U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Overview of ACMUI Activities

Hossein Jadvar, MD, PhD
ACMUI Chair/Nuclear Medicine Physician
April 21, 2026

Today's Agenda

- Hossein Jadvar, MD, PhD, ACMUI Chair
  - Overview of ACMUI Activities

- Richard Harvey, DrPH, ACMUI Radiation Safety Officer Representative
  - ACMUI's Recommendations on Actions to promote Licensing and Inspection Efficiencies in line with Advanced Act.

Today’s Agenda (cont’d)

- Andrew Einstein, M.D., Ph.D., ACMUI Nuclear Cardiologist
  - ACMUI Recommendations on potential AI Applications for NRC Medical Enterprises
- Josh Mailman, ACMUI Patients' Rights Advocate
  - Patients’ Rights Advocate’s Perspectives on Patient Release involving Emerging Radiopharmaceutical Therapy

Role of the ACMUI

- Advise the U.S. Nuclear Regulatory Commission (NRC) staff on policy & technical issues that arise in the regulation of the medical use of radioactive material in diagnosis & therapy.
- Comment on changes to NRC regulations & guidance.
- Evaluate certain non-routine uses of radioactive material.
- Provide technical assistance in licensing, inspection & enforcement cases.
- Bring key issues to the attention of the Commission for appropriate action.

Current Medical Use of Byproduct Material

- Diagnostic Radiopharmaceuticals
- Therapeutic Radiopharmaceuticals
- Low-Dose Rate (LDR) Brachytherapy (permanent)
- High-Dose Rate (HDR) Brachytherapy (temporary)
- Gamma Stereotactic Radiosurgery
- Yttrium-90 Microsphere Radioembolization
- Emerging Technologies
  - Theranostics
  - Holmium-166 & Eye90 microsphere radioembolization
  - AI/DL-driven radiation dose reduction and image optimization

ACMUI Membership (13 members)

- Nuclear Medicine Physician, Chair (Dr. Hossein Jadvar)
- Nuclear Pharmacist, Vice Chair (Mr. Richard Green)
- Nuclear Cardiologist (Dr. Andrew Einstein)
- Brachytherapy Radiation Oncologist (Dr. Michael Folkert)
- Gamma Stereotactic Radiotherapy Radiation Oncologist (Dr. Harvey Wolkov)
- Diagnostic Radiologist (Dr. Joanna Fair)
- FDA Representative (Dr. Michael O'Hara)

ACMUI Membership (13 members)

- Nuclear Medicine Medical Physicist (Ms. Melissa Martin)
- Radiation Therapy Medical Physicist (Mr. Zoubir Ouhib)
- Patients' Rights Advocate (Mr. Josh Mailman)
- Agreement State Representative (Ms. Megan Shober)
- Healthcare Administrator (Vacant)
- Radiation Safety Officer (Dr. Richard Harvey)

ACMUI Consultant

- Interventional Radiologist (Dr. John Angle)

ACMUI Current Meeting Topics

- ACMUI's Recommendations on Actions to promote Licensing and Inspection Efficiencies in line with Advanced Act.
- Medical Events
- Subcommittee to Review NRC draft guidance on Alpha Radiopharmaceuticals
- Membership of an Interventional Radiologist

ACMUI Current Meeting Topics

- Potential Artificial Intelligence (AI) / Deep Learning (DL) Applications for NRC Medical Enterprise

- ACMUI Generic Reporting Process

ACMUI Topics from April 2025

- Yttrium-90 Microsphere Gastrointestinal Deposition Medical Events
- Generic Process Checklist
- Training and Experience Requirements for All Modalities on Emerging Medical Technologies

Staff Presentations to the ACMUI from June 2025

- Overall Update on Medical Activities at the NRC
- Medical events with an additional presentation on Yttrium-90 Microsphere Medical Events
- ADVANCE Act
- NRC’s Evaluation of Current Patient Waste Guidance and Regulations

Current ACMUI Subcommittees

- ADVANCE Act Recommendations
- Potential AI 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
- Subcommittee on Extravasations

Future

- ACMUI will continue to
  - Provide advice and technical assistance requiring specialized and clinical medical knowledge.
  - Continue to inform NRC of emerging medical uses and industry changes.
  - Comment on NRC's proposed regulations and guidance.
  - Bring key issues to the attention of the Commission.

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ADVANCE Act Subcommittee Report

Richard P. Harvey, DrPH
ACMUI Member/ Radiation Safety Officer

April 21, 2026

Subcommittee Members

- Richard Harvey, DrPH (Chair)
- Michael Folkert, M.D.
- Hossein Jadvar, M.D., Ph.D.
- Josh Mailman, MBA
- Megan Shober, M.S.

- NRC Staff Resource: Katie Tapp, Ph.D.

Subcommittee Charge

- The subcommittee will provide recommendations and advice to support the Nuclear Regulatory Commission's (NRC) implementation of the ADVANCE Act.

Background

- The subcommittee was established at the Spring 2025 ACMUI meeting in April 2025. The subcommittee will assist the NRC to develop mission statement implementation guidance as required by Section 501 of the ADVANCE Act.

Subcommittee Objectives

- Mission Statement Alignment: 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.

Subcommittee Objectives

- Efficiency Improvements: Identify recommendations, if any, for the NRC to streamline medical licensing as mandated by the ADVANCE Act.

Subcommittee Objectives

- 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.

SC Charge – Objective # 1

- Former Mission Statement – 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 defence and security and to protect the environment.
- Current Mission Statement – 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.

SC Charge – Objective # 1

- The NRC's updated mission statement is aligned with the NRC's medical regulatory framework, and the subcommittee has no recommendations regarding this charge.

SC Charge – Objective # 2

- The 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.

SC Charge – Objective # 2

- The subcommittee evaluated the ideas based on their importance (likely impact on improved efficiency and reduced waste) and feasibility (the amount of additional effort or potential cost required to make changes in the proposed area and/or other barriers to change).

SC Recommendations - Licensing

- Importance:
  - The ACMUI supports eliminating listing individual physician authorized users (AUs) for 10 CFR 35.100, 35.200 and 35.500 on medical radioactive materials licenses.
  - The ACMUI supports clarification and modification of the NRC 313a Forms, primarily NRC 313a (AUT). Specific recommendations include clarification of Table 3c on NRC 313a AUT forms to make parenteral supervised case requirement more explicit (NRC 313a AUT form – clarify for licensees that only 3 total supervised cases are needed rather than 3 supervised cases per type of parenteral administrations) and draft clearer and streamlined NRC 313a forms to make implementation less challenging for NRC and licensees.

