



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

April 1, 2021

Dawn Edwards, M.S.
Radiation Safety Officer
Metro Health – University of Michigan Health
5900 Byron Center Ave. SW
Wyoming, MI 49519

Dear Ms. Edwards:

Enclosed is Amendment No. 70 to your NRC Materials License No. 21-12829-01 in accordance with your request dated December 21, 2020.

As requested, we have authorized Dr. Bakalis for Y-90 microsphere use (TheraSphere and SIR-Sphere). However, please note that, with regard to use of Y-90 SIR-Spheres, Dr. Bakalis has conditional approval only. This is based on your letter dated December 21, 2020, in which you indicated that Dr. Bakalis had only completed three simulated (mock) cases for the Y-90 SIR-Spheres. Therefore, please be reminded that, as indicated in the Y-90 microsphere licensing guidance (Revision 10.1, dated March 20, 2020 – ADAMS Accession No. ML20080J208), ***“following conditional approval, the individual should complete the clinical casework described...within a year following the license issuance or amendment that names the individual as an AU for Y-90 microsphere use.”*** If casework is not completed within one year from the date of this letter, please contact us for a possible extension and further guidance.

Please review the enclosed documents 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.

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

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.

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 Title 10 of the *Code of Federal Regulations* Section 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 NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

**Bryan A.
Parker**

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Bryan A. Parker
Date: 2021.04.01
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Bryan A. Parker
Senior Health Physicist
Materials Licensing Branch

License Nos. 21-12829-01
Docket Nos. 030-02134

Enclosures: Amendment No. 70