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Date: February 4, 2009
To: Radiopharmacy and Medical Licensees
From: Radioactive Materials Unit
Subject: Molybdenum-99 Breakthrough in Generators

Information Notice 2009-01

The Minnesota Department of Health is issuing this Information Notice to inform radiopharmacy licensees and medical licensees about elevated molybdenum-99 (Mo-99) breakthrough following the elution of generators. Minnesota Department of Health expects that recipients will review the information for applicability to their facilities and consider appropriate actions. However, the suggested actions contained in the Information Notice do not constitute requirements; therefore, the Minnesota Department of Health requires no specific action or written response.

The Nuclear Regulatory Commission has been informed of an unusual number of reports made by medical licensees to a generator manufacturer during the period of October 2006 through February 2007, and in January 2008, concerning increased concentrations of Mo-99 in generator eluates. A number of licensees reported that their generators have failed the Mo-99 breakthrough tests. The measurement exceeded the limit in the Minnesota Department of Health's Radioactive Materials Rule, 4731.4435, which is 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m).

Some licensees reported measurements for Mo-99 breakthrough that failed at the first elution, while other reported Mo-99 measurements were within regulatory limit at the first elution, but failure during subsequent elutions. The majority of the reports involved concentrations of Mo-99 that did not exceed the regulatory limit at the time of elution but, due to the decay rate of Tc-99m, the ratio of Mo-99 to Tc-99m would have exceeded the regulatory limit of 0.15 μCi of Mo-99 per mCi of Tc-99m before the 12 hours post elution expiration time stated in the generator package insert.

Licensees are required to measure the Mo-99 concentration of the first eluate after receipt of a generator. However, package inserts that accompanied each generator recommended that customers test each elution for Mo-99 breakthrough. These recent occurrences of Mo-99 breakthrough, especially those measurements that failed during subsequent elutions, emphasize the importance of following the manufacturer's package insert and testing each elution for breakthrough. The majority of the Minnesota Department of Health licensees using generators perform breakthrough tests at each elution.

The Nuclear Regulatory Commission concluded that the safety significance of administering Mo-99 at the concentrations that were reported to the manufacturer between October 2006 and February 2007, and in January 2008, was low. However, the administration of higher levels of molybdenum-99 could potentially affect health and safety, as well as have an adverse effect on nuclear medicine image quality and medical diagnosis.

The Nuclear Regulatory Commission is considering rulemaking to require Mo-99 breakthrough measurements of each elution to demonstrate compliance with the limit of 0.15 μCi of Mo-99 per mCi of Tc-99m, rather than just the first elution. The Nuclear Regulatory Commission is also considering rulemaking to require reporting of noncompliance with the concentration limit. Minnesota Department of Health believes that the both requirements are essential to protect public health and safety.

The Minnesota Department of Health strongly encourages all licensees who use a Mo-99/Tc-99m generator to:

- measure each eluate for Mo-99 breakthrough before Tc-99m is administered to humans;
- report any concentrations that exceed the regulatory limits described in 4731.4435 to Minnesota Department of Health; and
- to notify the generator manufacturer.