SC Recommendations - Licensing

- Importance:
  - The ACMUI supports radioactive material activity/possession limits for medical licensees 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 systems that are not commercially available in the U.S. (e.g., ViewRay, NorthStar RadioGenix) would eliminate the need to maintain guidance for obsolete devices.

SC Recommendations - Licensing

- Importance:
  - The ACMUI supports decreasing frequency of license renewals. Medical licenses are more frequently amended than other RAM license types, mostly due to AU 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 or “tie downs”.

SC Recommendations - Licensing

- Feasibility:
  - The ACMUI supports clarification and modification of the NRC 313a Forms, primarily NRC 313a (AUT). Specific recommendations include clarification of Table 3c on NRC 313a AUT forms to make parenteral supervised case requirement more explicit (NRC 313a AUT form – clarify for licensees that only 3 total supervised cases are needed rather than 3 supervised cases per type of parenteral administrations) and draft clearer and streamlined NRC 313a forms to make implementation less challenging for NRC and licensees.
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SC Recommendations - Licensing

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  - The ACMUI supports radioactive material activity/possession limits for medical licensees 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.

SC Recommendations - Inspections

- The subcommittee will continue to evaluate this area of opportunity and will formulate recommendations as appropriate.

SC Recommendations - Administration

- Importance & Feasibility:
  - The ACMUI supports development of a medical event reporting form to support submission of the appropriate information to evaluate medical events.

SC Charge – Objective # 3

- The 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.

ADVANCE Act SC Report Summary

- The NRC's updated mission statement is aligned with the NRC's medical regulatory framework, and the subcommittee has no recommendations 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.

Acronyms

- 10 CFR – Title 10 of the *Code of Federal Regulations*
- ACMUI – Advisory Committee on the Medical Use of Isotopes
- AUs – Authorized Users
- AUT – Authorized User Training, Experience, and Preceptor Attestation
- NRC – Nuclear Regulatory Commission
- RAM – Radioactive Materials

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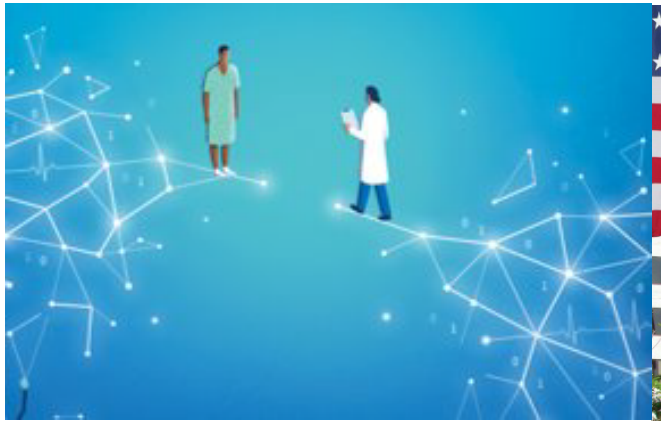
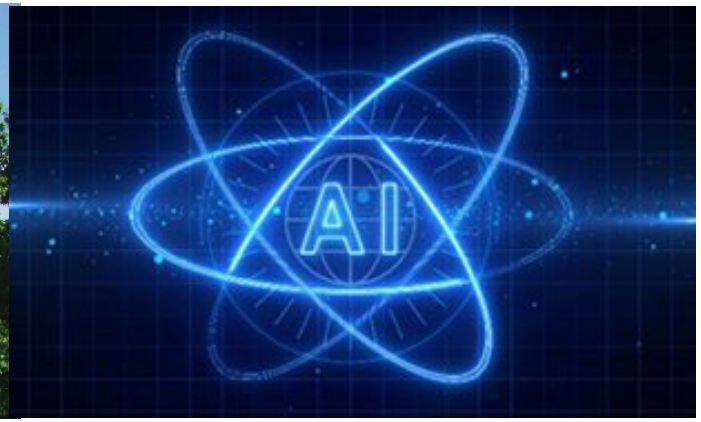
ACMUI Subcommittee on Potential AI Deep Learning Applications for NRC Medical Enterprise

Andrew J. Einstein, MD, PhD, FACC, MASNC
ACMUI Member/Nuclear Cardiologist

April 21, 2026





Subcommittee Membership

- Andrew Einstein, MD, PhD
- Joanna Fair, MD, PhD
- Michael Folkert, MD, PhD
- Josh Mailman, MBA
- Hossein Jadvar, MD, PhD

- Non-voting consultant
  John Angle, MD, interventional radiologist

- NRC staff resource
  Maryann Ayoade, MS

Subcommittee Background and Charge

- Artificial intelligence (AI) is revolutionizing technology as well as processes throughout society, and in the United States government in particular.
- The AI subcommittee was established 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.

