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Member, Horizon Healthcare Inc.

March 26, 1996

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Section
ATTN: Patricia J. Pelke
801 Warrenville Road
Lisle, Illinois 60532-4351

Re: License number 48-04193-01
Control Number 99668

Dear Ms. Pelke:

This correspondence is to respond to and provide additional information for your review as directed by your letter, dated March 1, 1996 regarding the amendment request to use the HDR therapy unit in either of two rooms.

With regard to your concern that the HDR unit is being relocated to a new location, we must emphasize that, in fact, the HDR device is not being "reinstalled" to a "new" location. The proposed locations for the use of the HDR are the currently approved location, room 37-5, and the location originally approved by the NRC, room 37-1. When the HDR unit was originally installed in room 37-1, in accordance with NRC license amendment 69, the installation was performed by Nucletron Engineering BV. When the unit was moved from room 37-1 to room 37-5, in accordance with NRC license amendment 72, all of the existing connections, terminals, interlocks, monitors, etc. for room 37-1 were left intact. New connections, terminals, interlocks, monitors, etc. were installed in room 37-5 by the manufacturer, Nucletron Engineering BV. The HDR unit will be literally "unplugged" from one location and moved to the other location and "plugged in". Therefore, this is not a "reinstallation" or even an " installation" to a "new location", rather it is the use of the device in two previously approved locations that were installed by authorized personnel in such a manner that to move from one site of use to the other requires minimum intervention.

The following are statements of our confirmations, descriptions and commitments to ensure the HDR unit will be moved safely and will be checked thoroughly to ensure safe operation upon being reconnected.

1. *Transport of the HDR unit between rooms 37-1 and 37-5.* The unit shall only be transported by or in the presence of an authorized medical physicist from the Radiation Oncology Department. Prior to transferring the HDR unit the physicist will ensure that all personnel in the area are aware of the transfer, that the pathway between the rooms is clear of obstacles and unnecessary traffic and that the head of the HDR unit is in the down position with the source mechanically locked in the device storage safe. As can be seen on the enclosed floor plan, the total distance the HDR unit will be moved is approximately 70 feet. There are no inclines in the floor between the rooms. The floor is concrete with unexcavated dirt beneath the floor.

2. *A description of the procedures for performing quality control checks.* Prior to treating a patient, quality control checks shall be performed by an authorized medical physicist. Attached is the current "**HDR Morning Checklist**" that is our written record of the quality control checks performed and maintained. Although the form may be changed as part of a ministerial change, the content of the form shall not change. In addition to the attached QC check, a radiation survey will be performed, in the same way as after a source change, to include the date and time of the survey, the initials of the authorized physicist performing the survey and the results of a radiation survey.

3. *A commitment that records of the quality control checks be maintained.* We confirm that records of the quality control checks will be maintained and, further, that they will be reviewed periodically by the Radiation Oncology Department Quality Assurance program.

4. *Confirmation that movement of the device shall be restricted.* We confirm that the movement of the device shall be restricted to that between rooms 37-1 and 37-5 and that the movement shall be the most direct route safely possible. The movement does not involve transport through unrestricted or" public" use areas nor does it involve the use of elevators.

5. *Confirmation that the source shall be mechanically locked.* We confirm that the source shall be mechanically locked within the device's storage safe and that the head shall be in the down position while in transit.

6. *Confirmation that a radiation survey will be completed.* We confirm that prior to and after relocation of the device, a radiation survey will be performed around the source safe at a distance of 10 cm. If the radiation levels exceed those normally expected by more than 5 mR/hr, use of the device will be discontinued and the device examined by competent service personnel.

7. *Confirmation of number of individuals for movement.* We confirm that movement of the device will require a minimum of two individuals. One will carry a radiation survey instrument for use in an emergency and an emergency shielded source container will also be transported with the device.

8. *Confirmation of safety checks.* We confirm that after completion of the device relocation and prior to patient treatment, we shall perform the safety checks outlined in VIII.B.(1) and (2) , except VIII.B.(2)(c), of Policy and Guidance Directive FC-86-4; Revision 1. We will modify our procedures to include all of the required safety checks outlined above and confirm that we will maintain records of the results of the safety checks.

With the option to use the HDR in two locations we will be able to more efficiently utilize our facilities to perform clinical services and thus more effectively serve our patients. The ability to move the HDR unit between therapy rooms provides three treatment modalities while employing only two specially designed and shielded rooms. Again, only one unit will be allowed to be operated at a time within each room. Additionally, approval of the requested amendment will help to reduce the potential for misadministrations and recordable events by permitting flexibility in a multi-faceted medical setting.

Sincerely,

Charles W. Runge
Vice President, Clinical/Support Services
Attachment

Attachment

HDR Morning Checklist

Day	M	T	W	R	F	S	N	M	T	W	R	F	S	N
Date	*Date QC check performed*													
Time	*Time QC check performed*													
Initials	*Initials of person performing QC check*													
Door Interlock	*check to ensure source can not be exposed when door to room is opened*													
Cable Attachment	*check to see proper cable attachment*													
Console Warning Light	*check to ensure function of console warning lights*													
Door Light	*check to ensure light above door to room is on when source is exposed*													
Door Interrupt	*check to ensure source retracts when door to room is opened*													
TV Monitor Works	*check to ensure video is functioning to maintain contact with patient*													
Primalert (AC)	*check of room monitor*													
Primalert (DC)	*check of room monitor with AC power off*													
Emergency Off	*check to ensure source retracts when Emergency Off button engaged*													
Treatment Interrupt	*test to ensure treatment interrupt functions properly*													
Timer Ends Tx	*test to ensure timer ends treatment*													
Wrong Channel CK	*test to ensure proper channel function*													
Position CK-Film	*test to ensure source position (radiograph & autoradiography)*													
Ion Chamber CK	*check source output*													
Source Retraction CK	*test source retraction function properly*													
Portable GM CK	*check GM survey meter with a dedicated check source to ensure function*													
Forceps & Cutters/Pig	*check to ensure equipment is present in the event of an emergency*													
Paper	*check to ensure enough treatment printout paper for treatments*													
KD / Ortho Check	*check to ensure other treatment unit can not be activated when HDR is on*													

Comments