additional content will be rolled out in webinars over the next few months. This includes an exciting Technologist Summer Program, as well as content from SNMMI's councils and centers.

The 2020 Annual Meeting provided a wealth of current and valuable information and offered attendees a meaningful, interactive virtual experience. With the tremendous success of this virtual meeting and the accessibility of the content, SNMMI will be considering holding meetings virtually in future months to offer its members and the nuclear medicine community the best possible education while ensuring their safety.

## NEWSBRIEFS

### FDA Approves Tau Pathology Imaging Drug

On May 28 the U.S. Food and Drug Administration (FDA) approved Tauvid (flortaucipir F18) for intravenous injection, for PET imaging in adult patients with cognitive impairment for evaluation for Alzheimer disease (AD). The FDA granted approval of Tauvid to Avid Radiopharmaceuticals, Inc. (Philadelphia, PA), a subsidiary of Eli Lilly and Company. The approval came through the Priority Review process, under which the FDA goal is to take action on an application within 6 months if the agency determines that the drug, if approved, would significantly improve the safety or effectiveness of treating, diagnosing, or preventing a serious condition.

"AD is a devastating condition that affects millions of Americans. This approval will provide health care professionals with a new type of brain scan to use in patients being evaluated for AD," said Charles Ganley, MD, director of the Office of Specialty Medicine in the FDA Center for Drug Evaluation and Research. "While there are FDA approved imaging drugs for amyloid pathology, this is the first drug approved for imaging tau pathology, one of the 2 neuropathological hallmarks of AD, and represents a major advance for patients with cognitive impairment being evaluated for the condition."

The safety and effectiveness of Tauvid imaging were evaluated in 2 clinical studies. The first enrolled 156 patients who were terminally ill and agreed to undergo Tauvid PET imaging and participate in a post-mortem brain donation program. In 64 of the patients who died within 9 months of PET imaging, evaluators' interpretations were compared with post-mortem findings from independent pathologists who evaluated the density and distribution of neurofibrillary tangles (NFTs). Results showed that the scans had a high probability of correctly evaluating patients with tau pathology and an average-to-high probability of correctly evaluating patients without tau pathology.

The second study included the same patients, with 18 additional participants with terminal illness and 159 patients with cognitive impairment being evaluated for AD, and focused on interobserver agreement in scan interpretation. Agreement was at 87% across all 241 patients in the study and 90% in a separate subgroup analysis that included the 82 terminally ill patients diagnosed after death and the 159 patients with cognitive impairment.

The most common adverse reactions in patients using Tauvid were headache, injection site pain, and increased blood pressure. Tauvid is not indicated for use in the evaluation of patients for chronic traumatic encephalopathy.

The availability of Tauvid will initially be limited and will expand in response to commercial demand and payor reimbursement. "The fight against AD requires precise and reliable assessments of the 2 key pathologies of the disease, because clinical assessments alone are limited in their ability to accurately diagnose patients," said Mark Mintun, MD, vice president of Lilly's pain and neurodegeneration research and development. "I am excited that Tauvid has now been approved to image tau NFTs, which is the other key pathology, allowing a more comprehensive evaluation of patients. Lilly and Avid Radiopharmaceuticals are committed to bringing innovative AD diagnostics to the patients who need them most."

*U.S. Food and Drug Administration*
*Eli Lilly and Company*

### Regulatory Relief for Imaging/ Localization Study Training

On June 11, SNMMI, along with the American Society of Nuclear Cardiology, the American Society for Radiation Oncology, and the American College of Radiology requested regulatory relief from the Nuclear Regulatory Commission (NRC) for training for imaging and localization studies during the COVID-19 Public Health Emergency (PHE). The current regulation reads: "Work experience must involve: Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs" (10 *CFR* Part 35.290 (c)(1)(ii)(G)).

The joint letter requested that NRC allow this requirement to be met using virtual technology (video/webinar) and add this as an already vetted area for regulatory relief when requested by licensees. This request is similar to the previous NRC Advisory Committee on the Medical Uses of Isotopes subcommittee recommendation for a 1-time modification because of the pandemic. That request stated, "In situations when hands-on training (hot lab) is not feasible, then video/webinar

observational training may be considered. Similarly, when work experience cannot be met in person, then virtual training may be considered."

