UNITED STATES

NUCLEAR REGULATORY COMMISSION

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MEETING WITH THE ADVISORY COMMITTEE ON THE

MEDICAL USES OF ISOTOPES

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TUESDAY,

DECEMBER 6, 2022

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ROCKVILLE, MARYLAND

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The Commission met in the Commissioners' Hearing Room at the Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, at 10:00 a.m., Christopher T. Hanson, Chair, presiding.

COMMISSION MEMBERS:

CHRISTOPHER T. HANSON, Chair

JEFF BARAN, Commissioner

DAVID A. WRIGHT, Commissioner

ANNIE CAPUTO, Commissioner

BRADLEY R. CROWELL, Commissioner

ACMUI MEMBERS PRESENT:

DR. DARLENE F. METTER, M.D., Chair

DR. HOSSEIN JADVAR, M.D., Ph.D., Vice Chair

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

MS. MEGAN L. SHOBER, Member

ALSO PRESENT:

BROOKE P. CLARK, Secretary of the Commission

BERNICE AMMON, Acting General Counsel

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

Mr. ZOUBIR OUHIB, Therapy Medical Physicist

P R O C E E D I N G S

10:00 a.m.

CHAIR HANSON: Good morning, everyone.

I convene the Commission's public meeting with our Advisory Committee on the Medical Uses of Isotopes, or ACMUI. This is a routine meeting to hear the views of the Committee members on significant issues that have come before them. The last meeting with the Committee was in October of 2021. I'll recognize each speaker and we will hold questions until the end of the speaker presentations, and then we'll hear questions from Commissioners.

Today, I am pleased to welcome the two newest members of the Committee, Dr. Richard Harvey, Radiation Safety Officer, and Dr. Andrew Einstein, a Nuclear Cardiologist. I also understand this may be Dr. Ennis' last Commission meeting as an ACMUI member. Dr. Ennis has served as one of two ACMUI radiation oncologists since 2015 and will finish his second term this coming March. Dr. Ennis, thank you for your service to the Committee and the Agency and to the country.

Before we start, I'll ask, first, if my colleagues have any remarks they would like to make. No? With that, we'll begin with Dr. Darlene Metter. Dr. Metter?

DR. METTER: Thank you, Chairman Hanson, and Commissioner Baran, Commissioner Wright, Commissioner Caputo, and Commissioner Crowell, for meeting with us today to review the topics that we discussed during our 2022 ACMUI meetings. So, could I have the first slide, please?

So, today's agenda will be the following: I will be giving an overview of the ACMUI 2022 activities. I'll be followed by Dr. Michael O'Hara, our FDA

representative, who will be giving a review of the ACMUI's Y-90 review of medical events.

Next slide. Dr. Hossein Jadvar is a ACMUI nuclear medicine physician who will be giving two presentations. The first will be on emerging radiopharmaceuticals in the expanding nuclear arena, and the second, impacts of the American Board of Radiology's request to terminate NRC recognition of the American Board of Radiology's Board certification processes.

Next slide, please. Our final presenter is Ms. Megan Shober. She's our Agreement State representative, and she will be speaking on the ACMUI comments on the NRC staff's regulatory basis for rulemaking on emerging medical technologies and Rubidium-82 generators.

Next slide. So, I'll start with the overview of the ACMUI, and this is the format I will follow: the ACMUI role, our current membership, the 2022 topics that were discussed during our meetings, our current active subcommittees, and comments about the future.

Next slide, please. So, the role of the ACMUI is to advise the U.S. NRC staff on policy and technical issues that arise in the regulation on the medical use of isotopes in diagnosis and therapy. We also comment on changes in NRC regulation and guidance, and evaluate certain non-routine uses of radioactive material.

Next slide. We also provide technical assistance in licensing, inspection, and enforcement cases, and bring key issues to the attention of the Commission for appropriate action.

Next slide. The ACMUI currently has 13 members. Our nuclear medicine physician is Dr. Hossein Jadvar. We have two radiation

oncologists, Dr. Ronald Ennis and Dr. Harvey Wolkov. Our nuclear cardiologist position is being filled by Dr. Andrew Einstein, who will be an active member later on in the year. The diagnostic radiologist is myself. Our nuclear pharmacist is Mr. Richard Green, and our FDA representative is Dr. Michael O'Hara.

Next slide please. We have two medical physicists. For nuclear medicine it's Ms. Melissa Martin; for radiation therapy, Mr. Zoubir Ouhib. Our patients' rights advocate is Mr. Josh Mailman; our Agreement State representative, Ms. Megan Shober. Our healthcare administrator, Ms. Rebecca Allen, and our Radiation Safety Officer, Dr. Richard Harvey.

Next slide, please. We also have an ACMUI consultant, and it is an interventional radiologist, Dr. John Angle.

Next slide, please. So, there are nine ACMUI topics presented by our subcommittees between December 2021 and October 2022. These are: Alpha DaRT licensing guidance; CivaDerm; emerging medical technologies/Rubidium-82 generator rulemaking; revision of Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material"; training and experience for all modalities; and impacts of the ABR's termination of NRC recognition of the ABR's Board certification processes.

Next slide. We also had presentations on Y-90 medical events, non-medical events, and minimizing the risk of medical events in Y-90 therapies.

Next slide. We had four presenters that were non-NRC entities during our meeting, and the topics were the following: TheraSphere Y-90 glass microspheres by Boston Scientific; SIR-Spheres Y-90 resin microspheres by Sirtex Medical; CORAR, which is the Council on

Radionuclides and Radiopharmaceuticals, comments on the NIST, which, as you know, is the National Institute of Standards and Technology, Radioisotope Measurement Assurance Program, or the RMAP, by CORAR; and then, an update on NIST RMAP by NIST.

Next slide. We had seven staff presentations to our meetings, and these are the following: review of the Lutetium-177-PSMA radiopharmaceutical; decommissioning financial assurance for sealed and unsealed radioactive materials; radioactive source security and accountability; medical-related events; the ACMUI reporting structure; medical team updates, and our annual INFOSEC ethics and allegations training.

Next slide. We have seven current ACMUI subcommittees, and these are as follows: Training and Experience for All Modalities; Medical Events; Y-90 Medical Events; Infiltrations/Extravasations and Medical Event Reporting; Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material"; Liberty Vision; and Emerging Radiopharmaceutical Therapy Knowledge Requirements in Theranostics.

Next slide. So, what about the future? ACMUI is really honored to help the NRC in providing assistance in technical aspects with their work, to comment on NRC regulations and guidance, evaluate the use of radioactive material, and bring key issues to the attention of the Commission.

And these are my acronyms. Thank you very much for allowing us to present.

CHAIR HANSON: Thank you very much, Dr. Metter. Next, we'll hear from Dr. Michael O'Hara. He's our representative from the Food and Drug Administration, and he'll be talking about ACMUI's review of the Yttrium-90 medical events. Dr. O'Hara?

DR. O'HARA: Good morning. Next slide, please. This is the agenda for my talk. I'll talk about the subcommittee membership, the subcommittee charge, key messages, background. And I'll talk specifically about the vendor consultation with Sirtex Medical and with Boston Scientific, and we'll talk about the further discussion with both vendors.

Next slide, please. The Subcommittee members are John Angle, Vasken Dilsizian, Josh Mailman, Melissa Martin, and Megan Shober. Our staff resource was Katie Tapp.

Next slide, please. The ACMUI Subcommittee charge was to evaluate the issue of Y-90 microsphere medical events in more depth and in consultation with the vendors, and propose new methods to decrease the number of Y-90 microsphere medical events.

Next slide, please. The key message is the reported number of medical events involving Y-90 microspheres is low compared to the number of treatments performed. However, it is important to evaluate the cause of the events to find ways to minimize the chance of similar types of events from happening again.

Next slide, please. The background: hepatic radioembolization uses Y-90 microspheres for treatment of primary and metastatic liver malignancies. Currently, there are two vendors that are approved by the FDA: Boston Scientific and Sirtex Medical. During the past few years, both vendors have increased their hepatic radioembolization businesses by approximately 20 percent. The medical events reported during 2020 were low compared to the number of treatments performed.

Next slide, please. Medical events involving Y-90 microsphere administration continues to be the most common medical event.

The types of medical events for Y-90 microspheres include: leaving greater than 20 percent residual activity in the delivery device; delivery device setup errors; wrong dose given or treatment plan calculation error; and wrong site treated through catheter placement error or wrong dose vial selected, and wrong site listed on the written directive.

Next slide, please. A past ACMUI Medical Events Subcommittee noted that performance of a timeout and the use of a checklist immediate before administration of byproduct material cold have prevented some medical events. The NRC staff issued Information Notice 19-07 to inform the licensees of past ACMUI recommendations.

Next slide, please; the vendor consultations. The ACMUI Subcommittee contacted both Y-90 microsphere vendors, Sirtex Medical and Boston Scientific, to discuss possible methods to reduce medical events. Both vendors voluntarily met and greatly supported the Subcommittee in this effort.

Next slide, please. The vendors were given the ACMUI Medical Events Subcommittee report presented on October 4th, 2021. There was a list of general questions just to start a discussion, and the ACMUI proposed recommendations to prevent 35.1000 Y-90 microsphere medical events. The vendors were specifically asked if these actions are appropriate and if they had any further recommendations.

Next slide, please. The Subcommittee proposed the following actions to the vendors as possible licensee actions to prevent future medical events: Review the mechanics of the Y-90 microsphere delivery devices and setup procedures; confirm all data and calculations in the treatment plan; and perform a timeout at the beginning of each procedure,

where the name of the patient is confirmed, the date of birth, the activity that's going to be used, et cetera.

Next slide, please. The first company that we talked to was Sirtex Medical. Sirtex evaluated the medical events reported by the licensees in the 2021 Subcommittee report. They identified four causes: greater than 20 percent residual activity remaining in the delivery device not due to vascular stasis; the wrong dose given, treatment plan calculating error; the wrong site treated through a catheter placement error; and the wrong site through a written directive error. Sirtex agreed that greater use of the ACMUI recommendations by licensees could prevent medical events due to device setup and procedural errors.

