



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

MAY 19 2014

Evan J. Boote, Ph.D.
Radiation Safety Officer
Spectrum Health Hospitals
100 Michigan Street NE
Grand Rapids, Michigan 49503

Dear Dr. Boote:

Enclosed is Amendment No. 97 to your NRC Material License No. 21-00243-06 in accordance with your request. Please note that the changes made to your license are printed in **bold font**.

In the letter dated March 3, 2014, you requested to add Drs. Kreuzer, Notarnicola, and Remes for 10 CFR 35.1000 limited to iodine-125 for temporary implants to localize non-palpable lesions. However, based on the information provided these doctors are not 10 CFR 35.490 trained nor they have received training in accordance with the NRC's guidance, "Iodine-125 and Palladium-103 Low Dose Rate Brachytherapy Seeds Used for Localization of Non-Palpable Lesions", published on our website at <http://www.nrc.gov/materials/miau/med-use-toolkit/seed-localization.html>. In the future, if you would like to add them for 10 CFR 35.1000 limited to iodine-125 for temporary implants to localize non-palpable lesions, please provide complete information using the guidance above.

The regulations specified in Title 10 of the Code of Federal Regulations Part 37 (Part 37) "Physical Protection of Byproduct Material," impose physical security requirements for the possession and use of the most risk significant radioactive materials. The most risk significant radioactive materials are referred to as Category 1 and Category 2, based on quantities, and are listed in Appendix A of 10 CFR Part 37. The list is based on the International Atomic Energy Agency's rankings of radiation sources. NRC licensees were required to fully implement the new regulation by March 19, 2014. The requirements of Part 37 supersede the requirements of the "Order Imposing Increased Controls" and the "Order Imposing Fingerprinting and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Materials."

Please note that we have amended your license to remove License Condition No. 17, which required implementation of the Orders listed above. Accordingly, you are now required to comply with the security requirements of Part 37.

New license applicants and licensees newly subject to 10 CFR Part 37 must implement the requirements before taking possession of an aggregated Category 1 or Category 2 quantity of radioactive material. The NRC would consider the licensee to have taken possession of an "aggregated" Category 1 or Category 2 quantity of radioactive material when and if it places an accumulated quantity at or above the Category 2 threshold behind a single physical barrier. A licensee that has not previously implemented the security orders or had not been subject to the provisions of Part 37 must notify the U.S. Nuclear Regulatory Commission, Region III, Materials Licensing Branch, 2443 Warrenville Road, Suite 210, Lisle, IL 60532-4352 in writing at least 90

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

E. J. Boote

-2-

days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold.

The new rule is available on NRC's public website at <http://www.nrc.gov/reading-rm/doccollections/cfr/part037/>. Also, NRC has created a website for 10 CFR Part 37 that can be found at <http://www.nrc.gov/security/byproduct/10-cfr-part-37.html>. This site contains helpful information, such as hyperlinks to the final rule language as published in the Federal Register (<http://www.gpo.gov/fdsys/pkg/FR-2013-03-19/pdf/2013-05895.pdf>), types of licensees that may be subject to 10 CFR Part 37 requirements, the implementation guidance for the rule (NUREG-2155) (<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr2155/>), as well as some frequently asked questions that have been developed during the implementation process. This website is updated as needed, and it is recommended that licensees review this information periodically. In addition, the NRC issued a Regulatory Issue Summary 2014-03 Notice of 10 CFR Part 37 Implementation Deadline for NRC Licensees on March 13, 2014 (ADAMS ML14052A157).

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 Code of Federal Regulations 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->

~~Official Use Only - Security-Related Information~~

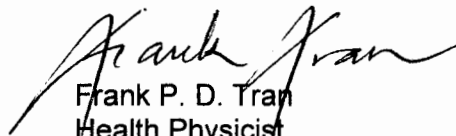
E. J. Boote

-3-

[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,



Frank P. D. Tran
Health Physicist
Materials Licensing Branch

License No. 21-00243-06
Docket No. 030-01989

Enclosure: Amendment No. 97