The NRC announced on May 20 the regulatory relief process (https://www.nrc.gov/docs/ML2013/ML20134H934.pdf) under its existing authority to consider granting relief from specific regulatory commitments when requested by a licensee under certain circumstances. Licensees were advised to reach out to the appropriate NRC point of contact as soon as possible upon identifying any potential compliance issues resulting from the COVID-19 PHE. In a June update, the NRC noted that "staff will work with the licensee to align around the information necessary to process the request and the needed timelines for relief. The NRC has assured and will continue to assure that licensed facilities operate safely during COVID-19."

*SNMMI*

*U.S. Nuclear Regulatory Commission*

## New Implementation Date for USP <825>

The United States Pharmacopeial Convention on June 1 updated the implementation date for General Chapter <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging to December 1, 2020. This General Chapter provides uniform minimum standards for the preparation, compounding, dispensing, and repackaging of sterile and nonsterile radiopharmaceuticals for humans and animals that occur as part of state-licensed activities. Originally scheduled for implementation on December 1, 2019, the start date has been delayed for appeals and comments. The text of the General Chapter <825> can be downloaded from https://go.usp.org/l/323321/2020-03-09/3125jw.

*United States Pharmacopeial Convention*

## NRC Identifies 9 FY 2019 Abnormal Occurrence Events

The U.S. Nuclear Regulatory Commission (NRC) on June 23 published its annual report to Congress for fiscal year 2019 regarding Abnormal Occurrences involving medical and industrial uses of radioactive material. Nine such occurrences were identified, 7 of which were medical events. U.S. law defines an Abnormal Occurrence as an unscheduled incident or event that the NRC determines to be significant from the standpoint of public health or safety. The NRC sets specific criteria, most recently updated in October 2017, for determining which events qualify, such as misadministration of radioactive material in diagnosis or treatment.

The majority of the medical events (4) involved higher-than-prescribed doses (including wrong site doses) in administration of $^{90}$Y microspheres. A fifth case involved incorrect flushing of an $^{82}$Rb generator, resulting in levels of $^{82}$Sr and $^{85}$Sr in the eluate, exceeding manufacturer-specified limits and affecting 8 patients. In the remaining 2 cases, patients received higher than prescribed doses in $^{103}$Pd brachytherapy and in $^{131}$I treatment.

The nonmedical events involved 1 worker exposure and the theft and subsequent recovery of a device containing a risk-significant radioactive source. No events at commercial nuclear power plants in FY 2019 met the criteria requiring an Abnormal Occurrence declaration. The Report to Congress on Abnormal Occurrences, Fiscal Year 2019, is available on the NRC website and includes details on each incident, as well as resolution and NRC actions. The full report is available at: https://www.nrc.gov/docs/ML2016/ML20162A165.pdf#:~:text=defines%20an%20abnormal%20occurrence%20%28AO%29%20as%20an%20unscheduled,from%20the%20standpoint%20of%20public%20health%20or%20safety.

*U.S. Nuclear Regulatory Commission*

## IAEA SAFRON Program Extended to Radionuclide Therapy

The International Atomic Energy Agency (IAEA) recently announced the launch of its SAFRON for Radionuclide Therapy program, an incident learning system to help medical facilities improve safety for patients and staff. The objective of this new platform is to "enhance the planning of radionuclide therapy used to treat, mitigate, or control cancer and other diseases by identifying potential safety issues from reported events."

"The complexity of radionuclide therapy could lead to unintended exposure pathways for the patient, worker, or the public," said Debbie Gilley, IAEA Radiation Protection Specialist, in a May press release associated with the announcement of the new program. "Sharing information is key to preventing future incidents in radionuclide therapy."

SAFRON, which stands for Safety in Radiation Oncology, is an integrated voluntary reporting and learning system originally created in 2012 to collect and disseminate information on safety-related events in radiation therapy. The current extension to events associated with radionuclide therapy recognizes the increasing global use of such treatments. Information submitted to SAFRON is dependent on facilities registering and sharing incidents that occur in their institutions. The IAEA lists more than 50 registered medical facilities and hospitals in the system, currently with more than 1,300 incident reports covering various occurrences, including errors and near misses. Incident submission is anonymous.

Although local and regulatory incident reporting systems are available, the launch of SAFRON for radionuclide therapy allows for sharing of information and learning from good practices across the broader medical community. "The reports available in SAFRON are a valuable resource for identifying events, and published documents can assist the reviewers in understanding the complexity of incidents and identifying methodologies that might be used to prevent future errors," Gilley said.

