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,

APRIL 21, 2026

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The Commission met in the Commissioners' Hearing Room, One White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 10:00 a.m. EDT, Ho K. Nieh, Chairman, presiding.

COMMISSION MEMBERS:

HO K. NIEH, Chairman

DAVID A. WRIGHT, Commissioner

BRADLEY R. CROWELL, Commissioner

MATTHEW J. MARZANO, Commissioner

DOUGLAS W. WEAVER, Commissioner

ACMUI MEMBERS:

HOSSEIN JADVAR, M.D., Ph.D., ACMUI Chair

ANDREW EINSTEIN, M.D., Ph.D., Nuclear Cardiologist

RICHARD HARVEY, DrPH, Radiation Safety Officer

JOSH MAILMAN, Patients’ Rights Advocate

PROCEEDINGS

10:00 a.m.

CHAIRMAN NIEH: Okay, good morning, I'll call this meeting to order. And this is an encouraging day today. Today is the first public meeting of the Commission in nearly one year. I'm really honored to be here with my colleagues on the Commission.

And today we'll be hearing from the Advisory Committee on the Medical Uses of Isotopes, the ACMUI. And the ACMUI plays a very important role in advising the Nuclear Regulatory Commission on safe and effective uses of radioactive materials in medicine.

And medical use is the largest category of materials licenses in the United States. And each year, radioactive materials support nearly 20 million medical procedures in this country alone, from diagnosing disease to providing life improving treatments. And this is a prime example of how NRC's work directly enables technologies that improve and, in many cases, save millions of lives.

And I want to recognize and appreciate the NRC staff in our regional offices that support the medical licensing and inspection activities. Their work is essential to American welfare.

And today we'll begin with a presentation from the members of the committee, and then we'll go into questions from each of the commissioners. And before we begin, I'll ask to see if my colleagues have any comments that they would like to make.

All right, hearing none, then we are joined by Dr. Hossein

Jadvar, who serves as the chair of the Advisory Committee on Medical Uses of Isotopes, and nuclear medicine physician of the committee.

And he is joining us remotely. Dr. Jadvar, are you with us?

DR. JADVAR: Well, honorable commissioners, good morning. On behalf of myself and my colleagues in the ACMUI, we are delighted to be meeting with you today.

I'm sorry that I was unable to be there at the NRC headquarters in person today, but I look forward to the next opportunity. I would like to congratulate Chairman Nieh and Commissioner Weaver for their recent leadership appointment to the NRC.

And further want to acknowledge and thank Commissioner Wright for our conversation as a part of the discussions with leaders that was just published in the Journal of Nuclear Medicine this month. And this was very well received by the JNM readers.

Finally, I start with my presentation by acknowledging all my ACMUI colleagues for the camaraderie, and the entire NRC medical team for their expertise and support. With that, can I have the next slide, please?

So this is today's agenda. I will go over the ACMUI activities. After that, Dr. Richard Harvey, the ACMUI radiation safety officer representative, will give the ACMUI's recommendations and actions to promote licensing and inspection efficiencies in line with the ADVANCE Act of 2024.

Next slide, please. Then, Dr. Andrew Einstein, the ACMUI nuclear cardiologist, will give the ACMUI recommendations on potential AI

applications for NRC medical enterprises.

After that, Mr. Josh Mailman, who is the ACMUI patients' rights advocate, will give the patients' rights advocate's perspective on patient release involving emerging radiopharmaceutical therapy. May I have the next slide, please?

This is an overview of the ACMUI activities, the role of the ACMUI. The ACMUI advises the U.S. Nuclear Regulatory Commission staff on policy and technical issues that arise in the regulation of the medical use of radioactive material in diagnoses and therapy.

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

May I have the next slide, please? The current medical uses of byproduct material include diagnostic radiopharmaceuticals, therapeutic radiopharmaceuticals, low-dose rate brachytherapy; high-dose rate brachytherapy; gamma stereotactic radiosurgery; yttrium-90 microsphere radioembolization; and emerging technologies, which include theranostics, these are diagnostic agents and therapeutic agents, which target the same or similar biological target on cancer, which is aligned with the concept of precision oncology and is a very growing field.

Then holmium-166 and Y-90 microsphere radioembolizations, which are currently not approved in the U.S., but are in clinical trials and may be used later on for radioembolization in place, or in

addition to, yttrium-90. Then of course, there's AI and deep learning driven radiation dose reduction and image optimization activities that are going on. May I have the next slide?

The ACMUI membership currently includes 13 members. The nuclear medicine physician and the chair is myself. Nuclear pharmacist and vice chair is Mr. Richard Green. The nuclear cardiologist is Dr. Andrew Einstein. The brachytherapy radiation oncologist is Dr. Michael Folkert. The gamma stereotactic radio therapy radiation oncologist, is Dr. Harvey Wolkov. The diagnostic radiologist is Dr. Joanna Fair. The FDA representative on the panel is Dr. Michael O'Hara. May I have the next slide, please?

The nuclear medicine medical physicist is Ms. Melissa Martin. The radiation therapy medical physicist is Mr. Zoubir Ouhib. The patient rights advocate is Mr. Josh Mailman. The agreement state representative is Ms. Megan Shober. The health care administrator is currently vacant after the completion of our previous health care administrator member. And the radiation safety officer is Dr. Richard Harvey. May I have the next slide, please? We also continue to benefit from the expertise and theclinical experience of Dr. John Engel, who is the interventional radiologist and consultant to the ACMUI.

May I have the next slide, please? The ACMUI provided recommendations to the NRC on licensing and inspection efficiencies, following the ADVANCE Act, and you will hear a portion of this presentation from Dr. Harvey today.

The ACMUI subcommittee on medical events gave a detailed overview of the recent medical events, and ACMUI evaluation of them.

An ACMUI subcommittee provided a summary of its review of the NRC draft guidance on licensing alpha radiopharmaceuticals.

With the rise of alpha radiopharmaceuticals clinical trials, the ACMUI found the guidance timely to address regulatory and industry questions on how applicants should apply to use them, and how they should use the alpha radiopharmaceuticals safely, and in line with regulations.

And finally, an ACMUI subcommittee provided its recommendations to add an interventional radiologist to its membership, due to the growth and questions associated with yttrium-90 microspheres.

May I have the next slide, please? Also, the ACMUI provided an overview and evaluation of potential artificial intelligence deep learning applications for NRC medical enterprise. You will hear a portion of this presentation from Dr. Andrew Einstein.

An ACMUI subcommittee provided recommendations to the NRC staff and full ACMUI, on how future subcommittees can use generic reporting process to make subcommittee reports better, and more efficient as time goes on. May I have the next slide, please?

These are topics from the spring meeting in 2025. The ACMUI provided the subcommittee's evaluation of the recent yttrium-90 microsphere medical events, after NRC staff identified a sudden increase in reported events involving unexpected gastrointestinal deposition.

Following the ACMUI recommendation in this report, the NRC staff issued an information notice providing the industry an overview of the events and recommendations to prevent reoccurrences.

The ACMUI subcommittee on generic process checklist provided a recommendation that licenses should develop a process checklist that is as specific to their practice and processes, to minimize medical events.

The subcommittee provided an example of the checklist, and the NRC staff has issued another information notice providing it to the industry to support increased safety and prevent medical events.

Finally, the ACMUI subcommittee provided a report on training and experience requirements for consideration in the emerging medical technologies rulemaking. And the rulemaking is still ongoing.

Unfortunately, our fall meeting in 2025 was cancelled due to the government shutdown. So the topics we were working on at this time, were included in the spring meeting.

Next slide, please. In addition to ACMUI presentations, NRC staff also provides presentations. At every meeting, the NRC staff provides an overview of updates on medical activities at the NRC, including ongoing rulemaking and guidance development progress and a scheduled overview of activities at the NRC that may impact the medical industry, such as teams initiatives to look for deficiencies in licensing and oversight. And updates to ACMUI policies and procedures.

From yesterday's updates, it seems that this team is very busy ensuring radiation safety for medical use, while looking for efficiencies in

the areas of licensing and inspection.

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

Mike King, of the NRC staff, provided an overview of the ADVANCE Act and the activities the NRC was taking in the spring. The NRC also provided an overview of their plans to develop guidance to address patient waste concerns, following the release.

May I have the next slide? These are the current ACMUI subcommittees. ADVANCE Act recommendations. Potential artificial intelligence deep learning applications for NRC medical enterprise; ACMUI generic reporting process; yttrium-90 microsphere gastrointestinal deposition medical event. Membership of an interventional radiologist; training and experience requirements for all modalities; patient release; ACMUI medical event subcommittee; and subcommittee on extravasations.

May I have the next slide, please? For future ACMUI, we continue to provide advice and technical assistance requiring specialized and clinical knowledge.

We also continue to inform the NRC of emerging medical uses and industry changes, comment on NRC's proposed regulations and guidance, and finally, bring key issues to the attention of the Commission.

Thank you very much. That concludes my presentation.

CHAIRMAN NIEH: Thank you Dr. Jadvar for your

presentation. Next, we'll hear from Dr. Richard Harvey, who is the committee's radiation safety officer.

Dr. Harvey, the floor is yours.

DR. HARVEY: Richard Harvey, thank you very much. I appreciate the opportunity to bring the ADVANCE Act committee, subcommittee report to you.

