



Oregon

Theodore R. Kulongoski, Governor

Department of Human Service
Public Health Division
Environmental Public Health
Radiation Protection Service
800 NE Oregon Street, Suite 64
Portland, OR 97232-216
Voice 971-673-049
FAX 971-673-055
TTY 971-673-037

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INFORMATION BULLETIN 2009-01

To: Nuclear Pharmacies Licensees

From: Terry D. Lindsey, Manager
Radioactive Protection Services Section



Subject: Molybdenum-99 generator breakthrough concerns

On February 2, 2009, The State of Oregon, Radiation Protection Services received an information notice number 2008-22 from the U.S. Nuclear Regulatory Commission (USNRC) discussing elevated molybdenum-99 (Mo-99) breakthrough following the elution of generators. The USNRC became aware of an unusual number of reports concerning increased concentrations of Mo-99 in generator eluates made by medical licensees to a specific generator manufacturer during the period of October, 2006 through February, 2007, and in January, 2008. These medical licensees reported that their generators have failed the Mo-99 breakthrough tests exceeding the regulatory limit in Title 10 of the Code of Federal Regulations, Part 35, Section 35.204 (Oregon Administrative Rules - OAR 333-116-0330).

The U.S. NRC concluded that the safety significance of administering Mo-99 at the concentrations that were reported to the manufacturer 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 U.S. NRC 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 and to report any concentrations that exceed the regulatory limits described in the Federal Regulations to the generator manufacturer.

The U.S. NRC also encourages voluntary reporting by each generator manufacturer to the U.S. NRC.

The NRC staff is considering initiating rulemaking to require Mo-99 breakthrough measurements of **each** elution to demonstrate compliance with the limit of 0.15 uCi of Mo-99 per mCi of Tc-99m rather than the just the first elution.

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