Registered contributors using SAFRON will be able to collect and analyze their reports to track, trend, and benchmark activities within their centers and with other SAFRON participants in radiotherapy and radionuclide

therapy. Registration for SAFRON radionuclide therapy incident learning is through IAEA NUCLEUS (https://nucleus.iaea.org/Pages/Help/Registration.aspx). Detailed instructions are available at: https://www.iaea.org/sites/default/files/20/05/safron-nm-registration-instructions.pdf.

*International Atomic Energy Agency*

## FDA Pilot Program for Patient Reported Outcomes in Cancer Trials

The U.S. Food and Drug Administration (FDA) announced on June 23 the launch of Project Patient Voice, an initiative of the FDA Oncology Center of Excellence (OCE). Through a new website, Project Patient Voice will create a consistent source of publicly available information describing patient-reported symptoms from cancer trials for marketed treatments. Although patient-reported data have previously been analyzed by the FDA during the drug approval process, such data are rarely included in product labeling and, therefore, are largely inaccessible to the public.

"Project Patient Voice has been initiated by the OCE to give patients and health care professionals unique information on symptomatic side effects to better inform their treatment choices," said FDA Principal Deputy Commissioner Amy Abernethy, MD, PhD. "The Project Patient Voice pilot is a significant step in advancing a patient-centered approach to oncology drug development. Where patient-reported symptom information is collected rigorously, this information should be readily available to patients."

Patient-reported outcome (PRO) data are collected using questionnaires that patients complete during clinical trials. These are designed to capture important information about disease- or treatment-related symptoms and include severity and frequency of such symptoms.

The Project Patient Voice website (https://www.fda.gov/about-fda/oncology-center-excellence/project-patient-voice) will include a list of cancer clinical trials with available patient-reported symptom data. Each trial will include a table of patient-reported symptoms that can be selected to display a series of bar and pie charts describing symptoms at baseline and over the first 6 mo of treatment. This information provides insights into side effects not currently available in standard FDA safety tables.

In the first phase of the pilot website, only 1 trial will be included while the FDA seeks public feedback on the way in which information is presented. Visualizations and data included on the website are voluntarily provided by the drug companies that conducted the clinical trials. AstraZeneca is the first company to provide patient-reported outcome data for an FDA-approved drug and has collaborated with the FDA to identify optimal methods for information display.

"There have long been calls to provide information to patients about how they may feel and function when receiving a cancer treatment. By initiating Project Patient Voice, we are moving towards standardized methods to display these outcomes, starting with patient-reported symptomatic adverse events," said Paul Kluetz, MD, deputy director of the FDA's OCE. "We encourage sponsors to collect this data systematically and look forward to welcoming additional sponsor collaboration as we work to help further serve the patient community."

*U.S. Food and Drug Administration*

## SNMMI and Partners Continue Support for H.R. 3772

On June 18 SNMMI and its Appropriate Payment Coalition Partners, the Medical Imaging Technology Alliance and the Council on Radionuclides and Radiopharmaceuticals, Inc., described renewed joint efforts to continue promoting H.R. 3772, the Medicare Diagnostic Radiopharmaceutical Payment Equity Act of 2019. This act would extend equitable reimbursement for approved PET agents and thereby stimulate development of new diagnostic radiopharmaceuticals. Three radiopharmaceuticals used to diagnose Alzheimer disease are currently scheduled to be bundled on September 30.

Participants in these joint efforts have been organized into teams—each including perspectives from industry, providers, and patients—that virtually visit specific congressional offices. In all, the teams intend to participate in more than 50 meetings, educating congressional representatives and staff about the importance of nuclear medicine and molecular imaging, as well as about the financial burden of COVID-19 on hospital systems. Severe reductions in revenue-producing elective procedures, coupled with the demands of COVID-19, may mean hospitals will be reluctant to support innovative nuclear medicine services because of inadequate reimbursement.

The SNMMI and its partners urged interested individuals to send a letter of support to congressional representatives before the end of the current session. More information and instructions on submitting such letters is available at https://snmmi.quorum.us/campaign/23260/ and https://www.snmmi.org/IssuesAdvocacy/content.aspx?ItemNumber=34002&navItemNumber=34003.

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