June 26, 2013

Ms. April Chance, CHP
Senior Manager of Radiation Protection/Environment
Health & Safety
PETNET Solutions, Inc.
810 Innovation Drive
Knoxville, TN 37932

Dear Ms. Chance:

This is in response to your March 29, 2013, letter in which you provided additional information to the U.S. Nuclear Regulatory Commission's (NRC's) ongoing concerns over PETNET's ground level release of radioactive air effluent from cyclotron operations into a garden area located on property owned and controlled by Tenet St. Louis University Hospital (SLUH).

On February 28, 2013, NRC staff and management toured the PETNET cyclotron facility and radiopharmacy located on SLUH property and held discussions with you, members of your staff, and SLUH management and staff regarding the radioactive air effluent. The NRC staff also discussed your May 3, 2012, letter in which you stated that PETNET would reduce the radioactive air effluent released into the garden by installing a gas collection and compression system that would collect the exhaust gases, compress the gases in a tank, and hold the gases for decay prior to release. The letter stated that the proposed gas collection and compression system combined with the existing filtration system, would significantly reduce the radioactive air effluent discharged into the SLUH garden area and unrestricted dose limits would be achieved in the garden area.

However, despite the commitments made in your May 3, 2012, letter, you informed us during our February 28, 2013, visit that PETNET had determined that installation of the gas collection and compression system was not feasible due to space constraints within the cyclotron facility. Instead, PETNET chose to conduct periodic air sampling in an attempt to demonstrate compliance with radiation dose limits specified in Title 10 of the *Code of Federal Regulations* (CFR) Part 20 in the garden and the restricted area boundary between May 2012 and March 2013 to further evaluate the concentration of air effluent released. Air sampling results were submitted as an attachment to the March 29, 2013, letter.

We have completed our review of the March 29, 2013, letter and attachments and have concerns over the validity of the air sampling results that were used to demonstrate that the annual average concentration of radioactive air effluent released is within limits specified in Title 10 CFR Part 20.

The purpose of this letter is to describe in more detail the technical basis for our concerns over PETNET's methodologies that were used to evaluate the radioactive air effluent released into the SLUH garden area and the validity of the conclusions that were reached. Specifically, Section I of this letter addresses the following: (1) The use of hydrogen fluoride (HF) gas to determine air sampling filter collection efficiency; (2) The air sampling that was conducted between May 2012 and March 2013 in and around the SLUH garden area; and (3) The use of COMPLY code to estimate radiation dose for a ground level release.

In addition, Section II of this letter discusses ongoing concerns that the NRC has had over access control to the garden area where radioactive air effluent is released, and PETNET's failure to address ALARA in the evaluations submitted to date.

Please address the concerns described below in Sections I and II.

Finally, we noted that near the very end of your March 29, 2013, letter, your marked two pages as "Proprietary." The information in those two pages pertained to tests that were run in 2003 to determine the fraction of fluorine-18 labeled FDG that is released through an unfiltered, air effluent release path during the manufacturing process. In order for the NRC to withhold this information from public disclosure as proposed, you will need to follow the provisions outlined in 10 CFR 2.390(b). If you do not address the provisions specified in 10 CFR 2.390(b), the NRC cannot withhold the information from public disclosure.

I. Evaluation of Radioactive Air Effluent and Radiation Dose

A. Use of Hydrogen Fluoride Gas to Determine Air Sampling Filter Collection Efficiency

In Attachment C to your March 29, 2013, letter, you indicated that hydrogen fluoride (HF) gas was used to determine the collection efficiency (CE) of the TEDA-impregnated carbon cartridge. Please provide the basis for determining that HF is representative of the radioactive air effluent released from your cyclotron operations. If HF gas is not the predominant air effluent released, we question the validity of the results of the CE. In the section "Description of Effluents" of Attachment A to your letter, which described air sampling conducted in May of 2012, you stated that the "chemical form is believed to be hydrofluoric acid." Please provide evidence that verifies and confirms the form of the radioactive air effluent.

