UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

DEC 3 1 2018

Jonathon Berger, M.D.
Radiation Safety Officer
Daviess Community Hospital
1314 E. Walnut St.
P.O. Box 760
Washington, IN 47501

Dear Dr. Berger:

This refers to the letter dated October 2, 2018, ("the letter"), signed by Ethan Penn, CNMT, in which you have requested an amendment to your NRC Material License No. 13-16138-01 changing the authorized facilities on your license to remove an area of use.

We have reviewed your request and find that we will need additional information in order to complete our review.

As this letter is addressed to you, Dr. Burger, we are sending this letter in regular mail to you. In addition, we are also transmitting a courtesy copy of this letter to the point of contact referenced in the letter, Mr. Penn, by scanning it and emailing a PDF version to him.

Please provide only one complete, written response that is currently dated and signed by a senior management official for this license. Your response must include a business-style transmittal letter that identifies this license and contains appropriate information about the unresolved issues below (please also see Item 3 below). This will help ensure that your response is processed correctly in our offices.

Under no circumstances should you submit more than one, complete, written response, even by different means of transmission. To do so may introduce confusion and delay in the processing and review of your response.

Your written response should be addressed to my attention at the above address within 7 days of the date of this letter (January 6, 2019), as "additional information to control number 610183."

If an alternative timeframe to respond is needed, please contact me at (630) 829-9841 or colleen.casey@nrc.gov to make other arrangements. My fax number is 630-515-1078, if you need it.

Upon receipt of your written response, we will then continue our review.

This also refers to the telephone call between Mr. Penn and me on December 28, 2018, concerning this same request. This call enabled me to better understand the intent of your letter and to prepare this request for additional information (RFAI) with greater focus.

1. Your letter instructs us to remove what is labeled as the "New Nuclear Medicine" room from your license and to release it for unrestricted use. However, the uses of licensed material in this room were not characterized and no close out survey information was provided to support this request and demonstrate that this area was free from residual contamination and sources of radiation.

   As this license also authorizes materials in 10 CFR 35.300 and your letter does not indicate whether such materials were ever used in the room in question, the notification rules in 10 CFR 35.13(e) and 35.14(b)(5) do not appear to apply.

   If no materials in 10 CFR 35.300 were received, used, injected into patients, stored or contained in patients receiving imaging in this room, as appropriate, in the past 3 years, please so state explicitly in your response.

   Please also confirm explicitly that only materials in 10 CFR 35.100 and 35.200 were received, used, injected, stored or contained in patients receiving imaging in this room, as appropriate, in the past 3 years. If this is the case, then the notification rule does apply here and no closeout survey is required.

   If materials in 10 CFR 35.300 were received, used, injected into patients, stored or contained in patients receiving imaging in this room, as appropriate, in the past 3 years, then we will need the following information:

   a. Diagrams of each facility (area(s) of use with exposure rate survey and wipe test results keyed to specific locations, as appropriate.

      Meaningful units (milliroentgen, millirem, dpm, etc.) should be stated. Gross results and/or net results should be stated and described appropriately. "Counts per minute (cpm)" and similar units are unacceptable.

   b. The name of the person(s) performing the survey.

   c. The date(s) the survey was performed.

   d. The instrument(s) used for exposure rate measurements and for analysis of the wipes. It is expected that instruments used will be appropriate for the types of radiation being detected; the exposure rate levels and sensitivity anticipated; and the removable contamination levels and sensitivity anticipated.

   e. Background readings and each instruments' efficiency or correction factor.

   f. The date(s) that the survey instrument(s) were last calibrated and the radionuclide(s) each was calibrated with. *Please do not* state when the instrument(s) are "due" to be calibrated in the future. Please *do* state when the instrument(s) were last calibrated.

   g. The action levels for exposure rate measurements and the action levels and efficiency (cies) for wipe test measurements. Include the functional identity of areas exceeding these levels, corrective actions taken and results of corrective

actions taken. A reasonable sampling of all surfaces likely to exhibit residual radioactive material or to contain radiation sources should be taken.

