NEBRASKA

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DEPT. OF HEALTH AND HUMAN SERVICES

Jim Pillen, Governor

TO: Medical Licensees

FROM: Becki Harisis, Manager
Radiation Control Program

DATE: November 1, 2024

SUBJECT: EXEMPTION FROM 180 NAC 3 AND 180 NAC 7 REQUIREMENTS ON PROCUREMENT AND TRANSFER OF TECHNETIUM-99m, AND CALIBRATION OF INSTRUMENTATION USING TECHNETIUM-99m

Under the authority granted by Nebraska Revised Statute § 71-3507(4), the Department of Health and Human Services is issuing exemptions from 180 Nebraska Administrative Code (NAC) 7-029, 180 NAC 3-014.01, 180 NAC 7-041, and 180 NAC 7-044 to all Nebraska medical use licensees during times of molybdenum-99 shortages affecting the United States. The intent of these exemptions is to make needed technetium-99m available to patients.

As of October 2024, the supply of technetium-99m in the United States is anticipated to be at only 30% of the normal supply due to an unexpected shutdown of global suppliers of molybdenum-99. Therefore, these exemptions may be needed intermittently until the supply of molybdenum-99 stabilizes. These exemptions cover the procurement, transfer, and dose calibrator requirements of Diagnostic Nuclear Medicine. These exemptions should be kept with the license and discussed with the licensee's radiation safety officer and authorized users. These exemptions only provide relief from the regulations; **it does not provide relief from specific license conditions.**

Contact the Department 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 exemptions.

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Enclosure: Exemption

November 1, 2024

STATE OF NEBRASKA

Department of Health and Human Services

In the Matter of: All medical use licensees under 180 NAC 7

EXEMPTION FROM 180 NAC 3 AND 180 NAC 7 REQUIREMENTS ON PROCUREMENT AND TRANSFER OF TECHNETIUM-99m, AND CALIBRATION OF INSTRUMENTATION USING TECHNETIUM-99m

The Department of Health and Human Services (the Department) is issuing exemptions from certain requirements in 180 NAC 7-029, 180 NAC 3-014.10, 180 NAC 7-041, and 180 NAC 7-044, governing the calibration of devices using technetium-99m, and sourcing and transfer of technetium-99m. Each of these exemptions and the safety basis for exempting the licensee from these requirements is discussed below.

RATIONALE

180 NAC 3-014.10

180 NAC 3-014.10 specifies the requirements for manufacturing and preparing radioactive drugs distributed to 180 NAC 7 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 180 NAC 3-014.10 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 must be prepared and transported in accordance with the radioactive materials transportation requirements using adequate shielding, appropriate containers, and the proper radioactive shipping labels.

This exemption is in the public interest because it makes needed radioactive material available for necessary patient treatment.

180 NAC 7-029

180 NAC 7-029 requires licensees to calibrate the instrumentation in accordance with nationally recognized standards. 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 180 NAC 7-091. 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.

Once adequate supplies become available and the licensee performs the test 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. 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.

This 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.

180 NAC 7-041 and 180 NAC 7-044

180 NAC 7-041 and 180 NAC 7-044 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 180 NAC 3-014.10 or equivalent Nuclear Regulatory Commission or 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 to obtain needed technetium-99m from a local medical use licensee that has a surplus. This exemption will only be in effect when a 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.

These exemptions will not constitute a significant risk to public health because they do not relieve licensees from the Department requirements regarding worker dose or public dose, handling or securing the radioactive materials, or handling or securing radioactive waste associated with performing the test. Further, the activities and short half-lives of the molybdenum-99 and technetium-99m mean these exemptions will not cause a significant risk to public health and safety.

180 NAC 1-003.01 authorizes the Department to issue exemptions from the requirements of Title 180 as it determines are authorized by law and will not result in undue hazard to public health and safety of property. For the reasons above, the Department concludes that exemptions from the regulations found in 180 NAC 3-014.10, 180 NAC 7-029, and 180 NAC 7-041 and 180 NAC 7-044, as set forth below, are authorized by law and will not endanger life or property and are in the public interest.

EXEMPTIONS

I. Notwithstanding the requirements in 180 NAC 7-029, 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.

The licensee must perform the calibration test as adequate supplies become available, and document results of the test in accordance with 180 NAC 7-091. 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.

II. Notwithstanding the requirements in 180 NAC 7-041 and 180 NAC 7-044, 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 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.

III. Notwithstanding the requirements in 180 NAC 3-014.10, a licensee may transfer surplus technetium-99m, or dosages of technetium-99m radioactive drugs, to other medical use licensees, for administration to patients after the transferring licensee obtains 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 from the receiving medical use licensee. The licensee shall maintain a record of the transfer and the receiving licensee's certification for 3 years.

Nothing in these exemptions relieve licensees from complying with the requirements in 180 NAC 7-005. These exemptions are 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.

These exemptions should be kept with the license and discussed with the licensee's Radiation Safety Officer and Authorized Users.