From: Weidner, Tara
To: newmann@ors.od.nih.gov
Subject: Request for additional information concerning NRC license renewal
Date: Thursday, May 30, 2013 4:10:00 PM

License No.: 19-00296-10
Docket No.: 030-01786
Control No.: 577840

********** PLEASE CONFIRM RECEIPT OF THIS E-MAIL **********

Dear Ms. Newman,

This is in reference to your renewal application dated June 28, 2012. In the letters dated March 20, May 23, and June 13, 2006, the high dose rate remote afterloader (HDR) program was described. Since it has been a number of years since the HDR program was initiated, please review these letters and address the following questions, in one up-to-date document, describing the current program.

1. On a detailed version of your Radiation Oncology department diagram please provide the information listed below. Drawings should be to scale, and indicate the scale, plane, and elevation.

   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, beside, and below therapy treatment rooms, including room elevation heights. Indicate whether each room or area is restricted or unrestricted, as defined in 10 CFR 20.1003.

2. Specific to the HDR treatment room, provide:

   a. Shielding calculations, 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.

   b. The location of the source used in calculations (simulate worst case source position during patient treatment).

   c. Other radiation producing equipment housed within the same or adjacent rooms (e.g., linear accelerator, orthovoltage machine).

   d. Location of area radiation monitoring equipment (Primalert) that indicates the presence of radiation to an individual entering the treatment room.

3. 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, door signage, warning lights and alarms, interlock systems) for each therapy treatment room;

b. 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;

c. Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and

d. Emergency response equipment.

4. 10 CFR 35.12(b)(2) requires that licensees submit procedures for periodic spot checks for remote afterloader units. Please provide your detailed, step-by-step, spot check procedures to be performed before the first use of the unit on a given day and after each source installation. The procedure should describe the methods and the acceptance criteria used to determine that the equipment is operating appropriately.

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

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

c. viewing and intercom systems;

d. emergency response equipment;

e. radiation monitors used to indicate the source position;

f. timer accuracy;

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

h. decayed source 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.

5. 10 CFR 35.610 requires that licensees develop written safety procedures for emergency response for remote afterloader units. The actions specified for emergency response should give primary consideration to minimizing exposure to the patient and healthcare personnel while maximizing patient safety. Please submit written safety procedures that you will implement for emergency response for your remote afterloader unit includng:

a. the circumstances when emergency procedures are to be implemented (i.e., when the source cannot be returned to a fully shielded position with controls from outside the room, source decoupling, console indicates source is not retracted);

b. step-by-step instructions/actions for responding to single and/or multiple equipment failures and the individual(s) responsible for implementing each

action. Clearly specify which steps are to be taken under different scenarios (i.e., exposed source versus a detached source);

c. the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

d. the names and telephone numbers of authorized users, authorized medical physicists, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

6. Describe the emergency response equipment that you will possess for use with your HDR unit. Consider the various equipment failures described in your emergency response procedures. For remote afterloaders, emergency equipment should include at a minimum, shielded storage containers, remote handling tools, and supplies for removal of applicators or sources from patients, such as scissors and cable cutters.

7. Confirm that all scheduled service recommended by the manufacturer will be performed in accordance with the manufacturer's instructions.

8. In your application you stated that the Nucletron representative was responsible for packing the old HDR source for shipment to a licensed recipient. Prior to the return shipment, who is responsible for securing the source and where will the source be stored prior to the return shipment?

9. Please note that the device Registry No. stated in your application is incorrect. The correct Registry No. is MD-497-D-108-S for the Nucletron Model 105.999 remote afterloader. Also, the sealed source manufacturers have been updated. The current manufacturers of the sealed sources are Mallinckrodt Medical, B.V. and QSA Global, Inc.

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 577840. If you have any technical questions regarding this deficiency letter, please contact me via e-mail.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Tara L. Weidner
Senior Health Physicist
U.S. Nuclear Regulatory Commission