to lutetium-177. There's lower energy electrons involved.

This ratio increases to about 4.4-fold for small cell clusters and singular cells. Terbium-161 is also a SPECT-imageable emitting isotope.

Rhenium is the last naturally occurring chemical element that was discovered in 1925. Rhenium-186 is a 3.7-day half-life beta-emitting isotope. Next slide, please.

Four more we'll cover. Lead-212 is a 10.6-hour half-life radioisotope that has a decay chain that includes two beta particles and culminates in a single alpha particle. Lead-203 can be used as a SPECT-imaging diagnostic analog diagnostic pair.

Bismuth-213 can be isolated from an actinium-225 generator. It has a 45.6-minute half-life, and the decay chain has three beta particles and one alpha particle.

Actinium-225, which I'm sure you've heard much about, is a 10-day half-life, with a decay chain with three beta particles and five alpha particles. It can be obtained either from a thorium-229 decay or from accelerator production.

Cerium-134 is a PET-emitting diagnostic analog that can be used as a diagnostic half of this theranostic pair.

The last one we'll discuss is thorium-227, an 18.7-day half-life, with an extensive decay chain with five beta particles and eight alpha particles. Cerium-134 is also a possible PET-emitting diagnostic analog. Next slide, please.

Here's a published graph showing the distribution of therapeutic radiopharmaceutical clinical trials and the radioisotopes utilized. Next slide, please.

From the graphic we reviewed on slide seven, it can be seen that there's a great deal of interest in therapeutic radiopharmaceuticals, especially theranostic agents that utilize the same molecule to localize the cancer attached to either a diagnostic or a therapeutic radionuclide.

There are over 275 therapeutic clinical trials currently underway. During 2025, this year, data will be released from 15 completed clinical trials.

Oncology targets could include head, neck, gynecologic, genital urinary, gastrointestinal, lung, and skin cancers.

There are all kinds of applications for therapeutic radiopharmaceuticals. It could be said that we haven't even scratched the surface of what radiopharmaceuticals can do.

Just a few weeks ago in late February, it was announced that the FDA has accepted the biological license application, or BLA, of a breakthrough clear cell renal carcinoma PET-imaging agent that is labeled with zirconium-89.

It was granted a priority review, and provided a PDUFA date in August of 2025, just a few months away, paving the way for a possible U.S. commercial launch in 2025.

There are clinical trials currently underway for both a lutetium-177 and an actinium-225 labeled therapeutic version of this kidney agent.

So, we're going to see the diagnostic first and then one if not two therapeutic versions of that agent. Next slide, please.

So, what challenges might licensees or the NRC encounter with all this involvement in radiotheranostics and new agents coming?

The first, is the ability to accurately measure radionuclides in our dose calibrator. This is essential for radiopharmacies and for the clinic.

Thankfully, we have NIST. Dr. Brian Zimmerman, leader of the Radioactivity Group Medical Measurement Laboratory at the National Institutes of Standards and Technology, reported recently that NIST has completed the development of their standard for actinium-225.

And, this radionuclide was added to their list of calibrations available. They've already performed two calibrations for external customers and provided several calibrated sources to the company that sponsored this project.

It is imperative that the final product container vial is NIST calibrated so that radiopharmacies and clinical licensees can accurately measure these radioisotopes in their dose calibrators. This is true for all radioisotopes that come to market.

As we mentioned, there's new ones coming. And, these new ones are not clean, clear, crisp, 140-keV, like tech-99m, which is 80 percent of what nuclear medicine is. These have lots of betas, and alphas, and small components of other emissions.

So, it's essential that we have support from NIST and that each commercial manufacturer takes the time and effort to make sure that the product vial that goes to the end user clinic or pharmacy is NIST traceable and we can measure accurately.

The next item that, I think, might be a challenge, is that older radionuclide therapies were often small volume injections, typically less than 10 milliliters, and were easily accomplished in existing unit dose pigs.

Newer radiotherapies are higher volume infusions, sometimes reaching 20 to 30 milliliters, that will require larger patient-ready unit dose syringe pigs, and the corresponding DOT type-A shipping containers to get them from the pharmacy to the clinic.

The other issue that is before the industry, is the fact that the IAEA is currently revising SSR-6, which includes revisions to many of the A1 and A2 values found in table two, basically, radionuclide values.

Most notably are the significant reductions in the A2 values for medical radionuclides that emit high-energy alpha particles through radioactive decay, either directly or indirectly, through their short-lived progeny.

The significant reduction in A2 values for some alpha-emitting radionuclides in the current revisions of SSR-6, will present significant challenges to the development, production, and distribution of

innovative medical radionuclides and radiopharmaceuticals utilizing radioisotopes such as lead-212, actinium-225, and astatine-211.

If these proposed changes to SSR-6 are carried out, manufacturers and nuclear pharmacies will potentially need to migrate to Type-B containers packaging for supply chain shipments, as well as radiopharmaceutical deliveries to healthcare providers for these short-lived nuclides. Next slide, please.

Often, there are multiple methods to produce radioisotopes used in therapy. Some production methods can also produce undesirable long-lived radionuclidic contaminants, such as we were encountering with lutetium-177m, which is 160-day half-life impurity found in lutetium-177, which is 6.6 days.

And, in the future, we may see actinium-227 with a 21.7-year half-life as a radionuclidic contaminant in actinium-225, which is 9.9 day half-life.

The presence of these long-lived contaminants will preclude decay in storage as permitted by 10 CFR 35.92, and will require the services of a waste broker to assist in disposal. Let's cross our fingers that we get clean isotopes. That would help.

Radionuclide therapy is no longer one and done. It's not a single injection and you're done. It is often now a multi-course treatment regimen, sometimes involving pretreatment with renal protectants, anti-emetics, et cetera, and will require multi-disciplinary coordination.

Yesterday, the ACMUI subcommittee on Generic Checklists, recommended the creation of an information notice or other

means of communication to licensees that recommends that all licensees develop tools or checklists to prevent medical events, including those involving radiotherapeutics.

These procedures are not just analog paper checklists, but should employ all the usual digital advancements that are common elsewhere in the hospital, such as computerized prescription order entry, electronic medical records, EMR, intravenous workflow management systems, barcode medication administration.

We think the use of these electronic tools will help prevent and reduce medical errors. And, we certainly want to do that with therapeutic radiopharmaceuticals.

I appreciate the opportunity to speak with you this morning on the exciting future of theranostic radiopharmaceuticals.

These next three slides, list all the acronyms used in the presentation. Thank you.

CHAIRMAN WRIGHT: Thank you very much, Mr. Green. I can't wait for the question part of this.

(Laughter.)

CHAIRMAN WRIGHT: Next, we'll hear from Dr. Michael Folkert, who is the Committee's radiation oncologist. Thank you very much.

DR. FOLKERT: Thank you, Chairman Wright and Commissioners Crowell, Caputo, Hanson, and Marzano.

I will be presenting on the Subcommittee on Training Experience for All Modalities. Let's see. Go ahead to the next slide.

This is the membership of our subcommittee, myself, Dr.

Richard Harvey, Dr. Jadvar, Mr. Ouhib, Ms. Shober, and our NRC staff resource for the committee has been Maryann Ayoade. So, let's move on. Next slide, please.

So, the current charge of the subcommittee, is to review and evaluate the training experience requirements for all modalities in 10 CFR Part 35.

On August 20, 2024, we received an expanded charge to provide recommendations to the NRC on knowledge topics encompassing the safety-related characteristics of emerging medical technologies, or EMTs, required for authorized users to fulfill their radiation safety-related duties and supervision roles, the methods on how these knowledge topics should be acquired, the consideration for continuing education, vendor training for new medical uses, and training on the NRC regulatory requirements. Next slide, please.

Continuing innovation in the uses of radioactive byproduct material, has led to new applications and indications in areas such as Gamma Knife radiosurgery technology, ophthalmic treatments, diffusing radioactive particle implants, and as so eloquently presented by Dr. Green, an increasingly diverse array of diagnostic and therapeutic radiopharmaceuticals. Next slide, please.

