



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**

REGION III  
2443 WARRENVILLE ROAD, SUITE 210  
LISLE, ILLINOIS 60532-4352

June 5, 2009

Mr. Roger Moroney, CHP  
Manager, Radiological Compliance  
Corporate RSO  
PETNET Indiana LLC  
801 Innovation Drive  
Knoxville, TN 37932

Dear Mr. Moroney:

We have completed our review of your application for a new commercial radio pharmacy license, and find that we will need the following additional information in order for us to complete our review.

As we discussed during our site visit conducted on June 2, this letter has been slightly revised from the initial deficiency letter issued on May 26, 2009. The revision addressed issues that were discussed during that site visit. Also as we discussed on June 2, please resubmit your application within 60 days with a new NRC Form 313, and clearly identify areas within the new application that address the items in this letter.

**Organizational Structure**

Submit an organizational chart that describes PETNET's management structure, reporting paths, and the flow of authority between executive management and the Radiation Safety Officer (RSO). Also, relative to radiation safety responsibilities and management control of licensed operations, please describe the joint venture between Indiana University and PETNET Solutions. Include the delineation of responsibility between both organizations.

**Authorized Users**

In your application you did not identify any authorized users who are not registered pharmacists (authorized nuclear pharmacists). Please confirm that PETNET is not requesting to name non-pharmacist authorized users on the license, or submit names and qualifications.

**Training**

1. Describe the frequency of training that will be provided to ancillary personnel. As a minimum, training should be provided initially and annually thereafter.
2. Please submit a response to Item 8.8.2 of NUREG-1556, Volume 13, revision 1 to address training for personnel involved in hazardous materials package preparation and transport.

### **Facilities and Equipment**

1. Describe safety-related equipment that is used to conduct chemical synthesis of radionuclide labeled compounds. Include a description of containment that is used to compound drugs, e.g., hot cells, fume hoods, glove boxes, etc., your methods used to evaluate for airborne contamination in worker breathing zones, and remote handling equipment that will be used to keep exposures ALARA.
2. Submit the calibration procedures for the FHT 3511 stack monitor, and demonstrate how you determined the sensitivity range of  $5 \text{ E-8}$  to  $1.3 \text{ E-2}$  micro curies per cc. What is the alarm set point and describe actions that will be taken to ensure that public dose will be less than 10 mrem/year.
3. Submit a revised facility diagram that includes the floors above your facility. Include more detail in the diagram with regard to the space that you occupy. For example, identify areas designated for production, receipt and storage of material, preparation and measurement of radiopharmaceuticals, waste storage areas, locations of shielding, and the proximity of radioactive materials and sources to unrestricted areas. Also include in the revised diagram, an illustration of the delivery lines that feed PET nuclides into Indiana University Laboratory space.
4. Submit a second diagram of your facility that is a "birds eye" view of building where you are located which illustrates areas outside the perimeter of the building, e.g., residential neighborhoods, other businesses, schools, etc.
5. The ventilation drawing (Attachment I) indicates that there is a fume hood which is exhausted through the general exhaust system. Please indicate if the fume hood will be used to handle, process, or store radionuclides, and if so, submit an evaluation, including calculations of expected concentrations of radionuclides that will be released at the exhaust point, including any plans to filter and monitor the exhaust.
6. Submit a schematic drawing that illustrates the location of the exhaust point that services the mini cell, hot cell, and cyclotron, relative to the exhaust point that services the fume hood. For both exhaust points state the height of each stack measured from the point each exits the building and the location/distance from each point of release to the nearest air intake of the building.
7. Based on statements made in your application regarding the replacement of the filtration system currently located on the roof, the new system will be located in the cyclotron room. Resubmit a facility diagram that includes the location of the new filtration system. Will the new system also service exhaust released from the mini and hot cells? If not, how will the exhaust from the mini and hot cells be filtered?

### **Procedures**

1. Confirm that you have developed and will implement and maintain written procedures for safely opening packages that meet the requirements in 10 CFR 20.1906.
2. Confirm that you have developed and will implement and maintain written procedures for licensed material accountability and control (ref. NUREG-1556, volume 13, revision 1).

