nature of nuclear medicine/molecular imaging practice is changing, requiring new knowledge and more interaction with patients.

Although we face challenges ahead, including economic factors, all the speakers are extremely passionate about growing the field and optimistic that, working together, we can enhance our education and training for future nuclear medicine physicians in the United States and around the world. Through our Value Initiative, we will continue to strengthen our pipeline and outreach to medical students and residents, demonstrating the value and exciting opportunities in our field. A diverse, broadly trained new generation of nuclear medicine physicians, scientists, and academics is essential to ongoing innovation and advancements that will improve patients' lives.

NEWSBRIEFS

Srivastava Receives ACS Seaborg Award

Brookhaven National Laboratory (BNL; Upton, NY), released on July 23 an article about Suresh Srivastava, PhD, senior medical scientist emeritus in the Collider-Accelerator Department and Medical Isotope Research & Production Program at BNL, who earlier in the year was awarded the American Chemical Society (ACS) Glenn T. Seaborg Award for Nuclear Chemistry. Presented by the ACS Division of Nuclear Chemistry and Technology, the Seaborg Award recognizes and encourages research in nuclear and radiochemistry or their applications. Srivastava was honored for his "outstanding accomplishments in the production and development of many radioisotopes and radiopharmaceuticals that have and continue to provide medical benefit to patients worldwide." The award was presented at the ACS 255th national meeting.

"Conceiving, developing, and promoting radioisotopes to diagnose disease and treat patients helped create new ways to fight disease and help humanity," said Srivastava in the BNL release. "It feels very good to receive this Seaborg Award. I am grateful for all the support and encouragement I have received from managers, coworkers, colleagues, family, and friends over the years. And I am not done yet." In the photo, Seaborg (left) and Srivastava posed with the first ^{99m}Tc generator at a history session at the 1996 SNM meeting.

The BNL profile focused on Srivastava's achievements in advancing theranostic radioisotope applications and on his long history (almost half a century) with the laboratory, citing, among other innovations, his development of chemistry for "shake and bake" radiopharmaceutical kits. These kits made clinically feasible many of the ^{99m}Tc procedures used around the world today. "More than 40 million nuclear medicine procedures are done each year. ^{99m}Tc—which was developed at BNL and is used to diagnose heart disease and other ailments—accounts for about 80% of those procedures, according to the World Nuclear Association," Srivastava said. "Looking back, it makes me feel so good that I had the opportunity to do this research, to help treat people who are sick and help save their lives."

Scientists from BNL who have also received the Seaborg Award include National Medal of Science awardee Joanna Fowler, PhD; Nobel Laureate Raymond Davis, PhD; Gerhart Friedlander, PhD; Richard Hahn, PhD; and Alfred Wolf, PhD, whose discoveries were instrumental in developing PET.

Brookhaven National Laboratory

FDA Approves Magnetic Device System for SLN Biopsy

The U.S. Food and Drug Administration (FDA) on July 24 approved a magnetic device system for guiding lymph node biopsies in patients with breast cancer undergoing mastectomy. The Magtrace and Sentimag Magnetic Localization System (Sentimag System; Endomagnetics, Inc., Austin, TX) uses magnetic detection during sentinel lymph node (SLN) biopsy procedures to identify specific nodes for surgical removal. "SLN biopsies are crucial for determining whether a patient's breast cancer has spread and helping the provider determine the most appropriate course of treatment," said Binita Ashar, MD, director of the Division of Surgical Devices in the FDA's Center for Devices and Radiological Health. "Currently, an SLN biopsy is performed after injection of radioactive materials and/or blue dye. This magnetic system we're approving today will offer patients undergoing mastectomy an option for their SLN biopsy procedure that does not require the injection of radioactive materials."

The Sentimag System uses magnetic materials to guide the SLN biopsy procedure. The system includes a magnetic sensing probe and base unit designed to detect small amounts of Magtrace, the tracer drug that is injected into breast tissue. The Magtrace particles travel to

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lymph nodes, facilitating magnetic detection. After the tracer injection, the Sentimag probe is applied to the patients' skin in areas closest to the tumor site containing the lymph nodes. The sensing of the magnetic particles is indicated by changes in audio and visual alerts from the base unit, enabling the surgeon to move the hand-held probe and locate SLNs.

