HFR Outage and Isotope Supply

The Nuclear Medicine Europe (NMEu) Emergency Response Team alerted its stakeholders on January 24 to a delay in the restart of the High-Flux Reactor (HFR) (Petten, The Netherlands) that was expected to affect the supply of ^{99}Mo and ^{177}Lu for medical uses. The reactor supplies 60% of the European demand for these isotopes and 30% of the worldwide need. According to the accompanying release, the NMEu was informed by the Nuclear Research and Consultancy Group (NRG), which operates the reactor, that the delay was the result of discovery of a water leak in the reactor beam tube cooling system. Neither workers nor the general public was said to be at risk, and the reactor remained in safe standby status pending investigation of the cause of the leak. Inspections of difficult-to-access piping were performed but were not informative. Additional inspections were planned, and the NRG project team was in place to identify remedial actions and enable the reactor to return to service after regulatory review and approval. Targets had been scheduled to be irradiated in the HFR reactor during the week of January 24 for both ^{99}Mo and ^{177}Lu production, and the delay affected the supply of these radioisotopes. Medical institutions were advised to contact their radioisotope suppliers to determine specific impacts on orders. On January 31, NRG provided an update and noted that investigators had listed options for restoring functionality and intended to select an approach in early February. A target date for HFR restart, however, could not be provided. Some shortages of ^{99}Mo/^{99m}Tc were termed inevitable, with additional reports of effects on supplies of ^{177}Lu and ^{131}I.

Nuclear Research and Consultancy Group

FDA Guidance on Patient Engagement in Medical Device Clinical Studies

On January 25 the U.S. Food and Drug Administration (FDA) issued 2 final guidance documents containing recommendations for including patient perspectives in medical device clinical studies. Drafts issued in 2019 were modified by public comment and expert input to create the final documents. "Patient Engagement in the Design and Conduct of Medical Device Clinical Studies" describes how device developers, sponsors, and industry can voluntarily use patient engagement to improve clinical study design and conduct; provides examples of approaches to consider when device developers, sponsors, and industry wish to incorporate patient advisor input in clinical studies; describes which patient engagement activities are generally not considered by the FDA to constitute an activity subject to FDA regulations regarding institutional review boards; and clarifies how sponsors can receive feedback from the FDA on plans to voluntarily include patient advisors' input on their clinical studies. The FDA encouraged patient engagement in medical device clinical studies in appropriate circumstances, but the recommendations are nonbinding. The document provides an overview of the potential value, challenges, and potential solutions related to involving patient advisors in the design and conduct of clinical studies. Entities considering incorporating such input in medical device clinical studies were encouraged to engage in early interactions with FDA and to obtain feedback from the relevant FDA office/division on appropriate design and any applicable regulatory requirements. The guidance states "FDA believes appropriate patient engagement may lead to improved efficiency and quality in the design and conduct of medical device clinical studies and greater uptake of results by patients and providers when making treatment decisions about a legally marketed medical device, ultimately leading to earlier U.S. patient access to beneficial medical devices."

The second guidance, "Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation," describes principles that may be considered for instruments that capture and measure patient-reported outcomes; provides recommendations about the importance of ensuring that these instruments are suited to the purposes to which they are applied; and outlines best practices for selecting, developing, modifying, or adapting a patient-reported outcome instrument for use in medical device evaluation. In the document summary, FDA noted that "to further integrate patient voices throughout the total product life cycle of medical devices, it is important to consider concepts important to patients in the regulatory evaluation and surveillance of medical devices. Well-designed patient-reported outcome instruments facilitate incorporating patient perspectives as scientific evidence to support regulatory and health care decision-making." The guidance is intended to help ensure that patient-reported outcome instruments are developed, modified, adapted, and used in evaluation of medical devices in ways that generate "relevant, reliable, and sufficiently robust data to assess outcomes of importance to patients, regulators, and health care providers."

U.S. Food and Drug Administration