Next slide, please. Additional actions Sirtex has taken that may reduce medical events: Sirtex has developed a Microsphere Activity Calculator, which they propose will be a second check against the activity identified in the written directive.

Next slide, please. Further actions that Sirtex has taken are: they've been enhancing their Training Evaluation Certificate Program; they make sure that all the necessary nuclear medical and radiation safety support is present at the training; it includes in-service site visits and proctor assessment, and the proctor can recommend further training sessions, if it's necessary; minimum frequency of use to continue treatments, the company and the proctor can make recommendations and implement those kinds of changes; and more vendor staff is in closer contact with the licensees.

Next slide, please. For Boston Scientific, the vendor identified issues and currently available potential solutions. Greater than 20 percent volume of Y-90 microspheres left in the delivery device; they,

basically, believe that the licensee needs to have improved understanding of the device and its procedures. Events related to the delivery device; again, they need enhancements to the written directive and/or increased familiarization with the device. And wrong dose due to calculation errors, catheter placement errors, or wrong dose vial. The company has a number of software tools that they believe are helpful for this activity.

Next slide, please. In addition, the software tools that Boston Scientific has developed to assist the licensees in treatment planning and ordering microspheres are: TheraSphere Now, it's an online ordering tool; TheraSphere Treatment Window Illustrator, a spreadsheet ordering tool; and TheraSphere iDoc, an online dose ordering tool. So, there's three tools that they have recommended that can potentially decrease the number of ordering errors.

Next slide, please. Boston also says the IFU supported by training at new sites for physician-authorized users, RSOs, and support staff; (IFU is indication for use, is what that is); TheraSphere Administrator Checklist instructs users to confirm patient identity, instructions for administration of the set priming, dose vial preparation, administration assembly, final assembly and administration, and disassembly and cleanup. So, it's a checklist that covers the procedure.

Next slide, please. There should be further discussion with the vendors to understand fully how these programs can reduce medical events; how the vendor judges the effectiveness of these programs; how the vendor tests the accuracy of spreadsheet and/or software tools; and what steps are being taken to minimize the chance of clogged microcatheters, which causes residual activity to remain in the delivery device.

Next slide, please. Further recommendations are: Investigate the utility of software programs and checklists provided by the manufacturers of microspheres with the licensees; issue information notices; speak at conferences to alert licensees of past medical events, and share the ACMUI Subcommittee recommendations to reduce Y-90 microspheres. And this particular recommendation isn't for the ACMUI specifically to do the lecturing or writing a paper. It's for the medical team. I think that was the last slide. Yes. Thank you.

CHAIR HANSON: Thank you, Dr. O'Hara, very much.

Next, we'll hear from Dr. Hossein Jadvar. He's our nuclear medicine physician, and he's going to talk about emerging radiopharmaceuticals in an expanding nuclear medicine area, and also, the impacts of the American Board of Radiology's Board certification processes. Dr. Jadvar?

DR. JADVAR: Thank you very much. Good morning, and it's a pleasure to be here and thanks for the opportunity to present. So, my first talk is going to be on emerging radiopharmaceuticals in an expanding nuclear medicine arena. This is an update of a presentation I made some time ago, about approximately one year ago.

This is the agenda. I'm going to touch upon some of the recent FDA approvals of agents. Then, go over PSMA theranostics, showing you some of the key imaging trials and therapeutic trials, and then, I'll summarize.

This table I showed in my last presentation, and it's been updated. The red-color font, essentially, shows the new FDA approval since 2020. And you see, under the "Oncologic" column, that there has been a lot

of activity. One tracer, Detectnet, or copper-64 dotatate, was approved for imaging neuroendocrine tumors. F-18 fluoroestradiol, or Cerianna, was approved for patients with breast cancer who express estrogen receptors.

And then, there are three agents related to PSMA that have been approved since then, also. It's gallium-68-PSMA-11. That was approved for use locally at UCLA and UC-San Francisco. More recently, in 2021, there was an F-18 label of the PSMAs called Pylarify, DCFPyL, that was approved. And very recently, in May of 2022, we had the first PSMA-based therapeutic agent, which is commercialized as Pluvicto.

Just to go over what theranostics is again very briefly, again, we have a biological target that is relevant and is overexpressed, typically, in the disease process; for example, cancer. Then, there are molecular ligands that are designed -- this is usually in the arena of radiochemistry -- to be able to target these biological entities. And then, we have a linker, which is important. That linker determines the biodistribution of the agent. And then, at the end, we have the chelator, which is, basically, a radioisotope. It could be a reporting unit which is for imaging -- for example, it could be a SPECT or PET agent or it could be a cytotoxic unit, which is, essentially, either an alpha or beta emittor, basically, going to exactly the same place that you image. And you treat the patient in that way or the cancer in that way. In other words, the theranostics concept is quite aligned with precision medicine. We see what we treat and we treat what we see. That's what the idea is here.

PSMA has received a lot of attention, especially in the past few years. It is a Prostate-Specific Membrane Antigen. In fact, it's a misnomer. It's not a specific to prostate; it's not specific to cancer. But, the name has stuck with that PSMA designation.

In any case, it's an enzyme that has enzymatic activity. And it turns out that it overexpressed in prostate cancer quite highly over benign or normal tissue. But about 5 to 10 percent of prostate cancers do not express PSMA. So, it's not for all prostate cancers.

It is a biodistribution of the some of the tracers. Two of them I mentioned already: Gallium-68-PSMA-11, on the left-hand side, which was approved on December 1, 2020. There are two kits available now which are also FDA-approved, Illuccix and Locametz, that can be recombined with gallium-68 to produce gallium-68-PSMA-11 unit doses for patients. The other one is F-18-DCFPyl, or Pylarify, which, as I mentioned, was approved in 2021 for PSMA PET imaging.

There are two other tracers that I want to mention here. These are not FDA-approved, but there is much interest on them and they may get approval in the future. One is F-18-PSMA-1007. The difference in here is that the route of clearance is not renal; it is hepatobiliary. Therefore, there is not much urine activity which is very close to the prostate, and maybe that helps in looking at the prostate gland.

There's another one which is right now in process and there's anticipation that it gets FDA approval relatively soon. That's F-18-radiohybridPSMA-7.3. And the interesting notion about this particular tracer is that you basically have the same molecule, but you can put, if you want it for imaging, you put one molecule in one place; if you want it for treatment, you put it in another place. But it's exactly the same molecule. So, you can treat exactly what you see with this particular agent, when it gets approved.

Now, just to go over prostate cancer and why this is

important, this is, basically, the natural history of prostate cancer in three major phases: initial diagnosis and initial staging. Then, in the middle is biochemical recurrence. A man has already been treated with curative intent, usually radiation therapy or radical prostatectomy, but the PSA starts going up. That happens in about 30 percent of patients in a decade after treatment. And finally, the last phase is metastatic disease, when patients develop castration-resistant metastatic disease, which is, unfortunately, terminal. But in imaging, it appears in main PET that I just talked about is relevant to all these three phases of the disease.

Just to show you some of the relevant clinical trials. This is proPSMA that was performed in Australia, a very, very important trial. It showed that PSMA PET can replace conventional imaging. Conventional imaging is bone scan plus CT scan of abdomen and pelvis.

The other trial is OSPREY. This was one of the trials behind the approval of the F-18-DCFPyl that showed that using PSMA PET instead of conventional imaging can detect disease in about 12 percent of patients which would have otherwise been missed with conventional imaging.

The CONDOR trial also was behind approval of the Pylarify. In this case, it showed that if the PSMA PET is inserted into the diagnostic algorithm, there will be about a 65 percent change in management of these patients when that information is available.

This other very interesting trial showed that, if you use PSMA PET, you may detect disease which will be outside of the radiation therapy. In this picture, you see the green area over the pelvis. That would have been the area that a radiation oncologist would have treated without knowing all the other, the yellow spots, that are distant from that area. So,

that would have made a change in treatment.

Because of that, there is a clinical trial going on right now. I think we are in the second year of a five-year trial -- it's called PSMA-SRT -- which is a randomized trial comparing those patients who are treated with a standard of care and conventional imaging compared to when PSMA PET is inserted into the diagnostic algorithm. Because PSMA PET has been so important over the past several years, an appropriate use criteria was developed. I and Dr. Tom Hope from UCSF co-chaired this panel, the expert panel, and to be published, that appropriate use criteria, in The Journal of Nuclear Medicine in January of this year. And then as soon as the Pluvicto became approved in May of 2022, he and I also updated that AUC because of that. And that was published in JNM.

Now, just a few slides on Lutetium-177-PSMA-617, which is the same as Pluvicto, just showing you the remarkable responses we see in some of these patients. So, you can see this patient at baseline had a very diffused disease, essentially, involving every bone, as very, very intense dots. And then, after receiving this treatment, after four cycles, the scan looks much better. A lot of the disease is gone. His PSA level, which was 1,000 at the beginning, went down to below zero with this kind of treatment.

And these are other important trials in the space of therapy. Lu-PSMA was done in Australia, showing that these patients can have dropped by more than 50 percent in their PSA level in approximately 60 percent of these patients. Very significant treatment effect.

TheraP was also, another trial was published in Lancet, and this is also from Australia, comparing this new treatment with a radioactive PSMA agent compared to the FDA-approved cabazitaxel, which is a non-

radioactive chemotherapy. And it showed that it actually is better than cabazitaxel, both in treatment effect efficacy and, also, in adverse events.

The most important trial was the VISION trial that was a randomized trial comparing Lu-PSMA, or Pluvicto, the commercial name, in comparison to standard of care. This was published in The New England Journal of Medicine and was the basis for the approval of Pluvicto. And it just shows you here the benefit from having this treatment, with an overall survival benefit of about four months.