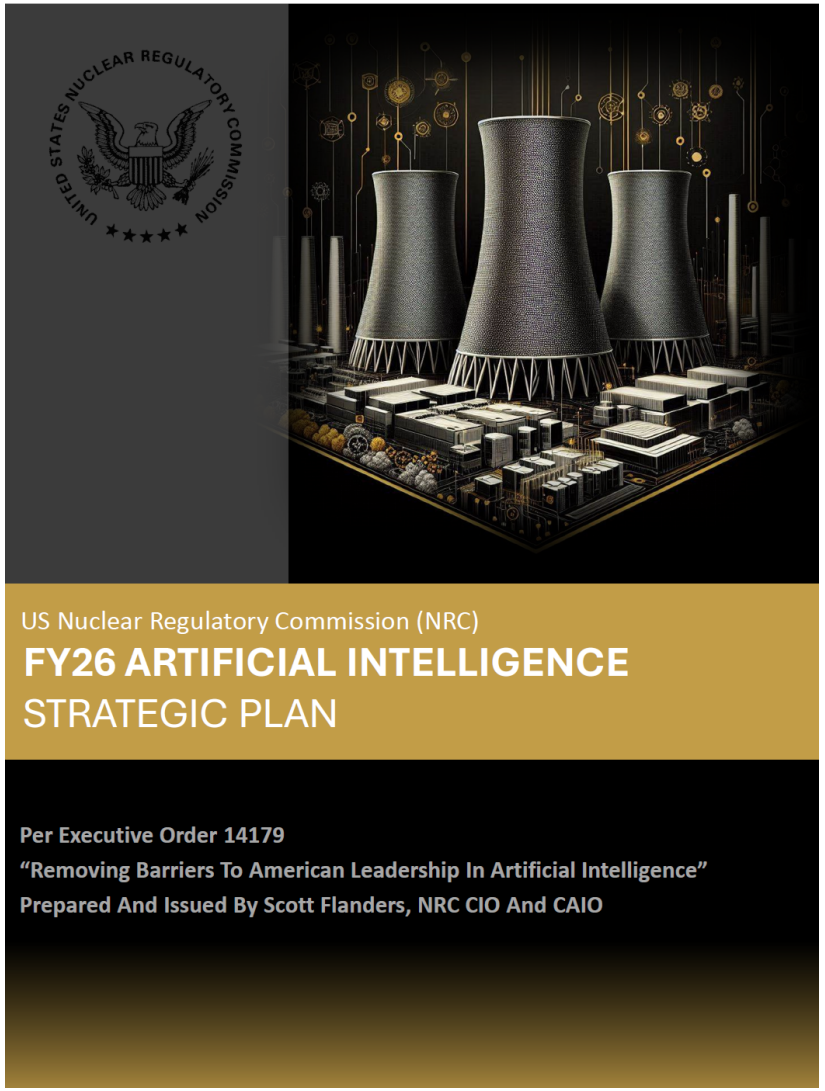
Subcommittee Specific Objectives

1. **Data Analysis and Efficiency:** Investigate how AI tools can be utilized to streamline the analysis of NRC medical data, including but not limited to the National Materials Events Database (NMED), to identify trends, gaps, or areas of concern.
2. **Process Optimization:** 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.
3. **Knowledge Gap Identification:** 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.

Subcommittee Specific Objectives

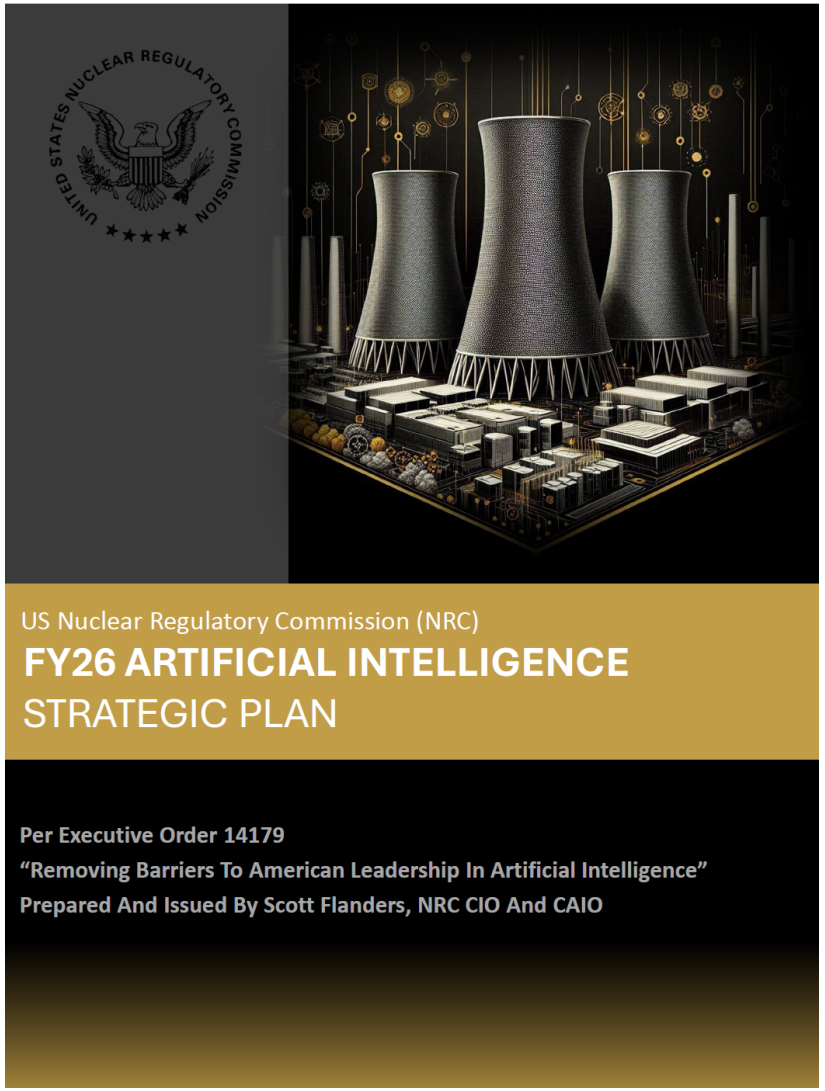
4. **Benchmarking and Best Practices:** Review existing AI applications in similar domains, such as the FDA's MAUDE database, to identify models or approaches that could be adapted for NRC use.
5. **Recommendations:** Develop actionable recommendations for the NRC staff and ACMUI can take regarding the adoption, implementation, or further exploration of AI tools, including considerations for agency policies, technical feasibility, and resource requirements.
6. **Agency Alignment:** 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.

Current NRC AI Strategic Plan: Vision



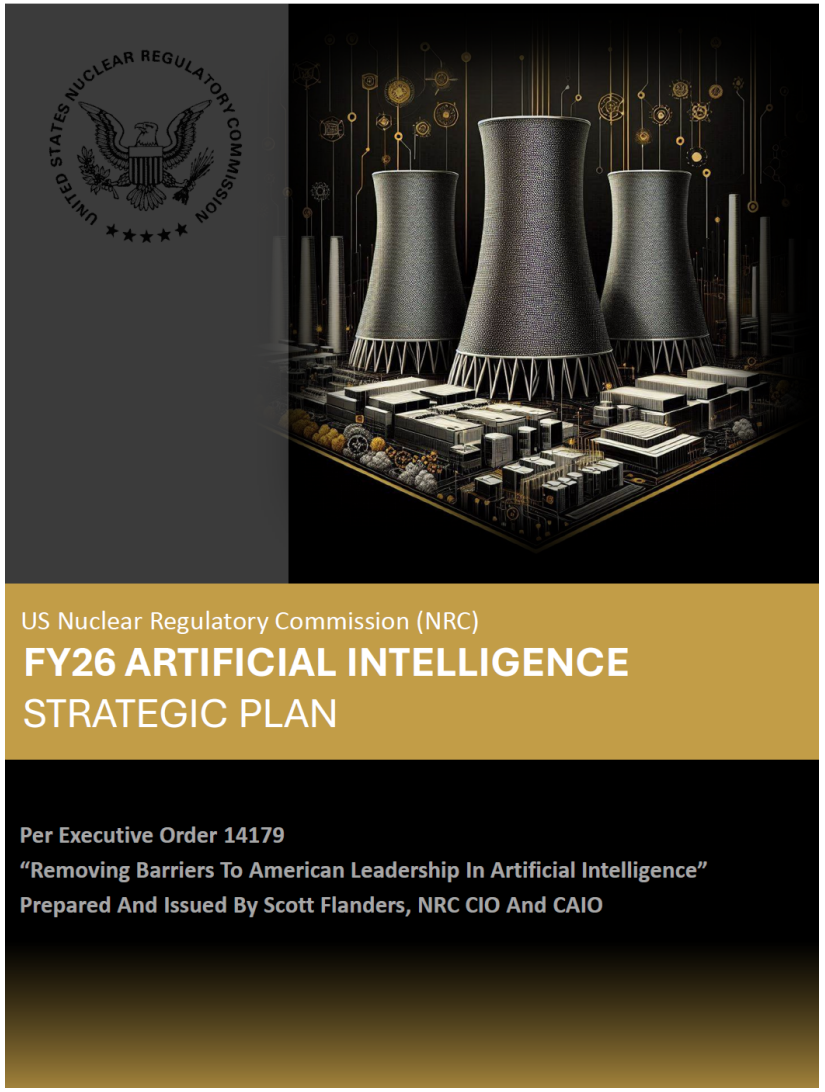
- To responsibly leverage artificial intelligence in support of the NRC's mission, empowering
- staff to efficiently make risk-informed decisions, drive regulatory innovation, and protect
- public health, safety, and the environment. AI supports NRC's mission by:
  - Enhancing decision making
  - Strengthening regulatory oversight
  - Increasing efficiency
  - Fostering innovation
  - Supporting public confidence

