PETNET Solutions

October 3, 2014

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

Re: C/N 580329 and follow-up response to the telephone conversation conducted on September 12, 2014.

Dear Mr. Null:

Please accept this letter as PETNET's response to the Nuclear Regulatory Commission's (NRC) Conversation Record (580329) for September 12, 2014 received September 22, 2014.

Concern 1:

The data in the spreadsheets that you provided above still indicates the inconsistency of the discharge increment vs. detector response for the software generated data. The manual calculation, based on Raw CPS, calibrated concentration conversion factor (pCi/ml per cps), background concentration, and duct flow rate, appears to be a reliable and accurate way to determine the release activity.

After additional review, we have made a determination that daily air effluent releases of no more than 1200 microcuries of flourine-18 will not result in an annual dose to a member of the public that exceeds the 10 millirem per year constraint limit from air effluent.

Since your manual calculations appear to be a reliable and accurate way to determine release activity, we request that you perform manual calculations of activity released when software calculations indicate any daily release which exceeds 1200 microcuries, and that you will use results of the manual calculations to report activity released.

Response 1

PETNET agrees with the NRC's assessment that releases below 1200 microcuries of fluorine 18 will not result in an annual dose to a member of the public that exceeds the 10 millirem per year constraint limit from air effluent. However, PETNET respectfully disagrees with the assertion that performing manual calculations using Lab Impex (LIS) data is a more reliable and accurate way of determining the release activity in lieu of using the reported concentration.

810 Innovation Drive Knoxville, TN 37932 Tel: (800) 738-0488 Fax: (865) 218-3018 There exists no significant difference between the reported concentration and manually calculated concentrations. As such, PETNET has full confidence with the functionality of the LIS Effluent Monitoring System and accuracy of the reported concentration.

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Therefore, PETNET rejects the NRC's request to perform manual calculations when the daily release exceeds 1200 microcuries.

Concern 2

Please confirm that calibration of the Lab Impex System with be performed in accordance with the manufacturers recommended procedure.

Response 2

PETNET confirms that the LIS will be performed in accordance with the manufacturer's recommended procedure. The LIS recommendation requires that Cs-137 Check Source Verification Tests are frequently conducted with a pass criterion of ±10% from the last recorded conversion factor. PETNET commits to performing quarterly Cs-137 Check Source Verification Tests. If the test fails, PETNET will perform a positron gas calibration of the monitoring system as recommended by the manufacturer.

Concern 3

Based on the calibration done on February 7, 2014, the documented concentration conversion factor (CF) is 0.40 pCi/ml/cps. In the attachments to your August 8 letter, you used a CF of 0.33 pCi/ml/cps. Please provide the certification of the calibration tests that indicate the CF is 0.33 pCi/ml/cps.

Response 3

PETNET has been unsuccessful with locating the initial calibration report. This includes searching all files stored at the St. Louis facility and all documents maintained by Lab Impex. These documents were not provided to the site and have been purged from Lab Impex records in accordance with internal standard operating procedures and regulatory requirements.

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 For April Chance April Chance, CHP-

Senior Manager of Radiation Protection/Environment, Health & Safety Molecular Technologies Division of Siemens Molecular Imaging (PETNET, Cyclotrons and Sources) 810 Innovation Drive Knoxville, TN 37932 (865) 308-3887 mobile (865) 218-6355 office april.chance@siemens.com

Attachments

cc: Tigran Sinanian, RPh, BCNP, Sr. Director of Manufacturing Operations Ramón Davila, MBA, RRPT, Regional Health Physicist John Beyer, RPh, RSO, Regional Operations Director

Null, Kevin

From: Sent: To: Cc: Subject: Attachments: Davila Jr, Ramon <ramondavila@siemens.com> Tuesday, October 07, 2014 3:27 PM Null, Kevin Chance, April Siemens response to C/N 580329 2014-10-03 Siemens response to Gas Detection System CN 580329.pdf

Kevin,

The latest response is attached for your review.

Take care!

Ramón Davila, Jr, MBA, RRPT Regional Health Physicist Siemens MI / PETNET Solutions 865-332-6594 (cell) 865-218-3295 (office) 865-218-3018 (fax) ramondavila@siemens.com

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