Chairman Nieh, Commissioner Wright, Commissioner Marzano, Commissioner Crowell, and Commissioner Weaver, thank you.

If we could bring the slides up, that would be great. Thank you very much.

All right, so again, the ADVANCE Act subcommittee report and our recommendations. The next slide, please.

The committee is composed of Dr. Folkert, Dr. Jadvar, Mr. Mailman, Ms. Shober, and myself, along with Dr. Tapp as our NRC staff resource.

Next slide, please. Subcommittee's charge. The subcommittee will provide recommendations and advice to support the Nuclear Regulatory Commission's implementation of the ADVANCE Act.

Next slide, please. Background. The subcommittee was established at the spring 2025 ACMUI meeting in April 2025. The subcommittee will assist the NRC to develop the mission statement, implementation guidance as required by Section 501 of the ADVANCE Act.

Next slide, please. Our objectives. First is mission statement alignment. We have to evaluate the ADVANCE Act's mission

statement and guidance, and provide recommendations if any, to ensure the NRC's medical regulatory framework complies with the updated mission statement.

Next slide, please. Next objective is efficiency improvements. So we want to identify recommendations if any, for the NRC to streamline medical licensing as mandated by the ADVANCE Act.

Next slide, please. The next objective, emerging issues. Monitor and assess any emerging issues arising from the ADVANCE Act's implementation that may require further ACMUI exploration, or the formation of additional subcommittees.

Next slide, please. For our first charge, objective 1. We've got the former NRC mission statement there on the slide.

The NRC licenses and regulates the nation's civilian use of radioactive materials to provide reasonable assurance of adequate protection of public health and safety, and to promote the common defense and security, and to protect the environment.

The new and current mission statement reads as follows. The NRC protects public health and safety, and advances the nation's common defense and security by enabling the safe and secure use and deployment of civilian nuclear energy technologies, and radioactive materials through efficient and reliable licensing, oversight, and regulation for the benefit of society and the environment.

Next slide, please. The NRC's updated mission statement is aligned with the NRC's medical regulatory framework. And the

subcommittee has no recommendations regarding this charge.

Next slide, please. For objective number 2. Subcommittee examined the NRC's regulations and licensing requirements in order to determine possible recommendations for improving efficiency, timeliness, and effectiveness without compromising safety for radiation workers or members of the public.

Next slide, please. Regards to objective 2. The subcommittee evaluated the ideas based on their importance, meaning the likely impact on improved efficiency and reduced waste, and feasibility.

Defined as the amount of additional effort or potential cost required to make changes in the proposed area, and/or other barriers to change.

Next slide, please. So with regards to licensing and we're going to start off in order of importance.

The ACMUI supports eliminating listing individual physician authorized users for 10 CFR 35.100, 35.200, and 35.500 on medical radioactive materials licenses.

Next in order of importance, the ACMUI supports clarification and modification of the NRC 313A forms, primarily focused on NRC 313A(AUT) form. Specific recommendations include clarification of table 3.c on NRC 313A(AUT) forms, to make parenteral supervised case requirements more explicit.

The NRC 313A(AUT) form, we're asking for clarification that only three total supervised cases are needed, rather than the belief that exists

out in the communities, out in the workplace, that three supervised cases per type of parenteral administrations are required, and draft clearer and streamlined NRC 313A forms to make implementation less challenging or daunting, for NRC and licensees.

Moving to the next slide, if you would, please. Again and still working on the order of importance. The ACMUI supports radioactive material activities or possession limits, for medical licensees based on the amount of, excuse me, based on the amount a licensee can manage safely and effectively, rather than limits based on current need.

This would reduce the number of license amendments for NRC and agreement state regulatory organizations.

The ACMUI supports moving appropriate emerging technologies to intended 10 CFR 35 designations.

In addition, retiring 10 CFR 35.1000 guidance for obsolete systems that are not commercially available in the U.S.

Some examples of those are ViewRay, NorthStar, RadioGenix. This would eliminate the need to maintain guidance for obsolete devices.

Next slide, please. The ACMUI supports decreasing frequency of license renewals. Medical licenses are more frequently amended than other radioactive materials license types, mostly due to authorized user changes.

Many medical radioactive materials licenses have few procedural modifications, and therefore, license amendments.

Thus, performing a license renewal provides minimal benefit, with all the necessary effort required by the NRC to renew the license.

Instead of performing license renewals on a time period requirement, the recommendation is to renew licenses after 25 amendments, which are also called tie downs.

The next slide, if you would, please. Now we're going to talk on the, about feasibility. So it's the same initiatives but in order, ranked in order of feasibility.

So the ACMUI supports clarification modification of the NRC 313A forms, primarily NRC 313A(AUT). Specific recommendations include clarifications on table 3.c, on NRC 313A(AUT) forms to make parenteral supervised case requirements more explicit.

Again, the NRC 313A(AUT) form clarify for licensees that only three total supervised cases are needed, rather than three supervised cases per type of parenteral administrations. And draft clear and streamlined NRC 313A forms to make implementation less challenging for NRC and licensees.

The next is as you've heard these before, the ACMUI supports eliminating listing individual physician authorized users for 10 CFR 35.100, .200, and .500, on medical radioactive materials licenses.

Next slide, please. The ACMUI supports decreasing frequency of license renewals. Medical licensees again, are more frequently amended than other radioactive materials license types mostly due to changes in authorized users.

Many medical radioactive materials licensees have few procedural modifications, and therefore, license amendments.

Thus performing a license renewal provides minimal benefit with all the necessary effort required by the NRC, to renew the license.

Instead of performing license renewals on a time period requirement, the recommendation is to renew licenses after 25 amendments or tie downs.

Next slide, please. The ACMUI supports moving appropriate emerging technologies to 10 CFR 35 designations.

In addition, retiring 10 CFR 35.1000 guidance for systems that are not commercially available in the U.S. ViewRay, NorthStar, RadioGenix, would eliminate the need to maintain guidance for obsolete devices.

The ACMUI supports radioactive material activity or possession limits for medical licensees, based on the amount of licensees, amount a licensee can manage safely and effectively, rather than limits based on current need.

This would reduce the number of license amendments for NRC and agreement state regulatory organizations.

I apologize for being a little bit redundant there, going through with the two rankings, sets of rankings.

Next slide if you would, please. Oh, you've got it. Okay, so subcommittee will continue to evaluate the area of opportunity, and will formulate recommendations as appropriate. This is for inspections.

Next slide, please. For administration, importance and feasibility. The ACMUI supports development of a medical event reporting form to support submission of the appropriate information to evaluate medical events.

On occasion when we get medical events, there is incomplete information. And so if we had more complete information, this would help in the review of those medical events, and help the NRC as well as the ACMUI, make recommendations for improvement.

Next slide if you would, please. Objective number 3. Subcommittee will continue to monitor and assess any emerging issues arising from the ADVANCE Act's implementation.

There are no additional recommendations at this time that require further ACMUI exploration, or the formation of additional subcommittees.

Next slide, please. In summary, the NRC's updated mission statement is aligned with the NRC's medical regulatory framework, and the subcommittee has no recommendation regarding this charge.

Recommendations regarding efficiency improvements based on importance and feasibility have been provided.

The subcommittee will continue to monitor and assess any emerging issues arising from the ADVANCE Act's implementation.

Next slide just lists our acronyms, and I would like to thank everyone for the opportunity to give the subcommittee's report at this time.

Thank you very much.

CHAIRMAN NIEH: Thank you very much, Dr. Harvey. Next, we will hear from Dr. Andrew Einstein, a nuclear cardiologist for the ACMUI. Dr. Einstein, please.

DR. EINSTEIN: Thank you, Chairman Nieh, and thank you to the commissioners as well for the opportunity to present the work of the ACMUI subcommittee on potential AI deep learning applications for NRC medical enterprise.

Okay, great, next slide, please. The members of our subcommittee were Dr. Fair, Dr. Folkert, Mr. Mailman, Dr. Jadvar, a non-voting consultant was Dr. Engel, our interventional radiologist consultant, and our staff resource was Ms. Ayoade.

Next slide, please. AI is really revolutionizing technology as well as processes throughout society, and in the United States government in particular.

So the AI subcommittee was established by Dr. Jadvar, and tasked with exploring and evaluating the potential applications of AI and deep learning technologies, to enhance the efficiency and effectiveness of the NRC medical staff, and ACMUI.

Next slide, please. Six specific objectives were defined for the subcommittee. One was data analysis and efficiency to investigate how AI tools can be utilized to streamline the analysis of NRC medical data, including but not limited to the nuclear material events database, to identify trends, gaps, or areas of concern.

A second objective is process optimization to assess how

AI can improve the efficiency of NRC medical regulatory processes, such as event reporting, compliance monitoring, and data management, to support faster and more accurate decision making.

Third objective was knowledge gap identification. To explore AI's capability to mine existing NRC medical data to uncover potential gaps in knowledge, regulations, or oversight, that could enhance safety and regulatory effectiveness.

Next slide, please. The fourth specific objective was benchmarking and best practices to review existing AI applications in similar domains, such as the FDA's MAUDE database to identify models or approaches that could be adapted for NRC use.

In this context, we spoke with a number of other federal agencies to understand what they're doing in the AI space.