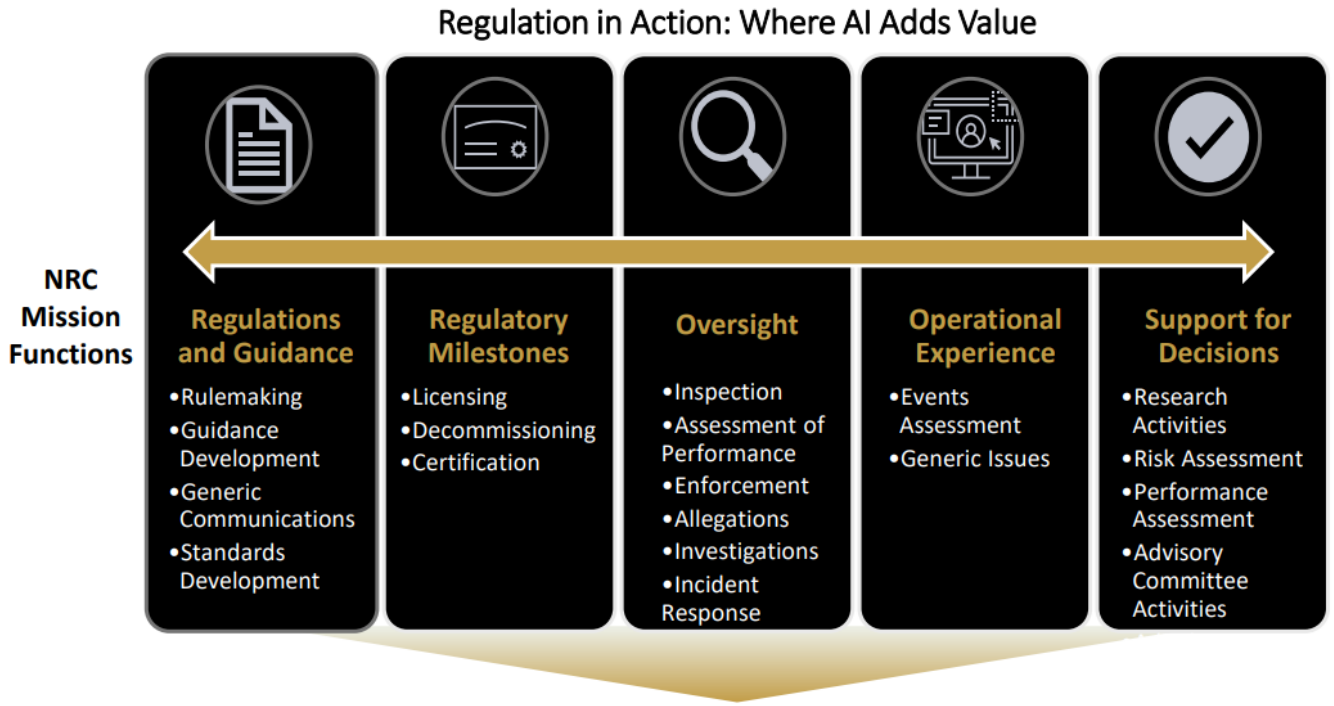
Current NRC AI Strategic Plan: Goals and Objectives



- **1:** Enhance NRC Staff Productivity and Operational Efficiency
  - 1.1: Accelerate AI adoption through prioritized, mission-aligned use cases.
  - 1.2: Ensure robust infrastructure, high-quality data, strong cybersecurity, and a skilled workforce underpin all AI activities.
- **2:** Empower NRC Staff for AI Integration
  - 2.1: Foster a workforce ready to adopt and integrate AI tools that enhance productivity and streamline operations.
  - 2.2: Provide training, resources, and support to ensure staff can confidently and responsibly apply AI in daily workflows and decision-making.
- **3:** Build a Sustainable AI Ecosystem
  - 3.1: Ensure robust infrastructure, high-quality data, strong cybersecurity, and a skilled workforce underpin all AI activities.
  - 3.2: Establish long-term workforce development strategies that align AI skill-building with evolving organizational needs and technology trends.

Current NRC AI Strategic Plan Goals





Medical Events Background

- 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 (NMED).
- These reports are organized and reviewed first by NRC staff, and then the 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/trends of such events,
  - potential causes,
  - and potential interventions.
- Even with coordinated effort of medical experts with extensive experience in this area, there are gaps in information that limit the conclusions that can be drawn and the recommendations that can be made by the subcommittee and the NRC staff.

Medical Events and AI: FDA

- Analysis of medical events through AI is an emerging area of research and administrative application.
- In the subcommittee's meetings with representatives from the U.S. 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 (MAUDE) Database for medical device issue reporting.
- While these efforts are in their early stages and there is much work to be done to improve 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.

Potential Roles of AI to Improve Reporting and Analysis of Medical Events

- **Data Entry:** AI could be incorporated at the initial reporting step to analyze submissions and trigger requests for additional/more specific information.
- **Filtered Reporting:** Using NLP (Natural Language Processing): automated summaries and analysis of trends in medical events over time can simplify the review process and identify areas of concern, as well as facilitate categorization of the events. AI tools could be used to summarize the data that is already in NMED and significantly reduce the time it takes to create the reports.
- **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.
- **Presentation and Public Review:** AI can also simplify the process of organizing the materials for presentation and public review.

