UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

JAN 24 2019

John Phillip Cox, D.O.
Radiation Safety Officer
DLP Marquette General Hospital, LLC
d/b/a UP Health System – Marquette
580 West College Avenue
Marquette, MI 49855

Dear Dr. Cox:

Enclosed is Amendment No. 81 to your NRC Material License No. 21-05432-04 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9807 so that we can provide appropriate corrections and answers.

A. Please note that this amendment names you as the Radiation Safety Officer (RSO) for this license; expands your authorization to include the use of materials in 10 CFR 35.394; and authorizes certain proposed facilities for the new hospital location at 850 W. Baraga Avenue, Marquette, Michigan ("new hospital").

B. This also refers to the telephone discussion on January 23, 2019, between Renee Brundin, Ph.D. and Janice Chudy of your staff; Shan Marlette, your consultant; and me.

   Our discussion concerned several issues, as follows:

   1. The facility diagrams included with your letter dated October 21, 2018, did not designate space for the secure, shielded receipt, use and storage of materials listed in Subitem No. 6.D. of your license, iridium-192 permitted by 10 CFR 35.400.

      Even though you are not using this material presently and you haven't used it in many years, in order to continue to authorize it on your license after you move to the new hospital, you must designate appropriate space for the secure, shielded receipt, use and storage of these materials, including an appropriate description and diagram of this space.

      Please follow our previous guidance to you for the preparation of facility diagrams in our letter to you dated October 3, 2018, item B.1.

      Please also follow the instructions given below to prepare, identify, sign and transmit your response correctly.

   2. The Positron Emission Tomography (PET)/CT facility shielding evaluation and report submitted with your letter dated October 21, 2018, was incomplete in that several pages were "cut off" and information was missing.

In addition, the report was "prospective" in that it described what its preparers suggested that you "should" do to build out and shield the new PET facilities safely but it did not specify what you actually "did" to build out and shield the new PET facilities safely.

On January 24, 2019, I received an email from Dr. Brundin of your staff, transmitting a copy of the corrected PET shielding evaluation and some photographs of the PET shielding build-out.

Unfortunately, we were unable to accept this submission because it was transmitted without a document that completely identifies your license that is also currently dated and signed by either a senior manager or, in this case, a previously designated "point of contact." This submission was not reviewed for this amendment.

We also received a faxed transmission on January 24, 2019, from Janice Chudy of your staff that included an appropriate letter identifying your license that was also currently dated and signed by a previously designated "point of contact" for this control number. This transmission was reviewed for this amendment.

In response, please prepare an amendment request, marked to my attention at the above address as "additional information to control number 610396 (note, this is a different control number than you've used previously for PET department submissions)." This will help ensure that your response is processed correctly in our offices.

Your letter must completely identify your license and be currently dated and legibly signed by a senior management official or one of the previously designated "points of contact" for the PET department facilty issues.

Please refrain from submitting photographs of the PET shielding build-out as they are not necessary and we do not request them.

Please review carefully the corrected PET shielding evaluation report and insert appropriate specific information updating it as to what you actually did in the build-out. Merely stating what was "required" and/or "suggested" shielding may be very different from what you actually "did" so describing what was done should assist us in understanding the evaluation better.

C. If you have any specific questions concerning this letter or the information we are requesting, please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is 630-515-1078. My email address is colleen.casey@nrc.gov.

   Please do not resubmit any information beyond the scope of our specific requests, such as if you were to resubmit your letters in entirety again. Resubmitting in entirety, unless we request it, often delays the progress of our review without benefit to your licensed program.

D. Since there appears to be some misunderstanding between us regarding how to prepare, sign and submit licensing correspondence, the following information may be of assistance to you going forward. This is not official guidance, it is just language that I have had to use many times over the years in similar situations.

"Signatures required for Materials Licensing Correspondence and Best Practices"

(The terms "applicant" and "licensee" are used interchangeably in the following)

Please note 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 requires the typed or printed name 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-style letter containing all of the identifying information on the NRC Form 313 may be used instead. Please identify your license by name, mailing address and license number; control number, if known; the current date; and a physical and legible signature, as described below.

To help ensure that an application for a new, amendment or renewal materials licensing request is complete and may be acted upon by NRC, all incoming licensing correspondence must be signed by an appropriate certifying officer for the materials licensee in question.

An applicant's or licensee's legal representative, administrative assistant, outside consultant, etc. will not suffice as a certifying officer for an initial request. Such persons, if designated in writing by an applicant's or licensee's certifying officer first, may serve as point(s) of contact and/or signatories for responses to requests for additional information to a specific initial request.

However, it is simplest and best to have all licensing correspondence signed by an appropriate certifying officer for the materials licensee in question.

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

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.

Unsigned email messages, electronically generated or imposed "signatures," stamped signatures, etc. are not acceptable substitutes for an actual, physically hand-written 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 also note that 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 (i.e., the first request for a new license, amendment or renewal) licensing correspondence to: "ATTN: Materials Licensing Branch Chief" at the address shown above on our letterhead.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you.

This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions.

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture.

You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html.

We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Sincerely,

Colleen Carol Casey

Colleen Carol Casey
Materials Licensing Branch
Region III

Docket No. : 030-18133
License No.: 21-05432-04

Enclosure:
Amendment No. 81