

AAPM Spring Clinical Meeting

THE OFFICE OF NUCLEAR MATERIAL
SAFETY AND SAFEGUARDS

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March 7, 2015



Discussion Topics



- Changes & Trends at the NRC
- Rulemaking Activities
- Operating Experience
- Medical Policy Statement
- NRC Medical Outreach Initiatives
- Project AIM

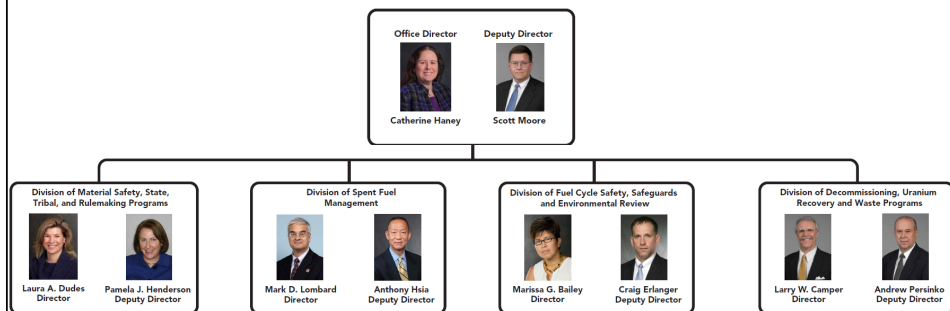
NRC Office Reorganization



The Offices of NMSS and FSME merged on October 5th, 2014.

- Reorganization Goals
 - Enhance agency communications
 - Meet anticipated future challenges
 - Enhance effectiveness and efficiency of regulatory operations
 - Minimal impact on regulated community

Current NMSS Office



Rulemaking Activities



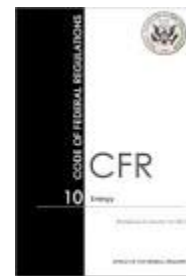
- 10 CFR Part 20 “Standards for Protection Against Radiation”
 - Advance Notice of Proposed Rulemaking published in July 2014, to seek public input on several technical topics
 - Comment period is still open; closes on March 24
 - Staff will develop a rulemaking regulatory basis document and provide to Commission for approval
- 10 CFR Part 35 “ Medical Use of Byproduct Material”
 - Proposed rule published for comment July 21 – November 18, 2014
 - Proposes amendments to the reporting and notification requirements for a medical event for permanent implant brachytherapy
 - Proposes changes to training and experience requirements
 - Proposes requirements for measuring molybdenum contamination and reporting of failed technetium and rubidium generators
 - Staff is currently preparing the final rule, due to the Commission for approval in December 2015

Rulemaking Activities



(continuation)

- 10 CFR Part 37 “ Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material”
 - NRC transitioned from post-9/11 security Orders to regulation
 - Final Rule published in March 2013, effective March 2014 for NRC licensees, March 2016 for Agreement States
 - Key requirements of the program include:
 - Background checks, including fingerprinting
 - Controlling personnel access to areas where radioactive materials in quantities of concern are stored and used
 - Documented security programs
 - Coordination and response planning between the licensee and local law enforcement agencies for its jurisdiction
 - Coordination and tracking of materials shipments
 - NRC continues to assess programs and will provide a report to Congress evaluating the effectiveness of Part 37 by December 2016.



Operating Experience



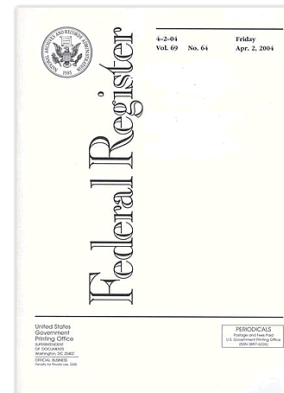
- Iridium-192 high dose-rate (HDR) afterloader event
- Yttrium-90 microsphere shunting event
- In 2013, NRC issued Generic Communication IN 2013-16
 - Importance of Verification of Treatment Parameters for High Dose Rate Remote Afterloader Administrations
- Seek opportunities to share best practices/lessons learned



Medical Policy Statement



- Regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public.



Medical Policy Statement (continuation)



- Will not intrude into medical judgment affecting patients, except as necessary to provide for the radiation safety of workers and the general public.
- When justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions.
- Consider industry and professional standards that define acceptable approaches of achieving radiation safety.

NRC Medical Outreach Initiatives



- NRC is exploring various outreach initiatives to enhance communications with medical licensees, regulators, stakeholders and other regulating agencies.
- Initiative Goals
 - Promote education on relevant topics
 - Information exchange among licensees and regulators
 - Seek more participation of medical licensees and stakeholders in regulatory processes



Advisory Committee for the Medical Uses of Isotopes



- Advise NRC staff on medical issues

Project AIM



- Initiative to provide more specific projections of the workload for the agency five years out
 - Primary goal is to prepare the NRC to excel long into the future
 - Provide a roadmap to improve NRC's operational excellence, agility, and culture, while also refining the basis for agency planning through 2020 and beyond
- Improve efficiency of operations
 - Right sizing the agency
 - Streamlining processes
 - Enhancing timeliness
 - Working as "One NRC"



Project AIM (continuation)



- **Applicability to Nuclear Materials Program**

- Consider consolidating materials program into 1 or 2 regions
- Enhance agility/mobility of staff
- Improve transparency in calculation of fees
- Clarify agency priorities
- Improve stakeholder interaction



BACK UP SLIDE

ACMUI Positions

Chairman: [Bruce R. Thomadsen, Ph.D.](#),

Medical Physicist, Radiation Therapy

Vice Chairman: [Philip O. Alderson](#), Health
Care Administrator

Members:

[Francis M. Costello](#), Agreement State
Representative

[Vasken Dilsizian, M.D.](#), Nuclear Cardiologist

[Susan M. Langhorst, Ph.D.](#), Radiation Safety
Officer

[Steven R. Mattmuller](#), Nuclear Pharmacist

[Michael D. O'Hara, Ph.D.](#), Food and Drug
Administration Representative

[Christopher J. Palestro, M.D.](#), Nuclear
Medicine Physician

[John H. Suh, M.D.](#), Radiation Oncologist

[Laura M. Weil](#), Patients' Rights Advocate

[Ronald Ennis, M.D.](#), Radiation Oncologist

[Pat B. Zanzonico, Ph.D.](#), Medical Physicist,
Nuclear Medicine

- Physicians 5
- Medical physicists 2
- Radiation Safety Officer 1
- Nuclear Pharmacist 1
- Patient advocate 1
- Hospital Administrator 1
- FDA representative 1
- Agreement States 1