Lessons from Other Organizations

- Executive Office of the President
- National Institutes of Health (NIH)
- General Services Administration (GSA)
- Conference of Radiation Control Program Directors (CRCPD)
- International Atomic Energy Agency (IAEA)

Executive Office of the President

- Summarizes the President's approach to AI.
- Encourages use of AI, calling for America to retain dominance in this global race, as reflected in Executive Order 14179, "Removing Barriers to American Leadership in Artificial Intelligence."
- 3 Pillars
  - Innovation
  - Infrastructure
  - International diplomacy and security
- Calls for US to innovate in AI more rapidly and comprehensively than our competitors, across every field.
- Places as a priority the prevention of our advanced technologies from being misused by malicious actors and monitoring for unforeseen risks of AI.

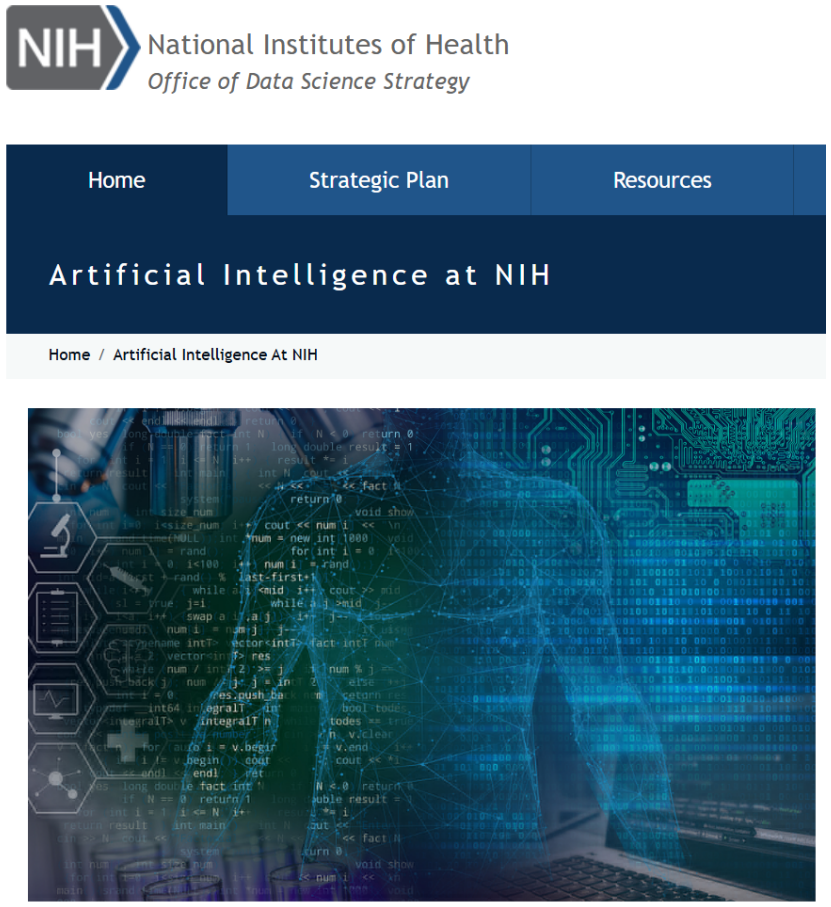
Selected Recommended Policy Actions

- Establishing regulatory sandboxes or AI Centers of Excellence
  - NRC has already begun efforts, involved in a collaborative regulatory sandbox project with international partners, including Canada, the United Kingdom, Japan, Korea, and France.
  - The project aims to bring together regulators and industry to work through enablers and disenablers for adopting innovative technology like AI in the nuclear domain.
- Launch domain-specific efforts, in areas such as healthcare and energy, led by NIST, to convene stakeholders to accelerate development and adoption of national standards for AI systems and measure the increase in productivity from AI

Advantages to NRC of Participating in Talent-Sharing

- A series of policy actions focus on accelerating AI adoption in the Federal government
  - Include creating a talent-exchange program designed to allow rapid details of Federal staff to other agencies
- Enable both sharing NRC's expertise in the AI space with other agencies, as well as drawing expertise existing in other agencies.
- These may 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 for NRC employees.

National Institutes of Health

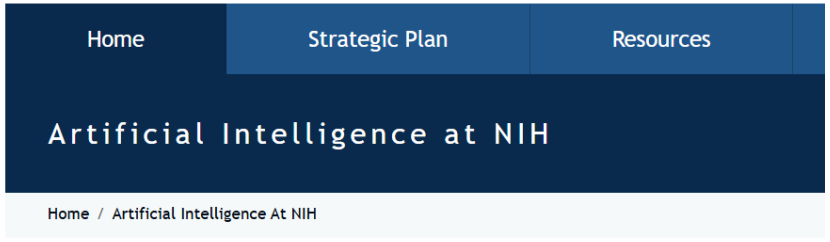


- AI has become a standard integrated tool rather than a specific point of research. The NIH Office of Data Science Strategy maintains a website that summarizes their initiatives in the AI front and the overall 2025-2030 strategic plan for data science, and links to a number of programs, including:
  - The Networking and Information Technology Research and Development (NITRD) Program, that is working to develop and apply advanced information technology (IT), computing, networking, and software capabilities for the US
  - "AIM AHEAD" program is working to establish coordinated multidisciplinary partnerships to develop AI/Machine Learning models, beginning with electronic health record data.
- Bridge to Artificial Intelligence (Bridge2AI), designed to propel biomedical research forward by facilitating widespread adoption of AI to address complex biomedical challenges beyond human intuition.

