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

June 29, 2020

James I. Monroe, Ph.D.
Radiation Safety Officer
Mercy Hospital South
10010 Kennerly Road
St. Louis, MO 63128

Dear Dr. Monroe:

Enclosed is Amendment No. 66 to your NRC Material License No. 24-01041-04 in accordance with your request.

This refers to your letters dated January 15, 2020, and June 5, 2020, and to the telephone discussion between you and me on June 24, 2020.

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) 829-9887 so that we can provide appropriate corrections and answers.

A. This refers to the letter dated January 15, 2020, requesting the addition of a new address of use and areas of use to your license for PET/CT studies and high dose rate (HDR) remote afterloading brachytherapy.

Your request for areas of use for PET/CT studies at the new location of use was minimally adequate. We approved the areas of use at the new location of use, limited to PET/CT studies only, but in order to complete our review, please submit the information below within 90 days of the date of this letter, by October 1, 2020.

Please provide only one complete, written response to the issues below that is currently dated and signed.

If an alternative timeframe for response is needed please contact me directly, email is usually best and scheduling a telephone call is most efficient. Or, if you have any specific questions concerning this letter or the information we are requesting, please contact me at either (630) 829-9841. My fax number is 630-515-1078. My email address is colleen.casey@nrc.gov.

Scheduling a telephone call with me to discuss the issues in this letter is strongly recommended.

**The enclosed document contains sensitive security-related information.
When separated from this cover letter this letter is uncontrolled.**

Please do not resubmit any information that we are already in possession of for this request, 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.

Your written response should be addressed to my attention at the above address, as "additional information to control number 617627" This will help ensure that your response is processed correctly in our offices.

We found that the information in your letter dated January 15, 2020, requires additional support and clarification so that we may more definitively ascertain the actual shielding used in the new PET/CT rooms and what the resultant radiation exposures would be during actual patient usage, both without and with shielding.

Your information and shielding evaluation appeared to be "advisory/recommended" and prospective. So it is not entirely clear what was actually built and installed in these facilities.

Your shielding evaluation was based upon a typical dose of F-18, 12 millicuries. In your response, please provide shielding evaluations based upon a worst case/highest dose scenario. For example, the maximum activity used per patient, maximum number of patients at the same time, distance assumptions, actual installed shielding utilized, maximum potential exposure rates with and without shielding adjacent to the nearest unrestricted area.

1. Please include equations, assumptions, constants, or substitutions that would permit us to independently evaluate the adequacy of the shielding in these spaces.

2. Please include a copy of your facility diagrams and shielding calculations that 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."

3. Please indicate which points on the diagrams are restricted areas and unrestricted areas, as defined in 10 CFR 20.1003.

4. Please also indicate which points are used for your calculations as primary barriers so that we may independently verify your calculations.

5. 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.

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

   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.

   Your diagrams and letter dated January 15, 2020, use the terms "controlled" and "uncontrolled" areas. These terms are not appropriate for the proposed PET/CT rooms as they are not defined according to expected radiation exposure levels.

Please note also that 10 CFR 20.1003 defines a "controlled area" as "an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason."

"Site boundary" is defined in 10 CFR 20.1003 as "that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee."

According to these definitions, the spaces on your diagram that you consider as "controlled" and "uncontrolled" do not constitute a "controlled areas" or "uncontrolled areas."

Please withdraw your characterization of these spaces as "controlled areas" and "uncontrolled areas" redesignate them appropriately in terminology consistent with 10 CFR Parts 20 and 35, i.e., restricted area, unrestricted area, etc

The more appropriate terminology is "restricted area" and "unrestricted area," which are terms defined in 10 CFR 20.1003 according to radiation exposure levels. Please incorporate the correct terminology in your response.

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

7. Your letter states that the space above the PET/CT suite is occupied fulltime but does not specify what functions occupy that space. Please specify these functions in your response.