And what are the trends now as far as next that we are looking into. It's actinium-225-PSMA-617. It's an alpha-based therapy using, again, the PSMA. And you can see some of the good responses that have been published, for example, in this case from South Africa. So, there's a lot of interest in that.

These are some of the trials that we are hoping to get results soon. One is the SPLASH comparing Lu-PSMA to antigen pathway inhibitors, abiraterone and enzalutamide. There is another trial called the PRINCE trial that is combining Lu-PSMA with immunotherapy, pembroluzimab. There's another trial going on right now. It's called LuPARP. This is combining Lu-PSMA-617 with olaparib, which is a DNA damage repair inhibitor.

UpFrontPSMA is another trial bringing the Lu-PSMA much earlier in the phase of the disease rather than at the very end and see if the earlier intervention would be helpful.

LuTectomy is another trial going on right now, again, bringing Lu-PSMA much earlier, in this case, even before prostatectomy, to see if that's useful. And for actinium-225, there is also a trial called TACTIST

that is ongoing right now.

There has been some concern about the supply of actinium-225 if this is taken off, but there has been a lot of activity, especially from the Department of Energy. This is a tri-laboratory effort at Brookhaven, Oak Ridge, and Los Alamos right now to try to use the accelerator-based generation of actinium-225 to increase the current supply. The current supply is approximately 1200 to 1700 millicurie per year, but if we actually use this for patients, we need more. And that effort is being done at this point.

Now at this point, there are also industry that are interested, and I show you some of these reports of these folks working to try to increase the supply of actinium-225. And so, in summary, Theranostics, as I mentioned, is aligned with the concept of precision oncology. It's growing rapidly. As I showed you, many agents got approved over the just past couple of years. And the expectation is that we are going to look beyond cancer. We have other non-oncologic diseases that would also be candidates for this type of treatment: see what you treat and treat what you see.

So, the focus areas will be on education of physicians, technologists, scientists, and physicists; also, the workforce pipeline; radioisotope supply, as I mentioned about the actinium-225; and possibly some regulatory ramifications, as these things develop. That has to be determined in the future. And these are my acronyms for this presentation. Thank you.

CHAIR HANSON: Thank you, Dr. Jadvar. I understand you'll be talking next --

DR. JADVAR: Yes.

CHAIR HANSON: -- about the American Board of Radiology's --

DR. JADVAR: Sure.

CHAIR HANSON: -- request to terminate the NRC recognition.

DR. JADVAR: Yes.

CHAIR HANSON: Okay.

DR. JADVAR: So, thank you again. And so, the next presentation is the impact of the American Board of Radiology decision.

These are the Subcommittee members. I chaired the Subcommittee, and I want to thank all the Subcommittee members listed in here for their intelligent and expert comments and contribution, including Dr. Ron Ennis, Dr. Richard Harvey, Dr. Darlene Metter, Ms. Megan Shober, and Ms. Melissa Martin. And our NRC staff resource was Maryann Ayoade. Thank you all.

The Subcommittee charge was to identify any potential impacts of the ABR's request to terminate NRC recognition and other inactive boards identified during the NRC's evaluation of the specialty boards and provide recommendations to mitigate any potential impacts. Another charge was to review and evaluate the NRC's current board recognition criteria and provide any recommendations for action. At this point, most of our work was based on the first charge, and we are still working on the second charge.

This is the list -- I'm sorry, next slide -- so, this is the list of the NRC-recognized boards. There are 11 boards listed in here. The ones in red are the ones that we're going to focus on today. One is, of course, the ABR, but there are two other boards at the bottom listed. One is the

American Osteopathic Board of Nuclear Medicine. This is a very small board. It has been inactive since March of 2019, and its recognition by NRC is currently under review. There was another board, Certification Board of Nuclear Endocrinology, which has been inactive for a long time and is currently no longer recognized.

So, with that, let's focus on ABR. The American Board of Radiology was founded in 1934 as a non-for-profit organization and a member of the American Board of Medical Specialties. So, ABR is one of the 24 specialty certifying boards recognized by ABMS.

ABR is involved in certifying physicians in diagnostic radiology; interventional radiology; medical physics, which is divided under diagnostic, nuclear, and therapeutic; also, radiation oncology. And there are also three subspecialties which, after an exam, they give a certificate of added qualification in nuclear radiology, neuroradiology, and pediatric radiology. The mission of ABR is to certify that our diplomates demonstrate the requisite knowledge, skill, and understanding of their disciplines to the benefit of the patients.

Prior to 2005 -- I'm sorry, next slide -- prior to 2005, ABR did not provide the Authorized User eligibility designation on board certificates. This actually started in 2005. But they are going to terminate this on December 31, 2023. That will be the last date when they have this eligibility designation on their certificates.

They have a webinar that is on YouTube -- it was published on March 30, 2022 -- where they go and explain the reasons why they did this. These are the summary of that video. The reasons were that they feel that this activity is not aligned with the core ABR mission and it diverts their limited

resources. ABR has never issued AU status. Most radiologists are not, and do not need to be AUs. ABR merely passed along documentation of training and experience, and a direct pathway already exists for becoming an AU.

AU requirement for 700 hours of T&E in nuclear radiology is a residency or ACGME requirement, not a requirement of ABR. IR-DR, which is interventional radiology and diagnostic radiology, there are forms that folks had to fill out before, and also, for radiation oncology, that was a verification form. They don't need to send that to ABR anymore. They can keep it and send it directly to NRC.

There was an exam called RISE, which is a radiation safety exam, and that's not going to be scored separately anymore by ABR, but the content will be incorporated into the rest of the exam. So, people have to know it, anyway.

Trainees and programs should continue to keep their training and experience documentation. However, ABR will require their training and experience documentations for those people who are embedded in the 16 months of combined nuclear medicine and diagnostic radiology pathway or those who have finished that nuclear radiology fellowship. So, if they want to get those designations, they have to give their training and experience documentation to ABR; otherwise, no.

This is -- next slide -- so, this is a relatively recent article on "All You Need to Know as an Authorized User," which is useful for some of these candidates to follow what they need to do, if they want to be an Authorized User in the wake of the ABR decision. And just to show you that, at least for the American Board of Nuclear Medicine, if you are ABNM-certified in nuclear medicine, that is, essentially, completely aligned with AU status

recognized.

As far as the pipeline -- this is the next slide -- this is the ABNM Certification Exam, American Board of Nuclear Medicine. There was some drop in the early 2000s, but it has been stable. There are approximately 70 to 80 Board-certified physicians in nuclear medicine which are completing this certification process. Right now, there are almost 6,000 total certificates that have been approved by ABNM.

The next slide shows the nuclear medicine versus nuclear radiology. Nuclear radiology is that fellowship I mentioned that ABR has an exam for, for certificate of added qualification. It is relatively minor, as you can see, only a very few, you know, maybe about 10, physicians a year will take that kind of exam. Most people take it through ABNM.

With regard to medical physics, the pipeline has been stable for the last decade or so at approximately 1,000 that are enrolled in these programs, and the graduates are approximately 250 to 300 medical physicists a year.

So, what are the potential issues with regard to the ABR decision? There could be potential confusion and challenges with the burden that are now put on applicants and institutions to secure the RSO, AMP, or Authorized User status for the new-hires. When the designation was on the Board certification, it seemed to be more rapid for proof of AU eligibility, and it was thought that maybe ABR may have underestimated the burden that is being placed on the applicants. However, this is their decision.

There may be situations where the preceptors may be deceased or they're unwilling to sign off if the greater-than-seven-year window is exceeded or if the preceptor is asked to sign an affidavit, when they were

not really involved to begin with, with the training and experience of that particular candidate.

So, potentially, there may be an increase in time reviewing T&E documentation, but we did receive some kind of preliminary data, one from California and one Wisconsin, to see how long really it takes to go through that process. In California, it takes approximately four hours per licensee amendment, and there are about 100 AUs that are added per year. And accordingly, there was no, at this time, no time difference through ABR certification or through an alternate pathway.

In Wisconsin, Ms. Shober told us that there's no apparent adverse impact on regulatory agencies. Most people go through the alternate pathway, but this data is based on 2020 and 2021. Of course, the ABR decision will take effect after January 21, 2024.

And also, the rulemaking plan for the training and experience requirement, as far as the numbers we have right now, it takes about 15 hours for the NRC to review an application; 11 hours for the Agreement States, and five hours for the licensees to complete this process.

So, next slide. At this time, approximately 80 percent of the certifications by ABR, included that AU eligibility designation. However, it is unknown what percentage of those physicians actually went on to become an AU. And we asked that question yesterday from Dr. Brent Wagner, who is the Executive Director of ABR, and he really did not know, either. So, it is something that we will find out perhaps in some way.

But there needs to be some alignment within ACGME and AAPM and NRC training and experience requirements. This is something that I think our Subcommittee is going to look into in more detail.

At this time, as I mentioned, there is no indication that the other boards are going to follow suit that ABR did. And I mentioned already about the two small boards that are inactive. There is a suggestion that either NRC or NRC and some of the Subcommittee members can provide information to physicians of regarding how to become an AU in the wake of this decision by the ABR. There may be channels to do that; for example, through the Association of University Radiologists or the American Roentgen Ray Society or through RSNA Radiological Society of North America. These are very large radiology organizations. We can, in fact, think of publishing in those journals and kind of give direction and some advice to those folks. Next slide.

So we had some questions for ABR, which we did ask yesterday when Dr. Wagner called in. And basically, bottom line was that this is the decision that they have made. As I said, they don't know exactly how many of those physicians with AU-E status or designation actually went on to become AU, but he said he offered help to try to find that out for us. And with that, we are going to continue our Subcommittee work in that space and especially focus on the alignment of the NRC T&E requirements with what is offered and experienced by physicians during the residency programs, especially in diagnostic radiology. And with that, these are my acronyms. Thank you so much for your time.

CHAIR HANSON: Thank you, Dr. Jadvar, very much for that and now we'll hear from Megan Shober. She's our Agreement State Representative; she's from the State of Wisconsin. I'll welcome back, she was here just a few months ago to talk to us about regulating fusion energy devices. So, she's going to talk about ACMUI's comments on NRC staff's

regulatory basis for the rulemaking on emerging medical technologies.

