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Division of Environmental Health

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RADIOACTIVE MATERIALS BRANCH

INFORMATION NOTICE 09-01

TO: Radioactive Materials Licensees Authorized for Medical Use of Radiopharmaceuticals Containing Technetium 99m for Uptake, Dilution and Excretion and Imaging and Localization Diagnostic Studies

FROM: W. Lee Cox, III, Acting Chief, Radiation Protection Section

DATE: July 20, 2009

RE: Exemption from 15A NCAC 11.0359(a)(2), 15A NCAC 11.0361(a), and 15A NCAC 11.0333 as permitted by 15A NCAC 11.0106(a).

I. CHANGES

During national shortages of technetium 99m (Tc-99m) and/or molybdenum 99/technetium 99m generators (Mo-99/Tc-99m generators) in the United States, part of the limited supply of Tc-99m necessary for medical use must be used for instrument quality assurance and quality control. This information notice provides an exemption to the rules and specific license conditions, where they exist, requiring dose calibrator calibration and permits the transfer of Tc-99m between medical use licensees for use on human patients.

II. IMPLEMENTATION

This notice is effective as of July 20 and thereafter, during national shortages of Tc-99m and/or Mo-99/T-99m generators in the United States, as documented in writing by the suppliers of Tc-99m and/or Mo-99/T-99m generators.

III. GUIDANCE

A. Notwithstanding the requirements in 15A NCAC 11.0359(a)(2) to calibrate dose calibrators in accordance with nationally-recognized standards or the manufacturer's instructions (10 CFR 35.60(b)), the licensee is not required to perform dose calibrator calibrations at the maximum activity or at the time interval specified in the national standard, the manufacturer's instructions, or specific license condition on their North Carolina medical use license, if:

- i. the licensee has not repaired, replaced or moved the dose calibrator since the last time it was calibrated and has reasonable assurance that the dose calibrator is functioning properly at the time of use;
- ii. the licensee would use Tc-99m that is needed to administer to patients to perform the calibration;
- iii. the licensee certifies in writing that the quantities of Tc-99m that the licensee is receiving from its supplier is less than what the licensee has ordered or sought to procure, and is not sufficient to

- perform the calibration in accordance with the national standard, the manufacturers instructions or specific license condition while providing the quantity of Tc-99m necessary for patient care; and
- iv. the licensee's supplier provides written documentation to the licensee that the supplier is providing reduced quantities of Tc-99m, or is unable to supply a Mo-99/Tc-99m generator, to the licensee as a result of production shortages of Mo-99 affecting its Tc-99m or Mo-99/Tc-99m generator production.

The licensee shall maintain records of A.i, ii, iii and iv-, above, for three years following the creation of the record, and make these records available for inspection by the Radiation Protection Section.

Note: The licensee must perform any scheduled dose calibrator calibrations not done under this exemption as soon as adequate supplies of Tc-99m or Mo-99/Tc-99m generators become available, and document the results of the calibration in accordance with 15A NCAC 11 .0359(b). Dose calibrator calibrations cannot be deferred until the next time they are 'due' on the licensee's schedule if a previous scheduled calibration was missed under this exemption.

- B. Notwithstanding the requirements in 15A NCAC 11 .0361(a) to obtain unsealed radioactive material prepared for medical use for uptake, dilution, excretion, imaging or localization studies from a manufacturer or preparer licensed under 15A NCAC .0333, or equivalent federal or Agreement State regulations governing the manufacture and distribution of radiopharmaceuticals, the medical use licensee may obtain Tc-99m or unit-doses of Tc-99m radioactive drugs (Tc-99m unit doses) from any other medical use licensee to administer to human patients if:
 - i. the licensee is unable to obtain Tc-99m and/or Tc-99m unit doses, from its normal radiopharmaceutical supplier because of production shortages of Tc-99m or Mo-99/Tc-99m generators;
 - ii. the licensee's supplier provides written documentation to the licensee that the radiopharmaceutical supplier is providing reduced quantities of Tc-99m and/or Tc-99m unit doses to the licensee as a result of production shortages of Mo-99 affecting its Tc-99m or Mo-99/Tc-99m generator production;
 - iii. the licensee certifies in writing that it is receiving reduced quantities of Tc-99m and/or Tc-99m unit doses from its radiopharmaceutical supplier and did not have enough to perform required medical administration(s) and calibration of its dose calibrator(s); and;
 - iv. the licensee maintains a record of all transfers of Tc-99m and/or Tc-99m unit doses.

The licensee shall maintain records of B.i, ii, iii and iv-, above, for three years following the creation of the record, and make these records available for inspection by the Radiation Protection Section.

- C. Notwithstanding the requirements in 15A NCAC 11 .0333, licensees may transfer (hereinafter the transferor) Tc-99m or Tc-99m unit doses to any other medical use licensee (hereinafter the transferee) licensed by the State of North Carolina, the NRC or any other Agreement State, in accordance with 15A NCAC 11 .0343, for administration to human patients, if:
 - i. the transferor obtains written certification from the transferee that the transferee is unable to obtain a Mo-99/Tc-99m generator, Tc-99m, or Tc-99m unit doses from its normal radiopharmaceutical supplier as a result of production shortages of Mo-99 affecting its Tc-99m or Mo-99/Tc-99m generator supplier;

- ii. the transferor verifies the transferee's authorization to possess the radioactive material being transferred prior to the transfer of radioactive material as required by 15A NCAC 11 .0343(d) through one or more of the means list in 15A NCAC 11 .0343(e);
- iii. except for physicians exempted by 15A NCAC 11 .0316(b)(2), the transferor prepares and packages the radioactive material for transport in accordance with 15A NCAC .0346; and,
- iv. the transferor maintains a record of all transfers of Tc-99m and/or Tc-99m unit doses to other medical use licensees.

The licensee shall maintain records of C.i, ii, iii, and iv, above, for three years following the creation of the record, and make these records available for inspection by the Radiation Protection Section.

Nothing in this exemption relieves the licensee from complying with other applicable federal and state requirements governing the receipt, possession, use, storage or disposal of radioactive drugs or radioactive materials.

This exemption should be discussed by the licensee with the licensee's radiation safety officer and authorized users. It should be maintained with the licensee's license and program records.

Applicable regulatory citations: 15A NCAC 11 .0106(a), .0316(b)(2), .0318(p), .0318(w), .0318(x), .0333, .0343, .0346, .0359 and .0361