
CONVERSATION RECORD

(time) (date)

|TIME |DATE

4/29/14

X VISIT

CONFERENCE

TELEPHONE

INCOMING
OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT

ORGANIZATION (OFFICE, DEPT.ETC.)

TELEPHONE NO.

April Chance

PETNET Corporate Office

RAMON DAVILA

PETNET REGIONAL HP

JOHN BEYER

PETNET ST. LOUIS, RSO

TIGRAN SINANIAN

PETNET CORPORATE OFFICE

SUBJECT

C/N 580329 and follow-up site visit to observe the operation and implementation of the gas collection system designed to trap and hold fluorine-18 labeled FDG and fluorine-18 labeled AV-45 gaseous effluent prior to being released at the PETNET St. Louis facility.

SUMMARY

The purpose of this site visit was to provide the NRC with an opportunity to observe the operation of the gas collection system that had been installed at the PETNET St. Louis facility to trap, hold, and decay fluorine-18 gaseous effluent prior to being released from licensed operations under NRC license number 41-32720-03 in St. Louis, Missouri.

This visit was in follow-up to PETNET's March 4 and April 10, 2014, responses to an NRC telephone conversation record dated January 23, 2014, which documented additional information that NRC staff needed to continue its review of PETNET's proposed engineering controls, the i.e., gas collection system..

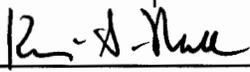
As a result of observations made by the NRC staff during the April 29 visit and discussions with PETNET staff, it is the NRC's understanding and expectation that PETNET will provide the following additional information regarding the gas collection system:

1. A comprehensive standard operating procedure (SOP) that will include, but not be limited to:
 - a. A commitment that the facility will control fluorine-18 gaseous effluent releases to no greater than 214 millicuries per year in order to demonstrate compliance with the limit specified in 10 CFR 20.1101 (d).
 - b. A commitment to perform a daily evaluation of the integrity of gas collection bags, associated tubing, and fittings, and include a description of the criteria that will be used to determine when bags, associated tubing, and fittings will be replaced.
 - c. A description of the minimum frequency that bags, associated tubing, and fittings will be replaced.
 - d. A description of the minimum amount of time that the gas will be held for decay in a collection bag prior to being released.
 - e. A clarification of the method that will used to evacuate the bag, i.e., manually or by a vacuum pump.
 - f. A commitment that the facility will maintain an operable backup vacuum pump for evacuating collection bags in the event of a failure of the primary pump.
 - g. A set frequency and protocol for checking the lab impex monitoring system detector's response to radiation using a check source.

- h. The protocol that will be followed if the exhaust fan fails.
 - i. A description of a corrective action program that will be implemented if there is an unexpected fluorine-18 gaseous effluent leak that is identified by the lab impex system.
 - j. A description of the threshold of fluorine-18 that, if released as a gas effluent, would result in an investigation and evaluation to determine root and contributing causes and development of corrective actions to prevent recurrence.
 - k. A description of ALARA considerations and limitations that will be placed on the amount of fluorine-18 that can be released, and actions that will be taken if those levels are exceeded.
2. A commitment to amend the NRC license before modifications are made to the gas collection system, or the effluent monitoring and filtration systems.
 3. A commitment that the lab impex effluent monitoring system will be calibrated using a positron emitting gas at a specific frequency, or that the device will be returned to the manufacturer for calibration at a specific frequency.
 4. A commitment that on a quarterly basis, PETNET staff will perform independent calculations to verify the lab impex system's assessment of activity that is being released.
 5. Provide the raw data generated by the lab impex system from 3 previous effluent releases. Also, provide an assessment of the activity released based on hand calculations, along with a comparison to the activity released according to the lab impex system for each corresponding time.

ACTION REQUIRED

Submit a written response and reference as additional information to Control Number 580329.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Kevin Null		5/5/14

ACTION TAKEN

SIGNATURE	TITLE	DATE