2024 DOE-NIH Joint Workshop on Computational Modeling to Advance Novel Medical Isotopes for Radiotheranostics

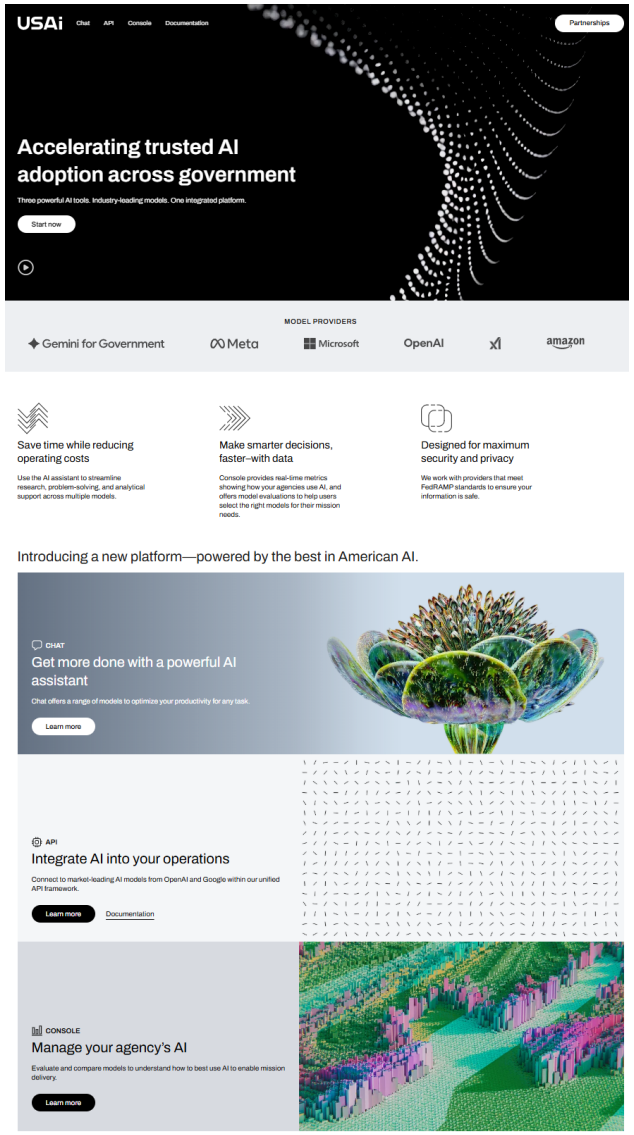
U.S. DEPARTMENT OF ENERGY

NIH National Institutes of Health
Office of Data Science Strategy



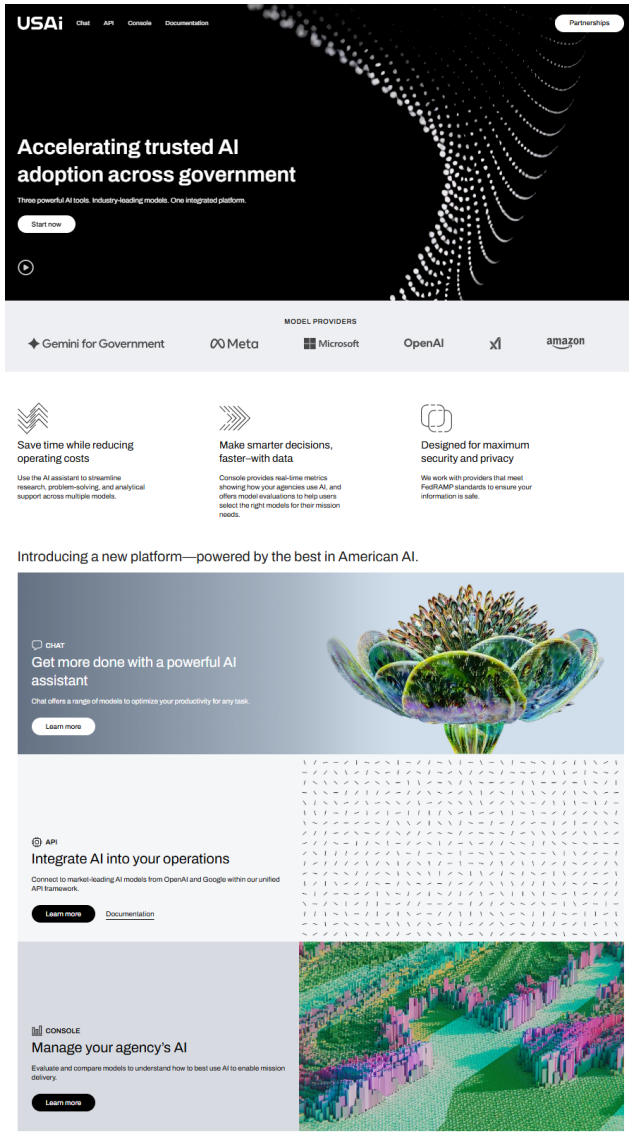
- DOE-NIH collaborating directly on projects related to medical use of isotopes
  - Brought together experts from government, academia, and industry
  - Emphasized role of DOE-NIH collaboration to address US infrastructure and supply for medical isotopes, improve efficiency of regulatory pathways, and investigate how to integrate computational tools into radiopharmaceutical-based therapies.
  - Specific to AI DOE-NIH collaborations
    - role of AI-driven modeling, machine learning, and digital twin technologies in optimizing dosimetry
    - dynamically personalizing treatments, and reducing time to clinical adoption.
- Workshop conclusions emphasized need for continued strategic collaboration and sustained resources to advance next generation radiotheranostics and ensure accessibility of safe and effective therapies.

General Services Administration



- GSA provides centralized procurement for the federal government, including technology services
- On August 14, 2025, GSA introduced USAi (usai.gov), including
  - Generative AI suite including an Application Programming Interface
  - Integrated platform providing government users with access to multiple large language models
    - Anthropic's Claude Haiku 3.5 and Claude Sonnet 4
    - OpenAI's GPT 4.1
    - Meta's Llama 3.2
    - Google's Gemini 2.5
  - Includes powerful tools for government users
    - chat-based AI
    - code generation
    - document summarization

General Services Administration



- Operates in Federal Risk and Authorization Management Program (FedRAMP) authorized environments, to leverage some of best AI technology while ensuring information safety
- Offering a 6-month free trial through June 2026 to help federal agencies adopt AI capabilities and improve mission delivery, which includes $25,000 in token consumption.
- Consideration of USAi 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.

Conference of Radiation Control Program Directors

CRCPD Working Group Fact Sheet

G-76 Use of Artificial Intelligence in Radiation Protection **December 2025**

Charges:

The Conference of Radiation Control Program Directors (CRCPD) charges a working group to explore the use of artificial intelligence (AI) in radiation protection. This working group will be comprised of CRCPD members and resource representatives from federal agencies with relevant expertise.

