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

OCT 0 9 2018

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

Dear Dr. Pap:

Enclosed is Amendment No. 80 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, although your letter dated August 17, 2018, stated that you have no iridium-192 sources in storage, the last seeds were shipped out on June 9, 2003, and you enclosed the return receipt for the last seeds from the vendor, you failed to direct us to amend your license with this information. We cannot take action on your license unless you specifically request what you want us to do.

   If you want us to remove this authorization from Subitem No. 6.D. on your license, you have to explicitly tell us that is your intention. We cannot amend your license based upon a guess or inference.

   As you no longer have these materials, we excluded authorization for these materials from the new hospital location in Condition No. 10.C. If you want to amend your license to remove them, please advise us specifically in a written amendment request letter. At that time, we will also amend Dr. James R. Baer's authorization to remove the authorization for materials in 10 CFR 35.400.

   Within 30 days of the date of this letter (by November 7, 2018), please prepare an amendment request, marked to my attention at the above address as "additional information to control number 609348." 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.

   If an alternative timeframe for response is needed please contact me directly. Or, 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.

B. We noted that your letters dated June 18, 2018, and August 17, 2018, were minimally adequate to describe the licensed activities proposed for your new hospital location that is expected to open in April 2019, especially with respect to your proposed use of Positron Emission Tomography (PET) materials. We were unable to approve the new PET/CT rooms at this time. We still need some additional information for the nuclear medicine and nuclear cardiology departments.

Within 30 days of the date of this letter, please follow the instructions above and provide a written response to the following issues:

1. Please resubmit your facility diagrams for the proposed areas of use in the new hospital and show the direction of north on each one, as well as specifying which level each department will be located on. Your diagrams should be either drawn to scale or show actual dimensions.

   Please always prepare your diagrams in accordance with NUREG 1556 Vol. 9, Rev. 2, entitled "Consolidated Guidance About Materials Licenses," sections 8.15 Item 9, 8.16 Item 9 and Figure 9.1. Please do not send us blueprints or copies of blueprints as they typically show much information that we do not need and relatively little of the information that we do need.

2. A shielding evaluation and calculations to support such were not included in your letters above for the proposed PET/CT rooms and areas. We understand that part of your proposed PET/CT operations will be conducted with a mobile service.

   We were unable to determine what the resultant radiation exposures would be during actual patient usage, both without and with shielding, in the rooms associated with the proposed PET/CT department at the new hospital.

   No equations, assumptions, constants, or substitutions were included that would permit us to independently evaluate the adequacy of the shielding in these spaces.

The facility diagrams and shielding calculations you submit for the proposed PET/CT areas must show compliance with 10 CFR Part 20.1101, "Radiation Protection Programs," 20.1301 and 20.1302, "Radiation Dose Limits for Individual Members of the Public," and 20.1501, "Surveys and Monitoring."

In providing this information, please consider and include the following, as appropriate:

The following is a listing of some peer reviewed literature that addresses PET/CT design and shielding considerations and factors. It may be used to assist you in preparing your PET and PET/CT facility design and shielding calculations.

It is our understanding that PET use is commonly combined with CT use. So when this document refers to "PET" it is also referring to "PET/CT" even if not explicitly stated.

This is not intended to be an exhaustive, all-inclusive list:

http://www.aapm.org/pubs/reports/RPT_108.pdf

http://www.crcpd.org/Pubs/PET-CT-Fusion/02-18-04_1330-Martin.pdf

http://www.radsafe.com/Papers/PETpaper.pdf"

Please be sure to characterize the rooms and areas involved as "restricted areas" and "unrestricted areas," which are terms defined in 10 CFR 20.1003 according to radiation exposure levels.

Show the functional identity of each room, space or area immediately surrounding the PET/CT rooms, including above, below and outside and whether they are restricted (R) or unrestricted areas (U).

Please provide shielding evaluations based on the "worst case scenario" for your proposed facility. For example, maximum activity used per patient, maximum number of patients injected and in queue at about the same time, distance assumptions, maximum potential exposure rates, etc.

F-18 will be the bounding isotope for any shielding evaluations provided.

Exposure results should be shown in units of millirem per hour and traditional units should be used throughout, but may be provided "in addition to" SI units.

