

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

MAY 06 2013



James I. Monroe, Ph.D.
Radiation Safety Officer
St. Anthony's Medical Center
10010 Kennerly Road
St. Louis, MO 63128

Dear Dr. Monroe:

Enclosed is Amendment No. 55 to your NRC Material License No. 24-01041-04 in accordance with your request. Please note that the major changes made to your license are printed in **bold** font.

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.

- A. **At this time we were unable to approve your requests in the letter dated January 11, 2013, to delete your authorizations for the iridium-192 source and depleted uranium shielding in your former GammaMed Model No. 12it high dose rate remote afterloading brachytherapy device (HDR).**

This is because the information needed to complete our review appeared to be insufficiently provided in your letter. Please submit the following requested information, addressed to my attention, as "additional information to control number 579941." We will then continue our review.

- 1. Please provide a copy of the last leak test for the final source in the HDR unit, prior to its return to the vendor for disposal.**
- 2. Please provide a copy of the signed acknowledgment of receipt letter from the vendor showing that the source, device and depleted uranium were received from you into their inventory, under their license (please provide a current, complete copy of vendor's license also) and on which date.**
- 3. We noted that your letter included attachments that were illegible and/or did not support your requests. The HDR service records and FedEx**

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

J. Monroe

documents were among these documents. Please see 10 CFR 30.41 and 30.51 for assistance, as necessary. Please note that such service records, bills of lading other records do not provide the specific information that we need to demonstrate that your licensed materials were free of contamination when shipped and were accepted by an appropriately licensed party into its inventory.

4. In addition, your diagrams for the new HDR storage area were only minimally adequate. The font for words on some of the diagrams was too small to be legible. The detail on the diagrams was somewhat illegible also.

In order for us to complete our review, please resubmit better diagrams, no blueprints or blueprint copies, please. Simple, hand-drawn diagrams are best. Please refer to our "Consolidated Guidance About Materials Licenses: Program - Specific Guidance About Medical Use Licenses (NUREG-1556, Volume 9, Revision 2)" on our website at:

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/>.

Section 8.16, item 9, "Facilities and Equipment," in this document contains information needed for such requests. A sample diagram showing the approximate level of detail is in Figure 8.1. To orient the diagram, the direction of north and elevation should also be provided.

Please note that you should be using this guidance document, and other guidance on our website, including our medical use licensing toolkit, to prepare all of your licensing correspondence, amendments and renewals.

- B. In addition, at this time we need to reformat Subitem Nos. 6, 7, 8 and 9 D for 10 CFR 35.400 authorizations and Subitem No. 8.C. on your license. Please submit the following:
 1. For Subitem No. 8.C., please respond by stating what your total possession limit for all materials in 10 CFR 35.300 should be, including iodine-131. This value should be realistic and allow for program growth as well as waste streams.
 2. For 10 CFR 35.400, we now have to separate your authorizations by radionuclide, with each radionuclide's corresponding manufacturers and model numbers and possession limits for each. Please respond with this information, as requested above.
- C. At this time we deleted Condition No. 13, as it appeared on Amendment No. 54, because it was no longer necessary for your licensed program and all authorizations requiring a possession limit now have one.

If you have any questions or comments, please contact me at (630) 829-9841 or my email address, which is colleen.casey@nrc.gov. My fax number is (630) 829-9841.

J. Monroe

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 (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>.

J. Monroe

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 Carol Casey
Materials Licensing Branch

License No. 24-01041-04
Docket No. 030-10108

Enclosure:

Amendment No. 55