[redacted]

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

February 25, 2022

Alan S. Jackson, M.S., CHP
Radiation Safety Officer
Henry Ford Macomb Hospital
15855 Nineteen Mile Road
Clinton Township, MI 48038

Dear Mr. Jackson:

Enclosed is Amendment No. 74 to your NRC Material License No. 21-11850-01 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.

If you have any questions or comments please contact me at either (800) 829-9500, ext. 9841 or (630) 829-9841. My fax number is (630) 515-1078. My email address is colleen.casey@nrc.gov.

If you wish to schedule a telephone call to discuss the items below, please contact me via email to do so.

This refers to your letter ("the letter") dated July 7, 2021, concerning an amendment request for your NRC Material License No. 21-11850-01.

This amendment corrects the spelling of Brian Bismack's name. Notation 1 on the enclosed marked up copy of the letter refers to your request to delete Tarita Thomas, M.D. as an authorized user (AU). This was not done because Dr. Tarita does not appear on your license in any capacity.

We approved the request to use materials in 10 CFR 35.1000, limited to yttrium-90 (Y-90) microspheres and we approved Drs. Schwartz and Shaikh as AUs for this program.

We added Dr. O'Brien to the license as an AU but did not authorize him for materials in 10 CFR 35.500 and 35.1000, limited to Y-90 microspheres.

We have many questions and issues to request additional information from you about.

To simplify this process, we made a copy of your letter and its attachments. We added our own notations and numbering system for each issue in order.

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

[redacted]

Drs. Dalal, Hong, Kalabat and O'Brien were not approved as AUs for the Y-90 microspheres program. There were other issues with your letter as well.

We noted that there was no overall pagination of your letter and its attachments. We have several questions and issues to request additional information from you about or to at least make you aware of. In the future, it would be helpful to paginate your submissions to us.

To simplify this process, we made a copy of your letter and its attachments. We added our own notations and numbering system for each issue in order.

1. Notation 1 concerned Dr. Thomas, as already described above.

2. Notation 2 refers to Item 6 in which you committed to the use of the TheraSpheres "as listed in the Sealed Source and Device Registry SIR-Spheres…." We excluded this reference in Condition No. 13.G.

3. Notation 3A concerns some apparent confusion regarding how to provide proof to NRC that an AU was named to a Type A broad scope license.

   Please see NUREG 1556 Vol. 9, Rev. 3, Appendix D. Section V, which states: "To identify an individual who is authorized under a broad scope license or broad scope permit of a Master Materials License, **provide a complete copy of the permit issued by the broad scope licensee/permittee.** Alternatively, provide a statement **signed by the RSO or chairperson of the RSC** similar to the following: "_____ (name of individual) was authorized under _____ (name of licensee/permittee) broad scope license number_____ to use_____ (materials) during _____ (time frame)." "

   To do this would be a simpler and more straight forward method to substantiate the status of an AU since such a record of the AU's permit under the Type A broad scope license is already required to be maintained under 10 CFR 33.17(b) and the conditions of the broad scope license itself. Please use this method to demonstrate an AU's authorization under a Type A broad scope permit going forward.

. Notation 3B concerns several pages of verbiage about, in part, preceptors. "Preceptor" is defined in 10 CFR 35.2 as "*Preceptor* means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, a Radiation Safety Officer, or an Associate Radiation Safety Officer. "

   As noted on the NRC Form 313A series forms, "The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required."

   The lengthy discussions about preceptors for various proposed AUs appeared to confuse "preceptors" with "supervising individuals." These discussions were largely unnecessary for this request as there was relatively little information that our guidance

for these AUs asked for. I really don't understand what the purpose of this overly detailed information was for – please explain in case I missed something.

4. Notation 4 appears to over-explain the planned implementation of the Y-90 microspheres program, which is unnecessary information. Again, I really don't understand what the purpose of this information was for – please explain in case I missed something.

5. Notation 5 explains that the documentation of proposed AUs was originally approved when NRC's training requirements for Y-90 microspheres users were different. The Y-90 microspheres guidance has undergone 13 different revisions in the 20 years it has been in existence. So we already have an appreciation for this circumstance. Besides, since the explanations for the AUs that this applies to in your letter are for persons who were previously approved by a Type A broad scope licensee, it is not necessary to provide this level of detail. Please see Notation 3A above also. This is a no-response item provided for your information.

6. Notation 6 concerns Ishani Dalal, M.D.. Your letter states "The original request to add TheraSphere use for Dr. Dalal and the original documentation of the Dr. Dalal's approval at Henry Ford Hospital is provided in Appendix C."

   Contrary to the statement above, the only documentation submitted was just an email from Dr. Karvelis to you and Donald Peck (not the full RSC) dated March 12, 2010, requesting that Dr. Dalal have Y-90 TheraSphere administration added to her list of authorized therapeutic procedures. The email does not state that she was ever approved by the Radiation Safety Committee (RSC) for such use; it only requests it. The "documentation" of her training and experience in the email is extremely minimal. It is unclear whether the RSC considered her application and approved or disapproved it. Again, please see Notation 3A above. Please provide appropriate documentation supporting Dr. Dalal's request to become an AU for Y-90 TheraSpheres on this license.

