### **PETNET** Solutions

December 6, 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 – Effluent Capture Status Update

Dear Mr. Null:

Please accept this letter as a status update for PETNET's proposed solution to reducing the amount of radioactivity released from the filtered effluent exhaust system located at the PETNET St. Louis facility.

On October 10, 2013 a Tedlar<sup>®</sup> Bag Gas Capture System (Attachment A) was installed for trapping and storing the radioactive gas produced during FDG synthesis, which occurs within the Explora Chemistry Box. A graph showing the radioactivity measured by the radiation effluent monitoring system is provided as Attachment B. These data show up to a 75% reduction in released radioactive effluent.

Please note that PETNET also produces F-18 Florbetapir (Amyvid [AV-45]), which uses a different chemistry box. The effluent from this production process is not currently being trapped. Upon NRC's approval, Siemens' plan is to install gas capture bags for all chemistry boxes with the goal of significantly reducing effluent concentrations below regulatory constraints.

The St. Louis pharmacy staff will receive procedural and policy training on properly using the Tedlar<sup>®</sup> Bag Gas Capture System from Siemens PETNET's Engineering & Development (E&D) Department and the Radiation Protection Department. At this time, the E&D Department is writing a formal procedure, which will be available for review upon request.

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.

RECEIVED DEC 1 3 2013

Tel: (800) 738-0488

Fax: (865) 218-3018

Sincerely,

April Chance, CHP

Senior Manager of Radiation Protection/Environment, Health & Safety

Molecular Technologies Division of Siemens Molecular Imaging

Ramón Davila For April Chance

(PETNET, Cyclotrons and Sources)

810 Innovation Drive

Knoxville, TN 37932

(865) 308-3887 mobile

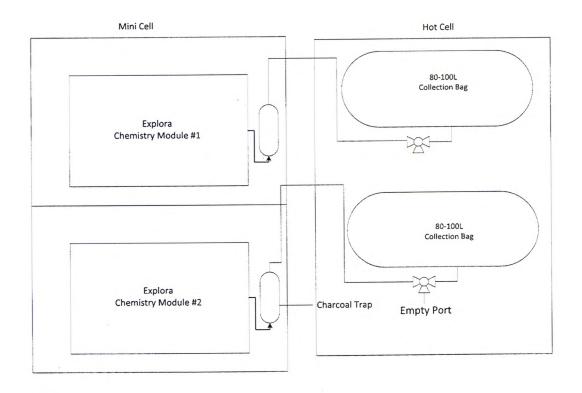
(865) 218-6355 office

april.chance@siemens.com

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

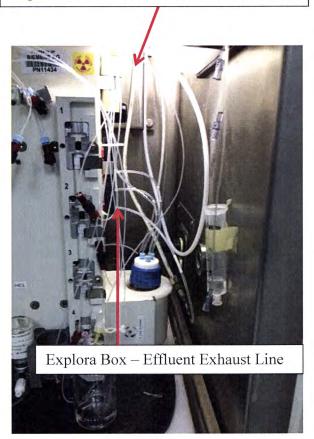
Ramón Davila, MBA, RRPT, Regional Health Physicist John Beyer, RPh, RSO, Regional Operations Director

# Attachment A Tedlar Bag Gas Capture System



### Attachment A, continued

Explora Box – Effluent Exhaust Line to Bag

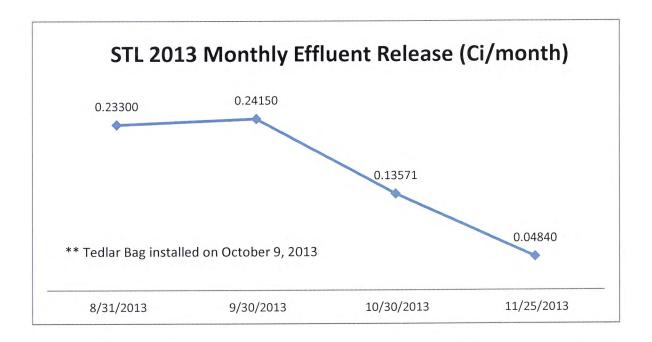


Tedlar® Bag within Hot Cell



Two Way Valve for Releasing Decayed Gas

## Attachment B Historical Effluent Graph



From: (865) 218-6355 April Chance 810 Innovation Drive

Origin ID: RKWA

Fed€x.

Knoxville, TN 37932

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Kevin Null US Nuclear Regulatory Comm. RIII 2443 WARRENVILLE RD STE 210

LISLE, IL 60532

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Ship Date: 11DEC13 ActWgt: 0.5 LB CAD: 105091792/INET3430

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