MS. SHOBER: Thank you. Yes, just a couple of months ago, the ACMUI formed a Subcommittee to look at the draft regulatory basis for the emerging medical technology rulemaking. So we had a really quick timeline to evaluate that document and provide some comments for that, which we've issued the draft report for and the ACMUI did approve that report yesterday. I had a lot of support on the Subcommittee from Dr. Ennis and Mr. Green, Dr. Jadvar, Mr. Ouhib, Dr. Wolkoff, Dr. Angle, and from NRC staff, Maryann Ayode. So I thank them for their support. It's sort of like eating an elephant and nobody can do it all by themselves.

To get started on the background here, the last structural revision to 10 CFR 35 was back in 2002, so that's been 20 years ago now. Since then, there are a lot of things that have appeared on the medical scene. One of the main drivers was the Energy Policy Act in 2005. This added accelerator-produced isotopes underneath the authority of the NRC for the first time. So, that included positron emission tomography, which rubidium-82 is an example of that. Rubidium-82 is used for cardiac imaging, and it didn't quite fit into the regulations in 10 CFR 35, due to the very short half-life of rubidium-82, which is about 75 seconds, I think.

So, there was a regulatory gap there. There were things that that product couldn't meet. And the NRC handled that via enforcement discretion, basically recognizing that this device couldn't meet the regulations and just said, okay, if you do these compensatory actions, we won't issue violations in those cases. So, that's how that was handled.

And then, just other examples of other major things that have changed a lot in the last 20 years. There's been several different types

of stereotactic devices that have appeared. These would be like large activity devices for cancer therapy. There's been, as we just heard earlier from Dr. O'Hara, an explosion of microspheres, more broadly termed microsources. And then, we've heard about the rise of alpha emitters, the rise of theranostics. So, the medical landscape looks really different than it did back in 2002.

So, the tool that NRC has for managing all these new things is with 10 CFR 35.1000. So, when technologies don't fit, they don't meet the regulations, they get, I guess, parked into 10 CFR 35.1000. And there's some examples here of the types of new issues, new radiation safety issues, that we've seen over the last 20 years.

The complexity in devices. You know, there's kind of expectations about whether something's liquid or solid, and there's been a growing need for device-specific training with some of these really more complex things.

And I just want to mention the last bullet point with the atypical Authorized Users. So, as we've heard Dr. Jadvar just mention with the residencies, you have a standard pathway for diagnostic radiologists; you have a standard pathway for a nuclear medicine physician; you have a standard pathway for a radiation oncologist. But some of these new medical technologies are wanted to be used by ophthalmologists, by maybe dermatologists, maybe urologists. People are wanting a slice of this pie, and the way the regulations are right now, there's just challenges with evaluating or accommodating those other types of Authorized Users.

So, time to clean house. Time to clear out 10 CFR 35.1000. What are we going to do with that? It kind of feels like, you know, your spare bedroom where things just -- you know, you've got your

packages you haven't opened yet and you've got your kid's trombone and violin, and the mail that you haven't gotten to. And all of a sudden, you're like, man, this place is a mess.

So, the rulemaking timeline here. The staff sent a paper up to the Commission in February of 2021 with three different options for rulemaking for the emerging medical technologies. Commission direction came down in January of this year. And based on that direction, the staff developed the draft Regulatory Basis. It was sent to the ACMUI in September, along with the Agreement States, and we're headed toward a public comment period in the spring of 2023 with that.

So, next slide, just talking about where we are now. That paper from the staff had three options, and the Commission selected option three, which was to incorporate the rubidium generators and, as well, to broadly incorporate emerging medical technologies. Commission direction also suggested to create added flexibility to accommodate future emerging technologies and to certainly incorporate all current well-established emerging medical technologies. The staff's draft Regulatory Basis focused on the current policies and regulations for these technologies, and there was a lengthy appendix with the proposed changes to address these identified issues.

So, next slide. So, this is just a visual of kind of some of the considerations that go into how we regulate things. So, really, as regulators, we have two options. We can regulate via rulemaking, which is the preferred option, everything else being equal. But we do also do a fair amount of regulating through guidance. So, when you have rules, there's consistency, there's compatibility, there's efficiency, and you know what to

expect. The licensees know what to expect, and, you know, you can read it. It's right there, right there to read.

The tradeoff is that it doesn't accommodate changes to new things that are coming along. So, we've used that guidance in 35.1000 to provide some of that kind of customized radiation safety for those specific technologies. So, with guidance, you have specificity. You can adapt it more quickly than with rulemaking, and it is more flexible. So now, when we're moving from guidance into rulemaking, we are going to have to make some things more general and we lose some of that ability to customize, but we do gain that consistency and efficiency. And so, that's a tradeoff; we know that going in. So, that was kind of the mentality that our Subcommittee came at with looking at this draft Regulatory Basis.

Okay. So, next slide, please. So, just a warning, I have like no graphic design skills. So, I'm a radiation regulator, but this is kind of how I picture 10 CFR 35 right now, okay?

So, on the bottom, you've got three boxes, you know, from left to right, 100, 200, 300. And so, with this rulemaking, then 400, 500, and 600, and 700, that black box kind of stuck on top. Okay? So, with this rulemaking, we took those EMTs, kind of put them into this like "best fit" subpart, and then, we kind of expand the regulations to accommodate those differences.

So, with 35.200, you know, we've just kind of stuck those rubidium generators, gallium generators -- they're not that different; you know, just a little bit new stuff. With the manual brachytherapy in 35.400, there's some pretty significant proposed changes. It looks a little different. You know, it doesn't stack cleanly sometimes. And in 35.600, which is that blue

box, you know, we're cutting a little bit of stuff out, spinning a little bit differently, stacking that new box on top with the microsources. So, really, that's just kind of how I picture the rulemaking. You know, it's conforming administrative updates to go along with all these things.

Okay. So, to then speak specifically to what our Subcommittee was evaluating, we really honed in on your direction to incorporate those well-established technologies. So, that, of course, begs the question, what is "well established"? And so, I considered really three different aspects of those technologies to come to an assessment about that.

So, first, we looked at how widespread these technologies are. If a technology is widespread, we have an opportunity for rapid accumulation of experience. We can learn what the kind of pitfalls are, the hazards. And if a technology is mature, the product isn't evolving very fast anymore. So, there's a more inherent stability with that.

And then, the last item that we considered was just really how different is it from the existing components of Part 35. So, is the regulatory gap significant? Is it really big? Or is it really just like really tiny? And among the things that are considered emerging technologies, there's the whole spectrum.

All right. So, what we came to, as a Subcommittee, we had a lot of discussion just trying to sort these things and we really ended up here with they're sorted in really like three different categories here. So, as part of our review, we determined, just that column on the right, that three of the technologies for which there is 35.1000 licensing guidance, those technologies are actually not available anymore. So, you know, that informs us to just be cautious when trying to put some things into regulation. Like if

nobody is using them, maybe we need to be a little more cautious about what gets attempted to slide in.

So, then, setting those aside for right now, the rest of them we kind of sorted here into well-established and limited scope. So, we had general agreement among the Subcommittee, the five technologies that are on the left -- the germanium generators, intravascular brachytherapy, radioactive seed localization, Gamma Knife -- that would be the Perfexion and the Icon -- and then, the microspheres, those all, we believe, met those three criteria of being widespread, mature technology, and, you know, there's a place for them that's not too different. So, like for example, germanium generators, there aren't as many of them, but really, their regulatory gap is very small. So, it was easy to accommodate.

When we looked at the limited technologies, so Alpha DaRT, that guidance was just issued in, I believe, January in 2022. And on the Subcommittee, we just didn't have that much experience with it. We aren't familiar as much with how that is actually working out there in the wild. So, we didn't really have enough experience to consider that well-established.

GammaPod is similar to other stereotactic -- it is a stereotactic device. But, again, there are many fewer GammaPod units in the country than there are the Gamma Knife, which is kind of all over the place. I just want to mention the RadioGenix device. That the NRC staff chose to leave in 35.1000. So, we didn't explore that very much. And Liberty Vision is a new technology. That guidance has actually not come out yet. And so, we don't really have the -- we haven't even seen what's been proposed for that Liberty Vision emerging medical technology license guidance. So, that's kind of the nuts and bolts of what we, as a Subcommittee, came to in our

review of this.

So, the Subcommittee had a number of recommendations for this. We support the creation of a new subpart for microsources. We do want those well-established EMTs to be incorporated into 10 CFR 35. We support the changes, the conforming administrative changes, that will go along with that. We do support requiring device-specific training in many of these cases with these complex devices and we definitely support the performance-based changes that are proposed for 35.600. That is really changing from a technology-component specific requirements to more like functional use, and the primary example of that with the gamma stereotactic devices.

So the current regulations talk about helmets and certain like microswitches that are on those, and really from a radiation safety standpoint it's not the helmet that matters, it's the function that it provides to immobilize the patient. So if we can transition the regulations to not talk about the helmets, the more modern devices don't have helmets, but instead to focus on their function in immobilizing the patient, you can be more inclusive with other technologies that may come down the line later. So that's an example of that. And then a few additional recommendations, we just want to caution the NRC to not add product-specific requirements until that EMT is well established. We do think, however, that the regulations can incorporate general requirements to address kind of more broad issues. So, for example, with manual brachytherapy that's traditionally seeds, but there are products out there that are liquid. So with the liquid, of course, you have a contamination control potential, or a potential contamination issue. So we do support adding, for example, contamination control measures to the

regulations, but not specific to any particular device, like that's something general that could be added.

We are encouraging the NRC to re-evaluate ophthalmic sources. That's just kind of in our position is a little bit murky right now. Then, also, re-evaluate authorized medical physicists. I want to be clear, authorized medical physicists are necessary, but the question is what's their entry point, like where do they become, where do they, where are they, when do they become necessary, and to broadly consider training for some of those more atypical authorized users.

