Official-Use Only - Security-Related Information.



UNITED STATES NUCLEAR REGULATORY COMMISSION REGION III

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

OCT 13 2016

Triston W. Dougall, M.S. Radiation Safety Officer Mercy Health Saint Mary's 200 Jefferson Ave. SE Grand Rapids, MI 49503

Dear Mr. Dougall:

Enclosed is Amendment No. 92 to your NRC Material License No. 21-01078-01 in accordance with your October 3, 2016 (ML16277A523) and October 4, 2016 (ML16280A387) requests, and your October 10, 2016 additional information letter (ML16285A240), with the exception of removing your authorization for sealed sources in a Nucletron MicroSelectron Model 105.999 remote afterloader. Additional information is needed to remove the authorization for that device and associated sources. Because the October 3, 2016 letter included a request to expedite review due to medical necessity, our office could not wait to issue this amendment while additional information is collected and prepared for review.

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 may provide appropriate corrections and answers.

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 <u>http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html</u>. 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.

To remove the authorization for Iridium-192 permitted by 10 CFR 35.600, for use in a Nucletron MicroSelectron-HDR Model 105.999 remote afterloading brachytherapy device, as listed in item 6.G. on your license, please resubmit your request. Additional information is needed as noted below:

- 1. Please provide the last date on which material was used for medical use.
- 2. Please provide a copy of the most recent leak test results for sealed sources used or stored under Item 6.G. to your license. Describe history of leaking sources, if any.
- 3. Please provide the dates on which sealed sources authorized under Item 6.G. to your license were shipped to and received by the manufacturer. Include a letter from the manufacturer confirming receipt of such sources.

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

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4. Please provide the date on which the device listed in Item 9.G. to your license was permanently removed from your facility.

Additional information requested above may be submitted via facsimile and under a signed and dated letter to the attention of the U.S. NRC, Region III office, Materials Licensing Branch, at (630) 515-1078. Do not hesitate to contact me at (630) 829-9892 or <u>sara.forster@nrc.gov</u> with any questions you have concerning this request.

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: <u>http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf</u> and the link for frequently asked questions regarding protection of security related sensitive information may be located at: <u>http://www.nrc.gov/reading-rm/sensitive-info/fag.html.</u>

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 <u>http://www.nrc.gov/reading-rm/adams.html.</u>

Sincerely,

Jana a. Forster

Sara A. Forster, M.S. Health Physicist Materials Licensing Branch

License No. 21-01078-01 Docket No. 030-08291

Enclosure: Amendment No. 92