General Charges

1. Conduct a thorough literature review of current research and development in the field of AI in radiation protection.(G1,O3), (G5,O1)
2. Consult with experts in the field of AI and radiation protection, including but not limited to researchers, practitioners, and stakeholders.(G1,O3), (G5,O1)
3. Share knowledge and insights among working group members and solicit feedback from CRCPD members and federal agencies. (G1,O3),(G5,O1)

Specific Charges:

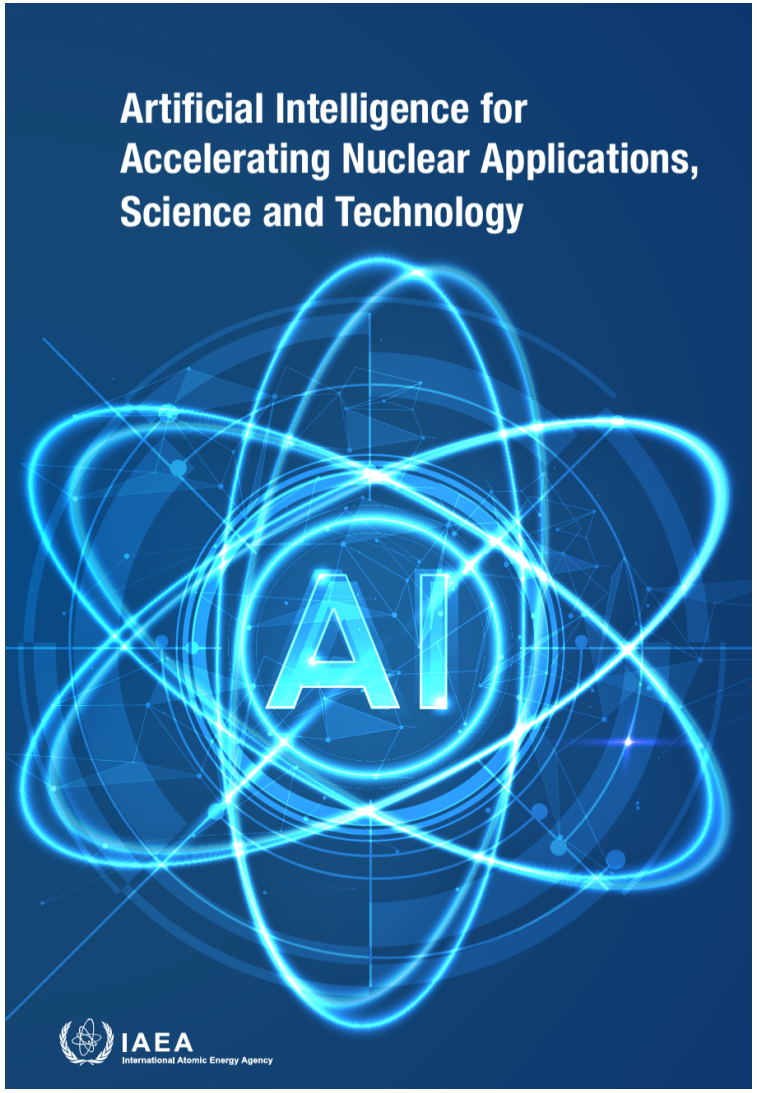
1. Identify potential applications of AI in radiation protection, including but not limited to radiation detection, monitoring, and assessment. (G1,O3),(G5,O1)
2. Assess the benefits and risks of using AI in radiation protection, including implications for public health and safety, regulatory compliance, and resource allocation. (G1,O3),(G5,O1)
3. Evaluate the current state of AI technology and its potential for advancement in the field of radiation protection. (G1,O3),(G5,O1)
4. Develop recommendations for the responsible use of AI in radiation protection, including guidelines for data privacy, transparency, and accountability. (G1,O3), (G1,O5),(G5,O1),
5. Developing a report summarizing the group's findings and recommendations and present the report to CRCPD and relevant federal agencies. (G1,O3), (G1,O5),(G5,O1)

Timeline:

The working group is expected to complete its work within 12 months of its formation. The group should provide interim progress reports to CRCPD and relevant federal agencies as needed.

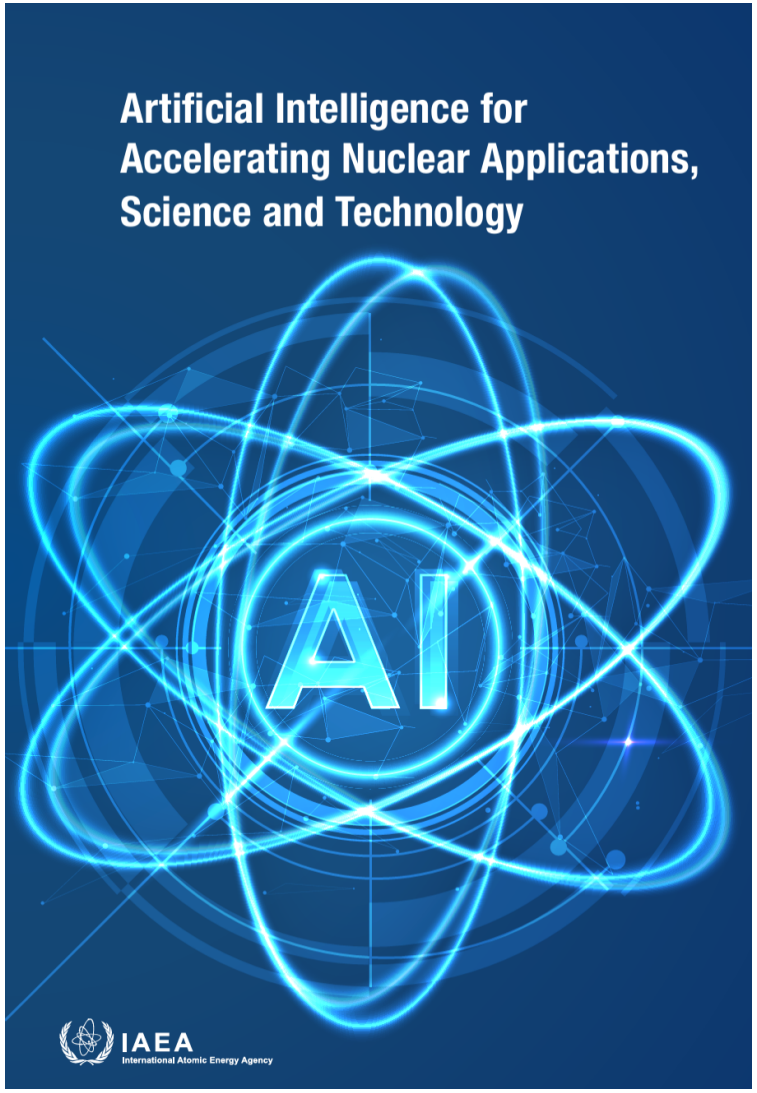
- Non-governmental 501(c)(3) professional organization
  - Primary membership is radiation professionals in state and local government that regulate the use of radiation sources
- Has established a working group, G-76, dedicated to exploring use of AI in radiation protection.
- G-76 has been conducting 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.

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.
- Discussed broad topics on human health, food and agriculture, water and environment, nuclear physics and data management, nuclear power and fusion, and nuclear safety and safeguard verification.
- 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 Ethics of Nuclear and AI Technologies (ENAI).

