

UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
OFFICE OF FEDERAL AND STATE MATERIALS  
AND ENVIRONMENTAL MANAGEMENT PROGRAMS  
WASHINGTON, D.C. 20555

January 12, 2009

NRC INFORMATION NOTICE 2008-22: MOLYBDENUM-99 BREAKTHROUGH IN  
MOLYBDENUM-99/TECHNETIUM-99M  
GENERATORS

## ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical, radiopharmacy, molybdenum-99/technetium-99m generator (generator) manufacturer, and master material licensees authorized to manufacture or use generators. All Agreement State radiation control program directors and State liaison officers.

## PURPOSE

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

The NRC is providing this IN to the Agreement States for their information, and for distribution to their medical, generator manufacturer, and radiopharmacy licensees, as appropriate.

## DESCRIPTION OF CIRCUMSTANCES

The NRC has become aware 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, i.e., the measurement exceeded the regulatory limit in Title 10 of the *Code of Federal Regulations*, Part 35, Section 35.204 (10 CFR 35.204), "Permissible molybdenum-99, strontium-82, and strontium-85 concentrations," of 0.15 kilobecquerel of Mo-99 per megabecquerel of Tc-99m (0.15 microcurie ( $\mu$ Ci) of Mo-99 per millicurie (mCi) of technetium-99m (Tc-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  $\mu$ Ci of Mo-99 per mCi of Tc-99m before the 12 hours post elution expiration time stated in the generator package insert.

**ML082480153**

## DISCUSSION

10 CFR Part 35, Section 35.204(b) requires licensees 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 NRC 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 NRC staff will consider initiating a rulemaking to require Mo-99 breakthrough measurements of each elution to demonstrate compliance with the limit of 0.15  $\mu$ Ci of Mo-99 per mCi of Tc-99m, rather than just the first elution. The NRC will also consider initiating a rulemaking to require reporting of noncompliance with the concentration limit. In the interim, the 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 10 CFR 35.204(a) to the generator manufacturer. NRC also encourages voluntary reporting by each generator manufacturer to the NRC of notifications provided to them by medical licensees who have measured concentrations of Mo-99 in the generator eluate that exceed the regulatory limits described in 10 CFR 35.204(a).

## CONTACT

This IN requires no specific action or written response. Please direct any questions to the technical contact(s) listed below.

**/Terrence Reis for /**

Robert J. Lewis, Director  
Division of Materials Safety and State Agreements  
Office of Federal and State Materials  
and Environmental Management Programs

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Enclosure: List of Recently Issued NRC Office of Federal and State Material and Environmental Management Programs (FSME) Generic Communications

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**R/A**

Robert J. Lewis, Director  
Division of Materials Safety and State Agreements  
Office of Federal and State Materials  
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<b>OFC</b>	FSME:DMSSA	FSME:DMSSA	FSME:DMSSA	Tech Ed (QTE)	RIII:DNMS
<b>NAME</b>	AMcIntosh	CFlannery	CEinberg	HSpencer	PPelke
<b>DATE</b>	9/04/08	09/22/08	11/12/08	10/31/08	09/02/08
<b>OFC</b>	RIII:DNMS	OGC - NLO	FSME:DMSSA		
<b>NAME</b>	SReynolds	BJones	RLewis		
<b>DATE</b>	09/02/08	11/19/08	01 /12/09		

<b>List of Recently Issued NRC Office of Federal and State Material and Environmental Management Programs Generic Communications</b>			
<b>Date</b>	<b>GC No.</b>	<b>Subject</b>	<b>Addressees</b>
05/13/08	RIS-2008-10	Notice Regarding Forthcoming Federal Firearms Background Checks	All U.S. Nuclear Regulatory Commission licensees, certificate holders, and applicants for a license or certificate of compliance who use armed security personnel as part of their physical protection system and security organization. All radiation control program directors and State liaison officers
05/12/08	RIS-2008-11	Precautions to Protect Children Who May Come in Contact with Patients Released After Therapeutic Administration of Iodine-131	All U.S. Nuclear Regulatory Commission medical-use licensees, master material licensees, Agreement State radiation control program directors, and State liaison officers
05/09/08	RIS-2008-12	Considerations for Extended Interim Storage of Low-level Radioactive Waste by Fuel Cycle and Materials Licensees	All holders of U.S. Nuclear Regulatory Commission fuel cycle and materials licenses. All radiation control program directors and State liaison officers
06/16/08	RIS-2008-13	Status And Plans for Implementation of NRC Regulatory Authority for Certain Naturally Occurring and Accelerator-Produced Radioactive Material	All U.S. Nuclear Regulatory Commission materials licensees, radiation control program directors, State liaison officers, and the NRC's Advisory Committee on the Medical Uses of Isotopes
07/18/08	RIS-2008-17	Voluntary Security Enhancements for Self-Contained Irradiators Containing Cesium Chloride Sources	All U.S. Nuclear Regulatory Commission materials licensees authorized to possess self-contained irradiators containing cesium chloride (CsCl) ; all Agreement State radiation control program directors and State liaison officers; all members of the Advisory Committee on the Medical Uses of Isotopes
05/16/08	IN-2008-03	Precautions to Take Before Sharing Sensitive Security-Related Information	All U.S. Nuclear Regulatory Commission licensees who are implementing U.S. Nuclear Regulatory Commission's Order Imposing Increased Controls (IC Order) or implementing IC requirements by license condition; all Agreement State radiation control program directors and State liaison officers
<p>Note: This list contains the six most recently issued generic communications, issued by the NRC Office of Federal and State Materials and Environmental Management Programs (FSME). A full listing of all generic communications are available on the NRC public Web site at the following address: <a href="http://www.nrc.gov/reading-rm/doc-collections/gen-comm/index.html">http://www.nrc.gov/reading-rm/doc-collections/gen-comm/index.html</a></p>			