Please provide revised diagrams (simple, hand-drawn diagrams are good) that clearly show the entire PET usage stream, from the receipt and survey of incoming packages/doses to the injection areas, prep/quiet rooms, patient rest rooms, PET console/control area, PET and/or PET/CT scanning rooms, "post-dosed" or "post prepped" patient waiting rooms (should be separate from "pre-dose" waiting room where non-injected patients wait), and waste storage facilities.

Please:

*indicate the expected path for a typical patient, such as waiting room, changing area, injection room, quiet area, rest room, PET scanner room, waiting room and/or changing room;

*describe for each barrier in each direction, including ceiling and floor:

**the specific composition (poured concrete, block concrete, Ledite (concrete with added metal aggregates enhancing shielding ability), lead, steel, gypsum board/drywall, etc.);

**thicknesses of each barrier (individually and total, expressed in inches, feet or centimeters); and,

*the distances from the patient/"exposed source" to the opposite, occupiable places for barriers/walls/ceilings/floors in all directions.

Please indicate clearly whether persons may gain access to any area above or below the proposed PET facilities. If these areas may be occupied during PET studies, please either submit exposure rate calculations to demonstrate that the doses received will not exceed the limits in 10 CFR 20.1301 or describe the administrative controls (training, posting, surveillance, closed circuit television surveillance, lock-out, etc.) that will be put in place to prevent occupation during PET use.

Please provide simple and complete shielding calculations, using traditional units (preferred), showing all of your work, barrier transmission factors (and calculation of them), appropriately detailed assumptions, defined terms, equations, constants, substitutions and parameters to demonstrate that radiation levels in all adjacent areas, including above and below the room, will not exceed levels in 10 CFR 20.1301.

It should be clearly shown what the anticipated worst case dose rates from PET/CT use are expected to be in each area before shielding is applied and then, after the specifically described shielding is factored in, what the shielded dose rates will be.

Please include the following details in your calculations:

a. expected radiation levels for each under the most adverse and typical source term usage and workload;

b. all parameters used to perform the calculations, including: dose rate constant values; typical dosage and expected worst case dosages amounts in millicuries; whether syringe shields, L-blocks, remote handling tools, portable shields, etc. will be used; distance to each area of concern, the type and thickness of material(s) used as shields, especially if portable shields will be used;

c. the number of patients expected per week(i.e., workload);

d. occupancy factors used for all adjacent areas, including areas above and below;

e. demonstrate by calculation that the dose received by an individual member of the public likely to receive the highest dose from PET procedures when present in unrestricted area (in mrem/hr and mrem/yr) will not exceed the limits specified in 10 CFR 20.1301(a);

f. sufficient information, in a readily understandable format to permit us to independently evaluate the adequacy of shielding in your proposed PET facilities.

Please describe the equipment (remote handling tools, syringe shields, portable shields, etc.) you will have available to keep exposures to all personnel, workers and patients, under the limits specified in 10 CFR Part 20.

It appears that personnel attending and working with PET patients will be likely to receive exposures exceeding the 100 millirem per year, as specified in 10 CFR 19.12.

Please describe your training program for these radiation workers, both initially and at least annually, as well as when the regulations affecting them and/or the license changes take place.

C. To remove a location of use from your license, such as when you want to delete the old hospital's address from the license after you have completely moved into the new hospital (for future reference):

1. Start with a master list of every authorization that has ever been authorized for the location of use, i.e., the old hospital, even those authorizations that have already been taken off before. This is an historical review.

2. State explicitly which of these authorizations you ever actually used (as in possessed, stored, handled, used, etc.) and if you used an authorization or more than one, when did you stop using the authorization, as in a date (month and year minimum).

3. If you did not use a specific authorization(s), tell us that explicitly also. Bear in mind that we will corroborate your responses with your inspection and enforcement history in our records.

4. For those authorizations that you used, you must account for each "from cradle to grave." In other words, you have to describe what you used and where (locations of use, areas of use, storage, etc.); prove that there is no residual leakage, if sealed sources were involved; prove that there is no residual, removable contamination; prove that all materials have been decayed, if allowed; prove that all materials have been disposed of to authorized/licensed entities, received by them and acknowledged by them; and provide copies of Agreement State license(s) for those recipient entities licensed by Agreement States, as NRC does not have access to these licenses to verify their licensure.

