

NRC Advisory Committee on Medical Uses of Isotopes Spring Meeting

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The Nuclear Regulatory Commission (NRC) held the spring meeting of its Advisory Committee on Medical Uses of Isotopes (ACMUI) on March 7 and 8. The ACMUI typically has public meetings each year during the spring and fall and holds public teleconferences as needed. At the spring meeting, the ACMUI discussed several topics of importance to the nuclear medicine community, including worldwide supply and domestic production of ^{99}Mo and training and experience requirements.

Status of ^{99}Mo Availability

Richard Green, PhD, provided an update on global supply and domestic production of ^{99}Mo , including an update on reactors currently in production: the High-Flux Reactor (HFR; Petten, The Netherlands), Belgian Reactor 2 (BR2; Mol, Belgium), South Africa Fundamental Atomic Research Installation (SAFARI; Pelindaba, South Africa), MARIA (Otwock-Świerk, Poland), LVR-15 reactor (Řež, Czech Republic), and the Open Pool Australian Lightwater reactor (OPAL; Lucas Heights). Green reported that challenges remain with irradiator disruptions (such as extended unplanned shutdowns) and rising prices from the switch to low-enriched uranium. Through the American Medical Isotope Production Act of 2009, the Department of Energy is helping to support domestic production of ^{99}Mo . The U.S. Food and Drug Administration recently approved the first domestically produced nonuranium-based ^{99}Mo , with the RadioGenix system from NorthStar Medical Radioisotopes (Beloit, WI).

Training and Experience Requirements

During the NRC Commission meeting with ACMUI, Christopher Palestro, MD, presented ACMUI's comments on training and experience requirements for all modalities (35,300 uses). He provided a brief background on the subcommittee charge for reference. The subcommittee recently noted 2 significant developments that warrant concern. The first was the recent approval of ^{177}Lu -DOTATATE for treatment of somatostatin receptor-positive gastroen-



At the table at the March ACMUI meeting. Viewed from back, left to right: Laura Weil, patients' rights advocate; SNMMI Vice President-Elect Vasken Dilsizian, MD; and ACMUI Chair Philip Alderson, MD, health care administrator representative; viewed from front, left to right, NRC Commissioner Jeff Baran and NRC Chair Kristine Svinicki.

teropancreatic neuroendocrine tumors, including foregut, midgut, and hindgut. The ACMUI indicated that it believes that these broad indications to treat the second-most-common gastrointestinal tumor could result in potentially high demand for ^{177}Lu -DOTATATE. The second concern was the waning number of nuclear medicine physicians in the United States. As a result, the subcommittee is considering developing an alternate pathway for 10 CFR 35.390 ("Training for use of unsealed byproduct material for which a written directive is required") and will provide another update in fall 2018.