The FDA evaluated data from a trial of 147 patients with breast cancer to compare the Sentimag System with conventional radioisotope-based methods using blue dye and/or a gamma probe. The lymph node detection rate for the Sentimag System was 94.3%, whereas for the conventional method it was 93.5%. The overall results indicated that 98.0% of patients had the same detection rates with the Sentimag system and the radioisotope-based method. Adverse events reported with the Sentimag system include temporary breast discoloration, cardiac disorder (bradycardia), and potential allergic reaction to the magnetic materials. In addition, Magtrace may travel to regions away from the injection site, such as liver or spleen, if injected directly into the bloodstream. In these cases the presence of the tracer may cause MR imaging artifacts.

The U.S. Food and Drug Administration

SPECT and Immune Status

A press release issued on July 12 by the National Institutes of Health (NIH, Bethesda, MD) reported on the results of an NIH-funded animal study suggesting that a SPECT-based imaging technique has the potential to become a useful tool to assess immune system recovery in individuals receiving treatment for HIV infection. These results were published on July 12 ahead of print in *JCI Insight* by Di Mascio et al. from the National Institute of Allergy and Infectious Diseases (Bethesda and Frederick, MD), Leidos Biomedical Research, Inc. (Frederick, MD), the University of Massachusetts Medical School (Boston), Memorial Sloan Kettering Cancer Center (New York, NY), and the NIH Clinical Center (Bethesda, MD).

The researchers used SPECT imaging and a CD4-specific imaging probe to assess immune system changes, including pools of CD4+ T cells, throughout the bodies of macaques infected with simian immunodeficiency virus (SIV) after initiation and interruption of antiretroviral therapy (ART). Their findings showed that CD4+ T-cell levels in the blood—a measure of human immune system health in HIV—often fail to fully reflect viral status in tissues. The new research detailed the complexity of the immune recovery process at the tissue-specific level.

SPECT imaging data were acquired in 2 sets of animals injected with either ^{99m}Tc-F(ab′)$_2$-OKT4A or ^{99m}Tc-F(ab′)$_2$-CD4R1. Imaging in monkeys chronically infected with SIV revealed that the timing of reconstitution of the CD4+ T-cell pool in the months after ART initiation varied among animals and among clusters of lymph nodes within the same animal. Reconstitution of CD4+ T-cell pools in the lymph nodes of animals receiving long-term ART appeared suboptimal, remaining smaller than pools seen in healthy control animals. Similar results were seen in the spleen in the 2 groups.

The scientists also assessed changes in CD4+ T-cell pools in the gut, a major target for HIV infection. In contrast to findings in lymph nodes and spleen, the investigators observed few differences in gut CD4+ T-cell pools between healthy and SIV-infected animals, challenging the notion that the gut is the major target of SIV infection. The authors concluded that, in the future, extension of this imaging technology to humans may aid scientists in evaluating immune reconstitution following standard and experimental HIV treatments.

National Institutes of Health

SNMMI Supports ^{99}Mo Bills

In a letter sent on July 18 to the Senate and House subcommittees on Energy and Water Development, SNMMI President Satoshi Minoshima, MD, PhD, joined with leaders of the American Society of Nuclear Cardiology, American College of Cardiology, American College of Radiology, patient groups, radiopharmaceutical manufacturers and distributors, and medical imaging companies to urge support of a provision in both Senate and House bills that would provide $20 million in additional funding to continue establishing domestic production of ^{99}Mo. The letter pointed out that despite the American Medical Isotope Production Act of 2012, a sufficient domestic supply of the radioisotope has not been established. In addition, the global ^{99}Mo industry has experienced and continues to experience challenges in maintaining reliable production and deliveries.

The signers requested language that clearly delineates the use of the entire $20 million for the National Nuclear Security Administration's medical isotope program and added the hope that the Department of Energy can be directed to use maximum flexibility in allowing preaward funding for those expenses directly related to projects from the beginning of Fiscal Year 2018.

SNMMI

CMS Proposes 2019 Payment Rule for Physicians

On July 12, 2018, the Centers for Medicare & Medicaid Services (CMS) issued its CY 2019 proposed payment policies and payment rates for services furnished under the Medicare Physician Fee Schedule (PFS). Once finalized, payment rates and policies will be effective January 1, 2019.

During July and August, SNMMI reviewed the 1,473-page proposed rule and prepared a detailed summary as well as payment rate charts. The society will also submit comments by the end of the comment period, which closes September 10.

