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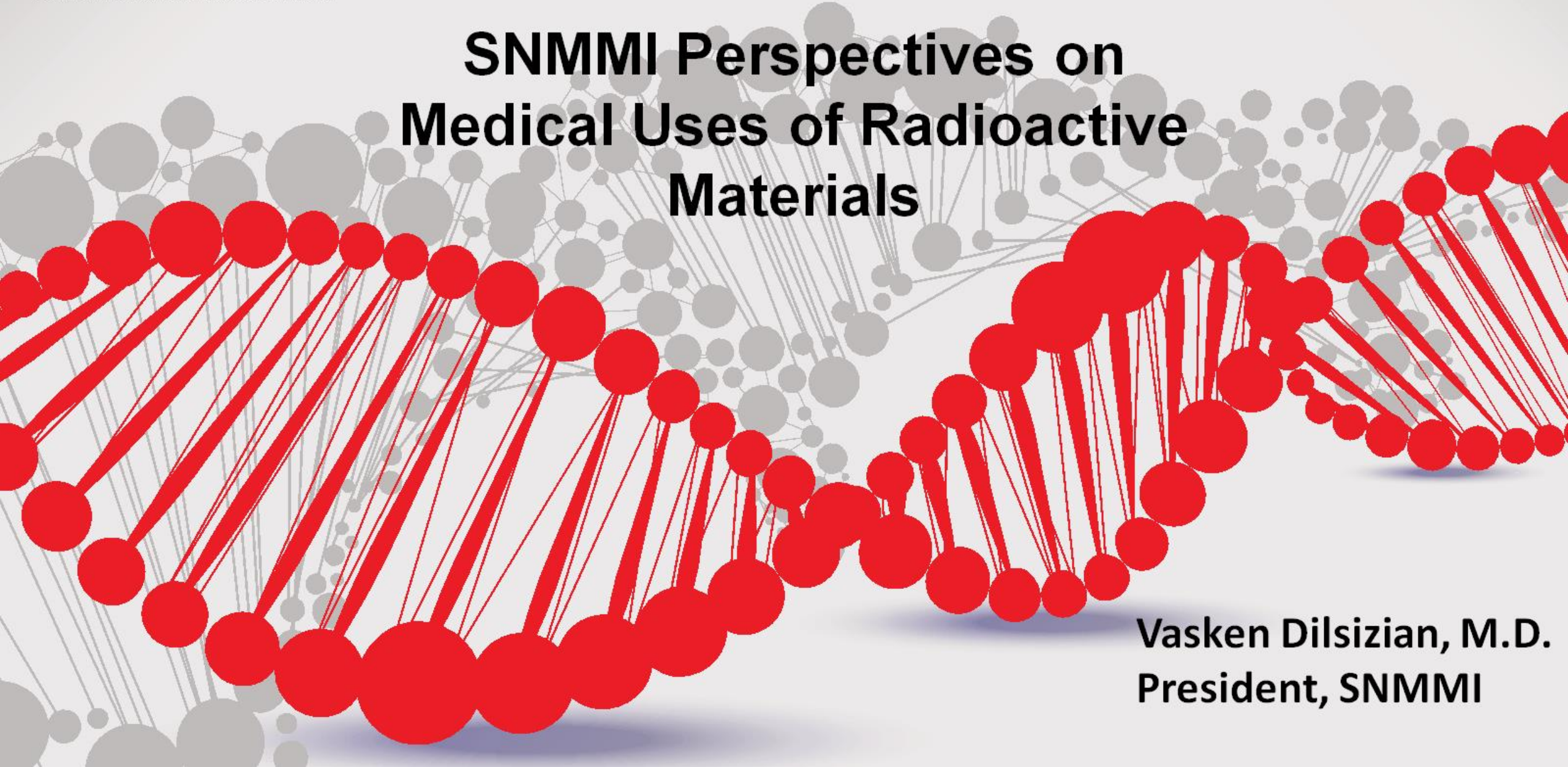
SNMMI Perspectives on Medical Uses of Radioactive Materials



