

## NRC ACMUI Fall Meeting

The Nuclear Regulatory Commission (NRC) held the fall meeting of its Advisory Committee on Medical Uses of Isotopes (ACMUI) on September 11 and 12 in Rockville, MD. The committee holds public meetings during the spring and fall, with additional public teleconferences as needed. At the most recent meeting, ACMUI members and NRC staff and officials discussed several topics relevant to nuclear medicine, including guidelines on radiation exposure to nursing mothers, an update on ongoing activities related to patient release after radioiodine therapy, and efforts to enhance communications with the medical community.

An ACMUI subcommittee was formed in early 2017 to review radiation exposure from diagnostic and therapeutic radiopharmaceuticals, including brachytherapy, to the nursing mother and child. The subcommittee addressed current guidance, radiation safety, lactation and breastfeeding precautions, patient information, and related concerns. The subcommittee received additional recommendations from the full ACMUI and will hold a conference call to finalize their report before the 2018 spring ACMUI meeting.

Donna-Beth Howe, PhD, from the NRC, provided an update on efforts to address requirements for patient release after radioiodine treatment. In the April 11 issue of the *Federal Register*, NRC posted 6 questions on this topic and received 132 responses. The 6 areas of NRC focus include: (1) development of an activity-based patient release threshold; (2) clarification of the time covered by the current dose limit in 10 CFR 35.75(a) for releasing individuals; (3) appropriateness of applying the same limit on dose from patient exposure to all members of the general public; (4) requirements for releasing individuals who are likely to expose young children and pregnant women; (5) requirement for timely discussion with the patient about patient isolation to provide time for licensee and patient

planning; and (6) requirement to ensure that patients are given instructions prior to the procedure. The NRC will use the responses from the *Federal Register* notice as the basis for a written issue paper on whether to pursue changes to 10 CFR 35.75. The paper is due in December 2017.

ACMUI member Christopher Palestro, MD, reported that the ACMUI is looking at the possibility of hosting a session at the SNMMI 2018 Annual Meeting in Philadelphia, PA. At the 2017 SNMMI Annual Meeting in Denver, CO, ACMUI held an ancillary session titled “What is the Advisory Committee on the Medical Use of Isotopes and what is its purpose?” ACMUI is currently seeking feedback on topics of interest to SNMMI members, who are encouraged to submit any suggested topics to [hpra@snmmi.org](mailto:hpra@snmmi.org).

In related news, on August 17, the NRC announced amendments to its requirements for medical uses of radioactive materials that modify 10 CFR Part 35 and make conforming changes to Parts 30 and 32. The changes amend the definition of medical events associated with permanent implant brachytherapy; update training and experience requirements for authorized users, medical physicists, radiation safety officers, and nuclear pharmacists; address a petition the NRC received seeking to recognize the qualifications of board-certified physicists and radiation safety officers not specifically named on a license; change requirements for measuring molybdenum contamination and reporting generator tests that exceed allowed concentration levels; allow associate radiation safety officers to be named on a medical license; and make several minor clarifications.

*SNMMI*

## SNMMI Responds to 2018 Proposed HOPPS and PFS

SNMMI announced on September 11 that it had submitted a comment letter to the Centers for Medicare & Medicaid Services (CMS) on the proposed rule for the 2018 Hospital Outpatient

Prospective Payment System, recommending improvements in the way that CMS pays hospital outpatient departments for nuclear medicine and molecular imaging procedures. The letter included requests to: (1) reconsider developing separate payment for diagnostic radiopharmaceuticals or to develop separate Ambulatory Payment Classifications (APCs) for groups of diagnostic radiopharmaceuticals (as proposed in an SNMMI letter and meeting in February 2015); (2) keep Current Procedural Terminology codes 78018, 78110, 78111, and 78121 in the new APC groups to ensure stability within the coding structure; (3) maintain pass-through status for 19 drugs and biologics on December 31, 2017, in order to complete the IDEAS study and streamline billing procedures for those studies; (4) not further reduce payments for items and services furnished in newer off-campus, provider-based departments; and (5) publish Healthcare Common Procedure Coding System code Q9969 volume and cost data in the proposed and final rule for “Drug Blood Brachytherapy Cost Statistics” filed yearly. CMS will publish the final rule around October 1, 2018.

Also on September 11, SNMMI released a comment letter to CMS on the proposed 2018 Medicare Physician Fee Schedule. SNMMI recommendations included: (1) finalizing the Relative Value Scale Update Committee and specialty society recommendations for work and practice expenses for 78300, 78305, and 78306; (2) exempting all nuclear medicine- and all Deficit Reduction Act-affected imaging services from the proposed 25% reduction; (3) exempting carrier-priced services from the 25% reduction and conducting code or family analysis in order to prevent access issues or shifting of care resulting from insufficient payment rates for important nuclear medicine services; (4) allowing practitioners more time to focus on and adjust to the appropriate use criteria mandate to allow for testing in 2018;

and (5) reducing the regulatory burden on nuclear medicine billing, because current complexity requires extensive time and training for providers and must also be a burden for Medicare and its contractors. CMS will publish the final rule around October 1, 2018.

