

HPRA Newsletter

Volume 9, Issue 7

August 2014

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SNMMI Tours MedStar Washington Hospital Center with Congressional Staff

On Tuesday August 5, 2014, SNMMI staff, along with various congressional staff, toured the MedStar Washington Hospital Center in Washington, DC. Nuclear medicine specialist, Douglas Van Nostrand, MD, led the tour of the Division of Nuclear Medicine, and shared information with Mary Neumayr and Peter Spencer (House Energy & Commerce), Paul Davis (Senate Energy & Natural Resources) and Kelly Perry (Senator Lamar Alexander R-TN) about the utilization of types of sensitive scanning equipment, advanced computing technology, and radioactive substances to produce high-quality images. The tour focused on the significance of nuclear medicine and molecular imaging as a diagnostic and treatment tool. The tour also afforded the Society the opportunity to share information about the various challenges the field currently is confronting. The Society reemphasized the need for a domestic source of Molybdenum-99 and continued funding for nuclear medicine research with human applications. As part of the day, the group also toured the Cardinal Pharmacy in Greenbelt, Maryland.



Left to right: Mary Neumayr, Peter Spencer, Dr. Van Nostrand (seated), Kelly Perry, and Paul Davis

NRC Releases Proposed Rule (10 CFR) Part 35 and Advance Notice of Proposed Rulemaking for Part 20

On Monday, July 21, 2014 the Nuclear Regulatory Commission (NRC) released the [proposed rule for Part 35: Medical Use of Byproduct Material](#)—Medical Event Definitions, Training and Experience, and Clarifying Amendments.

The NRC addresses three ongoing rulemaking projects as well as other related issues.

The rule proposes amendments to the reporting and notification requirements for a medical event for permanent implant brachytherapy. With this change, NRC is moving from dose-based criteria to an activity-based criteria, a change in line with the Advisory Committee on the Medical Use of Isotopes (ACMUI) recommendations.

Additionally, the rule proposes changes to the training and experience (T&E) requirements for authorized users, medical physicists, Radiation Safety Officers, and nuclear pharmacists; to the requirements for measuring molybdenum contamination and reporting of failed technetium and rubidium generators; and to allow Associate Radiation Safety Officers to be named on a medical license.

Lastly, the rule proposes changes to address a request filed in a petition for rulemaking (PRM), PRM-35-20, to exempt certain board-certified individuals from certain T&E requirements (i.e., "grandfather" these individuals) so they may be identified on a license or permit for materials and uses that they performed on or before October 24, 2005, the expiration date of the prior T&E requirements.

Comments for the Part 35 proposed rule must be submitted to NRC no later than 5 p.m. ET on November 18, 2014. Comments can be submitted electronically through <http://www.regulations.gov> or by mail to:

Secretary, U.S. Nuclear Regulatory Commission,
Washington, DC 20555-0001,
ATTN: Rulemakings and Adjudications Staff

On Friday, July 25, 2014 the NRC issued advanced notice of **proposed rulemaking for Part 20: Radiation Protection**. The NRC continues to seek information on its radiation protection regulations. Internationally standards have changed and the NRC is seeking to achieve greater alignment between their radiation protection regulations and the 2007 recommendations of the International Commission on Radiological Protection (ICRP) contained in ICRP Publication 103 (2007). Comments for the Part 20 advance notice of proposed rulemaking may be submitted to the NRC no later than 5 p.m. ET on November 24, 2014. Comments can be submitted electronically through <http://www.regulations.gov> or by mail to:

Secretary, U.S. Nuclear Regulatory Commission,
Washington, DC 20555-0001,
ATTN: Rulemakings and Adjudications Staff

If the NRC develops draft supporting guidance for a proposed 10 CFR part 20 rulemaking, then the public will have an opportunity to provide comment on the draft guidance. If the NRC decides not to pursue a 10 CFR part 20 rulemaking on this topic, the NRC will publish a document in the Federal Register that will generally address public comments and withdraw the Advanced Noticed of Proposed Rulemaking.

Department of Energy Funding for Nuclear Medicine Research

For nearly 60 years, the Department of Energy (DOE) has funded essential, fundamental nuclear medicine research in the areas of biomedical imaging and radiotherapy that has facilitated technological breakthroughs. However, this funding was not included in either of the House and Senate's Fiscal Year (FY) 2015 Energy & Water appropriation bill. The House approved their version of the appropriation bill on July 10 with a bipartisan vote of 253-170. The Senate Appropriation's full committee has yet to mark up their legislation.

However, it remains unlikely that the Senate will pass its legislation by September 30, the end of the current fiscal year. Instead, there will likely be a short term Continuing Resolution (CR) that funds the government at the same level as the current fiscal year. Recently, Senator Tom Harkin (D-IA), chairman of the Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, said he expects the Senate to pass a CR before September 30 and to extend funding until December, after the Congressional midterm elections.

SNMMI recently sent a **letter** to Chair and Ranking Member of both the Senate Appropriation Committee and Subcommittee on Energy and Water Development. If you are interested in contacting your members of Congress, you can find a draft letter **here**. Please personalize your letter and let Congress know your story. If you do not know your members of Congress, please search the **House** and **Senate** websites.

SNMMI Weighs In

SNMMI provides comments to government stakeholders on a multitude of issues. For more information, please visit the [SNMMI website](#) or contact the HPRA department directly.

- On September, 2, 2014, SNMMI submitted comments to CMS on the CY 2015 Hospital Outpatient Prospective Payment System ([HOPPS](#)) and the Medicare Physician Fee Schedule ([MPFS](#)) Proposed Rules.

Important Upcoming Events/Deadlines

- September 10: SNMMI will meet with CMS to discuss the implementation of Appropriate Use Criteria and the importance of utilizing a balanced multidisciplinary approach to guidance development by including various stakeholders in the development process.
- September 10: The CMS Open Payments review and dispute process **ends**. The review, dispute and correction process allows physicians and teaching hospitals to review and initiate any disputes regarding the data reported about them by applicable manufacturers and applicable GPOs before CMS makes the information public on **September 30, 2014**. Visit the [Dispute and Resolution](#) page for more information.
- September 24: SNMMI will meet with FDA to discuss guidance and recommendations for radiopharmaceutical compounding.
- September 29-30: SNMMI will **attend** the NRC's Advisory Committee on the Medical Use of Isotopes (ACMUI) **meeting**.
- September 30: SNMMI's Patient Advocacy Advisory Board (PAAB) will be holding their Capitol Hill lobbying day. If you are interested in attending as a patient advocate, please contact patientinfo@snmmi.org.

Contact hpra@snmmi.org to be notified by email of future newsletters.