   Please indicate clearly whether persons may gain access to any area above the PET/CT facilities. If these areas may be occupied during PET/CT 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/CT use.

8. If your PET room diagrams consist, even in part, of copies of blueprints, which we strongly discourage submitting (blueprints show a lot of information we do not need and very little of what we do need and they are often illegible), we will be unable to gain a full understanding of your PET facilities. Kindly refrain from submitting blueprint diagrams or copies of them.

   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 clearly show the location and functional identity of all contiguous rooms, areas and/or spaces surrounding the PET facilities, especially the areas above and below the afore-mentioned rooms where the PET materials will be used in patients.

Your diagrams should be either drawn to scale or show actual dimensions and should:

*provide room numbers (if none, please so state or identify the room by another means);

*show the direction of north;

*show the functional identity of each room, space or area immediately surrounding all of the PET facility rooms and indicate clearly whether they are restricted (R) or unrestricted areas (U);

*show the elevation/grade clearly described and what spaces are above and beneath the PET rooms, their functional identity and whether they are restricted (R) or unrestricted areas (U); please include whether the roof will be restricted or unrestricted;

*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.

9. 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.

g. 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.

h. It appears that personnel attending and working with PET/CT 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.

B. In the telephone call we had on June 24, 2020, concerning the new cancer center, it appeared that there might have been a misunderstanding concerning which authorizations under the license will be transferring to the new cancer center.

Your letter dated January 15, 2020, only stated that the PET/CT and HDR authorizations were going to transfer to the new cancer center.

However, you failed to account for any other changes, additions or deletions of authorizations between the existing main hospital and the new cancer center.

Please carefully review each and every authorization that currently appears on your license and determine whether it will transfer to the new cancer center; remain at the main hospital; be deleted from the license (which will require decommissioning and other related information to support); and/or be duplicated at both the new cancer center and the main hospital.

All authorizations must be correctly attributed to the locations of use where they are practiced. All locations of use must correctly reflect the authorizations practiced at each location.

The information in NUREG 1556 Vol. 9 Rev. 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses, Final Report," which can be found at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/ on our Medical Licensing Toolkit website, should be very helpful to you.

C. Your letters above also requested the deletion of your former HDR sealed source and device authorization in favor of replacing it with your new HDR sealed source and device authorization for the new cancer center.

In our telephone discussion on June 24, 2020, we reviewed what information would be needed to delete your former HDR sealed source and device authorization.

That information would include the last leak test on the former HDR sealed source, as required by 10 CFR 35.67, and documentation of that last leak test to contain all of the information required by 10 CFR 35.2067.

The "leak test" result included in your letter dated June 5, 2020, did not include most of the information required by 10 CFR 35.2067. Please provide this information in response.

You also stated in our call that you were going to obtain a copy of the license for the entity that took possession of your former HDR source for disposal. This license should be current and clearly indicate that the entity is authorized to perform the waste disposal and transfer activities already conducted.

Please forward a copy of the license for this entity to us in response also.

D. The information submitted with your letter dated January 15, 2020, to support adding the new HDR source and device and facilities was insufficient to permit us to complete our review.

For example, you submitted as "Appendix 3 HDR Vault Shielding" a report for proposed 18 MV linear accelerators at Mercy Hospital South Cancer Center St. Louis Missouri."

This report is entirely based upon shielding for an 18 MeV linear accelerator at your new cancer center and fails to address shielding for your proposed new HDR source and device. This is unacceptable.

In response, please do not submit a report like this one for the new HDR source and device, as we will have similar issues with it as we had for the PET/CT shielding report.

Instead, please use the following information to structure your written response.

1. As your HDR room diagrams showed relatively little of what we need in order to evaluate them, we were unable to gain a full understanding of your proposed new HDR facilities.

Please provide revised diagrams (simple, hand-drawn diagrams are good) that clearly show the HDR treatment room and the location and functional identity of all contiguous rooms, areas and/or spaces surrounding it, especially the area above it.