*SNMMI*

## **WINM Meet at SNMMI Annual Meeting**

Women in Nuclear Medicine (WINM) held its annual breakfast and educational events on June 11 as part of the SNMMI Annual Meeting in Denver, CO. Leonie Gordon, MD, chair of WINM, led the group. The breakfast event featured Cara Ferreira, PhD, MBA, a management consultant

at McKinsey & Company, who discussed issues related to women in the workplace. Following this event, the WINM attendees walked as a group to reserved seating at the SNMMI plenary session.

During the 2017–2018 academic year, WINM will focus on mentor/mentee matchups and other special projects, including awards and recognition. “WINM members can make an impact in marketing, education, and in providing great service to patients. Although the presence of women approaches 50% of the SNMMI membership, there are very few women in leadership positions,” said Gordon. “We need to identify, grow, and promote women leaders within the organization. It is my hope that the WINM

committee can in some way be part of or influence the SNMMI House of Delegates and Board to help with this effort.”

The WINM committee is charged with promoting women physicians and scientists in nuclear medicine and molecular imaging, fostering development of professional interests, addressing problems encountered in the practice of nuclear medicine, promoting leadership and career development in women, raising awareness of scientific contributions of women in nuclear medicine, recognizing the challenges of balancing career and family, promoting fair and equitable treatment, and improving the climate for women in nuclear medicine in all stages of their careers.

*Women in Nuclear Medicine*

## **From the Literature**

*Each month the editor of Newsline selects articles on diagnostic, therapeutic, research, and practice issues from a range of international publications. Most selections come from outside the standard canon of nuclear medicine and radiology journals. These briefs are offered as a monthly window on the broad arena of medical and scientific endeavor in which nuclear medicine now plays an essential role. The lines between diagnosis and therapy are sometimes blurred, as radio-labels are increasingly used as adjuncts to therapy and/or as active agents in therapeutic regimens, and these shifting lines are reflected in the briefs presented here. We have also added a small section on noteworthy reviews of the literature.*

### **<sup>18</sup>F-DPA-714 PET and Zika Neuroinflammation**

Kuszpit et al. from the U.S. Army Medical Research Institute of Infectious Diseases (Frederick, MD) and the National Heart, Lung, and Blood Institute (Bethesda, MD) reported on September 12 ahead of print in *Molecular Imaging and Biology* on a study evaluating the utility of <sup>18</sup>F-DPA-714,

a translocator protein 18-kDa radioligand, in detecting and quantifying neuroinflammation in the brains of Zika virus–infected mice. The researchers studied Zika virus pathogenesis in wild-type C57BL/6 mice that were administered an antibody to inhibit type I interferon signaling. PET imaging was performed on d 3, 6, and 10 after infection, with serial analyses for histology, microgliosis, and detection of viral RNA. In the Zika-infected mice, viral titers in the brain increased from d 3 to 10 after antibody injection, during which period PET imaging showed a 2–6-fold increase in global brain neuroinflammation despite limited histopathologic detection of viral RNA. Significant increases in ionized calcium binding adaptor molecule-1 were also noted by d 10. The authors concluded that “the results of the current study demonstrate that global neuroinflammation plays a significant role in the progression of Zika virus infection and that <sup>18</sup>F-DPA-714 PET imaging is a sensitive tool relative to histology for the detection of neuroinflammation.” They added that such PET imaging “may be useful in dynamically characterizing the pathology

associated with neurotropic viruses and the evaluation of therapeutics being developed for treatment of infectious diseases.”

*Molecular Imaging and Biology*

### **PET in FUO and IUO**

In an article e-published on September 19 ahead of print in *Annals of the Rheumatic Diseases*, Schönau et al. from Friedrich-Alexander University Erlangen–Nürnberg and the Universitätsklinikum Erlangen (both in Germany) reported on <sup>18</sup>F-FDG imaging in elucidating underlying causes in patients with fever of unknown origin (FUO) and inflammation of unknown origin (IUO). The study included 240 patients (72, FUO; 142, IUO; 26 with FUO or IUO previously) who underwent <sup>18</sup>F-FDG PET/CT and standard clinical assessments. Imaging results were classified as helpful or nonhelpful in establishing a definitive diagnosis. Such diagnoses were achieved in 190 patients (79.2%), with leading diagnoses of adult-onset Still disease (15.3%) in FUO patients, large-vessel vasculitis (21.1%) and polymyalgia rheumatica (18.3%) in IUO patients,