

**Re: IRI-09-01**

**MARYLAND ENDORSEMENT OF NRC “EXEMPTION FROM 10 CFR PART 32 AND 10 CFR PART 35 REQUIREMENTS ON PROCUREMENT AND TRANSFER OF TECHNETIUM-99M, AND CALIBRATION OF INSTRUMENTATION USING TECHNETIUM-99M”**

Dear Title and Name:

The Maryland Department of the Environment’s (MDE) Radiological Health Program (RHP) is issuing this Information and Regulatory Interpretation Notice (IRI) 08-09 to inform diagnostic medical licensees of RHP’s endorsement of the July 16, 2009 United States Nuclear Regulatory Commission’s exemption titled, “**EXEMPTION FROM 10 CFR PART 32 AND 10 CFR PART 35 REQUIREMENTS ON PROCUREMENT AND TRANSFER OF TECHNETIUM-99M, AND CALIBRATION OF INSTRUMENTATION USING TECHNETIUM-99M.**” In Maryland the exemption will be specific to COMAR 26.12.01.01 Part C and Part G requirements.

The recent shutdown of key nuclear reactors has demonstrated the fragility of molybdenum-99 production and has resulted in a current shortage and potential future shortage of technetium-99m. The reality of aging reactors has prompted the Nuclear Regulatory Commission to publish exemptions to 10 CFR Parts 32 and 35 concerning the transport of Technetium-99m and the performance of dose calibrator linearity. The Radiological Health Program has decided to allow Maryland licensees affected by the technetium-99m shortage to be covered by these exemptions, with the caveat that those licensees fully understand the licensing and documentation requirements needed to implement the exemptions.

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The NRC exemption document (attached) should be carefully examined for application to your licensed activities. A basic summary of the exemptions as applied in Maryland is listed below:

**1. Transportation of Technetium-99m or Technetium-99m**

Transportation of technetium-99m and technetium-99m radiopharmaceuticals is allowed between medical licensees, and licensees are exempted from commercial distribution regulations. **This exemption applies in times of shortages only, and the material must be prepared and transported in accordance with radioactive**

**materials transportation requirements using adequate shielding, appropriate containers, and the proper shipping labels. Proper documentation must be maintained.**

**2. Dose Calibrator Linearity**

Quarterly dose calibrator linearity may be postponed if certain conditions are met:

- a. **The licensee must request an amendment to the license requesting the exemption from performing quarterly linearity if a shortage prevents it, but with the provision that as soon as technetium should become available, the linearity will be performed.**
- b. The supplier must provide documentation to the licensee that the supplier is unable to provide technetium -99m for linearity.
- c. Time-dependent linearity can be performed with reduced activity in times of shortage.
- d. Time-dependent linearity can be postponed until sufficient activity can be obtained.
- e. Time-dependent linearity must be performed as soon as the supplier is able to provide sufficient activity
- f. Those with lead-sleeved linearity devices should be able to perform linearity measurements and use the technetium-99m used for performing linearity for patient dosing.

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Exemptions to the COMAR 26.12.01.01 Section G.60.B(b)(3) will be examined during inspections. Should you have any questions regarding this information notice, please contact Barbara Park or me at (410) 537-3301. You may also reach our office toll-free by dialing 1-800-633-6101 and requesting extension 3301. Also, you may contact this office via facsimile at (410) 537-3198.

Sincerely,

Raymond E. Manley, Chief  
Radioactive Material Licensing  
Compliance Division  
Air and Radiation Management Administration

Radioactive Material Use Codes: 02110, 02120, 02201, 02220, and 02200

Enclosure(s): NRC Exemption Notice dated July 16, 2009 titled, "EXEMPTION FROM 10 CFR PART 32 AND 10 CFR PART 35 REQUIREMENTS ON PROCUREMENT AND TRANSFER OF TECHNETIUM-99M, AND CALIBRATION OF INSTRUMENTATION USING TECHNETIUM-99M.