Objective 5, recommendations to develop actionable recommendations for the NRC staff and ACMUI can take regarding the adoption, implementation, or further exploration of AI tools, including considerations for agency policies, technical feasibility, and resource requirements.

And finally, agency alignment to coordinate with NRC staff to understand the agency's current stance and policies on AI adoption, and ensure recommendations align with broader agency goals and constraints.

Next slide. In fact, the current NRC AI strategic plan is well-articulated in the document FY26 Artificial Intelligence Strategic Plan, which was recently released.

The vision articulated in this document is to responsibly leverage artificial intelligence in support of the NRC's mission; empowering staff to efficiently make risk-informed decisions; drive regulatory innovation; and protect public health, safety, and the environment.

AI supports NRC's mission in five domains. Enhancing decision making; strengthening regulatory oversight; increasing efficiency; fostering innovation; and supporting public confidence.

Next slide, please. Goals and objectives articulated in this strategic plan are as follows. Really, there are three major areas of goals, each with two objectives underneath them.

The first goal is to enhance NRC staff productivity and operational efficiency. And under that are the two objectives, to accelerate AI adoption through a prioritized mission aligned use cases, and to ensure robust infrastructure, high quality data, strong cybersecurity, and a skilled workforce that underpin all AI activities.

The second goal area is to empower NRC staff for AI integration. And the objectives under that are to foster a workforce ready to adopt and integrate AI tools that enhance productivity and streamline operations, and to provide training, resources, and support to ensure staff can confidently and responsibly apply AI in daily workflows and decision-making.

And the third goal area is to build a sustainable AI ecosystem with specific objectives to ensure robust infrastructure, high quality data, strong cybersecurity, and a skilled workforce that underpin all AI activities, and to establish long term workforce development strategies that

align AI skill building with evolving organizational needs and technology trends.

Next slide, please. Really, AI can add value to many of the NRC's mission functions, ranging from regulations and guidance, regulatory milestones, oversight, operational experience and support for decisions. And under support for decisions falls Advisory Committee activities, such as activities of the ACMUI.

There are numerous examples of AI use cases which can be used. Many of them involving generative AI or its subcategory, large language models, which can ultimately lead to increased productivity.

Next slide, please. A particular area of interest is in Medical Events. Medical Events is a standing subcommittee of ACMUI, which meets regularly to review available data on medical events submitted primarily through the Nuclear Material Events Database.

These reports are organized and reviewed first by NRC staff, and then the subcommittee spends a substantial amount of time evaluating individual reports to derive as much information as possible on the types of events that are occurring, rates and trends of such events, potential causes, and potential interventions.

Even with coordinated effort of medical experts with extensive experience in this area, such as my colleague Dr. Harvey, there are gaps in information that limit the conclusions that can be drawn and the recommendations that can be made by the Subcommittee and NRC Staff.

FDA has a lot of experience which draws, brings to bear in

this realm, analysis of medical events through AI as an emerging area of research and administrative applications. In our subcommittee's meetings with representatives from the FDA they noted that efforts were underway to use AI to analyze their own datasets. An example of which is the Manufacturer and User Facility Device Experience, or MAUDE, Database for medical device issue reporting.

While these efforts are in their early stages and there is much work to be done, the access of the AI tools to the data sources, this represents an area where collaboration between the NRC and FDA could improve efficiency and avoid redundant work.

Next slide, please. There is several potential roles of AI to improve the reporting and analysis of medical events. These can include in the area of data entry where AI could be incorporated at the initial reporting step to analyze submissions and trigger requests for additional or more specific information.

For filtered reporting, using natural language processing. Automated summaries and analysis of trends in medical events over time can simplify review processes and identify areas of concern, as well as facilitate categorization of events.

We heard yesterday about a new categorization system for these medical events. As these systems change, AI could potentially provide great benefit in performing that categorization.

AI tools could be used to summarize data that is already in NMED and significantly reduce the time it takes to create the reports. For

corrective action plans. Given sufficient data on best practices for corrective actions, AI-generated corrective plans could be created, reviewed, and shared with licensees to improve safety.

And finally, for presentation and public review, AI can also simplify the process of organizing the materials for presentation and public review.

Next slide, please. So there are numerous lessons to be learned from other organizations. And I'd like to go through five of those organizations. The executive office of the President, the National Institutes of Health, the general services administration, the conference on radiation control program directors, and the International Atomic Energy Agency.

Next slide, please. Starting with the executive office of the President. In response to Executive Order 14179, removing barriers to American leadership in artificial intelligence, which in fact led to the recent NRC updated strategic plan regarding artificial intelligence, the Office of the President issued a report in July of 2025 entitled, Winning the Race, AI's -- America's AI Action Plan.

This summarizes President Trump's approach to AI and is built on three pillars. Innovation, infrastructure, and international diplomacy and security.

It calls for the United States to innovate in artificial intelligence more rapidly and comprehensively than our competitors across every field. And it places as a priority the prevention of our advanced technologies from being misused by malicious actors and monitoring for

unforeseen risks of AI.

Next slide, please. It establishes several recommended policy actions. I selected some here which are more relevant for the medical mission of NRC. Establishing regulatory sandboxes or AI Centers of Excellence.

And NRC has already begun such efforts, as I understand, in a collaborative regulatory sandbox project with international partners, including Canada, the U.K., Japan, Korea, and France. This project aims to bring together regulators and industry to work through enablers and disenablers of adopting innovative technology like AI in the nuclear domain.

Launching specific -- domain-specific efforts, in areas such as healthcare and energy, led by the National Institutes of Standard and Technology, to convene stakeholders to accelerate development and adoption of national standards for AI systems and measure the increase in productivity from AI.

Next slide, please. A series of policy actions in this report focus on accelerating AI adoption in the federal government. These include creating a talent-exchange program designed to allow rapid details of Federal staff to other agencies. This would enable both sharing NRC's expertise in the AI space with other agencies, as well as drawing upon expertise existing in other agencies.

These could include, for example, the expertise gained in the development of FDA's MAUDE database, and FDA's recently-introduced Elsa large language model-powered AI tool. Elsa is built within a

high-security GovCloud environment and offers a platform for FDA employees to access internal documents and assist with reading, writing, and summarizing, including summarization of adverse events. These activities would be of use potentially for NRC employees, as well.

Next slide, please. In the National Institutes of Health, AI has become a standard integrated tool rather than a specific point of research. The NIH Office of Data Science Strategy maintains a website that summarizes their initiatives in the AI front and the overall 2025-2030 strategic plan for data science, and links to a number of programs.

These include the Networking and Information Technology Research and Development Program, that's working to develop and apply advanced IT, computing, networking, and software capabilities for the U.S. And the AIM AHEAD program is working to establish coordinated multidisciplinary partnerships to develop AI and machine learning models, beginning with electronic health record data.

In addition NIH has a bridge to AI, or bridge to artificial intelligence program designed to propel biomedical research forward by facilitating widespread adoption of AI to address complex biomedical challenges beyond human intuition.

Next slide, please. NIH has partnered with the United States Department of Energy, as well. In 2024, they undertook a joint workshop on computational modeling to advance novel medical isotopes for

radiotheranostics. And this brought together experts from government, academia and industry and emphasized the role of DOE-NIH collaboration to address U.S. infrastructure and supply for medical isotopes, improve efficiency of regulatory pathways, and investigate how to integrate computational tools into radiopharmaceutical-based therapies.

Specific to AI collaborations between DOE and NIH include studying the role of AI-driven modeling, machine learning, and digital twin technologies in optimizing radiation dosimetry, and dynamically personalizing treatments, and reducing time to clinical adoption. The workshop conclusions emphasized the need for continued strategic collaboration and sustained resources to advance next generation theranostics and ensure accessibility of safe and effective therapies.

Next slide, please. General Services Administration, or GSA, provides centralized procurement services for the federal government, including technology services.

On August 14th of 2025, GSA introduced USAi, found at usai.gov, which includes a generative AI suite, including an application programming interface, integrated platform providing government users with access to multiple large language models. Anthropic's Claude, OpenAI's ChatGPT, Meta's Llama, and Google's Gemini. And this includes powerful tools for government users including chat-based AI, code generation and document summarization.

Next slide, please. USAi operates in the Federal Risk and Authorization Management Program, FedRAMP, authorized environments to

leverage some of best AI technology from these multiple vendors while ensuring information safety.

They offer a 6-month free trial through June of 2026 to help federal agencies adopt AI capabilities and improve mission delivery. And this includes $25,000 in token consumption per agency.

Consideration of USAi would enable NRC to go beyond current use of Microsoft Copilot to utilize the best features of AI products from Anthropic, OpenAI, Meta, and Google.

Next slide, please. The CRCPD, or Conference of Radiation Control Program Directors, is a non-governmental 501(c)(3) professional organization. Its primary membership is radiation professionals in state and local government that regulate the use of radiation sources.

CRCPD has established a working group called G-76, which is dedicated to exploring use of AI in radiation protection and has been conducting extensive research over the past year, collecting content from service providers on the use of AI in the medical field. This research is informing their assessment of the benefits and risks of using AI in radiation protection.

Next slide, please. The IAEA is also interested in this space. Our International Atomic Energy Agency.

