Walt, Geralyn

From: Gallaghar, Robert
Sent: Monday, October 24, 2016 9:14 AM
To: Lowe, Kim
Cc: Gallaghar, Robert
Subject: Request for Additional Information - Control No. 590901

License No. 47-15717-03
Docket No. 03028869
Control No. 590901

PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION BY RETURN EMAIL

Dr. Lowe,

This is in reference to your letter dated April 28, 2016 requesting renewal and amendment to License No. 47-15717-03. In order for us to continue our review of your request additional information is necessary.

1. Please submit written procedures for responding to an abnormal situation when the operator is unable to place the source in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include:

   (i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing correct actions;

   (ii) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

   (iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the radiation safety officer to be contacted if the unit or console operates abnormally.

2. Please provide a diagram which clearly depicts the location of the HDR unit during use and storage. On this diagram, provide the location of area radiation monitoring equipment that indicates the presence of radiation to an individual entering the treatment room from either entrance to the room (i.e., the entrance to the HDR vault from the hallway and the entrance to the HDR vault from the "Temporary Medical Records Storage" area). In addition, please describe how you shall control access to the treatment room from the "Temporary Medical Records Storage" area in accordance with 10 CFR 35.615(b) and how you shall permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist into the treatment room during treatment from this access point in accordance with 10 CFR 35.610(a)(2).

3. Provide the manufacturer name and model number for the area radiation monitor(s).

4. Please describe the areas below the HDR treatment room. Indicate whether this area is restricted or unrestricted as defined by 10 CFR 20.1003.

5. Please provide detailed information on the dosimetry system used for verification and periodic spot-checks of source activity or output. NUREG-1556, Volume 9, Rev. 2, Section 8.19 provides guidance you may find useful.

6. Please confirm that instruction will be provided initially and at least annually to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:

   (i) The procedures identified in 10 CFR 35.610(a)(4), and

(ii) The operating procedures for the unit

7. Please confirm that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

8. Please confirm that all licensed material has been removed from 3100 MacCorkle Avenue S.E., Suite V-1, Charleston, West Virginia.

9. Please confirm that you will develop, implement 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.

10. 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 with acceptance criteria which assure, at a minimum, proper operation of:

    (i) Electrical interlocks at each remote afterloader room entrance;

    (ii) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

    (iii) Viewing and intercom systems in each remote afterloader facility;

    (iv) Emergency response equipment;

    (v) Radiation monitors used to indicate the source position;

    (vi) Timer accuracy;

    (vii) Clock (date and time) in the unit's computer; and

    (viii) Decayed source activity in the unit's computer

11. Please confirm that you will develop and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of 10 CFR 20. Subpart K, and of 10 CFR 35.92.

12. Please confirm that either you will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or you will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, Vol. 9, Rev. 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," or provide a description of an alternative method for demonstrating compliance with the referenced regulations.

13. Please confirm that you would like to change the mailing address to 3415 MacCorkle Ave., S.E., Charleston, WV 25304.

We will continue our review up receipt of the above information. Please feel free to contact Robert Gallaghar at (610) 337-5182 with any questions.

Regards,

Robert Gallaghar, Health Physicist
U.S. Nuclear Regulatory Commission
Region I