

June 10, 2022

Frank Tran
Health Physicist/License Reviewer
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

**Re: Request for Additional Information Amendment Requests for License
No. 41-32720-06 and 41-32720-05MD PETNET Solutions**

Mail Control Nos. 630880 and 630882

Dear Mr. Tran,

Supplemental information is provided regarding our May 4, 2022, amendment requests and email dated June 3, 2022. The following responses numerically correspond to the email dated June 3, 2022:

1. PETNET confirms that the new mini-cells are similar to the current mini-cells in size, construction material, and radiation shielding. PETNET also confirms that the new mini-cells were built and tested in accordance with the industrial standards and codes prior to being placed in operation.
2. The supplied conceptual schematic is an oversimplified representation of the total air flow through the system. There have been no changes to the filter system as previously described.
3. Please find attached the COMPLY report for calendar year 2021 and an air effluent release evaluation utilizing the COMPLY code showing five times increase (5 Ci) of the current annual effluent released. This demonstration shows that with the added mini-cells and increase in production, air effluents remain within the dose limits of 10 CFR 20.1301 and 10 CFR 20.1101(d).
4. For clarification, the hood being moved is not a fume hood but a laminar flow hood. This laminar flow hood is not used for any radioactive material handling or storage and is only used as a sterile location for the preparation of product vials. In addition, this hood is not connected to the ventilation system. When the hood is removed, it will be surveyed to show that no removable contamination exists, and all surveys will be indistinguishable from background.

PETNET trusts that this information is sufficient for you to grant the requested license renewal. If you have any questions, please contact Neil Stubbs at 484-986-7681 or neil.stubbs@siemens-healthineers.com.

Sincerely,



Neil Stubbs, CNMT, RT(N)
Health Physicist
PETNET Solutions, Inc.
Phone: (484) 986-7681
neil.stubbs@siemens-healthineers.com

cc: Wayne Melchior, PETNET RSO, Royal Oak, MI
Elizabeth Gillenwalters, CHP, CRSO

Attachment A
2021 NESHAPS COMPLY Report and Current Air
Effluent Release Evaluation

COMPLY: V1.7.
12:24

3/25/2022

40 CFR Part 61
National Emission Standards
for Hazardous Air Pollutants

REPORT ON COMPLIANCE WITH
THE CLEAN AIR ACT LIMITS FOR RADIONUCLIDE EMISSIONS
FROM THE COMPLY CODE - V1.7.

Prepared by:

PETNET Solutions, Inc.
PETNET Detroit
3601 West 13 Mile Rd., Royal Oak, MI 48073

Neil Stubbs, CNMT, RT(N)
484-986-7681

Prepared for:

U.S. Environmental Protection Agency
Office of Radiation and Indoor Air
Washington, DC 20460

COMPLY: V1.7.

3/25/2022 12:24

DET2021

SCREENING LEVEL 4

DATA ENTERED:

| Nuclide | | Release Rate (curies/YEAR) |
|---------|---|-------------------------------|
| ----- | | ----- |
| F-18 | D | 1.141E+00 |

Release height 26 meters.

Building height 21 meters.

The source and receptor are not on the same building.

Building width 14 meters.

Building length 49 meters.

STACK DISTANCES, FILE: detdist.dat

| DIR | Distance (meters) |
|-----|----------------------|
| --- | ----- |
| N | 164.0 |
| NNE | 175.0 |
| NE | 194.0 |
| ENE | 114.0 |
| E | 37.0 |
| ESE | 153.0 |
| SE | 88.0 |
| SSE | 76.0 |
| S | 67.0 |
| SSW | 71.0 |
| SW | 109.0 |
| WSW | 20.0 |
| W | 194.0 |
| WNW | 206.0 |
| NW | 206.0 |
| NNW | 206.0 |

COMPLY: V1.7.
12:24

3/25/2022

WINDROSE DATA, FILE: detwind.dat

Source of wind rose data: Detroit Metropolitan Airport

Dates of coverage:

Wind rose location:

Distance to facility:

Percent calm: 0.00

| Wind FROM | Frequency | Speed (meters/s) |
|--------------|-----------|---------------------|
| ---- | ----- | ----- |
| N | 0.076 | 4.02 |
| NNE | 0.041 | 3.93 |
| NE | 0.034 | 4.05 |
| ENE | 0.050 | 3.94 |
| E | 0.061 | 4.03 |
| ESE | 0.051 | 4.03 |
| SE | 0.032 | 3.68 |
| SSE | 0.037 | 3.77 |
| S | 0.094 | 4.37 |
| SSW | 0.056 | 4.96 |
| SW | 0.083 | 5.61 |
| WSW | 0.069 | 5.61 |
| W | 0.127 | 5.16 |
| WNW | 0.081 | 4.70 |
| NW | 0.057 | 4.68 |
| NNW | 0.051 | 4.52 |

Distance from the SOURCE to the FARM producing
VEGETABLES is 1000 meters.

Distance from the SOURCE to the FARM producing
MILK is 1000 meters.

Distance from the SOURCE to the FARM producing
MEAT is 1000 meters.

NOTES:

The receptor exposed to the highest concentration is located
20. meters from the source in the WSW sector.

He gets his VEGETABLES from a farm located
1000. meters from the source in the E sector.

He gets his MEAT from a farm located

1000. meters from the source in the E sector.

He gets his MILK from a farm located
1000. meters from the source in the E sector.

Input parameters outside the "normal" range:

None.

RESULTS:

Effective dose equivalent: 0.4 mrem/yr.

*** Comply at level 4.

This facility is in COMPLIANCE.

It may or may not be EXEMPT from reporting to the EPA.

You may contact your regional EPA office for more information.

***** END OF COMPLIANCE REPORT *****

COMPLY: V1.7.

6/10/2022 10:35

40 CFR Part 61
National Emission Standards
for Hazardous Air Pollutants

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6/10/2022

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1000. meters from the source in the E sector.

COMPLY: V1.7.

6/10/2022 10:35

He gets his MILK from a farm located
1000. meters from the source in the E sector.

Input parameters outside the "normal" range:

None.

RESULTS:

Effective dose equivalent: 1.8 mrem/yr.

*** Comply at level 4.

This facility is in COMPLIANCE.

It may or may not be EXEMPT from reporting to the EPA.

You may contact your regional EPA office for more information.

***** END OF COMPLIANCE REPORT *****

Pavon, Martha

From: Tran, Frank
Sent: Friday, June 10, 2022 10:34 AM
To: Pavon, Martha; Pavon, Sandy
Cc: Tomczak, Tammy
Subject: FW: RE: Request additional information for NRC License Nos. 41-32720-06 and 41-32720-05MD
Attachments: PETNET Soln Royal Oak 41-32720-06 and 41-32720-05MD Mail Controls 630880and 630882.6-10-2022.pdf; 630880 Additional information 665.pdf

Dear IM Center:

Please add the attachment to ADAMS as additional information for CN 630880. Please let me know if you have any questions.

Thank you,
Frank

From: Stubbs, Neil <neil.stubbs@siemens-healthineers.com>
Sent: Friday, June 10, 2022 10:00 AM
To: Tran, Frank <Frank.Tran@nrc.gov>
Subject: [External_Sender] RE: Request additional information for NRC License Nos. 41-32720-06 and 41-32720-05MD

Good morning Mr. Tran.

Please find attached response to your request for additional information of amendment request dated May 4, 2022. Please let me know if any additional information is required.

Have a great weekend!

Neil Stubbs, CNMT, RT(N)
Health Physicist

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