



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

DEC 13 2017

Michael C. Brewer, MS, DABR
Radiation Safety Officer
Franciscan Healthcare – Munster
701 Superior Ave.
Munster, IN 46321

Dear Mr. Brewer:

Enclosed is Amendment No. 12 to your NRC Material License No. 13-32519-01 in accordance with your request.

Please note that at this time we are not able to authorize the addition of the 10 CFR 35.600 high dose rate remote afterloading device to your license because the information provided in letter dated September 12, 2017, was insufficient to complete our review. In addition, you requested to add Dr. Prock to the license as an authorized user for 10 CFR 35.400 uses, which are not currently approved on this license. 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).

The shielding calculations that were provided do not appear to be for the worst case scenario. The maximum source strength was lower than the source strength requested, you assumed only 10 minutes per treatment, and it was assumed that the closest person to the treatment room would be one foot beyond the wall. Please review your shielding calculations and either provide further justification for why they are adequate or revised shielding calculations.

In your request, you provided a description of the training that will be provided initially and annually to anyone authorized to operate the units, however, your procedures did not include a requirement that the operators, AMP's and authorized users participate in drills of emergency procedures as required by 10 CFR 35.610(d) and (e). Please provide a written commitment that drills of emergency procedures will be conducted.

In addition, you provided procedures that describe the safety precautions for the HDR Unit, however your procedures did not include a requirement for the Radiation Safety Officer and an Authorized User to be notified as soon as possible if a patient has a medical emergency or dies, as required by 10 CFR 35.615(f)(4). Please provide a written commitment that the RSO and authorized user will be notified if a patient has a medical emergency or dies.

You did not provide procedures on how full calibration measurements will be completed in accordance with 10 CFR 35.633. Please provide a copy of the procedures, as specified in the regulations, and ensure that all measurements required by the regulations are included.

In your request, you provided a procedure for how periodic spot checks will be completed, however, the following commitments were not included in your procedure:

- a) The required measurements shall be performed in accordance with a written procedure established by the authorized medical physicist, as required by 10 CFR 35.643(b).
- b) The authorized medical physicist shall review the results of each spot-check with 15 days. The authorized medical physicist shall notify the licensee as soon as possible of the results in writing of each spot-check, as required by 10 CFR 35.643(c).
- c) If the results of the checks required indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system, as required by 10 CFR 35.643(e).
- d) A licensee shall retain a record of each check required and a copy of the procedures required by paragraph (b) of this section in accordance with 10 CFR 35.2643, as required by 10 CFR 35.643(f).

Please review the guidance in NUREG 1556, Volume 9, Revision 2, "Consolidated Guidance about Material Licenses, Program Specific Guidance about Medical Use Licenses," and ensure that your application includes the information discussed in that document. Preparing your amendment requests carefully and in accordance with NRC's regulatory requirements and guidance, especially the documents in the NUREG 1556 series, as well as other information on our website at <http://www.nrc.gov>, will greatly help ensure that your correspondence is complete and accurate.

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.

M. C. Brewer

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In accordance with 10 Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure 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,

A handwritten signature in cursive script, appearing to read "Jennifer L. Bishop".

Jennifer L. Bishop
Health Physicist
Materials Licensing Branch

License No. 13-32519-01
Docket No. 030-36594

Enclosure: Amendment No. 12