3. Confirm that you have developed and will implement and maintain written procedures for the safe use of radioactive materials, and identifying and responding to emergencies involving radioactive material. **Also, you have established trigger points for what are considered minor and major spills, i.e., < 500 mR/hr @1 foot (minor spill) and > or equal to 500 mR/hr @ 1 foot (major spill).** It's difficult to define minor and major solely based on radiation levels, especially when dealing with and handling various radionuclides and/or compounded radionuclides. Spills that result in the radiation levels that you described could easily meet the criteria for high or very high radiation areas, which require specific procedures on control of access, special decontamination procedures, and may be reportable to the NRC. Please justify why you selected such high trigger levels, and indicate if you have experienced spills of this nature in the past that resulted in these radiation levels and how they were decontaminated. Please reference Appendix Q to NUREG-1556, volume 13, revision 1 for acceptable procedures for handling spills.
4. In your application you state that wipe surveys will be conducted "at appropriate times." In accordance with Appendix R to NUREG-1556, volume 13, revision 1, please clearly define frequencies for conducting wipe surveys for contamination, and revise action levels to be consistent with the values in Appendix R to NUREG-1556, volume 13, revision 1.
5. Confirm that you have developed and will implement and maintain a written procedure for the performance of dosage measurement system checks and tests that meet the requirements of 10 CFR 32.72(c).
6. Revise your procedure for the decay in storage of radioactive waste to include all radionuclides with a half-life less than 2 hours. Also, confirm that you have developed and will implement and maintain written procedures for customer return of pharmacy-supplied syringes and vials and their contents to specify that instructions will be provided to radiopharmacy customers for the proper preparation and packaging of the radioactive waste for return to the radiopharmacy.

### Distribution

For each product that will be distributed provide the radionuclide and the maximum activity for each type of container, e.g., vial, syringe, etc., and indicate the maximum radiation level to be expected at the surface of each "transport radiation shield" when the radioactive drug container is filled with the maximum activity.

### Occupational Dose

1. With regard to your personnel monitoring program, you state that PETNET will eliminate the potential for airborne activity by the use of engineering controls, such as a dedicated exhaust system. Please describe all engineering controls that will be in place and provide specific details as to how each control will eliminate the potential for intake of airborne radioactivity.
2. Describe how you will periodically evaluate the effectiveness of your engineering controls designed to prevent the release of airborne radioactivity into worker breathing zones, to verify that they have not failed. Also, In the event that one or more of your engineering controls that are designed to eliminate the potential for airborne activity fails

and a worker has a possible intake of licensed material, describe actions that will be taken to evaluate internal dose.

3. Describe how you will detect an accidental airborne release resulting from, for example, a defective valve in the transfer tubing between the cyclotron and hot cell, or a release due to manual intervention in a normally automated synthesis procedure. Also, describe how you will then evaluate internal dose to workers in a timely fashion. For example, in your application for the production license (cyclotron) you included a specific Emergency Procedure that addresses an accident involving radioactive material contamination or exposure. Presumably, such an accident could involve an accidental release of airborne or ingestible material, into worker breathing zones. A program should be in place that addresses possible intake of radioactive material in this scenario.
4. Conduct surveys within the pharmacy when operations are at their peak and radiation levels are expected to be at the highest of areas including transfer lines between the cyclotron and hot cells, areas where radionuclides are stored, areas where radio synthesis/compounding is conducted, mini cells, glove boxes, etc. Submit the results of the surveys for our review.
5. On page 31 of your application entitled, "Personnel Monitoring Devices", you state that "PETNET will evaluate the potential occupational exposures of all workers and monitor occupational exposure to radiation when required." Describe the criteria for determining when monitoring will be required. In addition, a statement is made that PETNET will monitor worker exposures for all workers who require routine access to restricted areas. Please define "routine", and describe the group of workers that this refers to.

### **Public Dose**

1. Provide the parameters that you used in the COMPLY code, and demonstrate that the dose to members of the public will be less than 10 mrem/year. Please also submit an evaluation of building wake effect and downwash of exhaust.
2. Please conduct a survey at the surface of, and 1 meter from the stack as effluent flows through each floor when production activities are at their peak during the day and when you would expect the greater amount of radionuclides to flow through the exhaust. The survey should be done at about the normal height of a person standing next to or near the stack. Submit the results for our review.
3. Submit a diagram that illustrates the location of the exhaust system as it goes through each floor of the building and describe the occupancy of each floor relative to the location of the stack. Describe how you will periodically evaluate the exhaust system to assure that there is no leakage at any point as exhaust passes through unrestricted areas between the floors above your facility.
4. Describe the occupancy of the floor directly above your facility. Be especially specific about occupancy that is located directly above the cyclotron, hot and mini cells, fume hood, and glove boxes. Conduct surveys in the areas directly above these processes and submit the results for our review.

**Financial Assurance**

We are in receipt of your March 19, 2009, letter in which you proposed a variance in the threshold activity for cobalt-57 as it relates to financial assurance (ref.10 CFR Part 30, Section 30.35). We will submit your proposal to our headquarters office for review under a technical assistance request. In the mean time, you will be required to comply with the current regulations as they pertain to financial assurance. Based on our review of the isotopes and quantities that you requested in your application, PETNET will need to submit a decommissioning funding plan (DFP). Please also note that financial assurance must be addressed before the NRC can issue PETNET a materials license.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

Please reference your response as additional information to Control Numbers 317654. Please contact me at 630-829-9854 if you have any questions.

Sincerely,



Kevin G. Null  
Materials Licensing Branch

Docket No.: 030-37860  
License No.: 41-32720-01MD

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Kevin G. Null  
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Docket No.: 030-37860  
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