MAR 01 1996

Ralph Grunewald, Ph.D.
Radiation Safety Officer
Froedtert Memorial Lutheran Hospital
9200 West Wisconsin Avenue
Milwaukee, WI 53226

Dear Dr. Grunewald:

This letter is a follow-up to your December 14, 1995 letter which included additional information in order to continue our review of your request for multi-room use of the HDR device. In order for us to further consider your request, it will be necessary for you to submit the following information:

Be advised that relocating remote afterloading devices to a new location requires the remote afterloading device to be "reinstalled". We further determined that the remote afterloading device is currently authorized for installation by the manufacturer only, Nucletron Engineering BV. In addition, our review identified the need to have, as part of your radiation safety program, specific quality control procedures to ensure that the device is functioning properly after relocation.

In order to ensure that the device is being relocated safely, it will be necessary for you to perform a safety analysis for our review. The safety analysis should include, as a minimum:

1. A description of your procedures for transporting the device, e.g., personnel involved along with a description of their training and experience relative to the use and transport of the HDR device, device lock-out (source in shielded safe position), route of transport (i.e., elevators), etc. The procedures submitted in your December 14, 1995 letter were not complete and lacked sufficient detail to ensure that you had developed adequate procedures to transport the device safely.

2. A description of the procedures for performing quality control checks (i.e., source exposure mechanisms, external radiation levels [source shield], interlock systems, etc.) on the device to ensure that, prior to treatment, all safety features are operating properly. Please specify whether these quality control checks will be performed by your radiation safety staff or the manufacturer.

3. A commitment that records of the quality control checks described above will be maintained.

4. Confirm that movement of the device shall be restricted to that between rooms 37-1 and 37-5. It is recognized that such movement may result in the device being transported through unrestricted and public use areas.



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5. Confirm that the source shall be mechanically locked within the device's storage safe, if possible, during each movement between locations.

6. 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. 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, such as, tip over of the device; and an emergency shielded source container will also be transported along with the device.

8. After completion of a device relocation, and prior to patient treatment, 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 (copy enclosed), shall be performed. Please modify your procedures to include all of the required safety checks outlined above and confirm that you will maintain record of the results of the safety checks.

We will continue our review upon receipt of this information. Please respond within 30 days and refer to Control Number 99668. Be advised that once we have received your response to the information outlined in this letter, we will forward your request to our Washington, D.C. office for further evaluation. If you have any further questions or require additional clarification, please contact me at (708) 829-9868.

Upon failure to file an answer within the specified time, we will consider that you have abandoned your request and will void this action. This is without prejudice to resubmission of the application.

Sincerely,

Original Signed By
Patricia J. Pelke
Licensing Reviewer

License No. 48-04193-01
Docket No. 030-03444

Enclosure: Policy and Guidance Directive
FC 86-4; Revision 1

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