In 2021, IAEA hosted a Technical Meeting on Artificial Intelligence for Nuclear Technology and Application with the aim to ascertain the current situation and identify priorities for future activities and how IAEA can support their implementation. This discussed broad topics on human

health, as well as other areas in different nuclear domains, such nuclear power and future, and nuclear safety and safeguard verification.

And it emphasized following the FAIR, findable, accessible, interoperable, and reusable, principles and open science best practices for data sharing, management, and analysis. A major emphasis was also placed on the ethics of nuclear and AI technologies.

Next slide, please. In the human health arena, the workshop acknowledged that AI tools are not widely used in radiotherapy and medical physics with challenges remaining in the clinical implementation of the AI-based tools and in technical, ethical, and legal domains. Similar opinions were expressed for the domain of medical imaging and nuclear medicine, but I point out that matters have changed considerably there since 2021.

In conclusion, IAEA is engaged in discussions on how to employ safe, effective, and ethically proper AI-based tools in all aspect of its mission driven activities, including those relevant to human health. IAEA and NRC share numerous priorities related to AI and the medical uses of isotopes, and partnerships addressing these commonalities could benefit both organizations.

Next slide, please. This background, which we have developed over the past year, I'd like to present to you six recommendations from our subcommittee in order of priority.

Our first recommendation is that NRC shares numerous priorities related to AI and the medical use of isotopes with other federal

agencies and international organizations. Additional partnerships addressing these commonalities could benefit NRC.

Participating in the recently-proposed talent exchange program in American's AI Action Plan will enable both sharing NRC's expertise in the AI space with other agencies, as well as drawing expertise existing in other agencies. For example, the expertise gained in the development of FDA's MAUDE

database.

Consideration -- a second recommendation is the consideration of the U.S. GSA's USAi platform would enable NRC to go beyond our current use of Microsoft Copilot to utilize the best features of AI products from Anthropic, OpenAI, Meta, and Google, as well.

Recommendation 3, the quality and quantity of data used for AI applications is critical. NRC has in the past faced challenges with legacy data. Priority should be placed on having AI solutions that can utilize legacy data collected by the NRC in any form for effective future AI use and moving to an ingestion pipeline that ensures data are in a usable format and of high quality. This is in line with AI -- America's AI Action Plan, which recommends establishing minimum data quality standards in AI model training.

Next slide, please. Fourth recommendation. The subcommittee sees an immediate opportunity for enhancing the medical event database to take advantage of AI resources, as we detailed earlier. The current medical events database is a PDF file, and putting it into a more

searchable format is recommended.

A fifth recommendation. While there is no currently-identified need for AI in the medical isotopes space within NRC, this should be further explored. In line with America's AI Action Plan, we need to innovate faster and more comprehensively than our counterparts elsewhere. For example, NRC is not currently using AI for dosimetry models, but AI has potential such use.

In Recommendation 6, NRC should aim to participate in national healthcare-specific efforts convening stakeholders to accelerate the development and adoption of national standards for AI systems and to measure the increase in productivity from AI.

Next slide, please. These are the acronyms which we've used in this presentation. Thank you very much.

CHAIRMAN NIEH: That's a lot of acronyms. Okay, thank you very much, Dr. Einstein. Next -- finally we'll hear from Mr. Josh Mailman who is the Committee's patient's rights advocate. Please.

MR. MAILMAN: It's how it's confusing to patient providers and manufacturers. And I actually hit on some of the points that Dr. Jadvar talked about earlier today, and the rise of nuclear medicine therapy in the United States.

So this is the agenda. Perspectives on the rights of patients receiving radioligand therapy, or RLT, and the number of sites offering them in the United States.

First and foremost, I want to thank the Commissioners for

their time today in listening to this. And thank you for the well wishes when I wasn't able to attend last year. I also want to thank my Committee members who have really taken care of me over the last eight or ten months as I have recovered from surgery. And I, lastly, want to thank the NRC Staff who has kept me up to date. They've done tremendous job of making sure I did not fall behind. So thank you to all of those.

So, disclosures. Next slide, please. The views and the contents that I am presenting on this slide deck, and the Q&A that may occur afterwards, are my own opinions as a patient right advocate relating to my own experience in those, with conversations with patients. They do not represent the views of the ACMUI. I just want to make sure we're clear on that.

You know, when I was first treated with radioligand therapy was in 2009. We've had our first approval in the United States of Lu 177 dotatate, which brand name is Lutathera 2018 where we had slightly, a hundred sites that were able to offer this type of advance therapy.

When we take a look at what happened after the release of Pluvicto or the Lu 177 PSMA product in 2002, that was at 600 sites. And now at this moment in time, 90 percent of all men are able to get Pluvicto within 30 minutes where they live. So we're at 900 sites and rising. And there is some references to that. So that can be looked up, as well.

So we're seeing a rapid expansion of where these, where these therapies, these new advance radioligand therapies, can be offered.

The instructions, the patient release instructions, which of

course have been the subject of several drafts that have come through, and we know we're waiting for the next draft to come through for public comment, but they're very close to the COVID safety rules. Sleep in separate bedrooms, use different bathrooms, stay three feet apart.

The challenges are, not all can do this. And some modifications need to be made, and are being made by centers that have worked in this area of therapy for a long period of time. However, with this new rapid expansion I'm hearing from patients, or patient leaders of different support organizations, that they are having patients that are being turned away because they're not able to adhere to what might be those three different areas.

And I wanted to, since we have the COVID data that was available, if I go to the next slide, please. This is, and I think you can read this, but this really affects people in the lower income scales.

The percentage of places that, or the percentages of households that cannot adhere to that during COVID were predominately the lower income classes. And you can see how that changes as their percentage of federal property level decreases.

So this is a study that was done by the Department of Housing and Urban Development in 2019 to take a look at those who could adhere to having a separate bedroom and bathroom during COVID for isolation, which is much like some of the patient release criteria.

Next slide, please. And I will say, you know, as a patient we get confused about these things. And even as a manufacturer or

producer of these items Pluvicto, Lutathera, and what's known as the RLT Institute, these are all Novartis' sites.

These are all discussing the same radioisotope and yet they're, whether you have two days of no contact or three days of no contact or three days somewhat of whether it's contact or limited contact, it's the same isotope. And yet the same manufacturer can list it three different ways.

And if that's where confusion starts, or if we're already confused there as it gets out into the marketplace into the providers and into providers who may not have as much experience as the research centers or centers that have been doing these therapies for years, it only leads to greater confusion. And I promise to keep my time short. And to also reduce the number of acronyms.

So next slide, please. That's my acronym slide. So I'm going to save you a lot of time in reading acronyms. And with that, I will turn it back to Chair Nieh for closing. Thank you so much.

CHAIRMAN NIEH: Thank you, Mr. Mailman, you win the prize for the fewest number of acronyms. And appreciate all the thoughtful and comprehensive presentations from all the members here before the Commission today.

As you all know we rotate questions from the Commission, so today I get to start first. And then the questions will be followed by Commissioners Wright, Commissioners Crowell, then Commissioner Marzano and then Commissioner Weaver.

Starts? Okay, I'll start first. Again, thank you for the

presentations. And as you all are well aware, the NRC is at a pivotal moment in its history with the degree of regulatory reforms that we are making.

You know, we've always been a risk-informed performance-based regulator, and we're moving even further in that direction. As well as, with the enabling component that you mentioned from your subcommittee's review of the NRC's new mission statement.

And the way we're viewing enabling is that in the regulatory context enabling is aligning our regulations with actual risks. It's adapting to new technologies. And it's adding flexibility where safety is maintained.

In your presentations you had mentioned that there is some ongoing rulemaking activities that I believe will address some of the things that are important to the Committee, as well as the -- your community and patients receiving treatment. So I do appreciate the feedback that you provided on our implementation of the ADVANCE Act.

And I want to get into a couple areas here. First, to Dr. Jadvar. With Part 35, in recognition that there are some ongoing rulemaking activities, two-part question. What would our -- what would be the biggest benefit in terms of improving the efficiencies and flexibility in part 35? That's the first part.

And then the second part. What are the new technologies that we need to be thinking about looking further ahead? I know there is things with alpha and beta emitters now and other treatment mechanisms, but what are some of the other technologies that we need to be thinking about?

DR. JADVAR: Thank you for your question. So as you

rightly mentioned, there is the alpha emitters. That -- we have only one agent at the moment that is approved. That's radium-223 dichloride for patients for bone dominant metastatic prostate cancer. However, there are numerous) --

I'm sorry, I'm repeating myself. Hello? There are numerous alpha emitter agents, both in prostate cancer and other cancers that are being explored within this country and other countries. And I do expect that these alpha emitters will be approved.

And one of the efficiencies within that Part 35, that I think was mentioned earlier within our subcommittee that was discussed yesterday, was that the alpha emitters regulation precautions is appropriate to be under the Part 35 300. And the radiation precautions are not separate or different from others that we already have, like beta emitters.

If -- alpha emitters are actually very high energetic and they really stop, you know, even with small paper. They don't get out of your body essentially. And all that there is, is they may have gamma rays associated with the decay as they decay. And that's the gamma rays that would perhaps expose others, but not the alpha emitters themselves.

So that's one thing that is emerging. And it's important to be included. And I think already the NRC medical team is on top of that. And I mentioned that we had the subcommittee on that. And we advised, the ACMUI advised the NRC on that topic.