International Atomic Energy Agency



- In the human health arena, 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 matters have changed since 2021!)
- In conclusion, IAEA is actively 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 isotope; partnerships in addressing these commonalities could benefit both organizations.

Recommendations

in order of priority

1. 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.
2. Consideration of the U.S. General Services Administration'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.
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 America's AI Action Plan, which recommends establishing minimum data quality standards in AI model training.

Recommendations

in order of priority

4. The subcommittee sees an immediate opportunity for enhancing the medical event database to take advantage of AI resources, as detailed above. The current ME database is a PDF file; putting it into a more searchable format is recommended.
5. 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.
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.

Acronyms

- ACMUI – Advisory Committee on the Medical Uses of Isotopes
- AI – Artificial Intelligence
- CRCPD – Conference of Radiation Control Program Directors
- DOE – Department of Energy
- FAIR – Findable, Accessible, Interoperable, and Reusable
- ENAI – Ethics of Nuclear and AI Technologies
- FDA – Food and Drug Administration
- GSA – General Services Administration
- HCA – Health Care Administrator
- IAEA – International Atomic Energy Agency
- LLM – Large Language Model
- MAUDE – Manufacturer and User Facility Device Experience
- NIH – Natural Institutes of Health
- NIST – Natural Institute of Standards and Technology
- NLP – Natural Language Processing
- NMED – National Materials Events Database
- NRC – Nuclear Regulatory Commission
- PDF – Portable Document Format

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Patient Release Criteria
Confusing to Patients, Providers and Manufactures

Josh Mailman
Patients' Rights Advocate
April 21, 2026


Agenda

- Perspectives on the rise of patient receiving Radio Ligand Therapy (RLT) and the number of sites offering these treatments in the US

Disclosure

The views and content presented in this slide deck and any Q&A are my own opinion as a patients' right advocate, relating to my own experiences and conversation with patients.

They do not represent the views of the ACMUI.

Continued Expansion of Centers offering RLT

Since the approval of Lu177 DotaTate (Luthathera) (2018) the US has gone from slightly over 100 sites offering this Therapy to over 600 sites since the release of Pluvicto (lutetium Lu 177 vipivotide tetraxetan) in 2022.

90% of all males in the continental US are within a 30 minute drive of a treatment site.[1]

1. https://www.pluvicto-hcp.com/psma-positive-mcrpc/access-and-support

Instructions for Safety are close to that of initial COVID Safety Rules

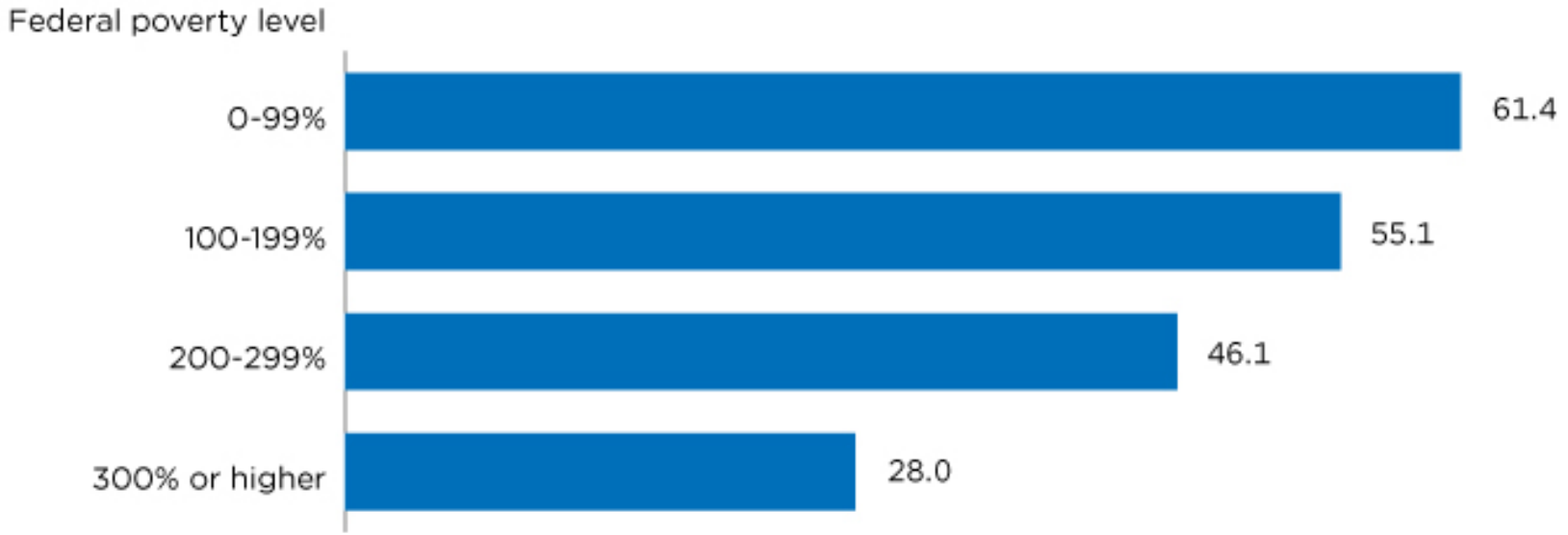
1. Sleep in separate bedrooms
2. Use different bathrooms
3. Stay at least three feet apart

Challenges is not all can do this and some modification need to be made.

I am hearing from advocates that patients are being turned away from treatment if they don't have seperate rooms or bathrooms.

Figure 1.

Percentage of Multi-Person U.S. Households Without Enough Bedrooms, Bathrooms to Quarantine One Member, by Household Income as Percentage of Federal Poverty Level



Source: U.S. Census Bureau, American Housing Survey, 2019, sponsored by the Department of Housing and Urban Development. Enough bathrooms is defined has having at least two full bathrooms. Enough bedrooms is defined as a two- or three-person household having at least two bedrooms, and a household of four or more having enough bedrooms to allow one person to isolate in a bedroom without forcing three or more people in the household to share a remaining bedroom. Income is annual household income.

Manufacture Confusion

1. Pluvicto website 2 days no contact.
   https://www.pluvicto-hcp.com/psma-positive-mcrpc/access-and-support
2. Lutathera, 3 days no contact.
   https://www.pluvicto-hcp.com/psma-positive-mcrpc/access-and-support
3. Generic RLT instructions 3 days
   https://www.rltinstitute.novartis.com/pdfs/FA-11374424_RLT%20Institute_Sample%20Patient%20Discharge%20Instructions_05%2025.pdf

No wonder patients and providers can get confused.

Acronyms

RLT - Radio Ligand Therapy