Emerging medical technologies are generally classified under 35.1000, but development of new radiopharmaceuticals, brachytherapy applications, and other devices utilizing radioactive byproduct material normally regulated under 10 CFR 35.200, 35.300, 35.400, and 35.600, may incorporate novel ligand, or radioisotope combinations, or

administration methods, that may pose additional patient and radiation safety risks and require additional training.

This is not limited just to therapeutic applications, but also the many new diagnostic applications, as well as an increasing array of diagnostic radioligands are integrated in the clinic. Next slide, please.

So, for each medical use modality, 10 CFR 35 regulations prescribe the minimum hours of classroom and laboratory training, as well as supervised experience.

Many of the core knowledge areas are included here. These are represented in 35.300, 390, and 396, training areas in particular.

The classroom and laboratory training elements are on the left and work experience on the right. We will refer back to these.

But, these are the core existing knowledge topics and knowledge areas that are expected for authorized users. Next slide, please.

So, in addition to these core knowledge areas, there's been an increasing complexity around aspects of patient selection, patient and caregiver education, interactions of radioactive material applications with other therapies and interventions, pre- and post-procedure dosimetry, patient monitoring and release, and reporting of adverse reactions and medical events.

The subcommittee also recognizes, but does not endorse, that the authorized user may not be physically present in some applications.

For example, the administration of radiopharmaceuticals by a certified nuclear medicine technologist, and may instead be monitoring the dose administration virtually.

As such, it is critically important that the independent educational needs of the entire healthcare team are also a consideration that must be met to ensure the safe utilization of EMTs using radioactive byproduct material. Next slide, please.

So, by way of background, for each of these medical use modalities, 10 CFR regulations detail the minimum hours of classroom and laboratory training, as well as supervised experience.

T&E requirements for EMTs are described in 10 CFR 35.1000 guidances. And, the current regulatory framework for AU training experience was established in 2002, following a comprehensive overhaul of 10 CFR 35.

Over the past few decades, the ACMUI has revisited the authorized user T&E requirements regarding board certification pathways, 10 CFR 35.300, radiopharmaceuticals and EMTs in various years. Next slide, please.

And so, with the rapid increase in development of novel radiopharmaceuticals that we saw in the late 2010s, stakeholders expressed concerns with the perceived burden of T&E requirements for authorized users.

The NRC staff engaged stakeholders, the ACMUI, and agreement states, and explored options to reduce the regulatory burden for physicians seeking to become AUs, while preserving training that was critical to radiation safety.

And, this led the NRC staff to submit a rulemaking proposal in 2020, SECY-20-0005, to modify T&E requirements in 10 CFR

35, subparts D and E, for unsealed radioactive byproduct material. Next slide, please.

In this proposal, goals were to establish high-level radiation safety training criteria in advance of the expected new EMTs and novel radiopharmaceutical therapies that we are now seeing rapidly coming down the pipeline, and eliminate the case by case approval of AUs in radioactive byproduct materials licenses.

This rulemaking would have eliminated the alternate pathway for unsealed byproduct material use and required AUs to be certified by a recognized specialty board.

A medical specialty board seeking NRC recognition would have needed to demonstrate that their programs met NRC training requirements for T&E. In 2022, the Commission voted to maintain the status quo, however.

But, they did recommend, as we, and this is very relevant to our current charge, the evaluation of current specialty board recognition areas criteria, and to evaluate knowledge topics required for AUs to fulfill their radiation safety-related duties and supervision roles, the methods on how knowledge topics should be acquired, and consideration for continuing education, vendor training for new medical uses, and training on the NRC requirement, which is the foundation of our updated charge. So, next slide, please.

So, in 2022, the Commission approved the initiation of an EMT rulemaking, SECY-21-0013, which would move many of the EMTs from 10 CFR 35.1000 to other sections of Part 35. This rulemaking would codify

the T&E requirements for AU physicians for these technologies.

In 2023, the NRC staff published a draft regulatory basis for this rulemaking. And, this EMT rulemaking remains in the proposed rule phase.

So, as a result, the NRC staff are assessing ways to make the existing EMT T&E requirements more generalizable, instead of having a customized set of T&E requirements for each 10 CFR 35.1000 licensing guidance document.

And so, this subcommittee's current charge to review knowledge topics for EMTs, is connected to this rulemaking in an effort to identify consistent T&E elements for authorized users. So, next slide, please.

So, moving onto the evaluation and recommendations regarding this current charge. So, and, specific to knowledge, acquisition and maintenance, while the subcommittee recognizes that the final review and approval of AUs too, is primarily the responsibility of the NRC and agreement states.

The subcommittee strongly feels that the acquisition of general safety content and continuing educational content, should primarily be the responsibility of medical boards such as the American Board of Radiology, the American Board of Nuclear Medicine, the Certification Board of Nuclear Cardiology, also very heavily involved; the accreditations councils, such as the Accreditation Council for Graduate Medical Education and the Commission on the Accreditation of Medical Physics Education Programs; and professional societies that are actively engaged in the

training and certification of AUs, RSOs, associate RSOs, authorized nuclear pharmacists, authorized medical physicists, and ophthalmic physicists. Next slide, please.

So, this is not an exhaustive list, but, these professional sites are actively engaged in developing this educational content that is focused on safety.

And, this is not an exhaustive list, as I said, but, many of these professional groups have been actively developing training in these areas, such as the SNMMI, ASTRO, and the many other groups that are listed here that are the professional societies that many of the participants on the ACMUI are also involved with. Next slide, please.

And so, as far as engagement of these professional societies, there is demonstrated interest and engagement in radiation safety educational development by the professional societies.

For example, the SNMMI and ACNM Boards that are primarily working with nuclear medicine, are circulating a joint practice guideline for the use of radiopharmaceuticals.

ASTRO, the primary society for radiation oncologists, has been developing a radiopharmaceutical safety white paper that was actually released this past Friday. And, also has looked into safety training through their APEx Accreditation and through the Radiation Oncology Incident Learning System®.

The American Brachytherapy Society is developing training objectives for radiopharmaceutical practice.

And, the ACR, the American College of Radiology, has

partnered with multiple societies across all specialties to develop practice parameter guidelines, for a range of diagnostic and therapeutic applications involving radioisotopes.

And, these are regularly updated in collaboration with multiple professional societies across the spectrum. Next slide, please.

So, while the NRC currently cannot endorse or preferentially favor any specific training pathway, it is the subcommittee's recommendation that the NRC evaluate whether educational materials or a program meets requirements for initial certification with the technology, to improve the efficiency for evaluating potential AU use.

This is a common thing that comes up with radiation safety officers and with initial credentialing is, has the prospective AU received the training that is necessary to meet all the requirements provided by the NRC.

And, there's no specific, basically checkoff that says whether or not any of these training pathways meet those requirements.

And, it is likely necessary that the NRC will have to develop a range of training scenarios that will depend on the time that has elapsed since professional training was completed by the prospective AU, as well as which training pathway the prospective AU has initially completed. This is in keeping with the case scenarios request.

So, that was present in the recent TE report from our subcommittee. And this was previously endorsed.

And, as per Dr. -- as per the NRC will be released this week, and so, for that guidance. This also would provide an opportunity to clarify scope or practice.

It is -- during the initial licensing of many authorized users, there are, it has been brought to our attention that it is not clear that people understand the scope that the training under 35.390 or 396 offers in terms of use of radioisotopes.

Many people feel that it is restricted to one isotope during initial training. And, this just simply does not allow us to meet the needs of all of these new radioisotopes coming down the pipeline. Next slide, please.

The subcommittee recognizes the role for ongoing continuing medical education for, in supporting quality of care and radiation safety.

In terms of CME, the subcommittee recognizes that professional societies are actively developing and providing CME for practitioners administering existing and emerging technologies through recorded, virtual, and in-person offerings. And, the AU will need to maintain the records of their CME.