Some of this information was included in your application's attachments but much of it was not, or was difficult to decipher.

Please clearly state and mark the street address for the HDR room on one of the diagrams and include with your response.

Your diagrams should be either drawn to scale or show actual dimensions;

*provide correct room numbers for all spaces (if none, please so state or identify the room by another means);

*show the direction of north;

*show the functional identity of each room, space or area immediately surrounding the HDR room and whether they are restricted (R) or unrestricted areas (U);

*show the elevation/grade clearly described and what space is above the HDR room, its functional identity and whether it is restricted (R) or unrestricted area (U);

*indicate clearly on the diagram where you anticipate the patient/"exposed source" to be located within the room;

*for each barrier in each direction, including ceiling/roof:

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

**thicknesses (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 adjacent to, or above the proposed HDR treatment room.

If areas may be occupied during treatment, 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, key control, etc.) that will be put in place to prevent occupation during HDR treatments or source exposures.

2. Please provide simple and complete shielding calculations, using traditional units (preferred), showing your work, barrier transmission factors (and calculation of them), 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.

Please include the following details in your calculations:

a. expected radiation exposure rates, in traditional units, for each adjacent area, under the most adverse and typical source orientations and maximum installed source activity, both without shielding and distance factored in and with shielding and distance factored in;

b. all parameters used to perform the calculations, including: 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 maximum "beam-on time" per hour and per week; the number of patients/treatments/exposures 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 HDR 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 room.

3. Please confirm that the postings required by 10 CFR 20.1902, based upon definitions in 10 CFR 20.1003, will be placed, for the new HDR room, the roof above it and for any immediately adjacent spaces where it may be necessary.

4. Your diagrams and letter dated January 15, 2020, use the terms “controlled” and “uncontrolled” areas. These terms are not appropriate for the new HDR facility as they are not defined according to expected radiation levels. The more appropriate terminology is “restricted area” and “unrestricted area,” which are terms defined in 10 CFR 20.1003. Please incorporate the correct terminology in your revised amendment request.

5. Please specify what your HDR source activity will be at the time of first medical use after the installation of a new source and after every new source exchange.

6. Please specify the terminal degree for Authorized Medical Physicist Gopal Subedi, as none is listed and we normally specify terminal degrees beyond the bachelor degree level.

7. The following is some general information, compiled from deficiency correspondence I’ve prepared over the years, to assist you in preparing not only this response, but also any future licensing actions, to minimize or eliminate requests we must make for additional information. This can greatly lessen the workload for you and for us and permit us to serve you better.

Please be reminded that USNRC is an independent and objective federal government regulator.

This is not intended to be "all-inclusive", nor is it a substitute for your reviewing our regulatory requirements and guidance as they apply to your particular license and situation and preparing your licensing requests in accordance with them.

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.

In preparing your response, please also be reminded of the provisions in 10 CFR 30.9(a), "Completeness and accuracy of information,"..."(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."

What this means, in part, is that the first vetting of any licensing request is expected to be made by the requesting applicant/licensee, against the regulations, license requirements and guidance involved.

Only after the request has been thoroughly vetted and corrected by the applicant/licensee should the licensing correspondence be transmitted to NRC.

This is the expectation that NRC uses to most efficiently process and review in a timely manner the many licensing actions received. The quality of the incoming request is a primary determining factor that only the applicant/licensee can control that enables NRC to serve and protect the public and the environment.

For HDR licensing specifically:

Please refrain from submitting copies of "off the shelf" licensing packages prepared by other licensees, vendors or consultants. We understand that these packages may seem to be convenient but HDR authorizations are not "one size fits all," considering that 37 Agreement States each have their own requirements and guidance, in addition to that of the NRC.

Experience has shown that these documents are not crafted to address current NRC regulations and guidance.

On the contrary, such documents are often based upon "guidance" that NRC used from 1993 – 2002. NRC discontinued that "guidance" when 10 CFR Part 35 was revised completely in April 2002 and HDR regulations were first promulgated.

