



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

MAY 31 2017

Saiyid M. Shah, Ph.D.
Radiation Safety Officer
St. Vincent Evansville
3700 Washington Avenue
Evansville, IN 47750

Dear Dr. Shah:

Enclosed is Amendment No. 42 to your NRC Material License No. 13-03226-04 in accordance with your request. Please note that we have changed the system used to prepare your license, which has resulted in several changes to your license. These changes include the removal of License Condition No. 17 as it appeared on Amendment No. 41, and changes to Condition No. 13.

Please note that we are unable to authorize yttrium-90 microspheres permitted by 35.1000 to your license because we are not able to approve Dr. Drozhinin at this time because the information provided in your letters dated January 12, 2017 and April 4, 2017, was insufficient to complete our review. If you wish to pursue this matter, please provide a complete, written response that is currently dated and signed by a senior management official for this license, pursuant to 10 CFR 35.12(a). Please reference Control Number 592789 in your response.

Dr. Drozhinin's request to become an authorized user for materials in 10 CFR 35.100, 35.200, 35.300, and 35.1000, must be fully supported by the description of his education, training and experience on the documents you submitted. Please note that at this time, the NRC cannot add authorized users to a license using the training criteria in 10 CFR 35.390 because supervised clinical case work cannot be completed in all modalities listed in the regulations. Specifically, the training required under 10 CFR 35.390(b)(1)(ii)(G)(4) does not currently have an approved usage with which an individual can complete training.

In addition, the board certificate provided does not contain the words "AU Eligible" above the American Board of Radiology (ABR) seal. As such, it does not meet the training and experience requirements in 10 CFR 35.290. His specialty board certification is not acceptable, according to the listing maintained on our website at:

<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

A key part of the supporting documentation consists of verification of his preceptor, Dr. Kent Friedman. His Forms NRC 313a (AUD and AUT) were signed by his "Supervising Individual," Dr. Kent Friedman who appears to be listed on an Agreement State licensee. NRC does not have direct jurisdiction over this license and does not have access to this license, which is needed to assist in the verification of the preceptor, Dr. Friedman.

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

S. M. Shah, Ph.D.

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Please submit a complete, current, signed and un-redacted copy of the license that shows it is authorized for materials in 10 CFR 35.100, 35.200, 35.300 and 35.1000 for the use of yttrium-90 microspheres and either Dr. Friedman's name on this license as an authorized user for these materials or a signed, dated letter from the Chairperson of the licensee's Radiation Safety Committee attesting that Dr. Friedman was an authorized user when he supervised and preceptored Dr. Drozhinin.

Your request also did not provide the name of the state in which Dr. Drozhinin is licensed to practice medicine.

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.

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.

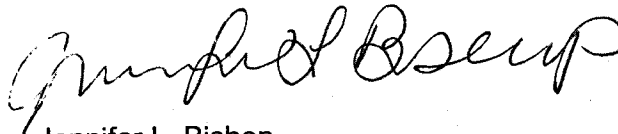
NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS, the NRC's electronic document system.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

S. M. Shah, Ph.D.

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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,



Jennifer L. Bishop
Health Physicist
Materials Licensing Branch

License No. 13-03226-04
Docket No. 030-20812

Enclosure: Amendment No. 42