

PUBLIC

030-02640

MAY 24 1994

The Ohio State University
Office of the Vice President
for Health Services
ATTN: Ronald L. St. Pierre, Ph.D.
Vice President for Health
Services and Academic Affairs
200 Meiling Hall
370 W. 9th Avenue
Columbus, OH 43210-1238

Dear Dr. St. Pierre:

This refers to your License Number 34-00293-02 authorizing a Nucletron Corporation MicroSelectron High Dose Rate remote afterloading brachytherapy unit for interstitial, intracavitary and bronchial radiotherapy. The remote afterloader device is approved for use in the dedicated treatment room and shielded surgery room, at your facility. It is our understanding from information obtained during your previous NRC inspection, that your remote afterloader device is currently being utilized in both the treatment room and surgery room as authorized.

During a recent review of our policy and procedures on licensing mobile applications of remote afterloader brachytherapy devices, we identified that relocating remote afterloading devices to a new location requires the remote afterloading device to be "reinstalled". 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. We are requesting that licensees, who relocate their devices, perform a safety analysis to determine if the devices are being relocated safely. Therefore, it will be necessary for you to revise your procedures and provide, for our review, your safety analysis for the relocation of your device. The safety analysis should include, as a minimum:

1. A description of the procedures for transporting the device, e.g., personnel involved, device lock-out (radioactive source in safe shielded position), route of transport (i.e., elevators), etc.
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 the your radiation safety staff or the manufacturer.
3. A commitment that records of the quality control checks described above will be maintained.

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4. A commitment that all device relocations will be performed by service representatives of the device manufacturer, Nucletron Engineering BV or that personnel performing the device relocation will receive specific training by the device manufacturer.

Upon receipt of this information we will perform an evaluation of your safety analysis, to determine the adequacy of the procedures for the relocation of the remote afterloader device. Please reply in duplicate, within 60 days.

If you have any questions or require clarification on any of the information stated above, you may contact Cassandra Frazier at (708) 829-9830.

Sincerely,

Original Signed By
Roy J. Caniano, Chief
Nuclear Materials Safety Branch

cc: J. E. Glenn, NMSS
R. L. Ayres, NMSS

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[Signature]
Frazier/bt
05/18/94

yes
RIII
[Signature]
Madera
5/23/94

yes
RIII
[Signature]
Caniano for
5/23/94