Using such documents now may "over-commit" your HDR program in several areas and "under-commit" your program in most others. This creates the need to contact you for additional information resulting in mutual delays and extra work.

In addition, please do not send us vendor's operations manuals, vendor's emergency procedures manuals, dosimetry equipment calibration information, lengthy procedure details, patient instructions and explanations, Department of Transportation (DOT) test results for the sealed source packaging to be used by the vendor for shipment of your source, patient records, resumes, college transcripts, purchase orders and brochures for non-NRC licensed activity supplies (such as computer tables, and wastebaskets, etc. and any personally identifiable information.

We never need or ask for such information but it is often submitted to us instead of briefly and concisely providing the information specifically called for in our regulations and our guidance. Your current application and subsequent letters contained multiple copies of such information so please refrain from doing so again.

When submitting the procedures required by 10 CFR 35.610 and 35.643, please include a brief description of the procedure/check itself.

In other words, the procedure should describe "how" you will do the particular task to meet the requirement. Simply stating that you "will" meet the requirement or perform the task is not a procedure.

Further, providing a copy of a checklist that you use to record the results of procedures/tests/tasks, etc. is not an acceptable substitute for providing commitments to perform procedures/tests/tasks, etc. and a description of how each will be done.

It is acceptable to describe how you will perform a procedure and to also state that you reserve the right to change the procedure so long as the regulatory requirement is met and safety is not degraded. Please see 10 CFR 35.26, for additional regulatory assistance in this matter.

It will be helpful for you to refer to 10 CFR 35.600-35.657 (Subpart H) and corresponding sections in NUREG 1556, Vol. 9, Rev. 3, above.

The technical quality, accuracy and completeness of your submission are primary factors that only you can control in order to enable us to help you more promptly and minimize delays in the reviewing process.

Please note that your submission should not include extraneous documentation, which only serves to delay the review process.

Please only submit information that our regulations and guidance specifically address. Please completely and concisely answer questions that we ask and provide information that we specifically request.

E. In the course of our review, we noted that that your authorization for an unspecified radionuclide permitted by 10 CFR 35.500 listed in Subitem Nos. 6. through 9.H. is for a gadolinium-153 source and is authorized "For storage only incident to disposal."

This change in authorization became effective in Amendment No. 63 dated November 17, 2016, so this source has already been in DIS for more than three and a half years.

This authorization was not expected to be in effect for an indefinite period of time.

It is expected that you are actively arranging the final transfer and disposal of this material because 10 CFR 35.92 restricts the disposal of licensed material for "decay –in-storage" (DIS) to only those materials with a half- life of 120 days or less, provided that those materials meet the other requirements in 10 CFR 35.92.

Gadolinium-153 has a half- life of approximately 240 days, which excludes it from DIS.

In your written response, please describe the measures you are taking to dispose of this source to an appropriately licensed entity.

Please also include a reasonable, approximate near term timeframe when you expect to have these materials disposed of to an appropriately licensed entity. We cannot authorize continued indefinite storage of this source.

The following references may assist you: 10 CFR 30.41; 10 CFR 30.51;10 CFR 35.92; 10 CFR 35.2092; NUREG 1556 Vol. 9, Rev. 2, section 11, "Termination of Activities and NUREG 1757, Vol. 1, Rev. 2 at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v1/.

NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS, the NRC's electronic document system.

Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390, the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability.

The RIS may be located on the NRC Web site at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf and the link for frequently asked questions regarding protection of security related sensitive information may be located at: http://www.nrc.gov/reading-rm/sensitive-info/faq.html.

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

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 C. Casey Digitally signed by Colleen C. Casey
Date: 2020.06.29 14:53:55 -05'00'

Colleen Carol Casey
Materials Licensing Branch

License No. 24-01041-04
Docket No. 030-10108

Enclosure:

Amendment No. 66