

Radioisotope Supply Update

NRG, which operates the High Flux Reactor (Petten, The Netherlands), indicated in February plans to restart the reactor for a new cycle of radioisotope production on March 17 after a 2-mo outage. The Nuclear Medicine Europe Emergency Response Team (NMEu ERT; Brussels, Belgium) held an update call on February 14 on the unplanned outage that resulted in cancellation of the reactor's first operating cycle of 2022. The cause of the defect (a cooling system leak in a basement ceiling), detected during an inspection on 21 January before the scheduled cycle start, had been identified, and analysis of the underlying cause would be submitted to the Authority for Nuclear Safety and Radiation Protection (ANVS), along with a solution to restore functionality. After approval by ANVS, the solution would be implemented and the reactor cooling system restored. After a planned 1-mo maintenance period, NRG intended to restart the reactor for a full cycle. Additional updates were planned during the review and start-up period.

On the February 14 call, the ERT also provided updates from other reactors in Europe that continued to work to address radioisotope shortages caused by the Petten outage. The Maria research reactor (Świerk-Otwock, Poland) added additional operating days to increase supplies of ^{99}Mo . The BR2 reactor (Mol, Belgium) resumed operations on February 12 (3 days earlier than planned) and announced that it would extend its radioisotope production cycle. Curium Pharma (London, UK) harvested ^{99}Mo targets from short irradiations at BR2 and processed ^{99}Mo for customers. Belgium's National Institute of Radioelements (IRE) reactor in Fleurus also announced it would resume production on its high-enriched uranium line in February. The NMEu indicated that as a result of these measures, supplies of $^{99}\text{Mo}/^{99\text{m}}\text{Tc}$ and ^{177}Lu were expected to return to normal in February, and ^{131}I supplies should be back to normal in the first half of March.

In the United States, University of Missouri Research Reactor (MURR) staff

announced on February 9 increased production of critical medical radioisotopes in an effort to help in alleviating disruptions in the global supply chain. J. David Robertson, executive director of MURR, anticipated that the reactor will maintain its increased production levels throughout the duration of the reactor shutdown in Europe. "MURR is fortunate to be in a position where we can increase our production when the global supply chain is impacted, because we operate 6 and a half days a week, 52 weeks per year," he said. "Our dedicated staff are committed to getting life-saving treatments delivered to the patients who need them."

*Nuclear Medicine Europe
University of Missouri Research
Reactor*

SNMMI Launches New Quality Systems Personnel Training Program

SNMMI announced on January 31 the launch of a new program designed to educate, train, and develop individuals with pharmacy or chemistry backgrounds in the production and release of clinical radiopharmaceuticals. The Quality Systems Personnel Training Program (QSPTP), conceived and led by Sally Schwarz, MS, RPh, BCNP, FAPhA, will provide participants with the theoretical knowledge and practical experience needed to assume responsibility for production, quality control, and release of radiopharmaceuticals. Topics in the program include production and quality assurance, synthesis and clinical formulation of radiopharmaceuticals, regulatory requirements, and research applications. Experiential training at Current Good Manufacturing Practice-certified sites will also be incorporated into the program.

Specific needs to be addressed by the program include cross-training in the principles and practice of radiopharmaceutical science; manufacturing and quality assurance of radiopharmaceuticals—both in the academic and commercial settings; synthesis and pharmaceutical formulation of radiopharmaceuticals, especially from cyclotron-produced

radionuclides; application of radiopharmaceuticals in biomedical research and clinical nuclear medicine; and compliance including all regulatory requirements associated with radiopharmaceutical manufacture and release.

"The manufacture and ongoing production of radiopharmaceuticals for clinical evaluation and use is dependent on skilled personnel who are cross-trained in several disciplines," said Alan Packard, PhD, SNMMI past president. "Currently, very few individuals have this type of training. To meet the growing need for qualified persons of this nature, SNMMI has developed a training program to cover the core competencies needed in this area of our field."