So just in conclusion, many of those current EMTs are well established and should be moved out of 35.1000. Some EMTs maybe should stay in 35.1000, due to limited operating experience and the NRC should periodically assess whether the EMTs are still in use.

And just a big thank you to the staff for all their efforts on this project. We know this is ongoing and it's going to take several years to see its way through and we appreciate the work they have put into that, so thank you very much.

CHAIR HANSON: Thank you very much. I really appreciate that and all of the presentations. We will begin our questions this morning with Commission Baran.

COMMISSIONER BARAN: Thanks. Well, thank you all for your presentations and all your work on the Committee this past year.

I thought maybe I would start by asking about the rulemaking that Megan was just talking about to establish generally applicable performance-based requirements for emerging medical technologies and rubidium generators and gamma sterotactics in radiosurgery units and Y-90

microspheres. I think this is an important rulemaking that has the potential to address some of the main challenges we have seen with the current regulation.

Megan, from listening to your presentation and reading the Subcommittee's report it sounds like there was a fair bit of discussion about, you know, what technologies are sufficiently well established to warrant having their own provisions outside of 35.1000. I guess we'll call that un-parking from 35.1000. You kind of walked us through kind of what you all looked at and where things ended up. Can you give us a sense, I mean was this a challenging sorting exercise or is this pretty clear? I mean was it a pretty clear consensus or were these tough calls about what fell into what category?

MS. SHOBER: Yes. So some of them were very simple.

COMMISSIONER BARAN: Okay.

MS. SHOBER: Some of them were very, very simple. Like for the gallium generators we just look at it and we're like, yes, okay, but especially for the GammaPod, we had a lot of discussion about that, we had a lot of discussion about intravascular brachytherapy and then the liquid diffusing brachytherapy. So I think it's a real mix, some of them, but some of them were hard and some of them were easy. The ones that made it to the list we had consensus on.

COMMISSIONER BARAN: Okay. And if you are kind of thinking ahead, you know, as a Subcommittee is there like, first because you had your factors, is there kind of a clear test about what moves, you know, out of 35.1000 or do you envision that every decade or two decades we're going to have to kind of go through this exercise of looking at the technologies and

figuring out what needs to be migrated via rulemaking out of that section?

MS. SHOBER: Yes. So I think there is a couple issues there. One is that the power of human creativity is limitless, and so I think it's really difficult for us to frame something that's not going to have an outlier. So that's one thing.

The second challenge that you face with medical devices in particular is that they pretty much universally show up in agreement states first, and so NRC is a little bit behind the curve sometimes with getting that practical experience to be the leader and how that plays out. So I think that is also a challenge, of course there is good communication between states and the NRC, but still like having that company in your state it goes a long way in some of that.

So I don't think it's reasonable to end up in a framework where you can account for everything that might come in the future, but I do think that some of that housecleaning, like 20 years, is maybe a long time to wait. I know the medical rules opened up more often than that, but that's just where I am coming from.

COMMISSIONER BARAN: Okay. And let me ask about, you were kind of walking through the Subcommittee recommendations and you had the one big red box of don't add product-specific requirements in regulation unless the technology is well established. Maybe that's obvious, but let me just ask you to kind of talk a little bit about that. What's the concern there?

MS. SHOBER: Sure. Okay, so the thing that really caught my attention in that specific case, so right now there is a product out there, it's an ophthalmic device the NRC is developing the guidance for, and it has some

really unusual authorized user training requirements and its dependent not on -- so the training requirements depend on the dose that the physician wants to deliver to the patient.

So Appendix A in that draft regulatory basis kind of describes how that was going to be incorporated in the rule. So for me that was really a red flag, like timeout, we haven't even tried this yet, and that would be really groundbreaking to have physician training requirements that depend on the dose that's prescribed, so I am really cautious about that. And kind of what I was saying earlier about when you move from guidance to rulemaking there, sometimes you need to become more general with some of those requirements, if you are not, then the regulations become like tentacles that go out. So I think it's a real art to rulemaking and a real balance. We just need to ask those questions now and during public comment period, like how specific should it be.

COMMISSIONER BARAN: Okay. And then as I kind of go down the list of the recommendations, it sounds like you kind of walk through the ophthalmic one a bit and kind of the concern there. Can you talk a little bit about the authorized medical physicists question?

MS. SHOBER: Yeah, so, as I was reading Appendix A with the proposals, I don’t know, like I am full of bad ideas. Maybe it’s a good idea, maybe it’s not a good idea. But right now, the way the radiation oncology is set up, you have manual brachytherapy and you have kind of these devices that are like higher dose rate. So you have Gamma Knife, high dose remote actuators; they’re in a separate category. But the oncologists that use it are the same; the same oncologists, they go through the same residency. So then my question is, well, when is an authorized medical

physicist necessary and should we maybe consider that 35.400 are the things that don't need an authorized medical physicists? And 35.600 might be the things that do need an authorized medical physicist. It's not how the rules are now, but why are these separations even in the rule and when does that authorized medical physicist, when do they need to enter the game? So, I just think it's a good time to ask that question and really maybe think more broadly, like why are these rules set up in these different silos?

COMMISSIONER BARAN: Okay. And let me close with maybe a broader question. When the Commission approved this rulemaking, I think we understood it was pretty complex. And in reading the Subcommittee's report, I got the sense that there were a range of views about whether this is too ambitious? Does anyone want to share thoughts about that – you or any of your colleagues? I mean, are we hitting the mark or is this going to be too hard trying to achieve, what we're trying to do in this rulemaking?

MS. SHOBER: Yeah, I can just quickly say my opinion, maybe, I don't know if somebody else wants to chime in. I think it's maybe a little ambitious. It's doable, it's a trade-off with how much you want your regulations to grow, so that's where I'm struggling with. How can we incorporate most of it, but some of it, I just don't know if we have enough experience to really smartly and elegantly, I don't know if that's a word I can use, but, craft those regulations for that purpose. Dr. Ennis, I don't know, during our discussions, you had a good perspective on that, if you'd like to share, that's be great.

DR. ENNIS: Sure, thank you. So, at the highest level, I'm not sold on the benefits of moving them out. Although I get why a regulatory

agency would want to do that, but I see a lot of benefit to the flexibility, and not that much downside other than, oh gosh, it doesn't fit in a nice, neat rule. But functionally, regulatory-wise, safety-wise, I'm not sold, really, that it's important. But, accepting the notion that we do want to do this, then I think where we landed, I think it's the three criteria, to me, that Megan laid out, really. It took us some kind of thinking it through. And then I felt very much that this was a very good decision or recommendation. It has to be widespread in use, so it can't be something brand new no matter how simple it looks because until it's used, and not just by experts who are at, you know, my institution and a few other high-end institutions, but just general practice, then we'll really know what the safety issues are. So it's got to be widespread, the technology has to be pretty mature. Like new technologies are evolving a lot. Bad idea to put it into a rule. We are opening up a rule every 10 or 20 years – it's going to change, but once it's stable, relatively, nothing is ever totally stable, but relatively stable. And what was our third criteria? Yeah, how different is it from the box that we are trying to put it in, so that's what Megan's talked about a lot – things that are very similar to the box, and just have to make a minor tweak to the box, or something, sure.

But, thinking about AlphaDART, for example, I don't know if we're ever going to be able to put that in, because it is, fundamentally, a nuclear medicine thing and a brachytherapy source. It's got really fundamental elements of both. And either way, it's going to be a very awkward squeeze.

Now, I don't think we should put it in rulemaking at this point, either, because it's too new. It's just in clinical trials only. And so, it's not out there, and who knows how it might evolve? But, aside from that, I'm not sure,

that might be an example of, to me, it's just too different from any category. So, I think those three criteria would hold the Committee and the Commission well in evaluating what goes in and what doesn't.

COMMISSIONER BARAN: Great. Well, thank you for all the work that you've put in on this so far. We're really just at the beginning of this rulemaking. And so, I hope you'll stay engaged and kind of follow it through. I know there was kind of a short period of time to look early on, but as we kind of move through the steps to rulemaking, I am hopeful that we'll hear more from you all on it and you'll stay engaged. Especially on these kind of tougher rules, where there's kind of a question about scope and other things, it's helpful to have your expertise. So, thank you very much.

CHAIR HANSON: Thank you, Commissioner Baran. Commissioner Wright?

COMMISSIONER WRIGHT: Thank you, Chairman. Good morning to everyone, and thank you for all that you're doing on this Committee. And welcome to the new members as well. I look forward to working with you.

But, outside of that, really, what you do outside just in your real world, as medical professionals, is just -- I'm very thankful for it personally because of my past, and that of my daughter as well. So, if it weren't for what you do, I might not be sitting here talking to you. So, I'm very grateful for that. This is very interesting to me.

I'm going to kind of go backwards today. I'm going to start with Megan, since you just finished. And again, welcome. It's good to see you again. You do a great job at working in your position with the Agreement States. And I know your State has got to just love having you up there.

You mentioned to me, or in the meeting here at the very end, "Broadly consider training for atypical AUs." Share a little bit. Give me one. What is an atypical AU?

MS. SHOBER: Sure. So, that would be the physicians that are not your diagnostic radiologists; they're not irradiation oncologists; they're not your nuclear medicine physicians. So, they would be the ophthalmologists that are using the disc sources. CivaDerm is like a surface you apply to the skin. So, there's dermatologists that are interested in that. There's urologists that are interested in the PSMA products. And so, they're not coming in with that like ingrained radiation safety as radiation is their core business. So, it would be everything that sits outside that.

COMMISSIONER WRIGHT: Okay. Thank you for that. And one last question for you. So, did the Subcommittee identify any lessons learned from the experience with the Y-90 events that could be applied to training for these AUs?

MS. SHOBER: So, we have been -- I'm on both committees -- so, we have been thinking about those issues a lot. I think with the interventional radiologists, they're the ones that are most central to those microsphere therapies. They head that way, but again, like radiation is still the core of their practice, so I think they have some advantages.

