Licensee: Wheeling Hospital, Inc.
License No.: 47-05322-02
Docket No.: 03012570
Control No.: 582254
Date: March 5, 2014

Dear Mr. Ostrum:

Please reply back to this email to confirm receipt.

This correspondence is in reference to your application dated September 23, 2013, requesting renewal of NRC License No. 47-05322-01. In order to continue our review of your application, we need the following additional information:

1. Your renewal application requests authorization to possess and use radioactive materials permitted by 10 CFR 31.11. In your letter dated November 16, 2006, you requested that we delete this authorization. In Amendment No. 40 dated January 3, 2007, we removed authorization for 10 CFR 31.11 materials. If you are requesting authorization for this material, please specify an authorized user(s) and a maximum possession limit.

2. Your renewal application did not specify who will be the Radiation Safety Officer (RSO), authorized users (AUs) or authorized medical physicists (AMPs) on your license. In addition, the authorized uses were not described. If there will be no changes from those currently listed, please so state.

3. Please provide a description of the radiation monitoring instruments (e.g. gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multi-channel analyzer, liquid scintillation counter, proportional counter, etc.) that will be used to perform radiation level detection, measurement, and contamination surveys.

4. Your application did not address radiation safety procedures. Please confirm the following:

    a. That radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations;

    b. That the equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions;

    c. That you will develop, implement, and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR

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20.1501 and that meet the requirements of 10 CFR 35.61. If you will be performing your own calibrations, please identify the source that you will use by source manufacturer and model number, nuclide, activity, and calibration accuracy;

d. For radium-223, unit doses only will be used, or if you plan to use other than unit doses, please provide the following statement: "Dosages will be determined by relying on the provider's dose label for measurement of the radioactivity and a combination of volumetric measurement and mathematical calculation";

e. In reference to occupational dose, that you will "Either perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in 1 year, radiation dose on excess of 10% of the allowable limits in 10 CFR Part 20 or will provide dosimetry that meets the requirements listed under 'Criteria' in NUREG-1556, Volume 9, Revision 2, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensee.';

f. In reference to area surveys, that you have "developed and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.";

g. That you will develop, implement and maintain written procedures for the safe use of unsealed byproduct materials that meet the requirements of 10 CFR 20.1101 and 20.1301;

h. That you will develop, implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR Part 20.1101;

i. In reference to your waste management procedures, that you have "developed and will implement and maintain written waste disposal procedures for licensed material, in accordance with 10 CFR 20.1101, that also meets the requirements of the applicable section of Subpart K to 10 CFR Part 20 and of 10 CFR 35.92."

5. Please describe areas above and below your Hot Cell room at the Schiffler Cancer Center.

6. Your application indicates that patients administered radioactive materials permitted by 10 CFR 35.400 may be housed in Rooms 201 or 225. Will this apply to 35.300 patients, or will only patients releasable pursuant to 10 CFR 35.75 be treated? Additionally,

describe the rooms that will be used to house non-releasable patients. Confirm that the patients will be housed in private rooms with private bathroom facilities. Provide room diagrams including adjacent areas on the same floor, areas above and areas below inpatient rooms. Also provide a description of any shielding and show that adequate steps have been taken to ensure that radiation levels will not result in doses to individuals in excess of those specified on 10 CFR 20.1301 when there are inpatients.

7. For Y-90 microsphere use:

   a. Please describe the location where yttrium-90 microspheres will be administered and describe areas located above, below, and adjacent to the location where yttrium-90 is used;

   b. Please commit to manufacturer's procedure for assaying patient dosages;

   c. Please confirm that if the procedure must be modified due to emergent patient conditions that prevent administration in accordance with the written directive (e.g. artery spasm or sudden change in blood pressure), the AU will document such changes in the written directive within 24 hours after the completion or termination or the administration. The modification to the written directive must include the reason for not administering the intended dose/activity, the date, and the signature of an AU for yttrium-90 microspheres;