7. Notation 7 concerns IXiaoni Hong, M.D.. Your letter states "The original request to add TheraSphere use for Dr. Hong and the original documentation of the Dr. Hong's approval at Henry Ford Hospital is provided in Appendix D."

   Contrary to the statement above, the only documentation submitted was just an email from Dr. Karvelis to you (not the full RSC) dated January 13, 2010, requesting that Dr. Hong have Y-90 TheraSphere administration added to her list of authorized therapeutic procedures. The email does not state that she was ever approved by the Radiation Safety Committee (RSC) for such use; it only requests it. The "documentation" of her training and experience in the email is extremely minimal. It is unclear whether the RSC considered her application and approved or disapproved it. Again, please see Notation 3A above. Please provide appropriate documentation supporting Dr. Hong's request to become an AU for Y-90 TheraSpheres on this license.

8. Notation 8 concerns John Kalabat, M.D., an existing AU on this license for other modalities. Your letter directs us to Appendix E for the documentation of Dr. Kalabat's TheraSphere training and experience. However, Appendix E consists solely of a largely

illegible copy of a TheraSphere Training Record that we are unable to correlate with the current TheraSphere training and experience requirements in our guidance. Please refer to sections 5.1 and 5.3 in the April 20, 2021, Revision 10.2 of our Y-90 Microsphere brachytherapy guidance in preparing your response.

9. Notation 9 concerns Kevin O'Brien. Item 7.4, Table 2, requests that we add approval for, among other things, 10 CFR 35.500 for Dr. O'Brien. However, this license does not authorize materials in 10 CFR 35.500. Please explain if this was an error that we should disregard or if you really want to add authorization for materials in 10 CFR 35.500 to this license at this time. If you do want to add this authorization, please provide the information requested in NUREG 1556 Vol. 9, Rev. 3.

   Your letter directs us to Appendix F for the documentation of Dr. O'Brien's TheraSphere training and experience. However, Appendix F consists solely of a largely illegible copy of a TheraSphere Training Record that we are unable to correlate with the current TheraSphere training and experience requirements in our guidance. Please refer to sections 5.1 and 5.3 in the April 20, 2021, Revision 10.2 of our Y-90 Microsphere brachytherapy guidance in preparing your response.

10. Notation 10 concerns what your letter describes as "Additional Facility Locations." It then describes some areas of use where the Y-90 TheraSpheres will be used.

    Please refer to 10 CFR 35.2, Definitions. "Locations" is not defined but is commonly used to describe "addresses of use," which is defined. "Areas of use" is also defined as a portion of an address of use, in part. This appears in several places in your letter and we are bringing it to your attention for the sake of clarity.

11. Notation 11 concerns your statement: "We reserve the right to update the procedure as needed." Please note that this statement was excluded from your license. If you wish to pursue this flexibility, please provide all of the information requested in section 6.9 in the April 20, 2021, Revision 10.2 of our Y-90 Microsphere brachytherapy guidance..

12. Notation 12 concerns the use of the word "should" several times in section 10.8 of your letter, which is prospective and without meaning in this context. Please replace your commitments here with the word "will" in your response.

13. Notation 13 concerns the submission of 17 pages of documents to support Scott Schwartz, M.D. These documents are largely unnecessary and inappropriate, considering that your letter states that Dr. Schwartz is already approved on the type A broad scope license for Henry Ford Hospital. Again, please see item 3A above as this is the only documentation that we need. This is essentially a no-response item unless you wish to explain the inclusion of these documents instead of the documentation asked for as in 3A above.

14. Notation 14 concerns the TheraSphere Training Record submitted for Dr. Shailkh. Our concern here is already described in the items above pertaining to your proposed AUs. However, the submission of internal clinical records (no licensee or institution is identified on any of the TheraSphere Training Records) is never useful documentation to

submit to us for any purpose. Attempting to review such documents, especially if they are illegible but even if they are legible, is time consuming and we are not able to translate whatever information they may show into the criteria in our guidance for Y-90 microsphere AUs. Please do not submit such documents again. They only serve to delay our review.

15. Notation 15 relates to item 6 for Dr. Dalal above.

16. Notations 16 and 17 relate to item 7 for Dr. Hong above.

17. Notation 18 concerns the inclusion of an email document from a vendor to Ms. Cheryl Martin dated June 28, 2021. This appears to have been submitted in error. However, it highlights the need for licensees to do the first vetting of all of their licensing correspondence to us, as NRC expects. This should have been caught and removed before sending to us.

    The many issues and concerns above should also have been identified, considered and incorporated into the final submission of this request.

    Please be reminded 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."

If you have any questions or comments please contact me at either (800) 829-9500, ext. 9841 or (630) 829-9841. My fax number is (630) 515-1078. My email address is colleen.casey@nrc.gov.

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 "Agencywide Documents Access and Management 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: 2022.02.26 18:19:36 -06'00'

Colleen Carol Casey
Materials Licensing Branch

License No. 21-11850-01
Docket No. 030-02106

Enclosures:

1. Amendment No. 74
2. Marked up copy of letter dated July 7, 2021