

From: [Tran, Frank](#)
To: [Jon Woodward](#)
Subject: Request additional information for NRC License No. 24-26241-01MD
Date: Wednesday, May 19, 2021 5:47:00 PM

Dear Mr. Woodward:

This refers to the license renewal application for Mid-America Isotopes, Inc., NRC License No. 24-26241-01MD. We reviewed the application in accordance with NRC regulations, NUREG-1556, Volume 13, Revision 2 and Volume 20, Revision 1 and will need the followings in order to renew your license in its entirety per NRC policy.

1. In Item 6.1, "Distribution and Redistribution of Sealed and Unsealed Materials", of the application, it states, in part, that a description of the procedures to ensure licensed material will be securely and safely delivered to the mobile medical licensee's locations such as a medical mobile van or coach (procedures should ensure that delivery directly to the van or coach will only occur if the van or coach is occupied by mobile medical licensee personnel at the time of delivery) was attached. However, we could not locate the description for the above. Please provide the information above.
2. In Item 6.4 of the application, it states, in part, that the licensee will provide its customers the leak testing services. Please describe the type of leak testings that the licensee will provide for its customers and information described in NUREG-1556, Volume 18, Revision 1, Section 8.10.5. Please note this request will result in an additional new program code to your license (03220) for leak test service and a new associated fee category 3P (see the description of license program codes at <https://www.nrc.gov/materials/miau/mat-toolkits.html> and the fee category in 10 CFR 171.16 at <https://www.nrc.gov/reading-rm/doc-collections/cfr/part171/part171-0016.html>).
3. Confirm that the licensee will ensure the ventilation system, fume hoods and glove boxes are operating, testing and maintaining in accordance with the manufacturer instructions and recommendations.
4. In section "Instrument Calibration" of the application, it states, in part, that scintillation counting systems will be calibrated in-house using NIST traceable standards. Please confirm that scintillation counting system and dosage measurement systems will be calibrated in accordance with the manufacturer instructions by qualified individuals who have been trained and familiar with the operations and calibrations of the systems. Alternatively, the licensee can submit its in-house calibration procedures and qualifications of the individuals who will perform the calibrations.
5. For Item 10.13, "Leak Tests", the application was marked "Yes" in the second box; however, additional information was not provided. Please provide the information noted in Appendix H of NUREG-1556, Volume 13, Revision 2, supporting a request to perform leak test sample collection and sample analysis and state that "The

applicant will follow the model procedures in Appendix H of NUREG–1556, Volume 13, Revision 2, “Consolidated Guidance About Materials Licensees: Program-Specific Guidance About Commercial Radiopharmacy Licenses”. Or, the licensee can submit alternative procedures.

6. The current license is authorized for Ge-68/Ga-68 generators containing Ge-68 unsealed material meeting criteria to maintain a decommissioning funding plan in accordance with 10 CFR 30.35. The licensee provided information and financial assurance instrument in accordance with the Germanium-68/Gallium-68 Pharmaceutical Grade Generators - Licensing Guidance, dated July 2019. In Item 5, “Materials to be Possessed”, of the application, the licensee referred to the license (Amendment No. 22) for financial assurance and recordkeeping for decommissioning but didn’t provide other commitments as required in the licensing guidance (those were previously provided in letters dated August 26, 2019, October 2, 2019, and November 20, 2019 (as seen in the tie-down condition in the previous amendment (Amendment No. 22))). Please provide the commitments in the Germanium-68/Gallium-68 Pharmaceutical Grade Generators - Licensing Guidance or resubmit the previous commitments with updates as necessary. This licensing guidance can be found at <https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html>.
7. The current license is authorized for Mo-99/Tc-99m in NorthStar RadioGenix System. This authorization is in accordance with NorthStar Medical Radioisotopes, LLC RadioGenix® Molybdenum-99/Technetium-99m Generator System – Licensing Guidance. In previous license (Amendment No. 22), the licensee provided the commitments in accordance with the guidance and tied down in the license in License Condition 21 (as seen in application dated March 27, 2018 and letter dated June 18, 2018). However, we couldn’t locate the commitments in the renewal application. Please provide the commitments in the NorthStar Medical Radioisotopes, LLC RadioGenix® Molybdenum-99/Technetium-99m Generator System – Licensing Guidance or resubmit the previous commitments with updates as necessary using Revision 1 dated January 2020. This licensing guidance can be found at <https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html>.

To continue review of your application, we request that you submit your response with date and authorized signature to this correspondence within 30 calendar days from the date of this email. In your response, please refer the license number, docket number and Mail Control No. 624224. We will assume that you do not wish to further pursue this licensing action if we do not receive a reply within the specified timeframe noted above.

If you have questions, require additional time to respond, or require clarification on any of the information stated above, please contact me at 630-829-9623 or reply to this email.

In accordance with Title 10 of the Code of Federal Regulations (10 CFR) 2.390 of the NRC’s “Rules of Practice,” a copy of this correspondence will be made available electronically for public inspection in the NRC Public Document Room or from the NRC’s Agencywide Documents Access and Management System (ADAMS), accessible from the

NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>.

Best regards,

Frank Tran

Health Physicist/License Reviewer

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