And the others parts of the efficiencies, not only for that Part 35, but also other activities of the NRC, especially the medical aspect, is

already very well summarized on our subcommittee on ADVANCE Act, which you heard today from Dr. Harvey. And I think if those are all the recommendations that we made to the NRC medical team, if some of those, or all of those, are implemented that would also increase efficiency and safety, I hope, in that realm. And in alignment with the ADVANCE Act.

CHAIRMAN NIEH: Okay, thank you, Dr. Jadvar. Next question I'd like to turn to Dr. Harvey. License renewals.

As I understand it, our framework for license renewals is really done through regulatory guidance. There is no existing regulatory requirement or any statutory requirement for a specific license time period.

So I'd like to understand what would be the safety impact of not having a licensed time period at all?

DR. HARVEY: Yes, thank you for the question. The -- I think that there is a license renewal frequency. I think it's about every 15 years if I'm not mistaken. So it does happen on a certain basis.

But often times some of the amendments or tie downs that occur are relatively minor in scope and nature. And they don't have a significant impact on safety. So renewing those licenses at a more frequent frequency, you know, at a greater frequency, just increases extra work for the licensee, for the NRC or the other state organizations.

Rather than take the approach of not renewing at all, because what happens is with these amendments as they accrue over time, it becomes more cumbersome and difficult to manage the license and inspect it for the NRC. The NRC comes and can look at the licensed document itself.

And the renewed licenses is there in its form at that time when it was renewed. But then there are subsequent amendments and different paperwork that have to be examined and looked at. And there is a deeper dive and more time and effort that's needed for the inspectors when they come out.

So we try to find a balance with the 25 tie downs or amendments where we wouldn't create something that was too unwieldy, but also reduce the frequency so that there was a benefit derived from regards to effectiveness and timeliness and efficiency. I hope I answered your question appropriately.

CHAIRMAN NIEH: Certainly great information, but I really want to explore this further. And keep in mind, you know, the framework that I've largely seen the world through is licensing of reactors. Which does have a statutory time frame for the duration of a license here.

So as I understood what you've said, you get a license for a particular technology, you can amend it through some regulatory review process, right, and you stack up a series of amendments. And there is always an ongoing inspection activity.

So I'm really trying to understand why we even have an end date if we have ongoing inspection and regulatory approvals through, you know, amendments to how you use the technology due to, you know, changes and innovations and how the treatments are performed. So what benefit are we really getting at by having a fixed end date?

Which I understand is actually in the Staff's guidance not

necessarily in the regulations themselves. So why even have an end date is my question?

DR. HARVEY: Yes. So I probably didn't answer that appropriately enough. And so have -- rather than having one document that you can go to and look at all of the parameters that define the license, right, when you do an amendment you have subsequent documentation on top of that.

There might be multiple documents, or at least one document for each amendment. And now you're building up a volume of paperwork that support that licensed document. And those tie downs or amendments need to be referred to, either by the licensee or by the inspector. Or if we have to share our licenses with other manufacturers or things, other places to get certain things to say we're able to get this new radionuclide that we just added through an amendment or a license, if we never renew that license that process becomes much more cumbersome. At least in my opinion.

So trying to find, again, that benefit to where we save some efficiency and we improve what we're doing rather than going too, too long and making it a more cumbersome process.

CHAIRMAN NIEH: Okay, thank you.

DR. HARVEY: Thank you.

CHAIRMAN NIEH: I'm running out of time quickly, so I want to ask a question about artificial intelligence. You gave six recommendations, and the two that stuck out to me was, one, that there was

no real need identified right now. It seems like we could have significant benefit in applying AI in the NMED database.

What does it take to start doing that? Is that a Staff action or is that something the ACMUI can initiate or, how do we start using this technology to better analyze the events for their content in the database?

DR. EINSTEIN: I think operationally it would be something that NRC Staff would do. Do we have appropriate staff, I know we've spoken yesterday, who can perhaps address that.

PARTICIPANT: Yes. We'd have to work at the Staff level for that. Our NMED database is an outside database. I see OCIO.

MS. SALL: Yeah.

PARTICIPANT: Yeah.

MS. SALL: Hi, Basia Sall from OCIO. Yeah, we would be able to use some of our new internal tools to apply to that dataset as long as it's curated in the right way. So we have a tool called Simplify. Which is Azure OpenAI that can use internal data to gather that same information.

CHAIRMAN NIEH: Okay. Thank you. And I'm out of time. And I just do want to say thank you, Mr. Mailman, for your perspectives from the patient's rights point of view. And I will share that it's -- the topic of making things less confusing and, you know, better for the patients so they receive appropriate care is something that the staff is treating with priority as it's looking at its regulations in this area.

Commissioner Wright?

COMMISSIONER WRIGHT: Thank you. Thank you,

Chairman. And thank you for your presentations. I enjoy this meeting. It brings a -- there is a lot of flavor here and a lot of things that I'm personally interested in myself just from my own background.

And, Mr. Mailman, you have been in my thoughts for the last year. It's good to see you here in person and moving around. It was an honor to meet your son and his friend this morning, as well. And I appreciate your recognition of the Staff keeping you up to speed because, you know behind a meeting like this takes a lot of work to prepare. Not just from the Staff of the NRC, but from my team, as well. And I appreciate them for having me as prepared as they can have me. Given I'm a Clemson man, right?

So with that, I would like to, I'm going to start with Dr. Jadvar. You know, ACMUI has highlighted the potential value of enabling relevant professional societies to develop curricula for initial training of authorized users.

And at the NRC we're exploring mechanisms to evaluate and potentially incorporate these curricula in the licensing process. So in your opinion, Dr. Jadvar, what are the relevant professional societies and maybe what specific strategies or criteria does ACMUI recommend the NRC consider?

And how might, especially for safety and competency, so -- and how might these, this approach improve consistency or licensing efficiency?

DR. JADVAR: Thank you, Commissioner Wright. And again, it is wonderful to see you. And I remember our conversation before

that was published recently.

Yes, so there are many professional societies that are already working in business space trying to come up with educational tools, both to support the initial training that is needed for somebody to become AU and eventually to treat patients, and also ongoing continuing education for these individuals.

And they -- and many of these professional societies work closely with the certification boards, such as the ABR, ABNM, and others. I mean, there are many of them, Society of Nuclear Medicine and Molecular Imaging, or SNMMI, is clearly focused on this.

The Radiological Society of North America, RSNA, anther very big conference that provides many of these educational tools. ASTRO, which is the American Society of Radiation Oncology, also is much involved in this. And many others. ACR and, I mean, I don't want to leave anybody out, but there are many, many of these that are already active in this area.

Many of them work together. There are collaborations between different societies. I know that SNMMI and ASTRO are now working collaboratively with regard to the very fast growing and evolving diagnostics to make sure that the folks, or AUs, that are there know what it takes to become a AU and be competent in delivering these type of therapies in the communities, academic centers, or other centers.

As Josh mentioned earlier, these centers are growing rapidly. And the providers that are in those centers should be trained adequately. And it would be very important that these type of educations are

provided to them. Not only in the major meetings that these societies have, but also at the local level and online. Many of these are already in the works and available for initial education and continuing education.

COMMISSIONER WRIGHT: And thank you for your response and for you naming as many as you did because that's kind of the point that I was trying to get to. If there is so many of these, you know, how do we settle on a curricula that covers the expanse of this?

Are you looking at -- are we looking at authorized user certification by certain groups of these people, these different societies because of, I don't know, their expertise or the expertise that that authorized user might have?

I'm trying to understand a little bit, especially because then you've got the continuing education piece of this. And how is that going to be developed?

I mean, I know there is benefits and probably, you know, as well as challenges in setting up a program like that, but I'm trying to figure out what is going to be the roll of the ACMUI and the Commission and facilitate that dialogue with these different organizations out there. You know, kind of, how do you see that happening?

DR. JADVAR: Well, the T&E subcommittee, which is still in the works and fluid, but we have mentioned many of these societies. And as I already alluded to, these societies are, the members of the societies are a different type of positions and with different focuses.

And all of them I think are very important to work together.

The curriculum is not very different. It's basically the same type of material you need to know, for example, to deliver competent care for a patient with prostate cancer. You know, let's say Pluvicto.

So that curriculum and how to do that is, the material itself is the same. But the way that it gets distributed in the community, depending upon where they're working or what type of physicians they are, for example, if they're a nuclear medicine physician or a diagnostic radiologist or a radiation oncologist.

So they all basically go to the same pool of information and data that they need. And they -- that is already recognized. That's why these societies are working together.

And in fact, many of these societies when they have the teachers to teach or educate their audience they draw from nuclear medicine, they draw from radiation oncology, they draw from, you know, medical oncology even. Some ancillary fields that are not directly working with patients, you know, treating patients with these types of things, but we also bring in medical oncology, urology.

So it's certainly a multidisciplinary field. And I think it is necessary that all the societies that are relevant be involved.

COMMISSIONER WRIGHT: Okay, thank you so much. And thank you for asking me to participate in the interview with you, that was a lot of fun.

DR. JADVAR: Okay.

COMMISSIONER WRIGHT: Thank you.

DR. JADVAR: Thank you. Thank you.

COMMISSIONER WRIGHT: Dr. Harvey, welcome. You know, your subcommittee recommended that radionuclide possession limits be based on what a licensee can safely and effectively manage rather than on current -- in order to, I guess reduce the frequency of amendment requests.

