

PETNET Solutions

February 4, 2019

Sara Forster
U.S. NRC Region III
Materials Licensing Branch
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Re: RFI for License Amendment Request, PETNET Solutions – Royal Oak, MI
NRC RAM License 41-32720-06, ML19008A257

Dear Ms. Forster:

This letter is in response to your email dated January 25, 2019 regarding our request to add Ms. Kelli Zauner to the subject license. The entirety of Ms. Zauner's handling experience (as detailed on her preceptor form) took place at the PETNET facility in Royal Oak, where she handled F-18 almost exclusively (as well as low-activity sealed sources). Since most pharmacists at PETNET are not trained to perform or participate in cyclotron maintenance or repair activities, they are not expected to handle any activation products. (Cyclotron maintenance and repairs are performed by the site's cyclotron engineer, who also handles the site's longer-lived wastes.) In the rare case a pharmacist is expected to perform these tasks, they receive training in advance.

If you have any further questions or additional information required, please contact me at 512.647.9971 or Christopher.walters@siemens-healthineers.com.

Sincerely,

A handwritten signature in black ink that reads "Chris Walters". The signature is written in a cursive style with a large, sweeping flourish at the end.

Chris Walters, CHP
Regional Health Physicist
PETNET Solutions, Inc.
cell : 512.647.9971
Christopher.walters@siemens-healthineers.com

cc: Wayne Melchior, RSO PETNET Detroit

Song, Taehoon

From: Forster, Sara
Sent: Wednesday, February 06, 2019 7:55 AM
To: Song, Taehoon; Pavon, Sandy; Sandrik, Lauren
Cc: Tomczak, Tammy
Subject: FW: RE: Additional Information request re PETNET Solutions, Inc., NRC Lic. No. 41-32720-06, CN610998
Attachments: 2019-02-04 Detroit 41-32720-06 prod response to Zauner RFI.pdf

Please scan in and return to me. Thank you.

Sara Forster

From: Walters, Christopher [mailto:christopher.walters@siemens-healthineers.com]
Sent: Tuesday, February 05, 2019 3:01 PM
To: Forster, Sara <Sara.Forster@nrc.gov>
Subject: [External_Sender] RE: Additional Information request re PETNET Solutions, Inc., NRC Lic. No. 41-32720-06, CN610998

Hello Ms. Forster,

Please see the attached response to your questions. If you have any further questions, don't hesitate to follow up with me via phone or email.

Thanks!

Chris Walters, CHP | Regional Health Physicist
512.647.9971 cel
christopher.walters@siemens-healthineers.com

From: Forster, Sara [mailto:Sara.Forster@nrc.gov]
Sent: Friday, January 25, 2019 9:20 AM
To: Walters, Christopher (SHS DI MI QT QA EHSFO)
Subject: Additional Information request re PETNET Solutions, Inc., NRC Lic. No. 41-32720-06, CN610998

Dear Mr. Walters:

We have reviewed the January 4, 2019 letter (ML19008A257) requesting to add Kelli Zauner, R.Ph., as an Authorized User (AU) on your the license referenced in the subject line of this message. Please note that additional information is needed to complete our review. Accordingly, please provide a response to the item noted below, to complete the review of your request:

- In the application, it is unclear the extent of experience Ms. Zauner has in the handling of radioactive materials relevant to accelerator activities. **Please provide additional training details for Ms. Zauner, including to clarify:**
 - The types, forms (including activated targets and incidentally activated products associated with accelerator activities), and quantities of material Ms. Zauner will be expected to handle, under the license; and
 - Ms. Zauner's experience with the types, forms, and quantities of material Ms. Zauner will be expected to handle, under the license.

Note that details of Ms. Zauner's experience should include the locations of that experience, dates on which that experience was completed, typical & maximum radioactive quantities handled, forms (such as accelerator targets or other accelerator-produced items) handled or used, and radionuclides handled or used. Experience should be specific to accelerator production and need not include experience towards her qualifications to be listed as an Authorized Nuclear Pharmacist (ANP) on NRC License No. 41-32720-05MD.

In order to add Ms. Zauner as an AU, please submit requested information within 14 days (on or before February 8, 2019). If you are unable to respond by then, please let us know as soon as possible when you will be able to provide a response. Additional guidance may be found in NUREG 1556, Vol. 21, rev. 1, "Program Program-Specific Guidance about Commercial Radiopharmacy Licenses," which may be found at:

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v21/>

Submission of your response as a pdf file attached to an email or via facsimile will allow for the quickest processing. Any response must be submitted under a signed and dated cover letter. Do not hesitate to call me with any questions you may have, or if you will need additional time to complete your response.

Sincerely yours,

Sara A. Forster, Health Physicist Licensing Reviewer
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Division of Nuclear Materials Safety
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