PETNET Solutions

July 31, 2013

Mr. Kevin Null
US Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: PETNET St. Louis Effluent Control and Monitoring Issue for Radioactive Materials License No. 41-32720-03

Dear Mr. Null:

Please accept this response letter as PETNET's submission for investigating and researching solutions to the Nuclear Regulatory Agency's (NRC) concerns with the filtered effluent exhaust system located at the PETNET St. Louis facility.

I. Evaluation of Radioactive Air Effluent and Radiation Dose (summarized)

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

The NRC concludes that the environmental air sampling test data are invalid since it is believed that HF gas is not the predominant air effluent and as such the collection efficiency of the air sampler's TEDA-impregnated carbon cartridge filters should not have been based on HF gas. The NRC believes the predominant gas is comprised of Trifluoromethanesulfonyl Flouride (CF3SO2F) based on a published Health Physics Journal paper (Volume 60, No. 5, May 1991, pages 657-660; Benedict and Kleck). NRC requests verification and confirmation of the radioactive air effluent.

Response

PETNET agrees with NRC's assessment that HF gas may not be the only chemical species present in the air effluent; however, PETNET's Biomarker R&D Group states that the information derived in the Benedict and Kleck paper is based on data Dr. Timothy Tewson gathered using a different chemistry box (CPCU) and a different chemistry procedure than that currently used at PETNET sites. The Benedict and Kleck paper also states the following, *"The form of this gaseous release has been suggested to be [18F]-CF3S02F (Tewson 1989)."*

PETNET realizes a degree of uncertainty exists regarding the exact chemical form of air effluents due to the complexity of determining the chemical species as

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stated in the 1989 Tewson paper ("[18F]-Labeled 3-Deoxy-3-Fluoro-D-Glucose: Synthesis and Preliminary Biodistribution Data").

The use of HF gas as the predominant surrogate for PETNET air effluents is based on a 2002 discussion between our Health Physicist and a PhD PET radiochemist at the University of Washington. This individual told our staff that the "most likely" chemical form of the effluent would be HF gas, based on PETNET's chemistry procedure and considering the possible contaminants present during synthesis and their behavior when heated.

B. Air Sampling

The air monitoring test data covering the periods for FY2012 (May, June, September, & December) and for FY2013 (March) are insufficient to provide an accurate picture of day-to-day releases based on meteorological variations seen throughout an entire year. Estimated radiation dose to members of the public, based on test data calculations, is not reliable nor representative of actual effluents released as a result of F-18 production.

Response

PETNET respectfully disagrees with NRC's assessment that the test data do not provide an accurate picture of day-to-day releases based on meteorological variations seen throughout an entire year. PETNET has demonstrated and provided visual verification, i.e., graphs of effluent release, of the typical production run, which takes an average of 2 hours. These graphs clearly show that only 20 - 40 minutes of effluent release is seen during each synthesis. The site consistently produces F-18 at the same time every production day. The first two runs are normally completed prior to 8 am and the third run is normally completed by 10 am. As such, the total time of effluent release is much less than 2 hours per day. The test data also covered all four seasons of the St. Louis, MO community for periods prior to production, during production, and post production.

PETNET agrees that variable wind conditions in the balcony and garden areas may have an impact on the air samples and calculated radiation dose to members of the public potentially standing in these specific areas.

PETNET disagrees that variable wind conditions in the sidewalk areas have a significant impact on the calculated radiation dose to the public potentially standing in this specific area. The sidewalks are far enough from the building where build up would be prevented by the natural effects of dilution.

Comply Code

The use of the Comply Code to estimate radiation dose to members of the public is not applicable for the radioactive effluent.

Response

PETNET agrees with this assessment and will not use this code to determine radiation dose to the public.

In February 2012 at NRC's request, PETNET placed dosimeters in the garden and patio areas. These results have shown radiation levels to be equivalent to normal background levels. In light of this historical data, PETNET requests to discontinue monitoring these areas with the use of dosimeters.

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

A. Control of Access to the Garden Area

The measures for controlling access to the garden/patio have been poorly or improperly implemented and require immediate attention.

Response

PETNET will continue to work with Tenet and SLUH to monitor progress on controlling access to the garden and patio areas until a permanent solution is implemented.

B. As Low As Reasonably Achievable

If PETNET is unable to satisfy NRC's concerns addressed in Section I of this letter concerning the assessment of radioactive air effluent concentrations being released in the garden, patio, and sidewalk areas and elects not to install the engineering controls of a gas compression system, then PETNET must implement other measures, e.g., engineering controls, that will reduce the amount of radioactivity exposed to the public.

Response

PETNET began work on a project to install a gas compression system at the same time the patio air sampling program began. After reviewing the system specifications available from Von Gahlen (http://www.vongahlen.nl/index.html) and Comecer (http://www.comecer.com/), it became clear the facility did not have adequate space for installation. At that same time the first round of air sample results showed that concentrations of effluent on the patio were so far below

regulatory limits, and are present for such brief periods of time, a plausible meteorological condition that would cause concentrations to increase above limits could not be identified. Based on these early results and the lack of a suitable gas compression system, further work on the compression system was halted.

At this time, due to the complexity of determining the chemical makeup of the air effluent, PETNET will not conduct further air sampling in the garden and patio areas. PETNET will implement other measures to reduce the amount of radioactive effluent exposed to the public. The PETNET R&D and Radiation Protection groups are currently working together to determine a suitable engineering control. PETNET commits to providing the NRC with a proposed solution by October 14, 2013.

Conclusions

PETNET concedes that additional chemical species could be present, however the best available information indicates HF gas is the predominant species produced during chemical synthesis. Consequently, PETNET is testing a solution to capture effluent from the synthesis process, at the point of generation, as a means of reducing release to the environment. The Lab Impex data indicate the effluent concentration to be 2.5E-7 µCi/mL for the previous year of 2012. PETNET is committed to reducing the effluent radioactivity detected by the Lab Impex system to less than the NRC Effluent Limit for F-18 (1E-7 µCi/mL) listed in 10 CFR 20, Appendix B, Table 2

Should you require additional information, please feel free to contact me at the number listed below or Ramón Davila at 865-218-3295 or ramondavila@siemens.com.

Sincerely,

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cc: Tigran Sinanian, RPh, BCNP, Sr. Director of Manufacturing Operations
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