UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 16, 2009

All 10 CFR Part 35 Licensees, Including
United States Nuclear Regulatory Commission (NRC)
Master Materials License 10 CFR Part 35 Permitees

SUBJECT: 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

NRC is issuing the enclosed Exemption from certain provisions in 10 CFR Parts 32 and 35 to all NRC medical use licensees, including NRC Master Materials License medical use permittees, during times of molybdenum-99 shortages in the United States. The intent of the Exemption is to assure that the available technetium-99m is used for patient administrations.

The supply chain for fission-produced medical isotopes is fragile and may shrink dramatically at any time when the aging international reactors that currently produce these isotopes are shut down for safety or routine maintenance. Therefore, this Exemption may be needed intermittently until the supply of molybdenum-99 permanently stabilizes. The Exemption should be kept with the license and discussed with the licensee's radiation safety officer and authorized users. The Exemption can only provide relief from the regulations; it does not provide relief from specific license conditions. Contact the Regional Office if you believe that there are license conditions that also affect the availability of technetium-99m for patient treatments or if there are any questions about the Exemption.

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and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Enclosure: Exemption

July 16, 2009

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of

All 10 CFR Part 35 Licensees, including NRC Master Materials Licensee 10 CFR Part 35 Permittees

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

I. INTRODUCTION

All 10 CFR Part 35 licensees, including NRC Master Materials License 10 CFR Part 35 permittees, are authorized for the medical use of byproduct material.

II. DISCUSSION

On May 14, 2009, the Chalk River National Research Universal reactor in Canada experienced an unexpected shutdown that has resulted in an extended shutdown for safety repairs. The Chalk River reactor produces approximately 50 percent of the United States supply of molybdenum-99 used to produce molybdenum-99/technetium-99m generators. This resulted in a United States and worldwide shortage of molybdenum-99 for generator production and technetium-99m for medical uses. The High Flux Reactor in Petten, Netherlands, also produces a substantial amount of molybdenum-99 used to produce generators in the United States and the world. The reactor in Petten is currently operating on a temporary operating permit and expected to be shutdown in early 2010 for a number of months for repairs. This will also cause molybdenum-99 and technetium-99m shortages in the United States and the world. The supply chain for fission-produced isotopes is fragile and may shrink dramatically at any time when these two, or the other three aging international reactors currently producing these isotopes, are shut down for safety or routine maintenance.

The NRC is issuing exemptions from certain of its requirements in 10 CFR 32.72, 10 CFR 35.60(b); and 10 CFR §§ 35.100(a)(1) and 35.200(a)(1), governing the sourcing and transfer of technetium-99m, and calibration of devices using technetium-99m. Each of these exemptions and the safety bases for exempting the licensee from these requirements is discussed below.

10 CFR 32.72

10 CFR 32.72 specifies the requirements for manufacturing and preparing radioactive drugs distributed to 10 CFR Part 35 licensees. Licenses issued pursuant to this regulation are for commercial distribution of radioactive drugs to medical use licensees. Exempting the medical

use licensee from the requirements in 10 CFR 32.72 permits the medical use licensee to transfer surplus molybdenum-99/technetium-99m generators or technetium-99m, or technetium-99m radioactive drugs, to other medical use licensees for administration to patients without requiring the licensee to meet the requirements for a commercial distributor of radioactive drugs. During times of technetium-99m shortages, this exemption will facilitate the transfer of surplus from a licensee that does not need it to one with patients that need technetium-99m procedures. The material has to be prepared and transported in accordance with the radioactive materials transportation requirements using adequate shielding, appropriate containers, and the proper radioactive shipping labels. Further, the activities and short half-lives of the molybdenum-99 and technetium-99m make it highly unlikely that granting this exemption will endanger life or property or common defense and security. The exemption is in the public interest because it makes needed radioactive material available for necessary patient treatment.

10 CFR 35.60(b)

10 CFR 35.60(b) requires licensees to calibrate instrumentation required in paragraph (a) of section 35.60 in accordance with nationally recognized standards. National standards specify that instruments used to measure patient dosages are checked for linearity at the maximum activities measured. The maximum activity may be for multidose vials, generator elutions, or high activity dosages of technetium-99m or other radionuclides, such as iodine-131. The calibration tests are most frequently performed with technetium-99m because it is normally easy to obtain from suppliers and has a short half-life. Under the exemption, the licensee will not be required to perform the calibration test at the maximum activity or at the time interval specified in the national standard if the licensee would use technetium-99m that is needed to administer to a patient to perform the calibration test. The exemption will only be in effect when the licensee is receiving reduced quantities of technetium-99m as a result of production shortages of molybdenum-99 affecting its generator or technetium-99m supplier, as documented in writing by the supplier. The licensee must perform the test when adequate supplies become available, and must document the results of the test in accordance with 10 CFR 35.2060. During shortage periods, it is expected that the licensee will perform the test with lower activities if the test can be performed using material that is either not needed for patient administration or at the completion of the test can still be used for patient administration. In this case, the licensee will have confidence that over those ranges the instrument is still operational and calibrated. In times of extreme shortage, the licensee may have to postpone performing the test altogether. Most instruments used to measure patient dosages today are stable if not moved and provided with reasonable climate controls. Not granting the exemption will make fewer dosages available to patients and result in licensees not being able to use these instruments even though they are calibrated at the levels of routine technetium-99m dosages. Once adequate supplies become available and the licensee performs the tests in accordance with the national standards, the instruments that pass the calibration test at that time can be assumed to have been calibrated while the exemption was in effect. The world supply of molybdenum-99 is very fragile because it depends on aging reactors that may be shut down for safety or maintenance at any time. Therefore, because of the uncertainty of continued availability, the test must be performed as soon as adequate supplies are available, as indicated in the provisions of the exemption. The test must not be postponed to the next specified time interval, to avoid conflict with a subsequent shortage. For higher dosages requiring written directives the licensee will have to depend upon the activity provided with the

radioactive drug to assure patient safety associated with the administration. The exemption will not endanger life or property or common defense and security because it does not relieve the licensee from NRC requirements for worker dose or public dose, handling or securing the radioactive materials, or handling or securing radioactive waste associated with performing the test. All of those protections remain in place. Also, both molybdenum-99 and technetium-99m have short half-lives and the proposed exemption does not affect how the licensee handles these radionuclides. The exemption is in the public interest because it provides for performing calibration test at levels of activity being used, makes needed technetium-99m available to patients, and assures that when the supplies of technetium-99m become available, the calibration is performed in accordance with national standards.