We recommend that professional societies develop guidelines for CME minimum contact hours. And, we would also recommend that the NRC explore the need to define minimum CME requirements for AUs. Next slide, please.

Verification of ongoing training experience and continuing medical education, must follow applicable state, local, and certification board requirements, as well as the authority of the hospital or practice clinical credentialing program.

Credentialing is a process where medical facilities grant healthcare professionals, such as physicians, non-physician, mid-level

providers, medical physicists, medical dosimetrists, and medical technologists, the ability to practice medicine and supportive services in their clinical sites.

And, credentialing and maintenance of an associated privilege is currently not regulated by the NRC. Next slide, please.

So, in addition to those core knowledge topics that we discussed earlier that are already integrated into the existing training requirements, the committee does recommend that the practical knowledge base for EMTs include, this application-specific content and documentation of training in these areas.

And, I apologize for the wall of text. Patient assessment and eligibility, patient and caregiver education on the procedure and radiation safety, this is particularly critical for protecting the public.

And so, for patients who have been administered radiopharmaceuticals, how to develop site specific protocols for administration and use of the medical technology, radiation safety and quality control for all aspects of the procedure, including ordering, preparation, administration, and disposal of contamination or waste, if present, components of the written directive for therapeutic administration, pre-procedure, assay and dosimetry, the role of post-procedure dosimetry, patient monitoring, discharge instructions and release, including the management of procedural events such as extravasations, follow-up protocols for therapeutic interventions, reporting of adverse reactions and medical events, and aspects of supervision of the team, of the healthcare team, including the NRC regulatory requirements.

And, some aspects of these are already included in the training, documentation, and safety education that's provided by SNMMI, ASTRO, and other professional societies. Next slide, please.

In terms of supervision, the administration and use of EMTs may require the direct involvement of a range of other specialties, including certified nuclear medicine technologists, registered nurses, RSOs, medical physicists, all under the, possibly under the remote supervision by the AU.

Understanding of the NRC regulatory requirements for these roles must be required for the AU, and the educational needs for the entire team must be met to ensure the safe utilization of the EMTs.

So, the AUs must have a clear understanding of the roles and limitations of each member of the team, and a documented plan for how they would interact with those members when they are physically present or managing remotely. Next slide, please.

So, in terms of the role of the vendors, for EMTs and for new radiopharmaceutical applications, the application vendor does have a significant role in recommending and providing the appropriate knowledge and technical training for the safe and effective use of their technology.

Vendor training should cover all aspects of how to correctly use the drug or the device. And, training should include contraindications to use, and a reminder to trainees not to modify or substitute aspects of the device or procedure without approval of the manufacturer.

This definitely has played into some of the medical events that we've seen. Next slide, please.

Hands-on. And so, it is also the recommendation of the subcommittee that training should be hands-on. And, this should be expected for any new therapeutic device or drug, or any therapeutic application that has a unique delivery program platform.

And so, this means that the prospective user would have to conduct mock use, or supervised patient use, of the device drug using the actual device or drug, or a model device that incorporates all practical aspects of the new technology.

Any training must include opportunities for the prospective AU to ask questions about the training material, and process and receive those answers in real time.

And, the trainer, either a vendor and/or a current authorized user, must be able to directly assess their prospective AU learning in the context of the training prior to unsupervised clinical implementation. Next slide, please.

And, it's the recommendation of the committee that the trainer, either a vendor representative or an authorized user, must be physically present, or in person, for the training of the prospective user and their team, even in situations where the standard of care administration or use of the technology may be performed with the AU supervising remotely. Next slide, please.

And, for medical events, the NRC should encourage licensees to encourage and to include information in annual refresher training for appropriate individuals, authorized users, certified nuclear medical technologists, et cetera, regarding the medical events involving

radiopharmaceuticals or devices used by the licensee.

And, we recommend that the information on known medical events should also be included in initial training for a new device or drug application. Next slide, please.

This is a summary of our recommendations. So, one, core knowledge-based topics, those where they were listed from lab class and work training, should be supplemented with the application specific content that we discussed previously for existing and future EMTs incorporating radioactive byproduct materials.

The NRC should enable the relevant professional societies to develop curricula for initial training. And, should explore how best to evaluate these curricula on an ongoing basis and how these curricula may be included into an efficient licensing process.

The NRC should explore the need to define minimum CE and CME requirements for authorized users. Training for new therapeutic devices or drugs that has a unique -- for any therapeutic application that has a unique delivery platform, should be both hands-on and in person, with a vendor representative or an authorized user for the new technology prior to unsupervised clinical implementation.

And, the NRC should encourage inclusion of information on known medical events, and annual refresher training for drugs or devices used by the licensee, and initial training of a new drug or device application. Next slide, please.

So, these are the abbreviations used in the presentation. And, thank you very much for your attention.

CHAIRMAN WRIGHT: Thank you very much, Dr. Folkert. That was a lot.

(Laughter.)

CHAIRMAN WRIGHT: Now, to finish up the presentations, we'll go back to Dr. Jadvar. But, this time he will be presenting on behalf of the ACMUI Patients' Rights Advocate, Mr. Josh Mailman.

So, Dr. Jadvar, go ahead.

DR. JADVAR: Yes. And, thank you. So, as was mentioned, I'm going to present a statement on behalf of Mr. Mailman, who we value very much for his activities as a patient advocate on this panel.

Dear Chairman Wright, Commissioners Caputo, Hanson, Crowell, and Marzano, members of the ACMUI and the NRC staff, I had looked forward to attending today's meeting in person, but due to a recent major surgery, I am not permitted to travel until May.

I appreciate Dr. Jadvar for reading this statement into the record. The topic that the Commission had wanted me to discuss included patient perspectives on the new isotopes as theranostic pairs.

This is an area where I am especially excited about recent progress and have spent a great deal of time looking at and creating tools to identify new clinical trials that are using theranostic pairs. As a reminder, theranostics is using same radioligand for diagnostics and therapy.

I have shared the tools that I have worked on with the NRC staff so that they can keep track of new clinical trials that are being registered with all nuclear isotopes, with the ability to track new isotope, and radioligand pairs. This is about one new trial in a day.

As recent as two weeks ago, the FDA has approved additional indications for prostate-specific theranostic treatment in PSMA Lu-177, showing just how important this new category of radiotherapy is for patients.

My involvement with theranostics dates back to 2007, when I was diagnosed with a rare neuroendocrine tumor. In 2008, I was fortunate to attend a patient conference in Toronto, Canada, where I was introduced to nuclear medicine physicians from several European centers already using gallium-68 dota imaging for better diagnosis and management of neuroendocrine tumors under compassionate care.

I traveled to Germany from 2008 to 2010, for both diagnostic and therapeutic care under compassionate care. I greatly benefitted from the theranostic approach, which significantly improved my quality and quantity of life.

In 2011, while attending a medical conference in Germany, I met with the United States researchers who were interested in bringing this theranostic approach to the United States.

Based on my personal experience, I then began working with these researchers as a patient advisor, where I saw firsthand the challenges of bringing short-lived radioisotopes to market.

My first interaction with the NRC was on behalf of community-based radiopharmacies that could not bring gallium-68 to market, as it would require a decommissioning plan.

At that time, germanium-68, the precursor to gallium-68, was not listed correctly in the NRC guidelines for decommissioning. Thanks

to the work of the ACMUI, NRC staff, and the Commissioners, this was rectified and the small radio pharmacists could use germanium-68 generators.

At the same time, the Department of Energy sent a notice that they planned to exit the germanium-68 supply market, as they felt commercial supplies were adequate to match the current demand.

I, as well as other patient advocates, launched a letter writing campaign to encourage DOE to maintain its position as a backup supplier for germanium-68.

DOE agreed to remain as a backup supplier given the impending approval of gallium-68 dotatate and the potential use of this isotope for other diseases, including prostate cancer.

June 1, 2025, marks the ninth anniversary of approval of gallium-68 dotatate, now part of the standard of care for neuroendocrine tumor patients. Tens of thousands of diagnostic scans are being done every year using dotatate with gallium-68 or copper-64.

