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DEPARTMENT OF HEALTH  
AND ENVIRONMENT

[www.kdheks.gov](http://www.kdheks.gov)

Division of Health

July 27, 2009

KANSAS INFORMATION NOTICE      09-01  
TECHNETIUM-99m GUIDANCE

### Addressees

This notice is addressed to all Kansas radioactive materials licensees who use Technetium-99m for medical use.

### Purpose

The purpose of this notice is to inform licensees of that the Kansas Department of Health and Environment Radiation Control Program intends to exercise its authority to use enforcement discretion from certain requirements of the Kansas Radiation Protection Regulations with respect to procurement and transfer of technetium-99m (Tc-99m) and the calibration of instrumentation using Tc-99m.

This enforcement discretion will be based on the conditions specified in the exemption published by the Nuclear Regulatory Commission (NRC) on 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](#).

### Description of Circumstances

Due to existing and anticipated supplier problems, the availability of technetium-99m is expected to decrease significantly creating shortages worldwide. The NRC has issued an exemption that will reduce the amount of technetium-99m needed for calibration and allow licensees to obtain technetium-99m from alternate suppliers should their normal supplier be unable to fulfill the needs of the license. To receive consideration for enforcement discretion, licensees shall follow the guidance listed below.

1. Notwithstanding the requirements in 10 CFR 35.60(b) as adopted by reference in K.A.R. 28-35-364, to calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards, the licensee is not

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required to perform the calibration test at the maximum activity or at the time interval specified in the national standard if:

- a. the licensee would use technetium-99m that is needed to administer to a patient to perform the test;
- b. the licensee certifies in writing that the quantities of technetium-99m that it is receiving from its 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
- c. 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 supplier.

[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 as adopted by reference in K.A.R. 28-35-364. 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) as adopted by reference in K.A.R. 28-35-364, to obtain unsealed byproduct material prepared for medical use for uptake, dilution, excretion, imaging or localization studies from a manufacturer or preparer licensed under the Kansas Radiation Protection Regulations or equivalent NRC or Agreement State requirements, the licensee may obtain technetium-99m, or dosages of technetium-99m radioactive drugs, from another 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 quantities 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 K.A.R. 28-35-180m and 28-35-280n, the licensee may transfer surplus technetium-99m, or dosages of technetium-99m radioactive drugs, to other medical use licensees, 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 relieves the licensee from complying with other requirements of the Kansas Radiation Protection Regulations or other regulatory agencies.
5. This guidance 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 for human use.
6. This guidance should be kept with the license and discussed with the licensee's Radiation Safety Officer and Authorized Users.
7. The licensee shall notify the Department when Tc-99m supply shortages require the application of this guidance.

If you have any questions please feel free to contact our office.