Attachment A to the March 29, 2013, letter included air sampling data from your May 30 and 31, 2012, evaluation of effluent released. That data indicated that the paper filter which was placed in front of the carbon cartridge had no positive counts, yet significant counts were identified on the carbon cartridge. Due to the highly reactive nature of HF gas and its affinity to adhere to any surface that it touches (as you indicated in Attachment C), it would appear that most of the activity should have been collected on the paper filter before it reached the carbon cartridge, if the effluent was truly HF gas. The fact that the filter paper was virtually void of any radioactivity indicates to us that HF gas is not the predominant effluent that is being released.

Lastly, if HF gas was the main air effluent from cyclotron operations, we expect that it would probably plate out on the detector of the real-time effluent monitoring system due to its affinity to adhere to any surface, and result in a gradual increase in detector response. Based on the real time effluent monitoring data (reference Attachment B, Technical Data to your letter; the Historical Data View screen shots) there was no indication of gradual increase in detector response due to plate-out. We believe that this is because HF is so reactive that it is completely removed by the KEP3S filter system prior to being released as effluent.

Note also that based on a paper published in Health Physics Journal, Volume 60, No. 5, May 1991, pages 657-660, CF_3SO_2F is the primary form of the exhaust.

Based on the reactivity of HF, the CE would be about 100 percent, regardless of the type of filter used or the sampling rate. However, due to the reactivity of the HF we do not believe it is the primary radioactive effluent that is released. The actual CE of the TEDA-impregnated carbon cartridge for radioactive gases that are released could be much lower depending on the chemical compounds and the sampling rate. Without knowing the actual CE of TEDA-impregnated carbon cartridge, an estimate of concentrations of radioactive air effluent in the garden and balcony areas would be flawed and the radiation dose to members of the public in the garden and balcony areas could be significantly underestimated.

In conclusion, it appears that HF gas is not the predominant air effluent from cyclotron operations and should not have been used to determine the CE of the TEDA-impregnated carbon cartridge filter.

B. Air Sampling

The periodic air sampling which was conducted on May 30 and 31, 2012, June 1, 2012, September 17, 18, and 19, 2012, December 18 and 19, 2012, and March 6, 7, and 8, 2013, was not representative. The limited number of samples collected did not account for the variability of wind direction and potential building wake effect trapping the effluent in the garden area**.** In order for PETNET to demonstrate to the NRC that the air sampling results represent the actual operational effluent release conditions to support the public dose calculations, you will need to provide representative sampling data that has been collected over the course of a year to demonstrate and account for the varying meteorological conditions. This data will then be used to demonstrate the radiation dose to members of the public.

We noted instances where there was no positive correlation between real-time stack effluent monitoring data (reference Attachment B, Technical Data to your letter; the Historical Data View screen shots) and air sampling data on May 30, 2012, September 17, 2012, and September 19, 2012. For example, on September 19, 2012, two air samples were taken on the balcony at 6:30 a.m. and 8:20 a.m. Results of the samples indicated that the air effluent concentration measured at 6:30 a.m. was a factor of about 100 times higher than the concentration that was measure at 8:20 a.m. These values do not correlate to the stack effluent monitor values for same time frames. The stack effluent monitor indicated that activity released during the 6:30 a.m. production cycle was about half the release of the 8:20 cycle. Also, the air sampling result on September 17, 2012, indicated that the concentration at the balcony from a 3:30 a.m. air sample was about ten times higher than an air concentration measured at 6:30 a.m. in the garden, yet the stack effluent monitor results during those air sampling time frames were about the same.

The inconsistencies that exist between the air sampling data and the stack monitoring data indicates that the variable wind conditions in the garden and balcony areas has an impact on your ability to collect representative air samples and to accurately assess radiation dose to members of the public. The air sampling that was conducted does not appear to reflect the concentrations of radioactive air effluent that is being released. Therefore, the estimated radiation dose to members of the public that you calculated from this data is not reliable nor representative of the actual effluents released as a result of the production of fluorine-18.

C. Comply Code

The use of the Comply Code to estimate radiation dose to members of the public is not applicable for the radioactive air effluent at the PETNET SLUH location due to the following:

- The release stack is 3 meters above the ground in the garden area;
- The effluent is discharged via a 90-degree bend in the stack, as opposed to a standard vertical release; and
- The stack is directly adjacent to a high-rise building.
  As a result, the release should be treated as a ground level release where the highest concentration would collect in the garden. The Comply Code would not be applicable for this scenario.