In 2017, the theranostic pair to gallium-68 dotatate, lutetium-177 dotatate, was approved. Since then, lutetium-177 dotatate has treated tens of thousands of neuroendocrine tumor patients.

The work on neuroendocrine tumors and gallium-68, led the foundation for other gallium-68 and lutetium-177 therapies in prostate cancer, which have treated tens of thousands of patients since their approval.

The work in theranostics is extending and improving the lives of hundreds of thousands of patients worldwide. The work of the

ACMUI and the NRC staff with the Commissioner's support, has been invaluable in allowing the safe use of these medical isotopes.

I look forward to hearing Mr. Green's presentation on growth in radiopharmaceutical therapy, and continuing my involvement with the ACMUI and the NRC staff, as we work on patient release criteria, decommissioning guidelines, and other areas that benefit patient care and public safety.

And, that's the end of his statement. Thank you.

CHAIRMAN WRIGHT: Thank you very much, Dr. Jadvar. I guess, this morning we start with questions from the Commission with Commissioner Hanson.

COMMISSIONER HANSON: Thank you, Mr. Chairman. Good morning everyone. Thanks for your presentations and particularly thanks for your service to the American people, for serving on the committee and so forth.

I really appreciated the discussion. And, I've also noticed the Pluvicto commercial, Mr. Green. I actually saw it during the Olympics last summer.

We've really, if you know what it is, it really jumps out like a neon sign.

MR. GREEN: I saw it last night in the hotel room. I've --

DR. JADVAR: It's been on for like, two or three weeks now.

MR. GREEN: I don't want much TV.

(Laughter.)

COMMISSIONER HANSON: Mostly during sporting events. I think, they're targeting a certain demographic, if I may.

But, it's really something, right? Because, as you know, the Pluvicto is really a, it's for, typically has been used for prostate cancers that are very far progressed and are arises in a whole number of ways.

And so, it kind of has this niche use at the moment. And yet, here's this commercial. Yeah. Anyway, I noticed it as well.

This is really, I've got to kind of, I want to zoom out a little bit, and I've got a question for any of the members, or any of the folks here who have given presentations.

Dr. Jadvar, you noted that Mike King from the NRC, gave a presentation on the ADVANCE Act to the Committee. I think, at your presentation last fall.

And, as you know, the ADVANCE Act really emphasizes the need for the Agency to be more efficient in kind of all aspects of our operations.

And so, in addition, I know Dr. Folkert, you mentioned one area in which we could kind of improve efficiency.

But, I'd be interested to hear your thoughts on, either additional thoughts on requirements, or licensing processes, et cetera, for the medical uses of radioactive material.

DR. JADVAR: Thank you for that question. Yes, we did have a presentation last fall. And actually yesterday also in our meeting we had another reminder or brief overview of the ADVANCE Act by Dr. Katie Tapp yesterday.

And for that, we actually formed a subcommittee now, a ACMUI subcommittee, to explore how the ADVANCE Act can help more efficient processes within the ACMUI and how we can help the NRC medical team in that regard using the new mission statement that really emphasizes efficiency.

I will let my other colleagues discuss it in particular matters.

MR. GREEN: I think we've taken ownership of that now that we have a subcommittee and saying what can we -- from our perspective, what can we see that we could alert and make more efficient. We are looking forward to what's coming our way to adapt to it. So we take ownership of that.

DR. FOLKERT: And as far as much of the training is concerned, so many of the elements are already there. The existing structure for 35.390, 35.396, radiopharmaceuticals, does allow for broad use. A lot of the bottleneck is actually happening far down the line at the level of the initial licensing of authorized users at the local setting.

I think the education actually needs to go out to those RSOs that, you know, once someone has met that training, once someone has gotten established an authorized user for these various different subsites that they have that scope to be able to practice using all the other radiopharmaceuticals. But they need to be educated in the safety and use of it. And that is where the professional societies come in, which have all been developing all of this content that we need.

Everything that we brought up is actually something that

the professional societies have already taken the lead on and are working on. So if we can capture that, if we can utilize those resources that are already there, I think we can get these moving very quickly and very safely.

COMMISSIONER HANSON: That's great. Thank you. Well, this is a great segue, actually, into my next question, which was really about the mission statement, right?

As you all know the ADVANCE Act directed the commission to revise our mission statement. And while, you know, it didn't change our kind of core safety protection of the public, protection of patients, protection of users of these materials, the key word that kind of did get added as a point of emphasis was enabling.

And certainly, in my travels to medical centers in the U.S. but particular internationally and in developing countries, you really get a sense of how important and enabling our ensuring mission is for a regulator, right?

If you are a country and a LINAC, for example, it is a really big deal, you know, and there is only one or two for the country allowing and ensuring and enabling access to that device for patient treatment is really a kind of a core part of their mission.

And while, you know, the NRC is in a little different position, we've got this big marketplace. We've got a lot of innovation in the U.S. We can't pick winners and losers. There is kind of still that need to not be an impediment to ensure access for patients and so forth.

So while you are getting and focusing on the ADVANCE Act and as you say, Mr. Green, the mission statement, can you talk a little bit

about how, you know, your perspectives, at least in an initial way, on maintaining the patient safety but also recognizing the language around enabling that the Commission has kind of elevated or put forward?

DR JADVAR: I think the eventual care delivery to the patient have many, many facets. You know, there will be availability, accessibility and also NRC plays a role in enabling, you know, availability and hopefully ready approval of these -- not approval by the FDA but also the AAU education and training that they need so that we have enough human resources, AUs, around in the country who can deliver these type of treatments.

And I think Dr. Folkert in that subcommittee was talking about how NRC can help work with the professional societies with the vendors and others to make sure that is enabled. That pathway is open and clear for all folks who are interested in these kind of treatments, an easy and efficient pathway for them to become an AU with appropriate knowledge and training so they can give competent care to our patient.

COMMISSIONER HANSON: Thank you.

MR. GREEN: I think the NRC has laid the foundation for allowing progress to happen. I mean, there are agreement states still that have line items where you have got to apply for using this and apply for using that. But you've got 35.300 and you've got alphas and betas, pure betas and mixed beta gammas and so all these other things that are coming down the pike are going to fit nicely in there. You are not impeding anything, and you are going to allow various new drugs, various nuclides, various new cancers to be treated without any change to that framework.

DR FOLKERT: I think as long as the message is clear from the NRC that this is the goal, that this is what you want, and this is communicated with a high level of communication to RSOs at the local level and state governments, you know, this is something that is going to help us progress forward.

COMMISSIONER HANSON: Yeah, thank you. And, again, you keep getting ahead of me on my questions.

But to your point, Dr. Folkert, I mean, I've seen this in conversations with RSOs about, hey, we've got clinicians and researchers who are kind of leading edge and trying to figure out, you know, and using different isotopes in different ways and still want to stay within -- you know, we're still trying to -- the RSOs are trying to guide those researchers and practitioners to stay within -- you know, how do we kind of stay in the box?

But I want to ask the question more explicitly. Mr. Green, you kind of previewed it a little bit. I want to make sure that the NRC's regulatory framework in our specific regulations are really flexible enough. I guess I will just go with flexible enough to kind of accommodate, really, the tremendous growth and innovation that we have seen in some of the slides that you presented.

MR. GREEN: I think the regulations are flexible enough. I love the use groups. I think the associated documents, as I said, the A1 and A2 values are going to be an issue and that we can work with the agencies and other international organizations too.

I know that Europe has a moly-99 maximum value that can be shipped in a moly generator. But in America, we have higher values,

which are essential for efficient operations. And we have an exemption or something in America only. We may have to do the same thing with the A1 and A2 for alpha emitters.

COMMISSIONER HANSON: Great. Well, thank you, very much. Thank you, Mr. Chairman.

CHAIRMAN WRIGHT: Yeah. Thank you, Commissioner Hanson for getting us started this morning.

Commissioner Crowell, you're next.

