



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I  
2100 RENAISSANCE BLVD.  
KING OF PRUSSIA, PA 19406-2713

August 16, 2017

Cary Trantalis, Regional Vice President, Operations  
and Clinical Services  
William W. Backus Hospital  
326 Washington Street  
Norwich, CT 06360

SUBJECT: VOIDANCE OF YOUR REQUEST FOR AMENDED LICENSE, MAIL CONTROL  
NO. 599651

Dear Ms. Trantalis:

This concerns your request for an amendment to your license dated March 15, 2017 and received in our office May 23, 2017. During a telephone conversation on August 16, 2017, Gene Cardarelli, Ph.D., Director of Medical Physics, informed Tara Weidner that additional time would be needed to provide the information required to complete the amendment. Therefore, we have voided your current request. Listed below is the additional information that we will need to complete the action.

1. The Nucletron microSeletron HDR may be operated in either a high dose rate mode or a pulsed dose rate mode. Please confirm that the HDR unit will not be operated in pulse mode.
2. Confirm that your Radiation Safety Officer will receive training in radiation safety, regulatory issues, and emergency procedures for 10 CFR 35.600 - remote afterloader uses prior to clinical use of the unit. This training may be provided by an authorized user or authorized medical physicist.
3. 10 CFR 35.610 requires, in part, all device operators, authorized medical physicists, authorized users, and Radiation Safety Officer participate in drills of the emergency procedures, initially and at least annually. Please confirm that the emergency drills will be done as part of the initial and annual training and specify who will participate in them.
4. 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.
  - 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. Figure

- c. 8.1 of NUREG-1556, Vol. 9 (enclosed) may be helpful in describing adjacent areas. 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 (enclosed).
  - d. The location of the HDR unit within the treatment room. The position of the source used in calculations should simulate worst case source position during patient treatment.
  - e. Other radiation producing equipment housed within the same or adjacent rooms (e.g., linear accelerator, orthovoltage machine).
  - f. Location of area radiation monitoring equipment that indicates the presence of radiation to an individual entering the treatment room.
5. 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. Area radiation monitoring equipment;
  - c. Viewing and intercom systems;
  - d. 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;
  - e. Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons;
  - f. Emergency response equipment (at a minimum, shielded storage container, remote handling tools, and supplies for removal of applicators or sources from patients, such as cable cutters, scissors, and/or suture removal kits); and
  - g. Methods to ensure correct placement of portable shields used for treatments with remote afterloaders, if applicable.
6. Describe the survey instrumentation available to measure the type and level of radiation for the HDR unit. In addition, confirm what dosimetry system will be used in calibrating the HDR (e.g., electrometer with chamber).
7. 10 CFR 35.12(b)(2) requires that licensees submit procedures for periodic spot-checks for remote afterloader units required by 10 CFR 35.643. Please provide *detailed step-by-step* procedures that describe how you will perform each test below and the criteria for acceptable results:
  - a. Electrical interlocks at 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 (also note on facility diagram);
  - f. Timer accuracy;
  - g. Clock (date and time) in the unit's computer; and
  - h. Decayed source activity in the unit's computer.
8. 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 including:

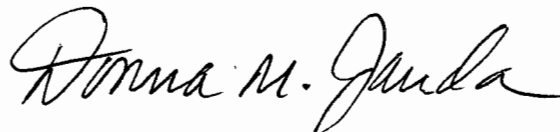
- a. the circumstances when emergency procedures are to be implemented (i.e., source cannot be returned to a fully shielded position with controls from outside the room, source decoupling, jammed source, console indicates source is not retracted);
- b. step-by-step instructions/actions for responding to single and/or multiple equipment failures and the individual(s) responsible for implementing each action;
- c. the process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure;
- d. confirm that extremity monitors will be provided to individuals who may be called upon to respond to an emergency involving an un-retracted or stuck source; and
- e. 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.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web Site at <http://www.nrc.gov/reading-rm/adams.html>.

We will continue our review upon receipt of the additional information. If you have any technical questions regarding this letter, you may contact Tara Weidner by e-mail at [tara.weidner@nrc.gov](mailto:tara.weidner@nrc.gov) or by telephone at 601-337-5272. Please reference Mail Control No. 599651 in your response.

Thank you for your cooperation.

Sincerely,



Donna M. Janda, Chief  
Medical Branch  
Division of Nuclear Materials Safety  
Region I

License No. 06-11734-02  
Docket No. 03001287  
Mail Control No. 599651

cc: Gene Cardarelli, Ph.D., Director of Medical Physics  
Phillip Kohanski, M.D., Radiation Safety Officer

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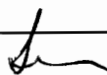

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**SUNSI Review Complete: TLWeidner**

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