UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 E. LAMAR BLVD
ARLINGTON TX 76011-4511

March 9, 2022

Scott Fuller, M.S., DABR
Radiation Safety Officer
St. Luke's Regional Medical Center
190 E. Bannock Street
Boise, ID 83712

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION, NRC LICENSE NO. 11-27312-01

Mr. Fuller:

We have initiated the review of your amendment request dated March 7, 2022 (ADAMS Accession Number ML22067A144, a non-publicly available document). Please note the following.

The Nuclear Regulatory Commission (NRC) has reviewed the licensee's amendment request letter dated March 7, 2022 containing procedure PC954 SLHS, "GammaTile Cesium 131 Brachytherapy" that was revised by the licensee on November 9, 2021 to define the requirements for "Supervision" to meet Title 10 of the *Code of Federal Regulations* (10 CFR) 35.27, "Supervision". Section I of procedure PC954 SLHS, "Preparation for Procedure", subsection H, states that the radiation oncologist (authorized user) will be present in the operating room to supervise radioactive source placement unless the neurosurgeon (supervised individual) meets certain training criteria including having received radiation safety instructions from the radiation oncologist, radiation safety officer or manufacturer of the sealed sources, and for the neurosurgeon to agree to follow all instructions that have been provided by the radiation oncologist, radiation safety officer or manufacturer of the sealed sources. The revision to procedure PC954 SLHS made by the licensee is not in alignment with the NRC licensing guidance for GammaTile dated August 26, 2019 (Agencywide Documents Accession and Management System accession number ML19198A305) and thus cannot be approved as written.

The NRC licensing guidance for GammaTile states: "The neurosurgeon must use the material under the supervision of a physician authorized for [under] 35.400 in accordance with 10 CFR 35.27, "Supervision." As required by 10 CFR 35.27, the authorized user must instruct the neurosurgeon in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material. The neurosurgeon is required to follow authorized user's radiation safety instructions and written radiation protection procedures established by the licensee, written directive procedures, regulations of this chapter, and license conditions with respect to the medical use of byproduct material."

Before we can take further action, we will need the following additional information.

1. Revise procedure PC954 SLHS, “GammaTile Cesium 131 Brachytherapy” to align with the NRC licensing guidance for GammaTile and resubmit procedure.

To continue review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter. In your response, please refer to the license, docket, and control number specified below. We will assume that you do not wish to further pursue this licensing action if we do not receive a reply within the specified timeframe noted above.

In accordance with 10 CFR 2.390 of the NRC’s “Rules of Practice,” a copy of this letter will be made 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 https://www.nrc.gov/reading-rm/adams.html.

If you have questions or require clarification on any of the information stated above, please contact me at 817-200-1189.

Thank you for your cooperation.

Sincerely,

Roberto J. Torres Digitally signed by Roberto J. Torres
Date: 2022.03.09 14:56:33 -06'00'

Roberto J. Torres, Acting Branch Chief
Materials Licensing Branch

Docket: 030-32196
License: 11-27312-01
Control: 630310