I will say that, just as a license reviewer, adding those Y-90 microsphere Authorized Users onto licenses, it's absolutely the worst license action. It's always complicated; it's never straightforward. It takes forever. There's a lot of deficiencies.

And so, I don't want those problems to then, like spring up all over the Authorized User landscape. So, I don't have a specific answer

for you, but there's a lot of those concerns that we are carrying through in these discussions.

COMMISSIONER WRIGHT: Okay. Thank you. Dr. Metter, good to see you. And you've been a member for several years of ACMUI.

DR. METTER: Yes.

COMMISSIONER WRIGHT: I mean, this is kind of a softball question in a way, but I think it would be a very interesting question for you, for me to hear from you about. Just your views about how things are going.

Are there any areas of improvement or areas of concern? Do you see any issues or challenges on the horizon that would require the NRC, require more of our attention? And we've talked about the rulemaking; outside of that. And is there anything that the NRC could be doing now, right, to be prepared for those issues? Just kind of broadly speaking, you know?

DR. METTER: Sure. Well, thank you for that question. First of all, I really need to commend the NRC on their incredibly competent, professional, and knowledgeable staff that's been very, very responsive and supportive to the work of our Committee, which is very important. And I just commend you on that.

And I also would like to commend you on supporting their NRC presentation at our professional meetings, because that gives them, gives the NRC a true face that they can interact with, and you become, you know, someone that they can -- you're not just regulators, but you're actually real people who really want to help the public and our society. So, thank you for that.

One of the things I do think that would be helpful is that, with our increasing information that we have, our new technologies, our new therapies, and other issues that have come up recently in our meetings that -- you know, we had the Subcommittee, as I mentioned. For this meeting, we've actually added three more, two new subcommittees, and then, we are reestablishing the Nursing Mother Guidelines Committee.

And so, with that, we have an incredible staff and we do have excellent work from them. They're responsive, but it does cause -- I think it's a lot of work for them. And so, I think, in my opinion, that you may want to consider increasing the resources, not only to have them continuing to go to our meetings and support us, but maybe also in staffing.

The other thing I would suggest, as you see with these incredible emerging technologies and therapies, there's increasing training and experience. And it's been alluded to here that perhaps we may have to look at the atypical or limited Authorized User; that may have to be revisited. And then, also our current Authorized Users, and looking at the training and perhaps updating it for some of these uses.

COMMISSIONER WRIGHT: Okay. Thank you so much. Appreciate it. Dr. O'Hara, so you noted in your presentation that -- and I think it was the Information Notice was 19-07; 19-07, I think it was?

DR. O'HARA: Yes.

COMMISSIONER WRIGHT: And it was about the Y-90 events. Specifically, did we see or did you see any impact on the number of types of events after issuance of that notice?

MR. O'HARA: I looked at that when we looked at the Medical Events Committee report for 2020, I think. And, one of the things

that I noticed was there was a slight decrement in events in one company, they went down from 11 to, I think, eight medical events -- and, the other one, it remained constant. The Committee basically thinks that it's still too early, that we didn't have enough time after the notification went out to see something.

COMMISSIONER WRIGHT: So, let me ask you about, how do you think issuing another generic communication or information notice would impact the number of events, you know, or would it have the same effect, in your opinion?

MR. O'HARA: I think that going out and talking about these issues and bringing them to more people's attention, more licensees' attention, and maybe more hospital administrators' attention, so that they see what the NRC has proposed. And, what -- at least with the microsphere companies -- what they've accepted. They both, really in their software designs, have accepted looking at the three items that the NRC has proposed. So, all of that exposure, I think, is a good thing.

COMMISSIONER WRIGHT: Right. So, I was -- you brought up the vendors and the software, I'm going to go right there. So, one of the recommendations you mentioned today was for the NRC to have further discussions with the vendors on their software programs, and then the administering of 190 treatments. And, I totally get the training part and the equipment that you use has to be, you know, good, too, right? So, it all has to work together. Do we know the number of licensees that use the software programs and checklists now?

MR. O'HARA: One of the vendors, I believe it was Boston Scientific, they basically had a general comment that, the folks that use the software have less medical events than the people who don't.

COMMISSIONER WRIGHT: So, that was going to be my next questions, do the licensees that use these tools have fewer medical events, and is there data to back that up?

MR. O'HARA: I think that's the question that the NRC and the medical team have to look at. They have to see, you know, what are we seeing over time, are we seeing an improvement in this. And, it's good to talk with the vendors as well, because they have close contact with their licensees, and the licensees may have ideas that the vendors have at their disposal that the NRC could use that could help to change things.

In the case from where I come from, the Division of Radiological Health at FDA, we were getting -- having more and more problems with some radiological devices. So, we did a review of one of our medical events type databases, we call it the Recall Database -- the Recall Database is where a device was recalled. And, we analyzed that data and what we found was that 70 percent of all the radiation oncology recalls for, I think it was an over 10 year period, were due to software errors. And, that focused our attention. And so, I'm saying that just the NRC's looking at the database, talking with the vendors and getting more information is, I think, a great way to -- and the Committee thinks is a great way to go.

COMMISSIONER WRIGHT: Okay. Thank you so much. I had lot of questions for you but I'm sure you're going to have plenty more.

My time is up, so thank you, Mr. Chair.

CHAIR HANSON: Thank you. Commissioner Caputo?

COMMISSIONER CAPUTO: Good morning, thank you all for being here. It was quite a lot of content to cover, particularly from Dr. Jadvar, who covered a lot of ground. I'm still trying to take it in a bit but I'm going to, I think, follow on what Commissioner Baron was asking about, and I'd like to get a better understanding of the process for emerging technologies.

Like you said, Ms. Shober, creativity is limitless, and I'm sort of struggling with the nature of whether or not our rulemaking framework for these technologies is really going to serve us well as more and more technologies are developed. So, I would like to start from a really basic question: if the Committee's position is something needs to be well-established before it's then addressed in rulemaking, then obviously it's become well-established under different regulatory treatment; so what's the actual benefit of having that technology incorporated into a rulemaking, what's the need or what's the benefit, if it's been allowed to become well-established already?

MS. SHOBER: That's a great question. I think there is a couple things at play there. So one is that when you regulate something via guidance, licensees commit to that guidance. So right now, you know, with the technologies that are in guidance, the licensees out there, there is several different versions of the guidance that different licensees are following, and so there isn't that universality with the regulated community. So I think there are some advantages to moving things to regulation, and that all of the licensees

out there are subject to the same requirements.

So I think that's one thing where moving it to regulation is definitely a better place to end up, but I do think that with these new things that are coming up, it is really hard to frame up that regulatory structure when a product is brand new. So 35.1000, you know, we can't love all of it, but I do think it serves a really good -- there is a place for it and I think that it's good for the NRC to exercise that space for what it is.

COMMISSIONER CAPUTO: Okay. So let me carry this another step further though. I get it that consistency across different states would be desirable. Does that hold if the rulemaking timeframe is ten years, because as a Commission we are wrapping up activity on an issue that is a fairly minor change in rulemaking, it's been under consideration for 20 years, and once the decision is made it will still take five years to actually execute the rulemaking.

MS. SHOBER: Yes. So --

COMMISSIONER CAPUTO: Is it worth the wait? As much as these technologies are going to evolve, or as you pointed out one or one of the doctors pointed out one that's already become obsolete, is it really worth it, or is there a need to look at how to sort of maintain that flexibility?

MS. SHOBER: So I guess are you asking if --

COMMISSIONER CAPUTO: Is the juice worth the squeeze --

MS. SHOBER: Yes.

COMMISSIONER CAPUTO: -- to get that consistency

given how much change we are going to be seeing here going forward?

MS. SHOBER: Yes. So that is a very fundamental question for how the medical regulations work. I have heartburn about only regulating medical technologies through guidance. Now, of course, there are a lot of new things that come out that fit just fine that go directly into regulations. It's not like everything that's new comes in through 35.1000. But I do think that there's just, at the end of the day, there's a lot of things with guidance, it's where, it's not designed as like a permanent resting place, and so we are using the rule for something that it wasn't designed for. Maybe your question is very valid --

COMMISSIONER CAPUTO: Well, I hear you on preferring not to simply regulate technologies through guidance, that's not ideal. I certainly would prefer rulemaking language and I would prefer that measure of consistency. But if we are in a position where we are incorporating technologies into rulemaking space, is there then a need to look at figuring out a way to have it be more performance-based?

MS. SHOBER: Right. And --

COMMISSIONER CAPUTO: Rather than technology-based?

MS. SHOBER: Yes. And that's exactly what this rule is doing with 35.600. It's taking that technology away and it is becoming more performance-based. I think that's the right place to lean. I think that's a really great place to go. I think that's also been harder for us to wrap our heads around with the manual brachytherapy. So maybe that's the place

where the next effort needs to be is how does that work with manual brachytherapy. So the NRC Staff has done that, is proposing that for 35.600 and I think that's exactly the right way to head for that.

COMMISSIONER CAPUTO: Okay. Thank you. It's great to see you again, fellow Wisconsinite. Glad to have you back.

MS. SHOBER: Thank you.

COMMISSIONER CAPUTO: Dr. Metter, you mentioned that there may be a need to reconsider training. That has obviously been a fairly controversial topic for the Board in the past. What in particular do you think may be worth reconsidering? Where do you see that evaluation going?

DR. METTER: Well, I think it's the overall increasing knowledge and training and experience that is being seen with all these emerging medical technologies and particularly therapy. I think that not only the current practicing physician needs to be updated, but you know, I see that the industry has -- like when Y-90 microspheres first came the industry was very supportive and, you know, I attended their sessions that were special training, added training and experience for us, and helping us in administering the therapy. So I think that's a focus there where I think we're going to be seeing when these new emerging technologies are going to probably be bundled with additional training and experience for current authorized users.