   We cannot authorize licensees to release the "locations/addresses of use" from licenses for unrestricted use (even by other staff members) until we have received and reviewed a copy of the results of final status surveys, i.e., "decommissioning" and "close-out surveys," for the affected facilities.

   The final status surveys must include a complete historical review of all actual licensed materials possessed, used, stored, etc., including sealed sources and unsealed materials, spills, and contamination.

   If sealed sources were transferred or disposed of as part of the close-out of the location of use, please provide a copy of the final leak test result for each sealed source; a copy of an acknowledgment of receipt from the licensed entity who took possession of each source, with an appropriate level of detail to identify the source and recipient; the NRC license number or license copy of the recipient/transferee; and if the recipient/transferee is an Agreement State licensee, please include a current, complete, unredacted copy of its license that clearly shows it is licensed to receive your sources.

If unsealed materials (such as in 10 CFR 35.100, 35.200, 35.300, 31.11 and carbon-14, hydrogen-3, etc.) were transferred or disposed of as part of the close-out of this location of use, please provide a copy of an acknowledgment of receipt from the licensed entity who took possession of each material; and if the recipient/transferee is an Agreement State licensee, please include a current copy of its license that clearly shows it is licensed to receive your materials.

Please note that bills of lading, shipment manifests and shipping papers do not usually contain sufficient information to demonstrate that materials have been safely received by an appropriately licensed entity. They typically indicate that materials were prepared for shipment or transfer only, not that they were received and accepted into the recipient's inventory under its license.

An assumption of decay for relatively short-lived materials is insufficient to support a termination request absent submission of appropriate surveys, source transfer documentation, etc., as outlined in this letter.

Please also be reminded that the "decay-in-storage (DIS)" provisions in 10 CFR 35.92 only apply to materials with a half-life of 120 days or less. For example, this provision may not be used for cobalt-57 sources, among others.

The following references may assist you: 10 CFR 30.41; 10 CFR 30.51; 10 CFR 35.13; 10 CFR 35.14; 10 CFR 35.92; 10 CFR 35.2092; NUREG 1556 Vol. 9, Rev. 2, section 11, "Termination of Activities," (if you have a medical program; check the "Termination of Activities" section in other volume(s) in the NUREG 1556 series for other than medical programs at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/); "NRC Form 314" at http://www.nrc.gov/reading-rm/doc-collections/forms/nrc314.pdf; and NUREG 1757, Vol. 1, Rev. 2 at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v1/.

Your complete historical review should specify when and where all licensed materials (such as in 10 CFR 35.100, 35.200 and 35.300 (please note these are the correct ways to designate subsections in 10 CFR Part 35, not "Part 100, Part 200, etc.") were actually possessed under the license and used, when the last use was for each material or modality and how, when and by whom were the materials disposed of (shipped off site, decayed -in-storage, sanitary sewer disposal, etc.) or transferred.

For licensed materials and waste that were "decayed - in – storage" (DIS), please include a copy of the final disposal record showing that licensed materials were decayed appropriately and disposed of in accordance with NRC's regulatory requirements and the terms of the license, such as 10 CFR 35.92 and 10 CFR 2092.

For other licensed material waste streams (only if appropriate), such as incineration (volume reduction), animal carcasses, shipment for burial, compaction, vial disposal, and so on, provide copies of appropriate records to demonstrate "cradle to grave accountability."

The final records needed will vary based upon the chemical and physical forms of materials; their associated half-lives; and the form(s) of disposal employed.

Unless you are specifically directed to do so, please do not submit "all" records from the beginning of the license to the present. For example, please only submit the last, or final, records for leak tests, DIS disposal, etc.

The final status surveys should consist of: exposure rate measurements to show that all sources of radioactive material have been removed; and, contamination checks (wipe tests) of areas where radioactive materials were used or stored.

Radiation levels associated with surface contamination and removable contamination should not exceed those specified in your license or in NUREG 1757 Vol. 1, Rev. 2 at: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v1/

Please submit the following information with your close-out survey:

a. Diagrams of each facility (area(s) of use and/or locations/addresses 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.

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. 80