

Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



Ron DeSantis
Governor

Joseph A. Ladapo, MD, PhD
State Surgeon General

Vision: To be the **Healthiest State** in the Nation

October 22, 2024

Bureau of Radiation Control
RADIOACTIVE MATERIALS SECTION
Information Notice 2024-01

Technetium 99m Shortage and the Calibration of Dose Calibrators

All nuclear pharmacy and medical licensee's radioactive materials licenses, require calibration of their dose calibrator with technetium-99m (Tc-99m) or any other readily available radionuclide. With the current shortage, if Tc-99m or other radionuclides are unavailable for non-patient use, licensees will not be found in violation of the dose calibrator linearity test requirements of 64E-5.614(4), Florida Administrative Code or any license condition having the same requirements as 64E-5.614(4), F.A.C., until the supplies of Tc-99m become more readily available or until the end of December 2024, whichever comes first.

All nuclear pharmacy licensees should share this information notice with their clients and advise them that they may obtain a copy directly from the Bureau of Radiation Control website located at FLHealth.gov/RAMforms.

Florida determined that this information notice was needed to provide for temporary relief from the dose calibrator linearity testing requirement due to a global shortage of Mo-99 to Tc-99m generators. On October 14, 2024, the industry association Nuclear Medicine Europe (NMEU) released a letter to their stakeholders stating that the Petten High Flux Reactor (HFR) located in Petten, Netherlands, would be delayed in their restart. Additionally, shortages could be as high as 40% without a specific planned restart date. This reactor provides the U.S. with a substantial amount of molybdenum-99 used in the production of technetium-99m. During these isotope production shortfalls, medical licensees should use available technetium-99m for patient studies instead of for dose calibrator testing.

Attachments:

10/14/2024 Communication from NMEU to EU Observatory for the Supply of Medical Radioisotopes.



Communication from NMEU to EU Observatory for the Supply of Medical Radioisotopes Restart Delay of the HFR Reactor

Brussels, 14 October 2024

The NMEU Emergency Response Team (ERT) met today to discuss a new update provided by NRG concerning the current delay in the restart of the HFR reactor originally planned for 10 October.

As previously communicated by NRG a technical solution was envisaged to be implemented in the December 2024 maintenance stop and is therefore in an advanced phase of development. The solution is however subject to a testing phase which is aimed at qualifying, amongst others, the materials used as part of the design. The qualification has not yet been successful. As long as this is not finalized, NRG cannot provide a planned start date and the current best estimate is that it will take at least a few weeks to finalize. Consequently, the start of the planned October cycle has become very unlikely. NRG will provide a new status update on late afternoon Friday October 18th.

The ERT meeting discussed possible modifications to the planned maintenance schedules of other reactors in order to mitigate the negative impact that will occur if the HFR cycle is cancelled. However, it appears unlikely that any significant changes are possible.

Nuclear Medicine Europe and NRG understand that there is likely to be a significant impact on the supply of medical radioisotopes in the coming weeks. We anticipate that shortages of Mo-99 to Tc-99m generator manufacturers will begin later this week and increase next week. Shortages could be as high as 40% of usual requirements though it will vary in different geographic regions with some areas experiencing little or no impact. It is advised that stakeholders communicate with their Tc-99m generator suppliers to understand the likely impact to each customer. Procedures used in past shortage situations should be reactivated including the use of alternate imaging modalities where appropriate.

Nuclear Medicine Europe will issue a new communication early the week of October 21 or earlier if significant new information becomes available.

SIGNED

Bernard Ponsard
Chairman SoS WG
Chairman ERT

Ira Goldman
Vice-Chairman SoS WG

The Emergency Response Team

For the Reactors:

For the Processors:

For the Generators:

By invitation

SOS Supervisor:

Rapporteur:

Bernard Ponsard, Chairman ERT, SCK CEN

Frank de Lange, Curium

Ira Goldman, LMI

Revital Melzer, GE Healthcare

Nil Neda Bedro, Monrol Europe

Ronald Schram, NRG

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Jayne Senior, ANSTO

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Erich Kollegger, IRE

Jocelyne Baldasso, NMEU

David Crunelle, NMEU