10 CFR 35.100(a)(1) and 10 CFR 35.200(a)(1)

10 CFR 35.100(a)(1) and 35.200(a)(1) require medical use licensees to obtain unsealed byproduct material prepared for medical use for uptake, dilution, excretion, imaging or localization studies from a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements. The exemption would permit the licensee to obtain the technetium-99m (or a technetium-99m radioactive drug) from another medical use licensee to administer to patients. This permits medical use licensees with patients that need technetium-99m procedures that cannot get technetium-99m from their normal supplier because of the shortage to obtain the needed technetium-99m from a local medical use licensee that has a surplus. This exemption will only be in effect when the licensee is unable to obtain technetium-99m (or a technetium-99m radioactive drug) from its normal supplier as a result of production shortages of molybdenum-99 affecting its generator or technetium-99m supplier, as documented in writing by the supplier. This exemption will give some relief on a case-by-case basis to a medical use licensee if its supplier is severely affected by the shortage but the other medical use licensee supplier is not. The activities and short half-lives of the molybdenum-99 and technetium-99m make it highly unlikely that granting this exemption will endanger life or property or common defense and security. The exemption is in the public interest because it makes needed radioactive material available for necessary patient treatment.

10 CFR 30.11 authorizes the NRC to issue exemptions from the requirements of, *inter alia*, 10 CFR Parts 32 and 35. For the reasons set forth above, the Commission concludes that exemptions from the NRC requirements in 10 CFR 32.72, 10 CFR 35.60(b); and 10 CFR §§ 35.100(a)(1) and 35.200(a)(1), as set forth below, are authorized by law and will not endanger life or property or the common defense and security, and are in the public interest.

III. EXEMPTION

1. Notwithstanding the requirements in 10 CFR 35.60(b) to calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards, the licensee is not required to perform the calibration test at the maximum activity or at the time interval specified in the national standard if: (i) the licensee would use technetium-99m that is needed to administer to a patient to perform the test; (ii) the licensee certifies in writing that the quantities of technetium-99m that it is receiving from it supplier is less than what the licensee has ordered or procured and is not sufficient to perform the test in accordance with the national standard; and (iii) the licensee's supplier provides written documentation, that the supplier is

providing reduced quantities of technetium-99m to the licensee as a result of production shortages of molybdenum-99 affecting its generator or technetium-99m. **[NOTE: IF THERE IS A CALIBRATION LICENSE CONDITION, THE LICENSEE NEEDS TO TAKE AN ACTION TO AMEND THE CONDITION TO ALLOW THE CHANGE IN CALIBRATION; THE EXEMPTION BY ITSELF WILL NOT ALLOW THE LICENSEE TO ACCOMPLISH THESE ACTIONS]** The licensee must perform the calibration test as soon as adequate supplies become available, and document results of the test in accordance with 10 CFR 35.2060. If adequate supplies become available, the licensee cannot defer performing the tests until the next time interval. The licensee shall maintain records of its certification and the underlying documentation supporting the licensee's certification, and the supplier's written documentation for 3 years.

2. Notwithstanding the requirements in 10 CFR 35.100(a)(1) and 35.200(a)(1) to obtain unsealed byproduct material prepared for medical use for uptake, dilution, excretion, imaging or localization studies from a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements, the licensee may obtain technetium-99m, or dosages of technetium-99m radioactive drugs, from another NRC-licensed medical use licensee to administer to patients when the licensee is unable to obtain technetium-99m (or unit dosage of a technetium-99m radioactive drug) from its normal supplier as a result of production shortages of molybdenum-99 affecting its generator or technetium-99m supplier, as documented in writing by the supplier. The licensee shall certify in writing that it is receiving reduced qualities of technetium-99m from its supplier and did not have enough to provide the administration(s). The licensee shall maintain a record of the transfer, its certification and the underlying documentation supporting the licensee's certification, and the supplier's certification for 3 years.

3. Notwithstanding the requirements in 10 CFR 32.72, the licensee may transfer surplus technetium-99m, or dosages of technetium-99m radioactive drugs, to other medical use licensees licensed by the NRC, for administration to patients, but only after the licensee obtains from the receiving medical use licensee a written certification that it is unable to obtain a generator, or technetium-99m or unit dosages of a technetium-99m radioactive drug from its normal supplier as a result of production shortages of molybdenum-99 affecting its generator or technetium-99m supplier. The licensee shall maintain a record of the transfer and the receiving licensee's certification for 3 years.

4. Nothing in this exemption relieves the licensee from complying with the requirements in 10 CFR 35.7.

5. This exemption is effective upon issuance and during periods of United States shortages of molybdenum-99 and technetium-99m as documented in writing by the suppliers of molybdenum-99/technetium-99m generators and technetium-99m radioactive drugs.

6. This exemption should be kept with the license and discussed with the licensee's Radiation Safety Officer and Authorized Users.

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