Individuals successfully completing the QSPTP will receive a certificate of training. In the future, SNMMI plans to collaborate with academic institutions to expand the program to include hands-on training in a production environment. "Having more professionals trained in the release of clinically important radiopharmaceuticals will benefit both academic and commercial entities," said Packard. "We hope that the QSPTP will provide a solid educational framework so that more individuals will become 'qualified persons' and will help to advance the field of radiopharmaceutical science." Detailed information on the program and its components is available at: www.snmmi.org/qsptp.

SNMMI

AI and Malpractice Liability

In an article published on February 1 ahead of print in the *Journal of the American College of Radiology*, Banja, from Emory University (Atlanta, Ga), and co-authors from Michigan State University (Grand Rapids) and the Penn State Milton S. Hershey Medical Center (Hershey) reported on ethical and legal implications associated with advances of artificial intelligence (AI) models and technologies in clinical practice, with a specific focus on exposure to liability for malpractice. The authors focused on 4 main considerations: (1) the importance of being able to explain AI models in patient care; (2) the

identification of strategies for diminishing clinician liability in poor patient outcomes that could be attributed to over- or under-reliance on AI; (3) the possibility of relieving liability burdens through legislation or regulation; and (4) conceptualizing AI models as “persons” with potential liability in legal proceedings.

Journal of the American College of Radiology

Thomas O’Dorisio, MD 1943–2022

Thomas M. O’Dorisio, MD, a pioneer in neuroendocrine cancer research and practice, died on February 2 in Ostrander, OH. He was a professor emeritus at the University of Iowa (Iowa



City), having served as director of the Neuroendocrine Tumor Program and coleader of the Gastrointestinal Neuroendocrine group. In 1971, Dr. O’Dorisio graduated from the Creighton University School of Medicine (Omaha, NE) and went on to compete a residency in internal medicine and a fellowship in endocrinology at The Ohio State University (OSU; Columbus). He remained at OSU, serving as director of the Division of Endocrinology, held numerous leader-

ship roles guiding components of the research mission, and received multiple teaching and education awards. In 1999, along with his wife, M. Sue O’Dorisio, MD, PhD, he was recruited to join the University of Iowa. His interest in nuclear medicine techniques in neuroendocrine cancer led to numerous collaborations with nuclear medicine and molecular imaging and therapy colleagues. He published more than 330 peer-reviewed articles, as well as texts and other scholarly works. Shortly before his final illness, he had begun work toward a master’s degree in religious studies from Regis University (Denver, CO).

University of Iowa

¹⁵³Sm-DOTMP Agent Receives Rare Pediatric Disease Designation

QSAM Biosciences, Inc. (Austin, TX) announced on February 2 that the U.S. Food and Drug Administration (FDA) had granted its Rare Pediatric Disease (RPD) designation to CycloSam (¹⁵³Sm-DOTMP), a clinical-stage drug candidate for treatment of osteosarcoma. The agent has demonstrated preliminary safety and efficacy in animal studies. In 2020 it was successfully used under a single-patient Investigational New Drug approval to perform bone marrow ablation prior to allogeneic marrow transplantation. In August 2021 the company received FDA Orphan Drug designation for use in osteosarcoma.

Douglas Baum, CEO of QSAM, said: “Combined with the orphan designation for osteosarcoma that we received last year from the FDA, the RPD Designation may allow QSAM to potentially bring CycloSam to market more rapidly through additional incentives and eligibilities that ultimately help these young patients for whom there is currently little hope. Patients with this disease are eligible to participate in our current Phase 1 clinical trial; however, we anticipate that we will initiate a separate clinical trial in the coming year specifically focused on primary bone cancers such as osteosarcoma and Ewing sarcoma. We are dedicated as a company to making a difference in the lives of children and their families battling these forms of bone cancer.”

The RPD designation, covering diseases defined by the FDA as primarily affecting <200,000 Americans under the age of 18 each year, can provide substantial financial incentives by making companies eligible for a Priority Review Voucher (PRV) upon drug approval by the FDA. A PRV grants accelerated FDA review of a drug candidate for any indication, reducing the review period to 6 mo and potentially gaining early market access. PRVs may be used by the recipient company for any drug development program or can be sold or transferred to larger pharmaceutical companies.

*QSAM Biosciences, Inc.
U.S. Food and Drug
Administration*