COMMISSIONER CROWELL: Thank you, Mr. Chairman, and thank you to all of the presenters today. This is a weighty meeting topic, and there are lots of directions to go in terms of questioning.

I first just wanted to extend my -- reiterate my thanks to the folks at Columbia/ Presbyterian Hospital in New York who were nice enough to give myself and Commissioner Hanson a tour last year. That was very enlightening for me on these topics and helped me see firsthand the opportunities and challenges in nuclear medicine.

So with that, and if I address my questions to the wrong person, anybody feel free to jump in, but Dr. Jadvar, maybe start with you and touch on microspheres.

So my understanding is the subcommittee didn't find a single common root cause among medical events involving unexpected deposition microspheres in the GI tract, and a draft ACMUI report last month stated improved technology and imaging may be why we are seeing more of these events reported.

Could you just explain a little bit about how these events

occur and what role technology plays in detecting these events? And my follow-up is how to look at being able to detect things versus -- detection versus something that used to be actually addressed as a best problematic.

DR. JADVAR: I would like to ask my colleague, Dr. Harvey, who was chair of the subcommittee to brief you on that.

DR. HARVEY: Testing. Is this thing on? Okay. Thank you.

If I understand your question correctly, you are correct in saying that there was no real trends or specific root cause analysis.

The yttrium-90 microspheres procedures are very challenging, complicated procedures that work with many different services, including interventional radiology.

Prior to treatment, there is an MAA, or macroaggregated albumin mapping study with technetium-99m performed first. They will look to see if there is any shunting away from the liver to the gastrointestinal tract.

So that MAA is not exactly the same as the microspheres, but it is the best that we have. So sometimes then treatments are done, and there may be shunting to the GI tract, which wasn't observed via the MAA mapping or some of the angiographic procedures that are done ahead of time.

Does that answer to your question as to how it occurs?

COMMISSIONER CROWELL: Yes, it does.

DR. HARVEY: Okay. Thank you. And you had a second question, I believe.

COMMISSIONER CROWELL: Yeah, my second question

is to the extent you can say how -- the interplay between being able to detect these things and to what extent being able to detect them is something that needs to be proactively managed or if it's just -- you know, just because we can detect something doesn't mean it's necessarily a problem that needs to be addressed. It just may be a known quantity. Does that make sense?

It's kind of like when we detect pharmaceuticals in our drinking water. Yes, we can detect it, but is it at a level that's problematic?

DR. HARVEY: Thank you very much for refreshing me on that second question. So after the treatments are done, what is typically performed, but not in all cases, is some post-therapeutic imaging.

In the past, there are some people that do the imaging, some that don't. Some that would do it with planar imaging and some that we might do it with SPECT or single-photon emission computed tomography. So larger sites will tend to perform this post-therapeutic imaging in the best way possible.

And we encourage, our subcommittee has encouraged, that the licensees perform that post-imaging.

Now that the post-imaging has become a little bit more prevalent, what we are seeing is potentially an uptick in the identification of GI deposition. So that may be one of the reasons why we have seen a slight uptick in the number of cases.

COMMISSIONER CROWELL: But not necessarily determinative in the sense of needing to address it beyond noting its detection?

DR. HARVEY: Well, if it is detected, right, then it should

be managed. There should be dosimetry done to understand what the radiation dose to the patient is. And then that patient should be managed accordingly going forward to make sure that they are safe.

GI deposition is certainly something not to be taken lightly, something that we don't want to have happen. Some of the doses have been very significant.

COMMISSIONER CROWELL: Okay. Understood. That's very helpful.

DR. JADVAR: May I add --

DR. HARVEY: Thank you.

DR. JADVAR: We have an interventional radiologist here, too, who actually practices this. And of course the issue is if it goes to the GI tract and it is severe enough, there is a high radiation dose, you can get necrosis. You can get some sort of damage or increased inflammation, which may be symptomatic. Sometimes it is asymptomatic. But it is something you want to avoid.

And at our center, we always do imaging to see if it has gone to -- if it was deposited in the liver only and not elsewhere. But if it is, we always monitor the patient for any symptoms that the patient may have. But if you would like, we can ask Dr. John Angle also to give a clinical perspective of what he has observed.

DR. ANGLE: John Angle from the University of Virginia.

So GI deposition is certainly something all practitioners are very aware is a potential problem, very keen to avoiding it. We certainly are concerned. In the medical events, we saw four this year where we had, you

know, zero the year before.

But the significance of that, as you heard, is not really clear at this point. The detection is certainly better.

The only thing that has changed a lot is that number of procedures being performed is probably a lot larger. So we are going to see more events because we are simply applying the technology more often.

The blood supply to the liver and the gut is very closely intertwined. These procedures are highly technical. I don't think this is a never event or a never can be but we certainly need to watch for trends as the procedure becomes more and more common.

COMMISSIONER CROWELL: Great. Thank you. I appreciate that. Can one of you also speak to how we're -- how things are evolving related to patient education and guidance following either diagnostic or therapeutic treatments with new drugs and such?

Like I worry sometimes that there is a disconnect between the application of a drug and its outcomes and what the patients are aware of, how patients are -- what kind of guidance they are given after a procedure is given. So, Mr. Folkert -- Dr. Folkert?

DR. FOLKERT: Yeah, this is an area that -- it is part of the recommendations of our T&E group is to actually expand on that, on the patient education and the caregiver education.

It is definitely going to be an increasing issue, especially with drugs such as PLUVICTO. They are often given to patients who have had a prostatectomy and have issues with urinary incontinence. So there is a lot more issues with leakage and contamination of diapers, contamination

of other continence aids.

And so one of the recommendations for example in the ASTRO safety white paper is to go through a social assessment of that patient to see what kind of washing facilities they have at home, if they have a bathroom that they can isolate into. You know, if they understand what they need to do with contaminated materials, how long they need to store it, where it needs to go.

And so there is a lengthy assessment of the patient's understanding of the radiation safety needs or their specific drug application and how it could affect the public. That has actually gone over every administration.

And so it is something where it is incredibly important. It is going to become even more important as these are used more and more because there is going to be more radioisotope entering into the common waste stream. And managing that and making sure that it is being taken care of safely is a big focus.

COMMISSIONER CROWELL: And each patient's unique social situation makes a notable difference in what kind of guidance is most important to them.

DR. FOLKERT: Mm-hmm.

DR. JADVAR: I would just add that, you know, not only patient but also the patient's security is very important. It turns out in my practice that the wives are really in tune with what's going on with their husband, and they really listen to follow all the, you know, guidelines.

And, of course, we see these patients every six weeks for

the next treatment and the next cycle. And we always ask them what was their experiences, what went wrong and also ask about certain symptoms that we may expect from that type of treatment.

For example, the prostate cancer treatment, the PLUVICTO, you can get xerostomia, which is kind of a dry mouth or dry eyes. So we ask about that and try to grade it and see if that's a problem, it's not a problem and how to care for that.

So continuum of care and make sure we get feedback from them and what worked, what did not work and try to educate them the best we can.

COMMISSIONER CROWELL: And I am out of time. That is the first time I have asked one question that took my entire 10 minutes, which I will attest to the importance of the topic.

So thank you, Mr. Chairman.

CHAIRMAN WRIGHT: Thank you, Commissioner Crowell. Next up, Commissioner Marzano.

COMMISSIONER MARZANO: Thank you, Mr. Chairman. Good morning and thank you all for your presentations today.

Mr. Mailman, if you're listening or -- I want to wish you a smooth and fast recovery. I hope you take good care of yourself, feel better soon, and I look forward to meeting you sometime in person in the near future.

I would like again to take a moment just to sincerely thank you all for the value of work that you do as members of this advisory committee but also the broader contributions you make in the field of nuclear

medicine.

The use of radioactive materials for diagnostic and therapeutic applications continues to expand and evolve at a rapid pace as is made clear today, making your expertise and insights even more critical.

Your continued engagement with the NRC staff is crucial to ensuring that our regulatory decisions prioritize patient safety, respond to the growth in the number and type of radiopharmaceutical treatments and avoid limiting patient's access to care.

