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030-09964

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The Community Hospital
ATTN: John Gorski
Director of Ancillary Services
901 MacArthur Boulevard
Munster, IN 46321

Dear Mr. Gorski:

This refers to your License Number 13-15882-01 authorizing a Nucletron Corporation MicroSelection-HDR remote afterloading brachytherapy device for interstitial, intracavitary or bronchial radiotherapy use. The remote afterloader device is approved for use in two separate shielded treatment rooms at your facility. However, it is our understanding from previous telephone conversations, that your remote afterloader device is currently being utilized in one dedicated treatment room. Your alternate treatment room is presently not in use.

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". It was further determined that the remote afterloading device currently is only authorized for installation by the manufacturer, 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. 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.

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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