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President, SNMMI

SNMMI's History

- Founded in 1954
- The largest international scientific organization dedicated to nuclear medicine and radionuclide therapy
- A multidisciplinary organization
  - Over 15,000 physicians, scientists, pharmacists and technologists

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Current Pathways for Obtaining AU Status

1. Certification by a medical specialty board whose certificate is recognized by the NRC or an agreement state (American Board of Nuclear Medicine, American Board of Radiology, and American Board of Osteopathic Radiology)
2. Completion of 200 hours of classroom training and 500 hours of supervised work experience in an ACGME accredited program (Nuclear Medicine, Diagnostic Radiology with 16 month NM/NR pathway, or Radiation Oncology)
3. Previous identification as an Authorized User on an NRC or Agreement State license of permit

Training and Experience (T&E) Requirements

NRC-2018-0230: Draft Approaches for Addressing T&E Requirements for Radiopharmaceuticals Requiring a Written Directive

- We thank the NRC for the opportunity to provide feedback
- Our main objective is to emphasize **Patient and Public Safety**, while ensuring **Access to Quality of Care**
- The NRC's advisor board (ACMUI) identified no Authorized User shortage in their revised report (ACMUI July of 2018) and **"strongly supported maintaining current AU pathways"**
- Thus, there seems to be no clearly defined or compelling need to develop a new tailored T&E pathway

NRC staff's SECY-20-0005 paper: SUMMARY

NRC staff's SECY paper, SECY-20-0005: "Rulemaking Plan for Training & Experience Requirements for Unsealed Byproduct Material (10 CFR Part 35),"

- The NRC staff finds that given the expected growth in the field of nuclear medicine and uncertainties in the safety-related characteristics of emerging and future radiopharmaceuticals, such as energy level, dose, half-lives, and administration protocol, **a less prescriptive and more performance-based approach to regulating T&E would be beneficial** because it could cover radiopharmaceuticals beyond those currently known or in use.
- In addition, increased involvement by the medical community in determining the appropriate safety criteria for radiopharmaceuticals and setting the associated T&E requirements could **help accommodate the increasing "interest" of non-nuclear medicine and non-radiation oncology physicians in using radiopharmaceuticals**. While the staff considered **stakeholder concerns** about patient access, the availability and geographic distribution of AUs did not drive the staff's evaluation of T&E.

NRC RULEMAKING PLAN - SECY-20-0005: RECOMMENDATION – 1/13/2020

- NRC staff's recommendation to initiate a rule making **to remove prescriptive T&E requirements and to eliminate the need for NRC review and approval of AUs**. The staff's recommended option would require that physicians be certified by an NRC-recognized or Agreement State-recognized **medical specialty board** to become AUs.
- As part of this recommended rulemaking, the NRC would revise its board recognition criteria so that certification by specialty boards other than the existing nuclear medicine and radiation oncology boards would be an acceptable T&E pathway for the use of radiopharmaceuticals.
- The staff's recommended rulemaking option would continue to protect public health and safety, better align the NRC's T&E requirements with the Medical Policy Statement, and position the agency for more effective and efficient regulatory decision making with respect to the expected increase in the number and complexity of emerging radiopharmaceuticals.
- The recommended option would also alleviate regulatory burden for the NRC, Agreement States, and licensees, resulting in an estimated cost savings of $2.4 million per year.

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Other Important Views to Consider

- Who will be training the current oncology, urology, or other medical specialties and how do we ensure that the next generation of residents and fellows in these area receive competency based training? There are no (or perhaps only a handful of) Authorized Users in these medical specialties at the present time.
- Expansion in medical specialty training requires ACGME review committee discussion and approval in each of these medical specialties. **NRC does not have jurisdiction to require changes in medical and surgical residency or fellowship training**.
- Nuclear Medicine, Radiation Oncology and Diagnostic Radiology with 16 month NM/NR pathway are **the only ACGME-approved training programs** that have specific goals and objectives pertaining to administration of radioactive material. These have to be completed **under the supervision of Board Certified physicians** who also have been trained in this area.

