From: Tran, Frank
To: neil.stubbs@siemens-healthineers.com
Subject: Request for additional information for NRC License No. 41-32720-02MD
Date: Friday, January 08, 2021 11:35:00 AM

Dear Mr. Stubbs:

We have reviewed your renewal application for NRC License No. 41-32720-02MD for PETNET Solutions, Inc. in accordance with the NRC regulations, guidance, and policies, including but not limited to NUREG-1556, Volumes 7, 9, 13 and 20. Based on NUREG-1556, Volume 13, Revision 2 (https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v13/index.html), we will need the following information to complete our review; some information are needed to confirm our understandings.

1. Since the proposed Radiation Safety Officer (RSO), Joe Readinger, R.Ph., has been appointed by the management and accepted the RSO's duties and responsibilities for this license, please provide a copy of the delegation of authority for RSO (a sample is listed in Appendix D of the guidance.)

2. Based on Section 8.6.1, please provide the following statement: "Radiopharmaceuticals will be prepared under the supervision of an Authorized Nuclear Pharmacist (ANP) or will be obtained from a supplier authorized pursuant to 10 CFR 32.72, or under equivalent Agreement State requirements". In addition, please confirm that (a) licensed material will be used by, or under supervision, of ANPs listed in the license or who meets the requirement in 10 CFR 32.72(b)(2); and (b) the licensee has developed and will implement and maintain written procedures to meet the license verification requirements specified in 10 CFR 30.41(d).

3. Describe procedures to ensure that radiopharmaceuticals are securely and safely provided to mobile medical licensees if they are transferred, distributed, or redistributed to a mobile medical licensee's mobile van or coach where there is no permanent structure for byproduct material storage. For example, 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. If the licensee will not transfer radiopharmaceuticals to mobile medical licensees, please state.

4. Based on Section 8.8.1, please provide the following statement: "We have developed and will implement and maintain written procedures for a training program for each group of workers, including (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v) initial training, and (vi) annual refresher training."

5. Based on Section 8.8.2, please provide the following statement: "We have developed and will implement and maintain records and written procedures for training personnel involved in hazardous materials package preparation and transport that meet the requirements in 49 CFR 172.700, 49 CFR 172.702, and 49 CFR 172.704, as applicable."

6. Provide a scale or dimension for the facility diagram and indicate the location where radioactive waste will be stored. Describe the following for the areas where materials authorized by this license will be used and stored:

   a) the adjacent areas to the restricted areas, including under, above, and surroundings;
   b) radiation shielding for the facility and equipment (locations of shielding, the shielding thickness, and the materials used for shielding, the proximity of radiation sources to unrestricted areas); and
   c) ventilation system with minimum pertinent airflow rates, differential pressures, filtration equipment, and monitoring systems (including in glove boxes, fume hoods, hot cells, etc., if applicable)

   In addition, please confirm that the ventilation system has been tested, is fully operable, and will be maintained in accordance with the vendor/manufacturer recommendations and industrial standards and that effluents, if any, are ALARA, are within the dose limits of 10 CFR 20.1301, and are within the ALARA constraints for air emissions established under 10 CFR 20.1101(d).

7. Describe the minimum training and experience for individuals who will collect and analyze the sealed source leak test samples.

8. Based on Section 8.10.3, please provide the following: “We will develop, implement, and maintain written procedures for safely opening packages that meet the requirements in 10 CFR 20.1906. We will conduct physical inventories of sealed sources of licensed material at intervals not to exceed 6 months. We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that: license possession limits are not exceeded, licensed material in storage is secured from unauthorized access or removal, licensed material not in storage is maintained under constant surveillance and control, and records of receipt (either from the licensee’s own production operations or from another licensee), transfer, and disposal of licensed material, are maintained.”

9. Based on Section 8.10.6, please provide the following statement: “We have developed and will implement and maintain written procedures for the safe and secure use of radioactive materials that address: facility and personnel radioactive contamination minimization, detection, and control; using protective clothing and equipment by personnel to support meeting the requirements in 10 CFR 20.1101; securing licensed material during use and storage in accordance with 10 CFR 20.1801, 10 CFR 20.1802; and posting the operating procedures applicable to commercial radiopharmacies (10 CFR 19.11(a)(3)). We have developed and will implement and maintain written procedures for identifying and responding to emergencies involving radioactive material, including: lost, stolen, or missing licensed material; exposures to personnel and the public in excess of NRC regulatory limits; releases of licensed materials in effluents in excess of NRC regulatory limits; excessive radiation levels or radioactive material concentrations in restricted or

unrestricted areas; radioactive spills and contamination; fires, explosions, and other disasters with the potential for the loss of containment of licensed material; and routine contacts with local fire departments and LLEA to meet the requirements in 10 CFR 20.1101, 10 CFR 20.2201-2203 and 10 CFR 30.50, and other requirements, as applicable."

10. Based on Section 8.10.7, please provide the following statement: "We have developed and will implement and maintain written procedures for a survey program that includes: (1) performance of radiation and contamination level surveys in restricted and unrestricted areas; (2) personnel contamination monitoring; (3) action levels; (4) survey frequencies; and (5) maintenance of survey records that meet the requirements in 10 CFR 20.1501, 10 CFR 20.2103, and 10 CFR 30.53, as applicable."

11. Based on Section 8.10.8, please provide the following statement: "We have developed, and will implement and maintain, a written procedure for the performance of dose measurement system checks and tests that meets the requirements in 10 CFR 32.72(c)."

12. Please confirm that the licensee will not accept any returned wastes from customers, including radiopharmacy-supplied syringes and vials and their contents.

Please provide the response in writing with authorized signature by February 5, 2021. To facilitate proper mailing handling in our office, please reference Mail Control No. 622889 in the cover letter. If you have any questions or need a clarification, please do not hesitate to contact me at 630-829-9623 or reply to this email.

Thank you,

Frank Tran
Health Physicist/License Reviewer
NRC Region III/Division of Nuclear Materials Safety
Phone: 630-829-9623
Fax: 630-515-1078
Email: Frank.Tran@nrc.gov

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