And this area is particular close to my heart. I, like millions of people across the nation and the globe, have a personal connection to the lifesaving potential of this suite of technologies.

My father was diagnosed with prostate cancer two years ago and has received radiation therapy as part of his treatment. And that has vastly improved his prognosis. In fact, the addition of this therapy to the course of treatment for prostate cancer, as you well know, has become the standard of care and has saved countless lives.

So this personal connection that I know I share with many others further underscores the importance of the work you are doing, and I thank you again for your ongoing commitment and dedication to this work.

So onto my questions. I think some of this will be around the theme of the projected growth and how to manage that growth because the increasing use of these radiopharmaceuticals and advanced treatment technologies, as we have kind of discussed right here or hinted at, means that the occurrence of medical events will arguably increase. We would expect it to.

Obviously, the NRC has its processes for event reporting, identifying the cause, corrective actions to prevent recurrence and facility notifications to other licensees so they can avoid similar incidents.

I just wanted to kind of maybe turn the conversation to some of the human performance and human error reduction techniques and specifically the checklist that was mentioned here and talk a little bit more in certain aspects of that.

As many people may expect, I am going to put on my former operator hat and kind of share. Human performance is one of the biggest things that we have to manage in the control room as a senior reactor operator in the safe operation of a nuclear facility.

Now I imagine it's no different in this case. And so, you know, I am aware of many different types of tools to help reduce this human error.

So, you know, you talked about this checklist for health care providers as they administer care. In particular, can you provide some other examples of methods -- well, first actually, can we cover a little bit of, like, how this checklist is actually used in practice and some other -- you know, discuss maybe some other methods to limit human error in the administration of nuclear medicine?

MR. GREEN: Thank you for the question. So the subcommittee's position was that we would encourage the NRC to make an informational notice. You can't regulate this, but we said, hey, to help reduce medical events, we recommend that each licensee in each section of the department -- there could be brachytherapy, there could be

radiopharmaceuticals, diagnostic, therapeutics, Gamma Knife -- each should have its own checklist specific for that device or for that technology that would incorporate all the things that they think are important to prevent, you know, is it the right patient? Is it the right drugs? Is it the right amount? And it could be paper. It could be a checklist, analog, if you want to call it that. But it could also involve digital technologies, electronic prescription order entry and barcode medication administration.

I mean, there were seven lutetium-177 overdoses that were reviewed yesterday. I think all of the could have been prevented with barcode medication administration. The vials of 200 millicurie, one size fits all from the manufacturer. But occasionally, because of platelets or other blood values, it is reduced, and the patients received the entire quantity in error.

So I think there are technologies -- so we were suggesting that licensees develop their own specific based on their SOPs. And if they want to involve a timeout process, stop, look, listen. Is everything correct? Check the written directive. That is up to them. But we are encouraging them to develop their own failsafes.

And hopefully to err is human. Let's see if we can't put some other technologies in there to help reduce the human error.

DR. FOLKERT: Yeah, I mean, we definitely when we reviewed the medical events yesterday, there was a significant number of them could have been avoided with the simple application of a timeout.

And that's something that is -- the professional side definitely pushes this a lot. It is something that I incorporate in all aspects of

my practice. When I am in the operating room, we do a timeout that we verify with the patient what we are doing. We verify the roles of every member of the team in that room and affirm that any one of them can put a hold on the procedure at any point during it. And we make sure that we are doing the right procedure to the right person in the right way.

And I think that is something that -- especially for any interventional, any therapeutic treatment, it is imperative to include it.

DR. JADVAR: I would just also add that although the generic dose is 200 millicurie for each cycle of both Lutathera and PLUVICTO, which are approved, you know, as Mr. Green mentioned, yes, there are situations where you have to reduce the dose. So 200 is too much because, you know, of some issue with the patient, maybe hematologic toxicity or something else.

And it is important that these places also have interdisciplinary model, disciplinary tumor boards where these unique situations are discussed so all the team knows what is going on. So that, you know, just don't get -- you know, grab 200 millicurie that comes, you know, from the street and just inject the patient.

You know, if these are discussed, hopefully some of these human errors are prevented.

COMMISSIONER MARZANO: I definitely appreciate it because the analogs are becoming more clear as I think about it. I mean, human performance is human performance. So, you know, I see a lot of opportunity maybe to kind of look across, you know, different high consequence activities and how those things are performed just broadly and

how human error is managed in those. Definitely a carryover here.

You know, in terms of reinforcing standards, can you talk a little bit about the role of maybe professional societies, individual hospitals, kind of just, you know, within disciplines of the healthcare system to, you know, holding others to those standards.

DR. FOLKERT: Like as far as radiation oncology is concerned, we do have an incident learning system. And it's a way that people actually enter their experience if there is a near miss, if there is an actual event, anything like that. It is a way of submitting those, and it's a way of facilitating review of those potentially harmful or actually harmful events and looking at ways to address it.

And that is something that it's actually a part of accreditation for many presenting and academic radiation oncology facilities. So it's already integrated in many ways. And I think there is also an instant monitoring system on the nuclear medicine side as well, yeah.

I mean, this is something that's -- we have -- I mean, the professional sides have a vested interest in keeping patients safe. And so it is something that has been integrated into their practice for quite some time.

DR. JADVAR: I think one of our members, Mr. Ouhib, has also a response. Please.

MR. OUHIB: Thank you. My name is Zoubir Ouhib. I am the mainly specialist in brachytherapy. But I actually like your question very much.

And we talk about checklists. We talk about timeout. But the whole thing about that is really an opportunity for those, you know,

authorized users, medical physicists and dosimetrists, technologists, whatever, to refocus because the culprit in a medical event or medical errors is really the lack of focus.

It is not that these individuals don't know what they are doing because after the fact, you talk to them and you say -- and they will tell you, yeah, I know. I know exactly what I was supposed to do. And I shouldn't have done this. And I should have done this and all that.

And then it was like, what exactly happened? There was some distractions. There was something in the mind of that individual. There was a phone call. There was an urgency to go to another unit to take care of another patient and so on.

And so it is really the key is we try and encourage people to really focus at that time. And when you are doing that, that is the only thing that you need to pay attention to. Everything else will have to wait. Thank you.

COMMISSIONER MARZANO: Thank you. That all makes a lot of sense to me. It is something that I can relate to in my previous experience as well.

Well, I am coming up on my time. And I am going to turn it over here in a second. But I just want to say I have a wealth of questions I would love to get a chance to discuss with you at some other point in time given that this is my first introduction to the Advisory Committee.

So, again, thank you all for your time today and for your presence here in Rockville. And with that, Mr. Chairman, thank you very much.

CHAIRMAN WRIGHT: Thank you, Commissioner Marzano. Your passion comes through. I like that. Very good.

Good morning, and thank you for your presentations this morning as well as the important work that you do on this committee, all of you that are here.

Before I jump into my questions, I would also like to join Commissioner Marzano and thank each of you for the important work that you do outside of the work on this committee as medical professionals. So, I mean, your selfless service, and it's obvious your compassionate care. You are very passionate about what you do as well. It can't be overstated. It just can't. And you are wonderful examples to each of us.

And I know it comes at the expense of time with your family and your friends. But I will tell you personally, I want to thank you on behalf of myself and my daughter, my oldest daughter, for your commitment to the health and safety of others because like me and my oldest daughter, others in this room, including Commissioner Marzano's father, we are the beneficiaries of the safe and secure use of nuclear medicine, nuclear technologies. And fortunately for me, the focus of my doctors as well because it is very important. So I wanted to personally thank you for that. And with that, I am going to dive right into my questions.

Dr. Jadvar, you talked about the newest subcommittee, right, on NRC mission and medical use licensing and oversight in response to the ADVANCE Act.

What are your thoughts generally? Where does this committee need to start its work? Have you all focused on that? Do you

have --

DR. JADVAR: Well, as I said, we just had a briefing on that, on the ADVANCE Act, and we formed a subcommittee to delve into it, really into detail and understand it completely, and certainly try to focus and see how we can align the ACMUI workflow and the process to match or align with very well with the new mission statement and efficiency.