So my question to you is, based on your expertise can you tell me a little bit more about operational or safety considerations that the NRC should prioritize when we are evaluating license requests for increased possession limits?

DR. HARVEY: So you typically have, if we're talking about just change in possession, you already have these radionuclides and those radiopharmaceuticals and certain amounts already on your license. So you have the proper safety precautions in place for those.

So rather than worry about adding a few extra millicuries here or there, the safety and the operational procedures that you have in place for safety are already there. So they're -- if you -- as long as you have the ability to use those things safely, you have the right equipment in place, the right amount of shielding, right amount of equipment for doing surveys, wipe testing, things like that to look for contamination and exposure, radiation dosimetry for staff, if you are already protecting your patients and your staff modifying your possession limits by, you know, minor amounts really doesn't change or have any impact on your safety.

Did I answer your question okay?

COMMISSIONER WRIGHT: Yeah. And -- we got about

20 seconds left. They're only getting more advanced, which means they're getting more, I don't know, the strength of them is improving but it's also more targeted and focused, right? We're prepared for handling all of that, as well?

DR. HARVEY: I would say that we are. Now, if you're going to -- if you've only had beta gamma emitting radionuclides and now you're going to add alpha, then you're going to amend your license so that you can add that.

So we were, you know, kind of just focused on the possession aspect of it. But we do need to be prepared, as you said, for the new therapies that are going on. So for example, we're bringing on alpha emitting radionuclides, but we're bringing it on in such a way that then if we want to add a few more where the safety and efficacy and those kinds of things are not changing, we'll be able to do those without additional amendments in our state organization.

Just citing my own example as that. So I'm trying to be respectful of the time.

COMMISSIONER WRIGHT: Thank you so much.

DR. HARVEY: Thank you. It's an honor.

COMMISSIONER CROWELL: Thank you, Mr. Chair. And thank you to all of our presenters today.

Before I jump into questions I just wanted to recognize and congratulate Chairman Nieh, Commissioner Weaver and our new general Counsel, Matt Pociask, on their first public open commission meeting. It feels like -- it's good to be back in this room again, it's been a little while. So

thank you.

Mr. Mailman, I'm going to start with you and then I'm going to probably move to AI for the balance of my questions. But it's good to see you again. I'm glad you're here today.

I will note, humorously for the record, that the patient release protocols that are similar to COVID are also similar to my wife's rules for me on a daily basis in our house. That being said, you note that you're hearing from patients, hearing from advocates that patients are being turned away from treatment if they don't have separate rooms or bathrooms. What's the primary driver of that disconnect, is it that insurance companies won't cover the cost of an extended hospital stay that -- to mitigate the patient release challenges?

MR. MAILMAN: So it would be hard for me to actually ascertain whether it's the insurance companies turning it away. It may be some people who are unfamiliar with, you know, how to mitigate these issues, whether it's treat a patient and try to get a hotel voucher as opposed to that they need hospitalization for the entire time. But just their own unfamiliarity with how to proceed.

So I'm not sure. I don't believe this is an insurance problem. I believe it's a knowledge gap problem. Which, I believe that those who produce the product might be able to help solve. But, yeah, I don't think it's an insurance problem.

COMMISSIONER CROWELL: So if the knowledge gap is addressed, what are some of the practical solutions that would be employed?

Is it through the drug manufacturers, through the hospital or wherever the treatment facility is, like what is the obvious way that you could do this?

MR. MAILMAN: I think it's multifactorial. I do think that you're going to have to have all of these people work together. Whether it's the drug manufacturers making sure that they let the facility know that there is some type of program.

I know that we've had discussions with a lot of hospital systems that do understand that -- how to take care of this. And I just think it will require, you know, more knowledge and more training as opposed to a change in what we're doing, but that we make these programs more available and accessible to patients.

COMMISSIONER CROWELL: So would -- I don't know if all radiotherapies and diagnostic tools are necessarily equal in this regard, but would, you know, for patients who don't have, can't follow the COVID derived guidelines, would 24 hours in a hotel or hospital help mitigate that or is it all over the board, is it longer? I mean, is it --

MR. MAILMAN: So I would leave that up to the, either the physicist or the committee that's working on that to say what that type of requirement is. Whether --

COMMISSIONER CROWELL: But my point is, if it's short-term it's probably more manageable than if it's like a week on average. So I don't know if -- who wants to address that with the fancy letters after their names.

MR. MAILMAN: A day or two.

COMMISSIONER CROWELL: Harvey?

DR. JADVAR: It's usually two or three days.

COMMISSIONER CROWELL: Thank you. Do you agree, Dr. Harvey?

DR. HARVEY: Yeah. I mean, most of the time frame is relatively short where there is more radioactivity being shed. I, you know, for example, at places like, Dr. Jadvar, USC or Roswell Park Comprehensive Cancer where I work, we're used to dealing with these patients.

And so if -- typically it's an outpatient treatment, as you cite, if we need to bring them in-house and treat them as an inpatient, even though we're not going to be reimbursed the same amount, we will do that. We'll make sure that somebody from a group home or someone that can't adhere to these requirements are treated. We want to make sure that everyone gets treatment. So, you know, whether it's dialysis or something, whatever we have to deal with we will deal that on an inpatient basis.

The great thing about what Mr. Mailman talked about is the expansion. How many more places are able to do this and bring this care, which is a great thing.

Probably what would need to happen is if they can't -- if they're only doing outpatient treatments, if they're -- you know, they should refer them to a hospital or a center that can accommodate that. So I -- hopefully, I answered your question.

COMMISSIONER CROWELL: Yes, you did. And it, you raised some other dynamics that have to be factored in here in making these

decisions.

Now that I've used half my time on that question I'll move to AI for a hot second here with Dr. Einstein. You mentioned, you know, some of the recommendations from the subcommittee on uses of AI.

One question I have is, it's hard to tell from the slides, but is -- are we playing catchup with IAEAs application and use of AI or are we keeping pace or leading the charge with respect to IAEA and AI initiatives?

DR. EINSTEIN: It's a good question. For technical reasons we couldn't formally speak to IAEA about this so we just used publicly available and emailed information from IAEA. We reached out to them for a meeting but it would have had to go through approval processes that didn't work with the timeline.

I think they're -- you know, the landscape is a little bit different for the two organizations, but I would say that they're, neither NRC nor IAEA is significantly ahead of the other one. And I think both have a fair amount of work which can be done in this space. So I don't think we're behind international norms, but I don't think we're the trailblazers yet, either.

COMMISSIONER CROWELL: Okay, understood. You talked a bit about partnerships within government looking at IAEA uses and sharing tools and learning. Is the NRC currently, I guess -- I'm assuming the NRC doesn't currently have any partnerships in that regard. Do you know if the NRC is pursuing such partnerships similar to like DOE and NIH?

DR. EINSTEIN: My understanding is that -- well we have Dr. O'Hara.

DR. O'HARA: We currently have an MOU with GSA on their USAi tool. So we are partnering with them. And we are part of the chief AI officer council. And we meet monthly with all agencies to discuss and share our best practices, as well.

DR. EINSTEIN: Did we participate -- sorry, don't sit down yet, did we participate in the GSA's six months free trial?

DR. O'HARA: So they came into a budget situation and they had to pause all, adding on any other additional agencies. They now have changed that model. That model is no longer providing those additional funds.

DR. EINSTEIN: Okay.

DR. O'HARA: Yeah.

DR. EINSTEIN: But, I think we haven't detailed any staff to FDA, for example, like we could have someone go there to learn MAUDE, for example, we haven't done that yet.

DR. O'HARA: Correct. But we do do a sharing of those tools. Yes.

COMMISSIONER CROWELL: Okay. With this little bit of time remaining here, Dr. Einstein, could you just take an opportunity to tell me what, you talked about the opportunities with respect to AI, what are your -- do you have any concerns that we need to be aware of as we look to leverage AI within the realm of NRC's jurisdiction? Anything that keeps you up at night or things that you want to flag for the Commission to be aware of?

DR. EINSTEIN: Nothing that keeps me up at night, but

certainly concerns. I think whenever we use AI it has to be done cautiously and safely. There is a phenomena of hallucination in AI where it can spit back the wrong information for use. I think, when the stakes are high, one has to be really careful in terms of checking. Like, AI can generate documents for you, which is great. It can save time. But you probably want a human being checking those documents, at the present time. And AI can come up with stuff which is completely incorrect in rare cases, as well. And malicious actors can try to do that.

I'll give you an illustration. Yesterday, there was a news report in Nature, which is one of the two leading scientific journals in the world. Nature is the European one; Science is the U.S. one. And there is a report, I think on April 7th, about a disease called bixonimania, which is not a real disease. But an academic investigator wanted to see how you can fool AI. And this was ChatGPT and Gemini.

And they basically published a fake paper, but it was formatted like a real paper. And because it's formatted right, it's given more credibility by these AI models, introducing this disease. And they put flags in the paper that you would have -- like, if a person read it, you would know that it's fake. In fact, they even mentioned -- I think they called it a fictitious disease in there. But they wanted to see what AI would do with it.

And by the middle of April, like, if you did a query in Google's Gemini or Open AI's ChatGPT asking about a certain constellation of symptoms, you'd be given information about bixonimania. And in fact, people cited this fake paper about it in other papers about it. So, like, it

spiraled on itself.