Important highlights of the 2019 Proposed Payment Rule include: (1) With the budget neutrality adjustment to account for relative value (RV) changes (required by law), the proposed 2019 PFS conversion factor is $36.05, a slight increase over the 2018 PFS conversion factor of $35.99; (2) CMS has proposed January 1, 2020, as the target start date of the Medicare Appropriate Use Criteria (AUC) Program; (3) CMS is proposing to add independent diagnostic testing

facilities to the definition of an "applicable setting" for the purpose of AUC-consulting and -reporting requirements; (4) When physicians report an evaluation/management service and a procedure on the same date, CMS proposes to implement a 50% multiple procedure reduction to the lower paid of the 2 services; (5) CMS is proposing to accept the RVS Update Committee (RUC) recommendation that CPT 77081 be reduced and also proposes to accept Practice Experience inputs from the RUC recommendations. If implemented, this will reduce payment for these services in CY 2019.

The proposed rule, as well as related documents and fact sheets, is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1693-P.html.

SNMMI
Centers for Medicare & Medicaid Services

Nuclear Medicine Representatives Meet at IAEA

The International Atomic Energy Agency (IAEA) recently reported on a meeting of heads of associations and societies in nuclear medicine, held July 16–19 at its headquarters in Vienna, Austria. This was a first-of-its-kind group meeting of such experts from all continents to examine opportunities and challenges in the field. At the conclusion of the meeting, the group issued a report containing recommendations endorsed by all participants with the aim of further harmonizing several areas of nuclear medicine, with a focus on training and education. "There is a need to facilitate the training of professionals involved in the practice of nuclear medicine, so they can stay up to date with the novel applications and technologies and thereby better serve their patients," said Diana Paez, Head of the Nuclear Medicine and Diagnostic Imaging Section of the IAEA Division of Human Health. "There are so many new developments coming to the field, therefore we have to provide life-long education plans."

Participants at the IAEA nuclear medicine meeting in July (Courtesy IAEA/T. Pascual).

Participants discussed issues including access to nuclear medicine in health care systems, challenges faced by professionals to remain up to date with rapid changes in the field, and the need to encourage and support research studies aimed at covering gaps in scientific and clinical knowledge. They also emphasized the importance of partnership and ongoing dialog about advances in nuclear medicine, as well as working together to establish a broad consensus to increase the impact of nuclear medicine in the management of illness and disease.

"It was the first meeting where heads of all major professional organizations in the world came together to talk about global strategy, how nuclear medicine can improve patient health, the challenges currently arising and how we can work in cooperation with the IAEA," said Andrew Scott, President of the World Federation of Nuclear Medicine and Biology, who chaired the meeting.

International Atomic Energy Agency

NRC Final Rule on Medical Use of Byproduct Material

On July 16, the Nuclear Regulatory Commission (NRC) released the final rule and guidance on Medical Use of Byproduct Material—Medical Event Definitions, Training, and Experience, and Clarifying Amendments. The final rule incorporates many changes recommended by SNMMI. It amends training and experience requirements in certain sections, provides new details on measuring molybdenum contamination, and amends Part 35 to allow a licensee to appoint a qualified individual to serve as an associate radiation safety officer (ARSO), among other provisions.

The training and experience requirements portion of the rule was amended to remove the requirement to obtain a written attestation for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State. The NRC determined that certification by a specialty board, coupled with meeting the most recent training requirement, is sufficient to demonstrate that an individual has met the training and experience criteria and has the requisite current knowledge so that, in this situation, additional attestation by a preceptor is unnecessary. Individuals who are not board certified still must obtain a written attestation; however, the language of the attestation has been modified. In addition, residency program directors will be allowed to provide these written attestations.

The provision regarding measuring ^{99}Mo concentration for elutions of ^{99}Mo/^{99m}Tc generators has been modified to include a requirement for reporting a notification of a generated eluate exceeding permissible concentrations. It also adds a new requirement for when to report a failed technetium and rubidium generator.

NRC also stated that the change to allow a licensee to appoint a qualified individual with expertise in certain uses of byproduct materials to be named on a license to serve as ARSO will make it easier to increase the number of individuals available to serve as preceptors for those seeking to become a radiation safety officer or associate radiation safety officer. SNMMI provided comments on each of the changed provisions during the rulemaking process and noted in a press release that the society is supportive of the final amendments issued by NRC. The final rule is available at https://www.gpo.gov/fdsys/pkg/FR-2018-07-16/pdf/2018-14852.pdf and will become effective on January 14, 2019.

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