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

January 24, 2024

MEMORANDUM TO: Anne DeFrancisco, Chief
Medical and Licensing Assistance Branch
Division of Radiological Safety and Safety
Region I

Robert Orlikowski, Chief
Materials Licensing Branch
Division of Radiological Safety and Safety
Region III

Neil O'Keefe, Chief
Materials Licensing Branch
Division of Radiological Safety and Safety Region IV

FROM: Chris Einberg, Chief
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Office of Nuclear Materials Safety and Safeguards

Signed by Einberg, Christian on 01/24/24

SUBJECT: LICENSING FOR TECHNEGAS AEROSOL AND TECHNEGAS PLUS SYSTEM

In September 2023, the U.S. Food and Drug Administration (FDA) approved Technegas® aerosol for oral inhalation use. Technegas aerosol is a technetium-99m (Tc-99m) labeled carbon inhalation aerosol used as a diagnostic agent for ventilation studies. The aerosol is prepared in the Technegas Plus System by heating up a Technegas crucible loaded with Tc-99m sodium pertechnetate. The recommended Tc-99m sodium pertechnetate activity to be loaded to the crucible is between 200 MBq and 900 MBq (5.4 mCi to 24.3 mCi), with a concentration between 2000 MBq/mL and 9000 MBq/mL. As the Technegas aerosol is prepared in the Technegas Plus System immediately prior to administration to a patient, the U.S. Nuclear Regulatory Commission (NRC) staff reviewed the safety and regulatory aspects of the medical use to determine its appropriate licensing pathway.

Through its evaluation, the NRC staff determined that the radiation safety concerns associated with preparing and using the Technegas aerosol are similar to other unsealed byproduct materials used for imaging studies for which a written directive is not required. Therefore, the NRC staff is recommending that the Technegas aerosol be licensed under Title 10 of the *Code of Federal Regulations* (10 CFR) 35.200, "Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required."

As the Technegas aerosol is prepared at the licensee facility in the Technegas Plus System, it must be prepared by one of the authorized individuals listed in 10 CFR 35.200(b). Licensees may allow individuals to prepare the Technegas aerosol under the supervision of an authorized

nuclear pharmacist (ANP) or authorized user (AU) as allowed in 10 CFR 35.200(b)(3). As specified in 10 CFR 35.27(b), the licensee is required to instruct the supervised individual in the preparation of the Technegas aerosol for medical use, as appropriate to that individual's involvement with byproduct material. The licensee must also require that the supervised individual follow the instructions of the supervising AU or ANP regarding the preparation of the Technegas aerosol, written radiation protection procedures established by the licensee, the regulations of this chapter, and license conditions, as appropriate. Unless the AU or ANP have directed the supervised individual otherwise, the Technegas Plus System user manual contains what should be considered the licensee's written radiation protection procedures.

The NRC staff also evaluated how licensees can ensure compliance with 10 CFR 35.63, which requires that a licensee determine and record the activity of each dosage before medical use. The prescribed dosage for diagnostic procedures is defined in 10 CFR 35.2 as:

> *the specified activity or range of activity of unsealed byproduct material as documented - (1) in a written directive; or (2) in accordance with the directions of the authorized user for procedures performed pursuant to §§ 35.100 and 35.200*.

In the case of the Technegas Plus System, the NRC considers the Tc-99m sodium pertechnetate activity to be added to the crucible, as directed by an AU, to be the prescribed dosage. This activity could be measured before medical use, in accordance with 10 CFR 35.63, and would provide the necessary safety assurance as intended in 10 CFR 35.63 because the Tc-99m activity that would be available to be administered to the patient could not be higher than the activity put into the crucible multiplied by the efficiency of the FDA-approved system. To comply with 10 CFR 35.63(d), the licensee would need to ensure the activity added to the crucible is within the AU-directed specific activity range or does not differ from the AU-directed specific activity by more than 20 percent.

If the NRC becomes aware of future developments related to the medical use of the Technegas aerosol or the Technegas Plus System that may negatively impact radiation safety, the NRC staff will consider revisiting this licensing decision for any additional actions.

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LICENSING FOR TECHNEGAS DATE January 24, 2024

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