I think a lot of these efficiencies are already in place, but maybe we can improve in many ways and also come up with topics that make other activities within the ACMUI and hopefully make some suggestions to the NRC for a more efficient pathway.

CHAIRMAN WRIGHT: So you haven't really yet identified the low hanging fruit areas?

DR. JADVAR: It is open to my colleagues if they want to have any thought on that, then please mention it.

CHAIRMAN WRIGHT: Is there anything that --

MR. GREEN: I will just mention that --

CHAIRMAN WRIGHT: Sure.

MR. GREEN; -- of the three new subcommittees that were established yesterday, this one that we are discussing now is the one with the highest priority and the most urgent time frame.

The other two were asked to report in the fall. This one is planning to have meetings in the very near future. Thank you.

CHAIRMAN WRIGHT: Good. What can we do to help the committee maybe be better prepared for that future that is coming? Do you have anything now or, you know, I am going to leave that open so that you

can come back to us as well, right? Because we stand ready to help. Okay. All right. And thank you.

Mr. Green, you have a previous background in the legislature in South Carolina, and I was a utility regulator and economic regulator in the state. And I remember a lot of things in that that happened during that time frame that you are experiencing now with all the new drugs that are coming and the new isotopes that are coming and how fast they are coming.

We experienced the same thing in this country with telecom. You could almost wake up every morning and something new in telecom was happening in the early 2000s. And then when the smart grid came and all these new smart technologies, they couldn't even put it up, install it, and work towards cost recovery on anything because it was out of date by the time they got it put up, right?

And you are experiencing the same thing, or you are seeing that happen with -- I think you mentioned that some of these medicines are kind of dying an economic death because new and better drugs are out there. So it is really mind blowing about that.

And given that, you know, they are coming every day, they will be coming this year, next year, given this potential influx of these new radiopharmaceuticals, what do you -- what can we, at the NRC, what can we do in cooperation maybe with the agreement states, what can we do now maybe to be ready to license and provide guidance for their safe use? Is there anything we can be doing right now?

DR. JADVAR: I am not sure if there is anything that needs

to be done immediately, whatever that definition of immediate is. But I think we are already on our way, at least in this committee, trying to address a lot of these flood of new radiopharmaceuticals for diagnosis and therapy that are coming through.

But also I want -- although it is very exciting and there was a nice chart that Mr. Green showed about all of these new trials, but, you know, there is going to be other drugs which are not radioactive, too. So there are going to be some competition. Not all of these are going to be, you know, blockbusters as he showed. There were 11 approvals for radiopharmaceuticals and half of them, almost half of them, you know, did not continue on long term.

So there is a lot of excitement with understanding of cancer biology and then, you know, you identify a biomarker and say, okay, I am going to try this. They try it. It works. It has to fill a gap. And there will be some of those. But I just want to kind of temper down a little of, you know, what we see is very exciting. Definitely, I am excited. That's my line of work.

But there are really some of this which will not be successful or will not fill a specific gap per se. And there will be other non-radioactive pathways that are also quite exciting that are going on, you know, antibody drug conjugates and things of that source that also use basically the same biomarkers and targets and all of that.

So I don't personally think there is anything immediate that needs to be done. But I think we are already on our way. But Dr. Folkert?

DR. FOLKERT: I do think one thing that can be done

immediately is that high level communication to the regulators to clarify the scope.

I mean, right now all these new drugs are coming in, but they are being investigated. They are undergoing research. And it is very, very difficult for the investigators to get the permissions to be able to deliver these radiopharmaceuticals to see if they are even worth exploring further.

And so making sure that that pipeline is open so that investigators can give an alpha particle based radiopharmaceutical, can give, you know, 15 different types of lutetium-based radiopharmaceutical so that their scope of practice is not limited in this period of time. That they are investigating these drugs to see which ones are good. That, I think, can be done.

And that is all within current guidelines, just making sure that the regulators know that they should not be arbitrarily limiting the access of investigators to these radiopharmaceuticals to do the research that has to be done.

CHAIRMAN WRIGHT: Well, I mean, you play a real important role. One of the things I don't want to see happen with the NRC is that our regulations and our procedures are behind the times, right? Because we need to keep up with the changes that are happening in the medical field. And I don't want to get to the point where we are stopping ourselves, right? So we are going to really need your expertise and your advice and those of the professional committees and societies that are out there to help us do what we need to do there so.

MR. GREEN: If I may, I know during our presentation

yesterday from Dr. Tapp, the health medical staff, there is a works in progress to make a guidance document for licensees on medical waste, talking about incontinence.

So that is something that I don't think has been approached yet by the NRC. I think it will be a very useful document and guidance for the industry.

CHAIRMAN WRIGHT: I am going to come right back to you. You spoke about the IAEA standards and the whole regulations on safe transport and all that.

So my question was about the potential impacts of manufacturers and the nuclear pharmacies are going to face possibly with the Type A packaging versus Type B. Is this is a cost or safety issue or is it the availability of common carriers to transport these types of packages? What can we do, you know, or do we need to do maybe in cooperation with DOT to help with the issue?

MR. GREEN: There’s a lot of pigs. There’s a lot of pigs in the circulation today. So whether it is bulk containers take raw isotope manufacturer of the nuclide to the CMO that is making the radiopharmaceutical, then they've got to have the containers that take those out to the clinics or to the pharmacies. And then there are pigs that have to take them from the pharmacies to the clinic if it's prepared unit dose patient specific. And so it is just going to cascade.

If we can use a DOT Type A, we already have those. There is no impediment to progress, to patient care. If we have to use Type Bs, you know, these are short lived. You got to have much more activity in

them so you are over that threshold, over that A1 rate, too. Then you are in a Type B. It may not arrive as a Type 1A or 1B quantity. It is now lower, but it still has to go in that other container.

So if we can get some way, whether it is collaboration with DOT, if we can get through that hurdle, that would be great.

CHAIRMAN WRIGHT: Well, maybe that's a conversation that needs to be had. Okay. Thank you.

And before I close, real quick, I also wanted to reach out to, and speak directly to Dr. Mailman's statement. One, I'm glad he is doing better, and I understand he is going to be coming back to work maybe in May, very soon if not. We have all been impacted by cancer at some level, either personally or family or friends or anything like that.

But I think we are all encouraged by what is going on in the whole radiopharmaceutical arena because it has the potential to just save lives, which is important.

So I found this is a bonus. When I became a commissioner, I found just how active we were on the medical side of things. I was, like, wow, this is really cool. So I am very proud of what we do here in this agency and what you do in trying to make sure that we are doing this safely and that hopefully we can -- if we can't beat it, we can sure, you know, make remission somewhat permanent and allow people to live forward.

So to Mr. Mailman, I look forward to seeing you again real soon. Take care. And we are proud of what you do. And with that, I am going to conclude my remarks and turn it over to Commissioner Caputo.

COMMISSIONER CAPUTO: Good morning. Thank you

for being here and thank you very much for your presentations. I am going to focus on training experience requirements.

We spend a lot of time and a lot of effort on that in making sure that there are adequate numbers of authorized users has been a point of concern, I think, for the commission for many years just based on the need, as several commissioners have talked about, enabling the benefits here for patients while ensuring radiation safety.

But I have to say, I am a little curious about a couple of the recommendations. So one recommendation was that the NRC should explore the need to define minimum continuing education requirements.

So as it stands now, physicians that completed their initial training experience more than seven years prior to requesting authorized user status. We require proof of continuing education and training for that, but the requirements here are flexible so the physicians are submitting continuing education and training in accordance with the authorization that they are requesting.

How does your approach supplement that? Because I am concerned here that if we are broadening our requirements here, we are adding regulatory burden. And I am looking for exactly why you think there is going to be efficiency and efficiency on the part of who?

DR. FOLKERT: I mean, so much of the inefficiency is not happening at the level of the NRC. It is happening much further downstream.

