



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

JAN 18 2017

Samuel S. Hancock, Ph.D.
Radiation Safety Officer
Southeast Missouri Hospital
1701 Lacey St.
Cape Girardeau, MO 63701

Dear Dr. Hancock:

Enclosed is Amendment No. 100 to your NRC Material License No. 24-00128-03 in accordance with your three requests dated December 7, 2016 (ML16343A654, ML16343A651, and ML16343A656) and your two requests dated December 27, 2016 (ML16363A259 and ML16363A251), with the exception of adding authorizations for TheraSpheres for Authorized Users (AUs) Kyle W. Sanders, M.D. and James B. Winblad, M.D. Please also note that we have deleted Condition No. 15 in accordance with current NRC policy to include the reference to Title 10 of the *Code of Federal Regulations*, Part 71, "Packaging and Transportation of Radioactive Material," in the preamble, on page 1 of the license.

Please review the enclosed license amendment 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) 829-9892 so that we may provide appropriate corrections and answers.

We have reviewed your December 7, 2016 letters requesting to add authorizations for the use of yttrium-90 as TheraSpheres for Drs. Sanders (ML16343A651) and Winblad (ML16343A656). Accordingly, we have noted your statements indicating that the AUs training – in accordance with Sections A(3)(iii)(a-g) and B of NRC's 10 CFR 35.1000 guidance document, "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance," dated February 12, 2016 (ML15350A099) – "will be" provided by either the TheraSphere vendor and/or one of the licensee's AUs, as applicable. There is no indication in either letter that the specified training had been completed as of the date of the letters or by the date of this amendment.

To add the TheraSpheres authorizations for Drs. Sanders and Winblad, please resubmit your requests, including all relevant attachments, subsequent to the physicians' completion of all training outlined in Section A(3)(iii)(a-g) and either hands-on experience outlined in either pathway 1 or pathway 2, under section B. Please provide additional documentation of training and experience:

- (1) For A(3)(iii)(a-g) training completed under the supervision of an authorized user, provide the dates on which such training was completed and the name of the supervising AU. Documentation should clearly indicate all topics that were covered during that training.
- (2) For A(3)(iii)(a-g) training completed under the supervision of the TheraSphere vendor, provide a copy of a training certificate or letter, signed by the vendor.

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

S. Hancock

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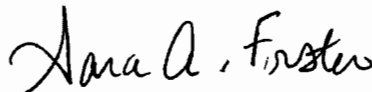
- (3) For B.1. (pathway 1) work experience, include the dates and supervising AUs for completed cases.
- (4) For B.2. (pathway 2) work experience, include a letter or certificate from the vendor representative listing dates on which in-vitro cases are completed. Please also confirm that each individual will complete at least the first three hands-on patient cases supervised in the physical presence of a manufacturer representative (and/or AU), and that the licensee will submit documentation from the manufacturer (and/or AU) to the appropriate NRC Regional Office within 30 days of when these three patient cases have been satisfactorily completed.

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 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>.

In accordance with Title 10 CFR 2.390, a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's ADAMS, which is accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,



Sara A. Forster, M.S., Health Physicist
Materials Licensing Branch
Division of Nuclear Materials Safety

License No. 24-00128-03
Docket No. 030-02264

Enclosure: Amendment No. 100