Now the issue of the atypical authorized users that Ms. Shober mentioned is, I believe, may be coming up again because of the non, the medical specialties that do not have a basis of knowledge in training and experience for radiation safety that we have in radiology, nuclear radiology

and nuclear medicine, radiation oncology, and that might be a challenge in the issue of protecting the public in regards to radiation safety.

COMMISSIONER CAPUTO: So, not to put too fine a point on it, so are you looking at maintaining the existing threshold of training and adding modules based on different groups of technologies or are you looking at somewhat of a reduced general education, with focusing on qualifying in different groups of technologies, or is it too early to say?

DR. METTER: I think it's too early to say, but my opinion is that the current training and experience is really the basics. It's sort of like I need to drive a car. I need to take my driver's license test, but I don't need to just learn how to drive straight and back up, I need to know how to turn, how to park, and things like that, and know the rules and things like that.

So I think if you are going to be utilizing radioactive materials for therapy or a diagnosis and therapy you really need to know the whole spectrum or the whole basis of radiation and radiobiology and radiation safety, just not only for our patients but to protect the public, too. And so for that I think that, you know, for those things we talk about in the future they still need a certain basic amount of radiation safety and training and experience.

COMMISSIONER CAPUTO: Okay, all right. Thank you. Dr. Jadvar, I have one more question for you. With the advent of theranostics, does our regulatory framework accommodate that technology, or do we need to look at more flexibility with that in mind?

DR. JADVAR: I think at this time, the regulatory framework is sufficient and adequate, but you know, I think we should be flexible, you

know, as time goes on and new things develop, but right now for example let's say the Pluvicto Lutetium-177, it's a beta emitter, you know, we had I-131 which we have been using for radioiodine treatment of thyroid cancer and thyroid diseases is also a beta emitter, and we have been doing that for almost 50 years and regulations worked very well with that and the training that goes into people who administer these types of treatments.

So this is another beta emitter in a different form for a different disease, but essentially as far as the radiation safety and other things that are underlying the use of that particular treatment is the same. So I am not sure about some, you know, changes in regulations say at this time, but you know, we should always be open as things develop and that should be discussed with my colleagues and at a broader kind of, you know, discussion.

COMMISSIONER CAPUTO: All right. Thank you.

DR. JADVAR: Sure.

CHAIR HANSON: Thank you. Commissioner Crowell.

COMMISSIONER CROWELL: Thank you, Mr. Chair. Thank you all for being here today. As you are probably aware, I am the new guy on the Commission and I have been in this seat about a little over three months and this is a weighty topic. That being said, Ms. Shober, I have only been there a little over three months and I've seen you twice, which just shows how much state regulators do and I appreciate you being here, as a former state regulator. It just shows the breadth of everything you have to manage and, obviously, Wisconsin is well represented on both sides of the table.

So I am trying to get my head around these things and

understand in practical terms how, you know, what we are doing that maybe isn't needed and what we are not doing that we need to do more of. One of the things that is going to be helpful for me to understand that better is to get a sense of the practical impacts of medical events. So, you know, over that four-year period where there is 212 medical events in that test case, 212 is either a big number or a small number, depending on your perspective. Obviously, if you are the patient it's a big number, but that also depends on what the impact of the medical event is on your health. I don't know who to direct this question to, but I could benefit a little bit from understanding more in real terms, like when a medical event happens what is the impact to the patient, what does it mean, how has it adversely impacted their health and well-being?

DR. O'HARA: You know, I think that's a very, very good question. The patient many times, and there is people in the ACMUI that treat more patients, I don't treat patients, but from where I sit by minimizing the number of medical events, we minimize the question that you are asking. We are not having to be concerned about how it affected the patient. At FDA, the worst case scenario that we deal with is deaths and, you know, when a patient dies, we'll say with treatment with radioactive microspheres, we start looking, we look at that in great detail, what can we learn from that death or that severe problem and how we can avoid it. I think the medical staff here and the ACMUI look at it the same way, where we are trying to find, to prevent the next patient from being affected as a patient that had a medical event now.

COMMISSIONER CROWELL: Dr. Metter?

DR. METTER: Thank you for that question. That's a very important issue that we do discuss on our meeting, and I would like to ask Dr. Ronald Ennis, who has been spearheading the medical event reporting every year and has done an excellent job in looking at that and looking at trends.

DR. ENNIS: Thanks, Darlene. So there's two parts. So from what we can tell in the review of the medical events that we see, a very high proportion of them do not lead to any significant medical consequence for the patient in the immediate time of the event. If I am not mistaken, if some acute event does happen then it becomes actually an abnormal occurrence and it gets reported to Congress, and there are extremely few of those per year.

However, the nuance is that we do not, you know, no one has the resource for it, there is no program, to follow patients long term for anything that might occur downstream after the acute episode. Particularly when it comes to dose delivery issues, overdosing and underdosing, the way radiation interacts with our bodies, some of those consequences are only years downstream, or can be. So, for example, a recurrence of your cancer because you were underdosed, might not show up for a few years and it might always be impossible to know if that is actually the cause also.

Long term consequences of radiation exposure can be delayed years. So someone may get a serious complication from an event, but we have no mechanism of knowing that or tracking that, so it's somewhat not answerable.

COMMISSIONER CROWELL: I appreciate that and note

these things aren't always black and white and I appreciate you being here and your service, because it will clearly be missed. Your input is helpful.

And, again, I don't know who to address this to either, but maybe Dr. O'Hara, it's going to be you, but are there controls in place to ensure that non-authorized users are not performing procedures without, you know, that require certification?

DR. O'HARA: I don't know the answer to that question.

COMMISSIONER CROWELL: I mean, it seems like we're -- you know, the process, the regulatory and restrictive process can take some time and it has an evolution that changes that we have to keep up with at, you know, the state and federal level. It just makes me wonder whether these procedures are happening by non-certified users or providers.

DR. JADVAR: Well, I just want to say at the institutions that I and many of my colleagues that I know and we work, you know, there is a procedure, you know, that you have to be credentialed for doing, you know, some sort of treatment or reading some scan, whatever it is, and we have to go through the credentialing and that if you are, for example, treating patients with thyroid cancer, prostate cancer, you have to show the training and experience and being an authorized user for that.

So there is a -- you know, you just don't go there and do it. There is definitely a procedure to do. Now whether in the community, somewhere in Iowa, you know, in a small private practice, you know, a clinic, somebody starts doing something, I don't know how that works. I mean that's really perhaps the basis of what you are asking, but I don't know how to

answer that question, but I know at major institutions, there is definitely a way to credential.

COMMISSIONER CROWELL: It seems like I've started a line to answer this question, so, please, fire away.

DR. ENNIS: I think it's more for maybe the NRC staff, but I think the control point really is the distribution of the radioactive materials. I mean not anyone -- you can't just order that, right. So the RSO who, you know, has to, he or she is ultimately the control mechanism I think, because any institution that is doing it you have to have the RSO, you have to follow the regulations to get it, and that person is controlling who then gets access to it. So assuming that process works it shouldn't be able to happen. I am sure things do happen, but like I don't think the regulations need to be revisited. I think that's the structure and I would think in general, it's working.

COMMISSIONER CROWELL: There is a good point and a topic for another discussion as well. Go ahead.

MR. OUHIB: Zoubir Ouhib, Radiation Therapy Medical Physicist. So the manufacturer before releasing or sending the isotope to the institution, they have to have a copy of the license with the authorized users. In the order they will ask who is the authorized users. There is a request in this. So unless they have that information they cannot send, you know, the Y-90 or whatever to that particular institution. So it's well controlled, actually, you know, and the state regulators really have all that information also, so that's one control.

COMMISSIONER CROWELL: Okay.

MR. OUHIB: But I would just like to add one more thing. When you asked that question regarding the patient, I think we need to think about the family of the patient also at the same time. That is also just as important because they go through a hard time perhaps, if the medical event was significant.

I would just like to add sort of that we are actually going to be looking at that, not within the NRC, but there is a working group within the APM that is looking at medical event in brachytherapy and that is one part that we are going to look into, is do we have any feedback on patient status, family, and so on and so forth. The purpose of that is really to educate users and medical physicists, especially, that unless you hear the story, you might not get affected inside sort of, but you hear one story that can actually change your attitude, your perception, your checklist of how you actually approach that, and so on and so forth. So I just thought I would add that.

COMMISSIONER CROWELL: Thank you. I think it's notable that the majority for all the medical events seem to be associated to be human error rather than a misunderstanding of the technology or the science being applied, and so to me, it's a manageable issue.

My last question, if I may, and this would either be to Dr. Jadvar or Dr. Metter, whoever wants to take it, you talked a little bit in your presentation about the pros and cons and some of the unanswered questions about a provider receiving certification through an established board or directly through say the NRC using T&E criteria. Could you just elaborate a little bit more on whether, what the pros and cons of having established boards doing

these certifications are versus having say the NRC or the agreement state?

DR. JADVAR: I think you are referring to alternate pathway, you know, versus -- so as far as I know for the diagnostic radiologists and nuclear medicine or nuclear radiologists, you know, who go through the training, it's basically within that training that they collect all the documentations, they need to do a certain number of radioiodine, for example, treatments, and they document all of that and they provide it to the program director which we keep it in a storage and then the candidate also keeps it and then eventually if they want to become an AU at some point in the future they basically have to gather all of those documentations they already have and either through the program that they attended or themselves to their institution where they are going to work and that office, their RSO usually at that place usually puts all this together and makes sure there is nothing, there is no gaps, and send it over.

I am not too familiar with the alternate pathway. You know, these are other pathways that maybe one of my colleagues can be better, you know, inform you about how that is done. I know, for example, Megan mentioned that many of the things that she sees in Wisconsin are true to alternate pathways, right?

MS. SHOBER: Yes. I think there is one interesting point. So all this uproar about the American Board of Radiology, what the -- there is a real difference. The radiation oncologist to get added to a radioactive materials license, they almost all, almost 100 percent of those come in via the alternate pathway, because when radiation oncologists graduate from their

residency they are not allowed to sit for the board for a full year after their graduation. Those physicians want to start treating their HDR patients. They want to start doing brachytherapy right out of the gate. So we see those physicians come in via the alternate pathway. I almost never see a physician via the board certification.

