AAPM Spring Clinical Meeting

THE OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

Cathy Haney
Office Director

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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
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 Dilisizian, 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