

Elliott, Robin

From: Elliott, Robin
Sent: Tuesday, July 23, 2013 4:40 PM
To: 'cmpineiro@himapr.com'
Cc: carwer41@hotmail.com
Subject: Amendment to License No. 52-25019-01

License No. 52-25019-01
Docket No. 030-30826
Control No. ~~579580~~ 580713 RE 7/29/13

Dear Mr. Piñeiro:

Please acknowledge receipt of this email. This is in reference to your request dated April 29, 2013 to amend Nuclear Regulatory Commission License No. 52-25019-01. As I discussed on the phone yesterday with Carmelo Pérez, your Radiation Safety Officer, on your behalf, in order to continue our review, we need the following additional information:

1. On a detailed version of your facility diagram please provide the information listed below. Drawings should be to scale, and indicate the scale, plane, and elevation. Drawings and diagrams that provide the exact location of materials or depict specific locations of safety or security equipment should be marked as **“security-related information – withhold under 10 CFR 2.390.”** (See Section 5.2 of NUREG 1556 Vol. 9 Rev. 2)
 - a. Location and room numbers for each dedicated remote afterloader treatment room and the dedicated remote afterloader storage room, including location of doors, windows, conduits, and viewing ports.
 - b. Location, distance, room numbers, and principal use of each adjacent room or area (e.g., office, file, toilet, closet, hallway), including areas above the therapy treatment room, including room elevation heights. Indicate whether each room or area is restricted or unrestricted, as defined in 10 CFR 20.1003. Figure 8.1 of NUREG-1556, Vol. 9 Rev 2 may be helpful in describing adjacent areas.
 - c. Shielding calculations for the HDR unit, with information about the type, thickness and density of all shielding materials, including walls, floor, ceiling, and viewing ports to enable independent verification of shielding calculations. Include information on the maximum “on time” per hour and per week and occupancy factors used for all adjacent areas. Additionally, include the location and dimensions of any portable shields used for remote afterloader treatments. Shielding calculations must demonstrate compliance with the limits specified in 10 CFR 20.1301.
 - d. The location of the isocenter or center of the source when used in treatments. For the remote afterloader, the position of the source used in calculations should simulate worst case source positioning during a patient treatment.
 - e. If applicable, a description of other radiation producing equipment housed within the same or adjacent rooms (e.g., linear accelerator, Cyberknife system).
 - f. Location of area radiation monitoring equipment and warning systems that indicates the presence of radiation to an individual entering the treatment room.
2. 10 CFR 35.12 requires that licensees submit detailed facility and equipment descriptions for remote afterloader units. Please provide a description of the following:

- a. Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room;
- b. Viewing and intercom systems;
- c. If applicable, steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) are in the treatment room;
- d. Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and
- e. Emergency response equipment (See Section 8.22 page 8.51 of NUREG1556 Vol. 9 Rev. 2)

Item 8.19 of NUREG 1556 Vol. 9 Rev.2 <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r2/> may be helpful in preparing your response.

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office by signed letter or fax and refer to Mail Control No. 579580. If you have any questions regarding the above items, please contact me at (610) 337-5076.

If we do not receive a reply from you within 7 calendar days from the date of this email, we will assume that you do not wish to pursue your amendment.

Regards,

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