2. Your letter included a diagram of your facilities that is from June 27, 2002, and it did not contain complete information for us to evaluate it.

In response, please prepare a new, updated facilities diagram that represents your authorized areas in accordance with the information in NUREG 1556, Vol. 9, Rev. 2, at: https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/

Sections 8.15 Item 9 and 8.16 Item 9 in this guidance document should assist you in preparing the diagram. There is a sample diagram in Figure 9.1.

Please note that this document is somewhat dated and in the process of being revised. The Draft version, Revision 3, of this document is not yet final and may not be used.

However, some details that should be included in the facility diagram but may or may not be shown in the current revision 2, are the direction of north; the actual dimensions of the rooms (or the scale); the functional identity of each space in the department and every space immediately adjacent to the nuclear medicine department spaces; the hot lab; locations and types of shielding; locations of lockable doors; room numbers; and elevation (which level in the hospital) of the department.

Simple, hand drawn diagrams are good; please do not submit blueprints, copies of blueprints or schematics. Such documents show a great deal of information that we do not need and very little, if any, of the information that we do need.

3. Signatures Required for Materials Licensing Correspondence and Best Practices

To help ensure that your materials licensing request is complete and may be acted upon by NRC, all incoming licensing correspondence must be physically and legibly signed by an appropriate certifying officer for the materials licensee in question. Signature stamps, electronic signatures, illegible signatures/initials only, etc. are not acceptable.

An applicant's or licensee's legal representative, administrative assistant, outside consultant, etc. will not suffice as a certifying officer.

As enumerated below, for all materials applicants and licensees, and as noted for medical/human use applicants and licensees, all licensing requests must be signed, in order to comply with the regulatory requirements listed below.

If a certifying officer/management representative signs an "initial" licensing request that names someone else as a "point of contact," then the designated point of contact may be the sole signatory for any written responses related to that initial licensing request only, unless the NRC reviewer requests otherwise.

All subsequent "new/initial" licensing requests must then be signed appropriately.

Please always sign every licensing document and communication submitted, even if you sign an email and transmit it to us via email/PDF or fax.

Sending us an email and/or a fax and/or a hard copy mailed document are simply "means of transmission" and not a substitute for an appropriate signatory on the actual documents being transmitted.

Unsigned email messages, electronically generated or imposed "signatures," stamped signatures, etc. are not acceptable substitutes for an actual, physically hand-written legible signature.

Submitting any licensing correspondence without a signature, or with an unacceptable signature, may delay the review process until an acceptable signature is obtained on the document(s) in question.

Please be reminded that 10 CFR 30.32(a) and (c) require:
" (a) A person may file an application on NRC Form 313, "Application for Material License," in accordance with the instructions in § 30.6 of this chapter." And,
"(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf."

Please note that the NRC Form 313 and the NRC Form 314 require the typed or printed name, position and signature of a certifying officer. The NRC Form 313 can be found at:
http://www.nrc.gov/reading-rm/doc-collections/forms/nrc313.pdf

If the NRC Form 313 is not used, then a business letter containing all of the information on the NRC Form 313 may be used instead.
The NRC Form 314 can be found at:
https://www.nrc.gov/reading-rm/doc-collections/forms/nrc314.pdf

10 CFR 30.9(a) requires: " (a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects."

For medical/human use applicants and licensees:

10 CFR 35.12 Application for license, amendment, or renewal requires:
"(a) An application must be signed by the applicant's or licensee's management."

10 CFR 35.2, "Definitions" states, in part:
"Management means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates."

Please address all initial licensing correspondence to: "ATTN: Materials Licensing Branch Chief" at the address shown below.

If you are directed to respond to a specific, named reviewer during the review process, then direct your written response to that reviewer by name.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Colleen Carol Casey

Colleen Carol Casey
Materials Licensing Branch

License No. 13-16138-01
Docket No. 030-10475
Control No. 610183