It's a good illustration of what can happen. So you could have a malicious actor, for example, submitting a piece of documentation to IAEA with certain pieces of information in it, which found its way here, or submitting data directly to NRC with malicious information into it.

So you got to be very careful about the data going in. And part of America's AI Action Plan is to ensure minimum standards of data quality. So you have to be very careful that people aren't playing with you by submitting data, either from partnerships outside or from data directly submitted to NRC, that can lead to a corruption of processes.

COMMISSIONER CROWELL: Interesting.

DR. EINSTEIN: So these are the kind of things which I think one has to be concerned about. At the same time, it shouldn't stop us from using AI, because we'll fall behind if we don't. So it's tempered by caution for security while still going full steam ahead.

COMMISSIONER CROWELL: Thank you. Those are helpful cautions to be aware of.

And, Josh, I'd go to you, but I'm well over my time. So thank you. Appreciate it. Yep.

COMMISSIONER MARZANO: Thank you, Mr. Chairman. Good morning, everyone. And I'll echo my colleagues' joy at being back at this table to discuss the issues of the day for the NRC.

And so I'd like to begin by thanking the panel for your presentations today. And then extending that thanks to each member of the

ACMUI for the valuable work that you do for the NRC. Your ongoing engagement with our staff helps ensure that our regulatory decisions maintain a strong focus on patient safety, respond appropriately to the expansion of radiopharmaceutical therapies, and support, not hinder, patient access to care.

As we embark on our wholesale review and revision under Executive Order 14300, we need your experience and expertise now more than ever. You know, I encourage ACMUI members, our broader stakeholder community, and members of the public who are listening today to be on the lookout for upcoming proposed rules that the NRC will be publishing in response to the EO.

I'll note that these proposed rules have not benefited from the normal practice of conducting early stakeholder engagement, one of the most valuable steps in our rulemaking process. And for this reason stakeholder participation during the public comment period on these significant rulemakings will prove invaluable. We need your input and feedback to develop final rules that are durable, technically sound, and responsive to the needs and reality to the medical community and the public we serve.

So I'll close and move to my questions by thanking you all again for your ongoing commitment, partnership, and the care that you bring to work. Again, your engagement truly strengthens our regulatory framework and, most importantly, supports the patients who benefit from the medical use of radioactive materials.

So I'll start with your, Mr. Mailman, and say that I'm really glad that your presentation highlighted how a lack of clarity in regulation can lead to actual consequences in terms of the administration of care. It is extremely important, as part of the exercise that we're undergoing with our rulemaking processes right now, is to improve that clarity. And so thank you for bringing that data and showing the practical effects of what it can mean to be more clear in our regulatory approach.

So, you know, I know we've already kind of talked about and laid out some of the concerns about patient release for this particular type of therapy, but, you know, we have a little bit limited time. I was just wanting to give you an opportunity to express any additional concerns that you would like to raise at this table today.

MR. MAILMAN: I don't necessarily have additional concerns, but I wanted to thank you for bringing up the public comment period. And I know that, certainly, when the next draft of the patient release criteria comes out, I also encourage patients to read through it as well, not only providers and not only medical society, so that they see this clarity or they can understand what's going on.

A lot has changed since the first -- or since the last release of this document officially. And, you know, patients share stories now a lot more easily than they did ten years ago. So the clearer we make both our examples -- and I know one of the areas is to make clear examples so that both those who provide care and those who receive care can understand them. And I want to make sure that those comments come in because I

know, myself and all my fellow Committee members, we read all of them.

So I'll turn back to you.

COMMISSIONER MARZANO: Well, thank you for that. Okay. I'd like to turn now to Dr. Jadvar. In the briefing material they mention a couple of information notices that have been released recently. You know, I think about our abnormal occurrence reports, and medical events make up the majority, if not all, year-over-year that I've seen in terms of abnormal occurrences as we define them.

These information notices address two particular topics that can help either clinicians avoid errors in the -- general errors in the operating room or the clinic, but then also specific to yttrium-90 microsphere administration. So I understand that some of the issues are necessarily outside of the NRC's purview and regulatory authority and are more issues of medical practice. But these information notices surely do have some value.

How do we, in general, measure the success of our communication strategy through these information notices? And how do we see, you know, measures other than abnormal occurrences or medical events to determine whether or not these tools have been effective?

DR. JADVAR: Thank you for that question. In fact, we had, yesterday, a subcommittee report by Dr. Harvey, who chairs the Subcommittee on Medical Events. As you know, this is an ongoing assessment of the medical events year-after-year. And as you rightly noticed, by far the Y-90 radioembolization was the dominant medical event that we saw over the years.

And there are many root causes for that that was enumerated by Dr. Harvey in his presentation yesterday to their subcommittee report. And some of it, you know, are usual -- are things that, you know, that can be taken care of by timeout procedures and paying attention and, of course, competent care and education and all that. But some of them are technical and I guess it's part of the medical practice and the things that may happen.

So it is quite possible that some of these medical events, especially in that arena, cannot go to zero. But there are things, certainly, that we can drive from, looking at the trends and seeing what are the major issues that we can address.

But maybe I can ask my colleague, Dr. Harvey, to chime in on here, because he was the chair of the subcommittee and he is very, very closely familiar with the medical events because he chairs it year-after-year.

COMMISSIONER MARZANO: Yes, Dr. Harvey.

DR. HARVEY: Thank you very much, Commissioner Marzano. So, I guess, for an example in yttrium-90, our real expert is Dr. Angle, our consultant. And he's tremendous at helping us understand this.

What we've seen is that -- we saw that surge where there were four or five medical events where we had deposition in the GI tract, which is, obviously, an unwanted area of radiation dose delivered. And so part of that is driven by the fact that we are trying to treat smaller and smaller segments and portions of the liver, therefore sparing more normal healthy liver tissue. Getting down deeper into the vasculature at smaller, smaller sizes of

the vessels, it becomes a big technical challenge, and making sure that they use the right size catheters and getting them placed in the right position is a very, very challenging difficult thing to accomplish.

And, again, I don't do this, so I can only speak at it from -- you know, from what I hear from Dr. Angle and others. And, you know, I think that the informational notices and the things that were posted after this uptick occurred, I think the informational notices had a real impact, because we haven't seen one since.

Now, again, maybe we're getting lucky, but I do believe that that information being out there is very important. And I think that the NRC's information has really had an impact on us, as a medical community, just through awareness. So I think that maybe be a measure of the benefit, that clear, concise guidance.

COMMISSIONER MARZANO: Yeah. Well, thank you for that. And I definitely see a clear overlap, you know, as we example training and experience requirements for aspects of the training program as well to kind of help establish best practices and reinforce those.

The time I have left, I'm going to stick with Dr. Jadvar and ask, you know, we had a -- the Commission met with one of the societies last week, the American College of Radiology. I understand that there is a subcommittee considering the addition of an interventional radiologist. Can you just talk a little bit about how that addition would fill a gap of knowledge, and then some of what the current interventional radiologist, as a consultant role, is providing to ACMUI?

DR. JADVAR: Yeah, thank you for the question. Yes. Again, yesterday we had a subcommittee report by Dr. Einstein, who chaired this subcommittee. And we also had Dr. Angle, who is our consultant right now, participating with this subcommittee.

And we have tremendously -- the ACMUI has tremendously benefited from the knowledge, expertise, and experience, clinical experience, of Dr. Angle with this microembolization with Y-90. And as I mentioned, there are new agents that are coming up. And I think this is expanding.

So the final recommendation of the subcommittee yesterday was to support an inclusion of an interventional radiologist/diagnostic radiologist into the makeup of the membership in the ACMUI, which the ACMUI knowledge base can certainly benefit from these additional members as the field evolves.

And in fact, yesterday Dr. Einstein gave a very, very nice review of the history of ACMUI and how, over the years, the membership changed its members and the experience that was evolving with the times. And I think this is the time to have this type of knowledge base added to our base.

Now, I don't know if Dr. Einstein wants to add anything to that. He was the chair of that subcommittee.

DR. EINSTEIN: Sure. I'm happy to provide the slides from that for you. But we ultimately provided five options in terms of changing staffing of ACMUI so as to include an interventional radiologist. But I think an interventional radiologist would be a critical addition, given the growth of Y-

90 microsphere use in the United States.

In 2023, looking at Medicare data, it was performed in 46 states and the District of Columbia. And the number of such procedures performed by interventional radiologists, or billed by interventional radiologists, in the Medicare data has grown, whereas the number from other providers has decreased. So I think, really, they're the key individuals performing this.

In addition to hepatocellular carcinoma, liver cancer, there are trials underway for renal cell carcinoma and glioblastoma multiform using Y-90 microspheres. There are other radioisotopes which are being studied in clinical trials besides Y-90. For example, holmium-166. And then there are novel microsphere radioembolization agents which are specifically targeted to tumor cells now; not just going to a lobe of the liver, but particularly focusing on the tumor cells.

So there's lots of stuff happening in this space. And I think we would really benefit from being guided by someone who routinely performs these procedures and knows the technical ins and outs of that. So Dr. Angle has been a very valid consultant to our Advisory Committee, but having a full membership, a voting membership, would be invaluable.