So that continuing education requirement for example, that is spelled out there. There is nothing specific about it. It just says you need

to have continuing medical education. But there is no guidance as to a minimum number or what, specifically, has to be covered in that continuing -- into that CME.

So when you get down to the regulators, when you have somebody who is more than seven years out and they are applying for it, a lot of time the regulators, and this is feedback I have gotten from people at professional sites, they are told by the regulators that we don't have any clear guidance on the training that you are supposed to receive.

So we are going to say that you have to do 200 hours. We are going to say that you actually have to go back and, you know, and you can only work with one radionuclide and that's it, nothing else.

And so I think part of that is -- what I was looking for, and at least what we were thinking, and this is by giving some more specific guidelines, it lets the regulators know what is acceptable, you know, what gives that clearance so that that person can move on to become an authorized user because right now it's nebulous. And when it's nebulous and there is no guidance, it is very easy for a regulator to just say no or to draw things out for a very long period of time.

COMMISSIONER CAPUTO: And this is going to get a little bit into my other question, the other recommendation here, because you said continuing medical education. So to what extent is it feasible to define our role in terms of safety versus having the commission delve into the practice of medicine, which is beyond our purview?

DR. FOLKERT: I think what we -- so in the prior T&E proposal, we had suggested providing some specific case scenarios. And

so that would represent training -- represent guidelines that would be considered safe and acceptable to the NRC. I don't know if that's addressing the question.

COMMISSIONER CAPUTO: Well, it can.

DR. FOLKERT: (Simultaneous speaking.)

COMMISSIONER CAPUTO: It can to a certain extent because I think once we get into having a range of scenarios, the further you go down that path, the more scenarios we are going to end up with. Well, this doesn't quite fit what the NRC has. So it is not acceptable?

I would be concerned that we end up being prescriptive and by being prescriptive, we are eliminating other scenarios that might be valid simply because they weren't anticipated.

DR. FOLKERT: Mm-hmm.

COMMISSIONER CAPUTO: Not to mention the fact that there is going to be a fair amount of regulatory burden because any range of scenarios would then not only need to be broadened, but they are likely to change over time. And they would have to constantly undergo revision.

DR. FOLKERT: Mm-hmm.

COMMISSIONER CAPUTO: So how do you thread the needle between ending up in that kind of a scenario versus having a flexible system that we don't have to constantly tinker with as regulators because as we tinker, then all of the agreement states have to update their regulations. And this becomes quite a paperwork exercise.

So how do you ensure that whatever approach it is going to be is the juice worth the squeeze in terms of what we are accomplishing?

And is it really directly contributing to a safety benefit?

DR. FOLKERT: I think one thing that was brought up in this more recent one is not so much setting up a pathway, but to validate the training that is being offered.

So if the NRC were to recognize that some of the curriculum meet the requirements, then all someone has to do is go through that curriculum and then that should satisfy the regulators. So that would be an efficient way of doing it, and you would touch on all of the different safety aspects that the NRC wishes to focus on. So that would be focusing on both efficiency and safety instead of by dealing with the materials itself.

COMMISSIONER CAPUTO: So --

DR. FOLKERT: It would still take some oversight. I mean, there would have to be some time to evaluate those curricula to see that they are -- that they meet the requirements. But then those curricula would apply to a vast swath of potential practitioners.

COMMISSIONER CAPUTO: Okay. But those curricula are not necessarily going to be focused on radiation safety. It is going to be a mix of --

DR. FOLKERT: Mm-hmm. Well --

COMMISSIONER CAPUTO: -- practice of medicine and radiation safety.

DR. FOLKERT: But if they don't include that radiation safety, then the NRC doesn't have to say that they meet the requirements.

COMMISSIONER CAPUTO: Okay. But then you've got 14 professional societies listed --

DR. FOLKERT: Yup.

COMMISSIONER CAPUTO: -- currently.

DR. FOLKERT: It is some upfront work.

COMMISSIONER CAPUTO: Those professional societies are going to be updating that curricula on a fairly regular basis.

DR. FOLKERT: Yup. And then --

COMMISSIONER CAPUTO: So we're going to have to update our review --

DR. FOLKERT: Mm-hmm.

COMMISSIONER CAPUTO: -- every time they update their curricula. Do you see where I am going here?

DR. FOLKERT: Oh, yeah. I understand.

COMMISSIONER CAPUTO: Are you really convinced that this is going to be beneficial?

DR. FOLKERT: I think it would be beneficial because that focus on that curricula will then have a downstream impact of thousands of potential practitioners. So it is -- and so that's -- and that's thousands of potential practitioners that would each have to be evaluated on an individual basis for their -- for the hodgepodge of education that they went through.

But if they had one that had been reviewed on a yearly basis, you know, I think that would speed things up.

COMMISSIONER CAPUTO: So has the committee looked at or considered the nature of how the agency would have to staff up to do what you are anticipating in terms of having people qualified to review all of these curricula and create these approvals?

DR. FOLKERT: Yup. And we thought -- and we do

recognize that it would require a significant amount of staff time.

COMMISSIONER CAPUTO: Mr. Green?

MR. GREEN: I just wondered if it would work more efficiently if we reversed the flow. On one of your slides, you've got a list of all the radiation safety functions that should be done, patient education, talk about incontinence, social histories, extravasations should be addressed with the patients. When you go home, be aware of this.

There is a list that we could easily make that could be provided to the medical education and the professional societies to the educational programs and just say this is a list that the NRC has prepared. It may have the citations of the regulations that are applicable that says make sure your material covers this.

So rather than looking at individual programs and having a staff burden, you make the document, this is radiation safety that is important to us. And you provide that to the providers and ask that they make sure it's in their programs.

COMMISSIONER CAPUTO: So with these societies, if they are going to have these various curricula, how do we manage a situation where one curricula might cover half of our requirements and another might cover 80 percent of our requirements, and we end up with sort of a hodgepodge?

DR. FOLKERT: I mean, that is unfortunately the situation that we have right now. That is the current situation. So, I mean, it wouldn't be creating more of a situation than we have as is.

I mean, I think the goal would be that each individual site

for the practitioners who work underneath, they would create a comprehensive curricula. And you should ask that. That would be something that could be spelled out.

DR. JADVAR: Or it could be a combination of societies that work -- if they know what the requirements are, as Mr. Green just mentioned, then a lot of these societies, SNMMI, ACNM, ACR, ASTRO, they can certainly work together to come up with a common curriculum that can be presented to the practitioners.

COMMISSIONER CAPUTO: Okay. But are we in a chicken and an egg because our requirements exist today, but they haven't tailored their curricula to make sure they meet our requirements, right, which is why we end up in this situation?

DR. FOLKERT: Actually, I would disagree with that. And so the specific requirements that are required for the NRC, the ACGME has actually encoded all the standards for us for radiation oncology.

In order for radiation oncologists to graduate, they all have to meet all of the requirements that are currently spelled out in the NRC. That is an across-the-board recommendation of the residency review committee for radiation oncology. So that --

COMMISSIONER CAPUTO: Okay. For that one, but what about the other 13?

DR. FOLKERT: I mean, that's -- then we would want to go to those. But the problem is that right now, that exists and so right now -- but there are still roadblocks because of the downstream regulators. They are not necessarily accepting it and that is one of the reasons why we need that

high-level communication to reaffirm that scope of practice from the NRC or to jump back on that topic. Yeah.

COMMISSIONER CAPUTO: Okay. I am not sure that I really see a clear resolution of this. But I'm out of time. Thank you.

CHAIRMAN WRIGHT: Thank you, Commissioner Caputo. So it appears we are out of time today. And I want to thank everybody for your presentations and for taking the time to be here today and for everything you had to do to get prepared for today as well because it was very informative. We probably could have spent another two hours on it to be honest with you. You might not like it, but we would have.

So before I close, I just want to ask my colleagues if anybody wanted to make any comments. Hearing none, I will adjourn this meeting.

(Whereupon, the above-entitled matter went off the record at 11:49 a.m.)