[redacted]

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

February 2, 2022

Brian Fedeson, M.D.
Radiation Safety Officer
McLaren Medical Center Bay Region
Nuclear Medicine
1900 Columbus Ave.
Bay City, MI 48708

Dear Dr. Fedeson:

Enclosed is Amendment No.72 to your NRC Material License No. 21-18585-01 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) 829-9887 so that we can provide appropriate corrections and answers.

This amendment authorizes Brooke Spencer, M.D. as an authorized user and changes your Radiation Safety Officer to Brian Fedeson, M.D.

We have reviewed your letter ("the letter") dated October 4, 2021, requesting authorization for a new high dose rate (HDR) remote afterloading brachytherapy device, as permitted by 10 CFR 35.600 for your NRC license number 13-17073-01.

We were unable to approve your request for a new high dose rate (HDR) remote afterloading brachytherapy device at this time as the information provided was insufficient to complete our review. We have determined that the following additional information is necessary to complete your request and continue our review.

If you wish to pursue this matter, please provide only one complete, written response that is currently dated and signed by a senior management official for this license. This will help ensure that your response is processed correctly in our offices.

Your written response should be addressed to my attention at the above address, as "additional information to control number 629144." We will then continue our review.

1. In the letter above, we noted that some extraneous documents were submitted that we did not and do not request when considering applications for new HDR authorizations. Your letter included the complete Sealed Source and Device Certificate (SSDR) for the proposed HDR device, as well as a complete copy of your most recent license

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

[redacted]

amendment. Since NRC maintains the SSDR and issues your license, we already have a copy of this certificate and your license. In the future, you can just provide the SSDR number and identify your license number in lieu of submitting the actual documents.

2. Please explain how the transition from your old HDR device and source will take place, i.e., will you need to retain authorization for the current HDR source and device until the new source and device are delivered and installed? Or have the old source and device been disposed of in an authorized manner already? Your answers will affect how your license is amended.

3. Item 7 of your license requests that only current authorized users (AUs) for HDR, Dr. Bergman and Dr. Gayar, in addition to newly authorized Dr. Spencer, are to be authorized for the proposed HDR source and device.

   Faheem Ahmad, M.D. is also an incumbent AU for HDR on your license but no mention is made in your letter to continue his/her authorization for the proposed HDR source and device. Please explain this discrepancy and if Dr. Ahmad is to be removed from this license, please so state explicitly.

   In addition, if Dr. Ahmad is to be removed from your license, please note that he/she is the only AU listed on your license for the use of materials in 10 CFR 35.300.

   Please advise us that you are aware of this concern in your written response. Please also advise us as to whether Dr. Ahmad is male or female.

4. Item 7 of your license requests that only current authorized medical physicists (AMPs) Ahmad Alkhatib, Ph.D. and Travis D. Schultz, M.S. are to be authorized for the proposed HDR source and device.

   Vijeshwar K. Sharma, M.Sc. and Terrence J. Dillon, M.S. are also incumbent AMPs on this license but no mention is made in your letter to continue either or both of their authorizations for the proposed HDR source and device. Please explain these discrepancies and if either or both AMPs are to be removed from this license, please so state explicitly.

   For both items 3 and 4 above, please be reminded of the notification rule in 10 CFR 35.13 and 35.14 for AUs and AMPs, among others, who have ceased to perform their duties under your license.

5. Please also clearly state what the maximum activity will be for the new HDR source at the time of installation and medical use. Your letter simply requests 15 curies but it is not clear whether that refers to the activity upon receipt from the vendor or the activity at the time of medical use.

6. As your HDR room diagrams consisted of copies of blueprints or architectural renderings, that we strongly discourage use of, they showed relatively little of what we need in order to evaluate them and 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 it was implied or difficult to decipher as the font was very tiny.

   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;

   Please clearly identify where the door to the treatment room is as it is not marked or shown on the diagram submitted;

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

   *show the direction of north clearly as this was only implied in your diagram;

   *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) – also see discussion below about restricted/unrestricted areas versus controlled or uncontrolled areas;

   *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.

Please state whether patients will be treated only on a fixed couch in the HDR room or whether patients may be treated on a moveable gurney or while seated in a chair. If treated on a gurney or in a chair, where will these be placed in the room relative to the treatment couch that appears to be the only assumed location of the HDR source for the purpose of your shielding calculations.

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.

Please provide simple and complete shielding calculations, using traditional units (preferred), showing all of 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, to include showing your work in substituting actual values in your equations at each step.

I was not able to fully understand your conclusions based upon the incomplete work provided.

7. Your letter refers us to Appendix E and to Appendix F attached to your letter. In fact, there does not appear to be an Appendix E; there is only an Appendix F, which is inferred by an Appendix E header. Please explain whether something is missing from your letter and attachments.

8. Your diagrams and letter use the terms “controlled” and “uncontrolled” areas. These terms are not appropriate for the new HDR room 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.

9. We were unable to identify some of the requirements procedures (“how you are going to do something”) in 10 CFR 35.610, 35.633 and 35.643 as being present in your letter. Some commitments (“statements that you are going to do something and, as appropriate, how, briefly”) required by 10 CFR 35.615 are also needed.

   The missing items are listed as follows, as links to the pertinent regulations:

   a. 10 CFR 35.610 (a)(2);
   b. 10 CFR 35.610 (a)(4)(iii);
   c. 10 CFR 35.610 (c)(2);
   d. 10 CFR 35.615 (e);
   e. 10 CFR 35.615 (f)(ii);
   f. 10 CFR 35.615 (f)(4)
   g. 10 CFR 35.633 (b)(5), with respect to whether determination of timer accuracy and linearity over the typical range of use should be limited to only 200 seconds as your procedure states;
   h. 10 CFR 35.633 (b)(6) and (b)(7);
   i. 10 CFR 35.643 (d)(2) pertaining to the source exposure indicator light on the control console;
   j. 10 CFR 35.643 (d)(5);
   k. 10 CFR 35.643 (d)(7) and (8); and,
   l. 10 CFR 35.643 (e).

10. 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.

For example, your letter includes a reference to “check source homogeneity.” This was a check that was in the old HDR guidance preceding the first inclusion of HDR regulations in 10 CFR Part 35 in 2002. We have not asked licensees to “check source homogeneity” in 20 years.

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, 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, and this is something you did not do but I’m only including it for the sake of completeness, providing a copy of a checklist used 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.

Your letter, and especially attachments, do not follow the ordering in our regulations very much, which makes your them very difficult to evaluate and review. You may want to consider updating them, if not now, then in the near future or at your next renewal.

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 available on our website in the “Medical Licensing Toolkit” at https://www.nrc.gov/materials/miau/med-use-toolkit.html for assistance.

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.

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. 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 http://www.nrc.gov/reading-rm/adams.html.

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 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.

If you have any questions concerning this amendment, or the additional information requested below, please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841.

My fax number is (630) 515-1078 and my email address is colleen.casey@nrc.gov.

Sincerely,

Colleen C. Casey

Digitally signed by Colleen C. Casey
Date: 2022.02.08 12:35:14 -06'00'

Colleen Carol Casey
Health Physicist
Materials Licensing Branch
Region III

Enclosure:

Amendment No. 72

License No. 21-18585-01
Docket No. 030-13900
Control No. 629144