UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

May 18, 2020

David H. Roehrs, M.D.
Radiation Safety Officer
Bothwell Regional Health Center
601 E 14th St.
Sedalia, MO 65302-1706

Dear Dr. Roehrs:

We have reviewed the licensee's request dated April 5, 2020, to renew its U.S. Nuclear Regulatory Commission (NRC) Material License No. 24-16275-01 for Bothwell Regional Health Center. Based on our review of the information, we have identified that additional information is needed to proceed with the renewal process.

In a signed by management and dated letter, please provide the following information by June 30, 2020:

1) Removal of Title 10 of the *Code of Federal Regulations* (CFR) 35.600 material:
   a) Please provide documentation pertaining to removal and receipt of 10 CFR 35.600 material (the high dose rate remote after loader unit and the associated iridium-192 source/s) by the vendor/waste facility.

2) Authorized Users (AUs):
   a) Please provide the medical license number for each Authorized User (AU);
   b) Please confirm that the 10 CFR 35.600 material should be removed from use by the AUs;
   c) Please acknowledgement that Harold A. Johnson, M.D. is to be removed from the license as an AU since he is only authorized for use of 10 CFR 35.600 material;
   d) Please confirm that Feraas Jabi, M.D. is to be authorized for 10 CFR 35.300 material (your letter dated April 5, 2020 stated the physician to be authorized for 10 CFR 35.300 limited to oral administration of sodium iodide I-131).

3) Facility diagram:
   a) Please describe the areas/rooms above and below the nuclear medicine department;
   b) Please describe storage of sealed sources in the hot lab versus storage of unsealed material;
   c) Please describe the process and areas where radioactive material will be injected, ingested or implanted (e.g. please describe the intake rooms for pharmaceutical therapies as well as rooms for brachytherapy);
   d) Confirm that no Positron Emission Tomography (PET) material will be used;

e) If PET material is used at the facility, please provide detailed facility diagram indicating restricted and unrestricted areas, occupancy factors for all adjacent rooms including above and below, distances between the source and the adjacent rooms, the type and thickness of the shielding material. Also, please provide an evaluation demonstrating that the dose levels in all directions from the radioactive source in adjacent rooms will not exceed Title 10 Code of Federal Regulations (CFR) Part 20 dose limits
f) For 10 CFR 35.300 and 35.400 material, please confirm that patients will be released in accordance with 10 CFR 35.75 requirements. If you will have in-patient rooms (patients will be hospitalized after injection/intake/implant of 10 CFR 35.300 or 10 CFR 35.400 material), please provide a diagram of the in-patient rooms and adjacent areas/rooms indicating restricted and unrestricted areas, occupancy factors for all adjacent rooms including above and below, distances between the source and the adjacent rooms, the type and thickness of the shielding material. Also, please provide an evaluation demonstrating that the dose levels in all directions from the patient in the adjacent rooms will not exceed 10 CFR Part 20 dose limits.

4) Commitments described in NUREG 1556, Volume 9, Revision 3, available at https://www.nrc.gov/docs/ML1925/ML19256C219.pdf. Please note that the commitments provided in your April 5, 2020 letter were based on revision 2 of NUREG 1556, Volume 9. Please review the attached table for summary of commitments:

a) Please submit the commitment, “Training for Individuals Working In or Frequently Restricted Areas” described in NRC guidance, NUREG 1556, Volume 9, Revision 3, Section 8.8;
b) Please resubmit the commitment/s, “Radiation Monitoring Instruments”, described in NRC guidance, NUREG 1556, Volume 9, Revision 3, Section 8.9.2;
c) Please describe the equipment that will be used to measure dosages, described in in NRC guidance, NUREG 1556, Volume 9, Revision 3, Section 8.9.3;
d) If PET material is used, please describe the equipment for handling and storage of the material as described in NUREG 1556, Volume 9, Revision 3, Section 8.9.5;
e) If sodium iodide I-131 will be administered in liquid form, please describe the equipment to control the hazards associated with airborne I-131;
f) Provide description of the emergency response equipment during manual brachytherapy procedures in accordance with 10 CFR 35.415, described in NRC guidance, NUREG 1556, Volume 9, Revision 3, Section 8.9.5;
g) Please resubmit the commitment, “Occupational Dose”, described in NRC guidance, NUREG 1556, Volume 9, Revision 3, Section 8.10.2;
h) Please submit the commitment, “Material Receipt and Accountability”, described in NRC guidance, NUREG 1556, Volume 9, Revision 3, Section 8.10.10;
i) Please submit the commitment, “Leak Tests”, described in NRC guidance, NUREG 1556, Volume 9, Revision 3, Section 8.10.11;
j) Please resubmit the commitment, “Area Surveys”, described in NRC guidance, NUREG 1556, Volume 9, Revision 3, Section 8.10.12;
k) Please resubmit the commitment, “Safe Use of Unsealed Licensed Material”, described in NRC guidance, NUREG 1556, Volume 9, Revision 3, Section 8.10.14;

l) Please resubmit the commitment, “Waste Management”, described in NRC guidance, NUREG 1556, Volume 9, Revision 3, Section 8.11.

In accordance with 10 CFR 2.390, a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Magdalena R. Gryglak

Digitally signed by Magdalena R. Gryglak
Date: 2020.05.18 11:59:42 -05'00'

Magdalena R. Gryglak
Health Physicist
Materials Licensing Branch

License No. 24-16275-01
Docket No. 030-10715