UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

November 25, 2013

St. James Healthcare
ATTN: Rod Wimmer, Ph.D.
Radiation Safety Officer
400 S. Clark Street
P.O. Box 3300
Butte, Montana 59702

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

The Nuclear Regulatory Commission (NRC) has initiated the technical review of St. James Healthcare renewal application of NRC License 25-13173-02 dated July 11, 2013, and additional information is needed to continue the review process. Please provide the following information within 30 days of receipt of this letter. Make reference to mail control number 580534 when providing your response.

1. The current license (Amendment No. 47) authorizes manual brachytherapy sources 3M Model 6D6A and Theragenics Models 125.S06 and 200. The license renewal application did not request renewal of this authorization nor requested that the authorization be removed from the license.

   A. Submit a written request to retain the current authorization as described in conditions 6.D., 7.D., 8.D., and 9.D., of Amendment No. 47, or

   B. Submit decommissioning records for these sealed sources if requesting removal of this authorization in the renewed license.

2. The current license (Amendment No. 47) authorizes one strontium 90 sealed source (Isotope Products Laboratories Model 4-850) for storage only pending disposal. The license renewal application did not request renewal of this authorization nor requested that the authorization be removed from the license.

   A. Submit a written request to retain the current authorization as described in conditions 6.E., 7.E., 8.E., and 9.E., of Amendment No. 47, or

   B. Submit decommissioning records for this sealed source if requesting removal of this authorization in the renewed license.

3. Identify any radionuclide in excess of 30 millicuries each that is used in calibration, transmission, and reference source. Provide manufacturer's name, model number, type of use, maximum activity per source and total possession limit.

4. The current license (Amendment No. 47) authorizes Keith C. Edwards, M.D. as authorized user for 10 CFR 35.100 and 35.200 uses. The license renewal application did not request renewal of this authorization nor requested that the authorization be removed from the license.

   A. Submit a written request to retain the current authorization as described in condition 12.B. of Amendment No. 47, or confirm the removal of this authorized user in the renewed license.

5. For patients receiving I-131 who cannot be released under 10 CFR 35.75, and for brachtherapy, provide the following:

   A. Diagram, room number, and principal use of each room or area, including areas above, beside, and below therapy treatment rooms.

   B. Indicate whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003.

   C. Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy including the dimensions of any portable shields, if one is used; source storage safe, etc.).

   D. For manual brachytherapy, provide a description of the emergency response equipment.

6. Provide the following commitments:

   A. “Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations.”

   B. “We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used.”

   C. “Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer’s instructions.”

   D. “We will provide radiation dose monitoring to individuals who are likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR 20. Dosimetry provided shall meet the requirements listed under ‘Criteria’ in NUREG-1556, Volume 9, Revision 1, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees”.

7. Provide copy of the procedures that describe processes in place to ensure that written directive are signed and dated by an authorized user prior to the administration of sodium iodide I-131 in quantities greater than 30 microcuries, or prior to any therapeutic dosage of unsealed byproduct material.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Thank you for your cooperation.

Sincerely,

/RA/

Roberto J. Torres, Senior Health Physicist
Nuclear Materials Safety Branch B

Docket: 030-12143
License: 25-13173-02
Control: 580534