II. Access Control and As Low As Is Reasonably Achievable (ALARA)

A. Control of Access to the Garden Area

During a January 25, 2012, site visit by NRC staff to conduct an additional review of the radioactive air effluent release pathway from cyclotron operations into the garden area, the staff evaluated PETNET's adequacy of controls to prevent unauthorized access into the garden. NRC staff noted the access control on the North end of the garden was easily bypassed by reaching through and around the fence to open the gate. The NRC staff communicated the issue to both PETNET and SLUH management, who stated that improvements in security would be made.

During the February 28, 2013, NRC visit, an NRC staff member was again able to access the North gate to the garden in the exact same fashion that occurred during the January 25, 2012, visit. Modifications that were made after the NRC's January 25, 2012, visit were inadequate in controlling access to the garden.

Adequate access control to the garden area, which is posted as a restricted area as a result of the radioactive air effluent being released into the garden, is critical especially in light of the continued concern the NRC has with regard to concentrations of radioactive air effluent being released and the resulting radiation dose to members of the public.

Describe the additional access control measures that will be instituted and the dates they will be in place to secure the garden area and prevent unauthorized access.

B. As Low As Is Reasonably Achievable (ALARA)

The NRC has established regulatory limits with respect to radiation exposure for occupational workers and members of the public. However, it is prudent on the part of licensees to take steps to avoid unnecessary exposure to radiation. The objective, therefore, is to reduce exposures as far below specific regulatory limits, ALARA. The most critical aspect of achieving ALARA in a licensee's radiation safety program is the commitment of licensee management to maintain doses ALARA, both for occupational workers and the public. Keeping doses ALARA from radioactive air effluent can be achieved through the implementation of effective radiation principles and procedures, through the use of engineering controls, or a combination of both.

As stated earlier in this letter and reiterated here for emphasis, you addressed our concerns over the radioactive air effluent being released into the SLUH garden area by committing to install engineering controls that, in combination with the existing filter system would, as you stated, "significantly reduce the activity discharged such that unrestricted dose levels would be met." PETNET determined that the proposed engineering controls were not feasible due to space constraints. As a result, air sampling was conducted in and around the garden area to evaluate the concentrations of radioactive air effluent that were being released in order to assess the resulting estimated dose from the effluent to members of the public.

As noted in Section I of this letter, NRC staff has additional concerns over PETNET's evaluation of the radioactive air effluent that is being released into the garden area, and the results of air sampling conducted to estimate concentrations of radiochemicals being released and the resulting radiation dose. Furthermore, based on commitments made in your May 3, 2012, letter to install engineering controls that would "significantly reduce" the activity being released into the garden and subsequent decision to not implement this controls, it is apparent that PETNET has not addressed nor embraced the ALARA concept at SLUH.

In the event PETNET cannot address the issues described in Section I to this letter concerning the assessment of radioactive air effluent concentrations being released into the garden area and associated radiation dose to members of the public, then PETNET must implement other measures, e.g., engineering controls, that will reduce the amount

of radioactivity that is being released to assure the NRC that radiation doses to members of the public will not exceed the regulatory limits.

If you are unable to provide a satisfactory response to our concerns described in Section I and elect not to install the engineering controls that were described in your May 3, 2012 letter, the NRC will consider modifying PETNET's license to restrict the processing and production of licensed material in a manner which will assure the Commission that the radioactive air effluent from licensed activities will not exceed 10 CFR Part 20 public dose limits.

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 NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Please respond within 30 days and reference as additional information to mail control number 580329.

You may contact me at (630) 829-9854 if you have any questions.

Sincerely,

/RA/

Kevin G. Null
Materials Licensing Branch
Division of Nuclear Materials Safety

License No. 41-32720-03
Docket No. 030-38230

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Kevin G. Null
Materials Licensing Branch
Division of Nuclear Materials Safety

License No. 41-32720-03
Docket No. 030-38230

cc: Todd Stirewalt

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