   d. Please confirm that the written directive shall include the patient or human research subjects name; the date; the signature of an AU for Y-90 microspheres; the treatment site; the radionuclide including physical form (Y-90 microspheres); the prescribed dose/activity; the manufacturer; and if appropriate for the type of microspheres used, the statement, "or dose/activity delivered at stasis";

   e. Please confirm that the administration of Y-90 microspheres will be performed in accordance with the written directive;

   f. If the administration is terminated due to stasis, please confirm that the record will be prepared within 24 hours after the completion or termination of the administration and will include the name of the individual who made the assessment, the date, and the signature of an AU for Y-90 microspheres, if terminated due to stasis; and

   g. Please confirm that you will follow the manufacturer's procedure for calculating/documenting the dose to the treatment and other sites, preparing the dose for administration, and performing pre/post vial dose measurements; or submit alternate methods.

8. Please specify what areas are above the HDR/Sim room. Indicate the location, room number, and principal use of each adjacent room or area (e.g., office, file, toilet, closet,

hallway, exterior), including areas above and beside the HDR treatment room. In addition, please indicate whether each room or area is restricted or unrestricted, as defined in 10 CFR 20.1003. Please provide shielding calculations for all areas and describe the content and thickness of all shielding in the walls, the ceiling and the treatment room door.

9. With regard to your HDR program, please provide the following information:

   a. Item 10 of your "HDR Brachytherapy Operating Procedures" states that treatments will not be performed unless both the authorized user and either the medical physicist, trained medical dosimetrist, or the radiation safety officer are physically present. Please note that 10 CFR 35.615(f)(2) requires:

      i. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

      ii. An authorized medical physicist and either an authorized user or a physician under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during the continuation of all patient treatments involving the unit.

   Please confirm that you will comply with 10 CFR 35.615(f)(2).

   b. In your HDR Emergency Procedures "Unshielded Source Not Completely Contained" you stated that you will evacuate and lock the room against egress. You did not state that you will put a sign on the door prohibiting admittance. Please confirm that you will place a sign on the door prohibiting admittance;

   c. In your section under *HDR Brachytherapy Operating Procedures*, *Calibration of HDR Source*, Item 1 a., you stated that calibration measurements and calculations will be performed by the authorized brachytherapy physicist or an individual experienced in the use of the dosimetry systems and calibration devices. Please confirm that full calibration measurements on the HDR unit will be performed by an AMP as required by 10 CFR 35.633;

   d. In your section under *HDR Brachytherapy Operating Procedures, Calibration of HDR Source*, Item 1 b., you stated that dose accuracy will be determined to within 10%. 10 CFR 35.633(b)(1) requires that the output determination will be within 5%. Please confirm that the output will be determined within 5%;

   e. Please confirm the methods to secure the treatment room door and console keys whenever the unit is not in use or is unattended. Specifically, describe how and where the HDR keys will be secured;

f. 10 CFR 35.12(b)(2) requires that licensees submit procedures for periodic spot-checks for remote afterloader units. Please provide your detailed spot-check procedures to be performed before the first use of the unit on a given day and after each source installation to assure proper operation of the following:

1. electrical interlocks at each remote afterloader unit room entrance;

2. source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

3. viewing and intercom systems);

4. emergency response equipment;

5. radiation monitors used to indicate the source position;

6. timer accuracy;

7. clock (date and time) in the unit's computer; and

8. decayed source(s) activity in the unit's computer.

In addition, please confirm that if spot-check results indicate the malfunction of any system, you will 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.

10. Describe the emergency response equipment available for manual brachytherapy facilities. This equipment should include gloves, reverse action tweezers, shielded containers, a low energy gamma scintillation survey instrument, and caution radioactive materials labels.

11. Please confirm that you do not require the use of PET materials. Alternatively, you may request this use and submit the facility diagram with shielding specifications for your PET facility and a description of equipment specific to 511 keV photons..

We will continue our review of your application upon receipt of this information. Please reply to my attention at the Region 1 Office and refer to Mail Control No. 582254. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5358.

In order to continue prompt review of your application, we request that you submit your response to this letter within 15 calendar days from the date of this correspondence.

Lester Tripp
Health Physicist
Region 1
Medical Branch
Division of Nuclear Materials Safety