COMMISSIONER MARZANO: Well, thank you very much. And I am well over my time. I appreciate the patience in giving me the opportunity to answer that question. Thank you.

COMMISSIONER WEAVER: All right, thank you, Chairman. Well, I'm not sure, going last has some disadvantages.

(Laughter.)

COMMISSIONER WEAVER: I also want to thank all of the presenters. This is my first time on this side of the table, but I've been on that side of the table before as a staff member and as a member of the industry. So thank you.

So, Mr. Mailman, you talked about patients being turned away in your slide, potentially. That's pretty concerning, because I assume this is care that could be life-or-death for the patient. And so I'm wondering -- and I believe the concern is then dose to family members or caregivers.

Is there something NRC should be doing in terms of allowable dose for those folks to minimize the chances of folks -- of patients being turned away? I'll open up to all of you, please.

MR. MAILMAN: Again, I'm going to speak on my own behalf, but certainly with, you know, having to spoken to colleagues as well. You know, I think it's a misunderstanding for them to be turned away. And no one should be turned away. And that will require education. And it will require what I said earlier, which is to make sure that anyone who is performing these procedures is well educated in the alternatives, if they don't have, you know, an extra hospital bed, or what they might need to do in order to not turn away a patient, and to say that this is not appropriate if it's been recommended.

And so I think it is something that can be solved. I don't think it's going to -- I think it's a training issue with the manufacturers to the centers that they are bringing these drugs to. And it's not a single one-time;

it is a reminder it takes a while for people to completely understand. But I think we have a lot of other places that understand it well.

COMMISSIONER WEAVER: Thank you. Any -- yeah, please.

DR. HARVEY: Thank you, Commissioner Weaver. Again, I'll just reiterate what I said earlier. I think it's very important to have the accessibility of healthcare to be as free-ranging as possible.

I think that the providers, if they have people that don't fit the outpatient criteria, they need an inpatient setting, hopefully they would refer them to a larger academic center where they'd be able to provide that care. So I think that is critical, in this situation, that providers know that, you know, if they can't accommodate this on an outpatient basis, it doesn't mean that the treatment can't be done.

COMMISSIONER WEAVER: Okay.

DR. HARVEY: Thank you.

COMMISSIONER WEAVER: Thank you.

DR. JADVAR: May I also chime in here regarding this question?-

COMMISSIONER WEAVER: Yes, please do.

DR. JADVAR: So, you know, actually, the percentage or the rate of patients being turned away is really not very well known. And I think it depends on the patient cohorts at different parts of the country.

I mean, many of the social net hospitals or, let's say, county hospitals, they tend to treat the patients and then bring them to the hospital

for whatever amount of a stay. Maybe one or two days. And in our practice, in academic practice in Southern California, we really haven't done -- we haven't really turned anybody away and it has worked pretty well. So I think it depends on the cohort of patients.

But it's a multifactorial thing. It depends on the, you know, cognitive abilities of the patient, for example. And usually that patient can still be treated even if they don't completely understand what's going on, because they have the caregiver who can take care of the potential issue, the radiation safety precautions, or even other medications which are not radioactive to take care of the patient. So usually we can work with the caregiver and that will be taken care of and the patient can receive the treatment.

Physical disabilities is usually not a problem. Again, if there is a good caregiver, let's say, with regard to urinary incontinence or other issues, if there is a responsible caregiver available.

There is an issue with noncompliance. If the patient, for some reason, is just not compliant with anything that he or she is being told to do, then that becomes more of a medical issue, because they're not going to follow-up, they're not going to come to the next session. And, you know, they can't report or follow up with potential toxicities of the medication that needs to be taken care of or mitigated.

So those are all really medical judgments, at that point, which may go beyond just considerations or radiation safety precautions.

COMMISSIONER WEAVER: Thank you. So a long time

ago, when I was a staff member here, I worked in the Ops Center and took many reports of medical misadministrations. And one of the ones that occurred over and over again were females who said they weren't pregnant, got, you know, a therapeutic dose and, lo and behold, they were pregnant.

And the corrective action was always, well, we're going to do a blood test on them, you know, this hospital. But then the next hospital would report the same thing and they would say the same thing, we're going to do a blood test next time, too.

And so that was a long time ago. And just hearing the discussion, there is obviously a lot more proactive reaction when something does go wrong.

I'm just wondering -- maybe this is for Dr. Harvey, but I'd invite others -- what is the process, when you see events coming in, what's the process to look at those -- I know the NRC does, but what do you do to say, hey, there's a trend here, we need to find out what's going on?

DR. HARVEY: Thank you, Commissioner Weaver. Yeah, I mean, we're going to take that internally, certainly examine it. Take it to our patient safety committees or radiation safety committees. We're going to adjust and modify our policies and procedures and the things that we do to make sure that we're addressing those concerns or those trends that might be out there.

If someone is having a therapeutic procedure at our facility, we'll do a serum hCG test to make sure. I mean, it could be critical. The example is I-131. You don't want to ablate the fetal thyroid, right? So, you

know, we make sure that's a serum hCG.

Now, if it's a diagnostic test, then we're not doing a serum hCG on every single patient. They're verbally asked. And they're still heavily, heavily reliant on the patients for that information. And things do happen. Fortunately, with diagnostic administrations, at least in mine, I've done many fetal dose calculations, and I've also followed up on those after the fact, and there haven't been any negative outcomes or impacts.

COMMISSIONER WEAVER: Excuse me. I think that problem's maybe been solved.

DR. HARVEY: Okay.

COMMISSIONER WEAVER: I meant more generally, in terms of where there have been medical events, what's the role of ACMUI in looking at those? And is it done in real-time or is it -- you know, I don't know when, how often you meet, that kind of thing.

DR. HARVEY: So, I mean, from an internal standpoint, the information that is disseminated out from the NRC, I think we all have an obligation to take that back to our organizations and then to examine it and put it out there. I am going to take back that information and I'm going to talk to the technologists that I provide annual training for and make them aware of the issues and bring that up.

So we're going to work on this in a real-time basis. And if it's something that is a concerning trend, we're going to -- it's really something that we're going to prioritize right there and then. And then we'll continue to not forget about it on refresher training.

COMMISSIONER WEAVER: Thank you.

DR. HARVEY: I hope that answers your question.

MR. MAILMAN: Commissioner Weaver, one -- if I may ask, Dr. Harvey? When I first joined the ACMUI, one of the things that I was very impressed with was, you saw some of the trends with the different microspheres. And I was impressed that the subcommittee that I was on actually brought in the manufacturers to discuss and have a teleconference and to understand what was going on, as opposed to -- and discuss what might be corrective actions.

So I was impressed in how quickly that happened for patient safety. So that was within my first year of joining this group.

COMMISSIONER WEAVER: Thank you. Currently, I'm out of time already. I'm very interested in the use of AI. I'm sorry I didn't get to probe that a little bit more, but --

CHAIRMAN NIEH: Commissioner Weaver, we all went over, so please.

COMMISSIONER WEAVER: Yeah. I just, I guess just real quickly then, would be the data quality. I think you mentioned a form as one of your recommendations, I think, to collect data. It seemed like maybe there is an interplay in terms of using AI then to mind the data to make sure that it's of -- maybe has some requisite fields or parameters in the quality of the data. I don't know if either one of you want to speak to that.

DR. HARVEY: Commissioner Weaver, I agree. I think that having that complete information mined and taken and be in the intake

form would be very helpful then to feed into what Dr. Einstein presented to us and being able to then use that data with AI. So I'll turn it over to him.

DR. EINSTEIN: And perhaps instead of having PDF forms, which, in principle, could, you know, use optical character recognition and try to put things in the right boxes, having more structured reporting, which lends itself to fields which are more amendable to analysis by AI, would potentially be useful. And that can even be done in the context of a PDF form now very easily.

But I think making it -- reporting in such a format that it's easier for analysis by AI will benefit the organization into the future, anticipating that AI tools will play an increasing role.

COMMISSIONER WEAVER: Well, thank you. Thanks, everyone.

MR. MAILMAN: But I must add, since I was on the subcommittee as well, I mean, AI is a large word, right? It means a ton of different things, whether it's front-facing, ChatGPTs, things like that, or backwards-facing and what types of models they are.

Much of what we're looking at is natural language processing. And that's actually something AI does pretty well. It looks at language and can actually process it and do summarizations or -- you know, I work in the clinical trial space where 177-Lu can be represented 22 different ways. AI is wonderful at figuring that part of natural language processing and putting that all as one type.

So in some sense, it does really well in some of the data that

we're looking at. Even plucking things out of PDFs. So it does have some real benefits, especially to back-end data that we're looking at. And using the word AI for everything is hard because there is so many different components of what you can use AI for or what subcomponent you can use inside of what you're looking for. That was it.

COMMISSIONER WEAVER: Yeah. Thank you, Chairman.

CHAIRMAN NIEH: Thank you, Commissioner Weaver. And I'd like to thank -- we've reached the end of our scheduled time here, and I want to thank the members of the Committee for your participation and dialogue today on this very important topic, which is, again, a very great example of where the NRC staff's work in carrying out its safety mission directly benefits the lives of American people.

So before we close, I'd like to ask my fellow Commissioners if they have any closing remarks? Okay, hearing none, we're adjourned. Thank you.

(Whereupon, the above-entitled matter went off the record.)