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Other Important Things to Consider

- **Independent of the medical or surgical specialty board**, the AU candidate must attest to the acquisition of § 35.390 knowledge topics & skills by successfully completing a formal competency assessment with continued formal periodic competency reassessment to maintain his/her limited-scope AU status (competency certification for radionuclide therapy).

- Given that this type of training is not part of standardized program requirements in these medical and surgical subspecialty areas, the question arises as to which organization is best suited to ensure competency and safe administration of these agents from individuals who have sought this additional training?

- Which subspecialty Board would be most qualified to certify these medical specialty candidates as qualified and competent for radionuclide therapy? American Board of Nuclear Medicine or Medical Specialty Boards without adequate mentors or educators to cover the § 35.390 knowledge topics & skills?

- Undoubtedly, organizations that have the most experience and expertise in these areas are Nuclear Medicine, Diagnostic Radiology and Radiation Oncology.

Release of Patients Administered Radioactive Material

NRC-2019-0154: Release of Patient Administered Radioactive Material

- We thank the NRC for the opportunity to provide feedback on the patient release criteria.
- The SNMMI submitted comments for this patient guide in June 2017 and again in September 2019, following the current revision, to provide licensees with more detailed instructions for their patients before and after they have been administered radioactive material
- This revision included new section on “Death of a Patient Following Radiopharmaceutical or Implants Administrations,” and “Dosages of Radiopharmaceuticals that Require Instructions and Records when Administered to Patients who are Breastfeeding an Infant or Child”

Release of Patients Administered Radioactive Material

- SNMMI submitted specific comments related to radiation monitoring of family members, breastfeeding interruption limits and guidance for families and children
- SNMMI agrees that the written and oral instructions must be provided to the patient far enough in advance of treatment, without compromising patient care, to ensure that the patient has sufficient time to determine whether or not he/she can actually comply with the instructions and to make whatever arrangements may be necessary for compliance
- **SNMMI is keenly aware of the usage and impact of social media on education**. Accordingly we are planning to develop a video clip that will be available on the Society's website and on **YouTube** for patients to view the entire radioactive material administration procedure and follow instructions in advance of their treatment.

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Targeted Radiopharmaceutical Therapies Growth Areas

- Targeted Radiopharmaceutical Therapies are expected to be an area of tremendous growth in the coming years with several new agents under testing and development, in clinical trials, or in clinical use.
- Some examples of alpha- and beta-emitting targets include:

  1) FDA-approved Radium-223 therapy for metastatic prostate cancer and other cancers in bone

  2) Other alpha-emitting therapeutics targeting a variety of receptors including prostate specific membrane antigen (PSMA)

  3) FDA-approved Lutetium-177-labeled somatostatin analog (Lu-177 dotatate) therapy for neuroendocrine and other somatostatin receptor expressing tumors

  4) Lutetium-177 PSMA therapies for metastatic or treatment-resistant prostate cancer

  5) Iodine-131 labeled antibodies to leukemia targets (such as CD-33)

  6) Other indications in Phase 2 or 3 trials include Colorectal Cancer,

  Non-Hodgkin's Lymphoma and Leukemia

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Potential Barriers to Patient Access

- Addition of new diagnostic and therapeutic isotopes to a Radioactive Material License (RAML) can be time consuming – up to 6 months – and can be variable from state to state
- Rulemaking related to generators can cause delays (decommissioning funding plans)
- Isotope/agent-specific training for targeted therapeutic dosing and patient administration

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Acronyms

- **ACMUI – Advisory Committee on the Medical Uses of Isotopes**
- **AU – Authorized User**
- **ACGME - Accreditation Council for Graduate Medical Education**
- **FDA - Food and Drug Administration**
- **NRC – Nuclear Regulatory Commission**
- **T&E – Training and Experience**
- **RAML – Radioactive Material License**
- **PSMA - Prostate Specific Membrane Antigen**
- **NM/NR – Nuclear Medicine/Nuclear Radiology**