It's very different from diagnostic radiology where the diagnostic radiologists don't have the same pressure to get on the license right away because they are for the most part not actually handling radioactive material themselves. So I just wanted to point that out, you know, we are talking about these different pathways, but depending on whether you are a radiologist or a radiation oncologist what's normal already right now is very different.

COMMISSIONER CROWELL: That's a helpful distinction. Dr. Metter?

DR. METTER: Yes. I would like to say that the alternate pathway, I actually and I think believe the other members said are ABR certified went to the alternate pathway, because this was before the NRC recognition status occurred. As far as that, you know, you have to fill out right now the NRC form, what, 313A to fill out for the alternate pathway, and right now the programs are currently used to collecting the data on the training and experience that is necessary for that. So in my opinion, it's more convenient that the ABR was a collector of these documentations, but at this point in time perhaps the program, the training programs, they already keep it anyway and the thing is that they sent it to the ABR to have the AU eligible connotation on

their certificate.

The other issue is that over the last several years the ABR -- to be certified by the ABR you take your two exams, one after your -- You take a core exam during training and then you can't sit for the certifying ABR exam till 15 months after training. So really if somebody wants to be an AU, after training they can actually go through the alternate pathway and do it that way and don't need to be ABR certified until 15 months later.

So there is a disconnect between the training and experience and then when you can get certified by the ABR. So in my opinion, you know, I think it's easier to have the NRC recognition status for the ABR for the diplomats that do want to pursue AU status. But, again, as Dr. Wagner had mentioned, you know, about 80 percent, there is about 1,200 radiology residents that graduate per year and about 80 percent get AU eligible on their certificate.

The conversion factor, however, is very small. How many of them actually get on a license is very small. In our program in my department, university department, we have like 40-plus faculty and maybe four or five of us are AUs.

COMMISSIONER CROWELL: That's helpful content. Thank you.

DR. METTER: So it's a very small percentage of people who actually convert, in my opinion, to being an authorized user on a license for radiology.

COMMISSIONER CROWELL: Understood. Thank you.

I apologize for going over time, Mr. Chair. This made our fusion briefing look easy, so thank you.

CHAIR HANSON: Not at all, Commissioner Crowell. This is actually quite good because you waded into the waters that I was going to wade into, so I may not even need all of my time.

This was I think just before you got here, the Commission had voted on this paper on training and experience and whether or not to stay with the Board's certification process or the alternate pathway and one of the issues at hand was, you know, should the NRC not be kind of the middleman anymore and have all the boards do it.

Well, and then we kind of decided more or less to stay with the status quo and then the American Board of Radiology kind of made this decision and I guess kind of at a basic level, Dr. Jadvar, is there a linkage between those two things or was this kind of a decision that ABR was going to undertake maybe anyway?

DR. JADVAR: I don't know exactly, you know, what went into the mind of the ABR, but essentially their reasoning for this is that it's not aligned with their mission and they don't have the resources at this time to continue with this. I mentioned that before 2005, they didn't even do this, so this is a relatively recent event. They decided to do it in 2005. In fact, Dr. Brent Wagner yesterday said I don't even know why we got into this, we should have not ever done this, but now that we got into it, we are trying to get out of it, you know.

CHAIR HANSON: I see.

DR. JADVAR: And that's why they said we are not going to just do it overnight. That's why we gave 18 months, you know, 18 months notice of what we are planning to do.

CHAIR HANSON: Okay. Well let me ask kind of a question I think that tees off of that. I mean given the discussion we have had around emerging medical technologies, a lot of this kind of references back to the training and experience requirements for authorized users and I guess -- part of the debate that we had when we looked at this paper that the staff had sent the Commission was the impact on the supply of authorized users, right?

Would one option or another in the paper constrain or expand the supply of authorized users, and I certainly don't have an opinion about what the right number is but I guess the overall -- noting that the training and experience requirements for authorized users are there to ensure patient safety and the safe use of radioactive materials, are the requirements enabling or constraining the supply of authorized users in the marketplace in the medical environment in your view?

DR. JADVAR: Well, the pipeline workforce is a major issue and that is being addressed by a number of organizations. I can tell you, for example, in the Society of Nuclear Medicine and Molecular Imaging, this issue has been, you know, discussed in detail. In fact, there is the SNMI Value Initiative Workforce Committee is working on this to try to assess what is the current situation, what we need in the future with these emerging technologies.

In fact, Dr. Chris Palestro, who is the previous chair of

ACMUI, he is chairing that committee at the moment. But we hope that with the increasing interest and increasing number of programs that involve the 16-month embedded diagnostic, or combined diagnostic radiology and nuclear medicine programs, you know, at least we get some more people who are interested and will be authorized user to, you know, alleviate some of the issues with the workforce.

But there is a perception of shortage at this time in general. We don't know exactly how much, but that is being addressed. As far as the education, you know, some of the people who work right now and they are in the, you know, physicians who are on staff at different institutions they also need to be educated regarding these new technologies. There is also efforts in that space. For example, there are specific therapy conferences. One of them was just in D.C. two weeks ago that was very well attended and supported by both academia and industry. There is an effort called Nuclear Medicine University that is going to provide webinars and seminars and other things for the current physicians to understand and be on top of what is going on the field at the moment so that they can deliver these treatments to our patients.

We are also identifying centers of excellence for therapy so that if, you know, we can channel fellows and residents through those programs which actually do these treatments so that they get the appropriate training. There’s efforts in supporting through philanthropy some theranostics fellows that can be supported for a year of fellowship at these centers for excellence. So there are a number of efforts that are happening

to try to address this issue. We don't know exactly what the shortage may be, but that is being assessed and actively looked into.

CHAIR HANSON: I see. Are there communication programs that the NRC can undertake about, you know, we talked about in kind of the absence of ABR doing this to the extent that there are ABR members or ABR, you know, board certified physicians who want to be AUs then are there kind of communication or outreach programs that the NRC can be doing to talk about what the alternate pathway requirements are, et cetera, and how that works?

DR. JADVAR: Absolutely. Absolutely.

CHAIR HANSON: Okay.

DR. JADVAR: That would be very, very helpful if that can be done. In fact, we discussed it. Especially now with the ABR decision, there may be some confusion among folks who, you know, don't know exactly what to do. You know, a few weeks ago I asked one of my residents, do you know about this ABR decision, what are you talking about. He didn't even know -- In fact, yesterday I asked Dr. Wagner have you communicated this with your program directors or do the residents the residents and he said, yes, they communicated this.

But I think it would be very helpful if through attendance of major conferences, radiology conferences, by NRC staff to tell them exactly what is needed to become an AU, especially now with this ABR decision, or, in fact, joint editorials that can be done with the ACMUI or anybody else, you know, to publish that in major journals, like radiology or others, that also can

show people what to do, you know, what are the steps that needs to be taken up, and kind of bring down the anxiety level that there may be in some corners.

CHAIR HANSON: Right. Go ahead.

DR. METTER: All right. As far as we had spoke with Dr. Wagner yesterday and he did mention and several of us had already viewed, there was a 1-hour podcast that the ABR did on YouTube, so I don't know if the NRC can maybe do a short one, but --

CHAIR HANSON: A few podcasts.

DR. METTER: Okay. But maybe focus a short one, doesn't have to be an hour, but a short one and, you know, maybe have the different sections that people can look at for their particular interests.

CHAIR HANSON: Thank you. That's very, very helpful. I really appreciate that and hopeful we'll be looking into that.

Getting back to this atypical, Ms. Shober opened the door on atypical users. I guess my question on that in terms of kind of follow-up or next steps on atypical users, is ACMUI going to or are you going to be working with the NRC Staff to think about what T&E requirements would be for atypical authorized users or do they kind of just get brought into the 700-hour tent or kind of what is the thinking on what the future looks like there?

DR. METTER: You know, our training and experience subcommittee we can give them a second look at this and give them a charge to re-look at this because I think it's an important issue that is going to be coming up. But we again have to look at what the new training and experience are and, you know, it's sort of like I said, you need a basic fund of

knowledge before you can add to the boxes.

CHAIR HANSON: Yes. Ah, the boxes. All right. Well, thank you very much. One last quick question. I think Dr. O'Hara and -- Dr. Ennis mentioned, you know, there are 212 medical events kind of reported a year. Just for context, out of roughly how many procedures?

MS. SHOBER: I think that was 212 over four years.

CHAIR HANSON: Oh, right, right, sorry. Yes, it is over four years. I'm sorry, it is not per year. Thank you, Ms. Shober. It's a lot.

DR. O'HARA: It's probably thousands.

CHAIR HANSON: Yes. Tens of thousands or thousands?

FEMALE VOICE: Probably tens of thousands.

CHAIR HANSON: Okay. Okay, yes.

DR. ENNIS: All the radiopharmaceutical imaging administrations and therapies and all the brachytherapy, I mean it's millions.

CHAIR HANSON: Okay. Okay.

DR. ENNIS: It's a tiny, tiny fraction.

CHAIR HANSON: Okay. That's helpful. I mean I wanted to get back -- I mean I think Commissioner Crowell raised a really good point about whether it's a big number or a small number --

DR. ENNIS: Right, yes, yes.

CHAIR HANSON: -- and the way in which it could be a big number and then I wanted just to make sure that we were also recognizing that in other ways it's a really small number, too. All right. Well thank you

all very, very much for your presentations. I thought this was a really good discussion and I think we touched on a lot of the major issues facing medical technologies and we appreciate the service that all of you and the expertise and perspective that all of you bring to the Advisory Committee.

Thank you all very, very much for your service. Thank you again, Dr. Ennis, for your service. Thanks to my colleagues as always for their thoughtful and insightful questions. With that we are adjourned.

(Whereupon, the above-entitled matter went off the record at 12:00 p.m.)