DEPARTMENT OF VETERANS AFFAIRS
Medical Center
Johnson City
Mountain Home TN 37684

November 9, 1993

In Reply Refer To: 621/115

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

30-19242

Dear Sir:

This is in reply to the notice of violation dated October 21, 1993.

1. Reason for violation:

a. On August 10, 1993, members of the nursing staff and respiratory care personnel were involved in the care of a patient who had I-25 brachytherapy for a right lung carcinoma. These personnel did not receive prior instruction by the licensee on matters specified by 10 CFR 35.410.

b. The circumstances surrounding the implant procedure need to be discussed further because extenuating circumstances occurred during this particular brachytherapy procedure. It is the policy of the institution to confine all brachytherapy patients to Room DG52, Building 200. Instructions to nurses including the size and appearance of the brachytherapy sources, safe handling of dislodged sources, and procedures for prompt notification of the Radiation Safety Officer (RSO) in cases of patient death, medical emergency and/or dislodgement of sources are routinely given to all nursing and other medical support personnel. The DG52 nursing staff and other personnel are familiar with these radiation safety regulations since DG52 brachytherapy room has always been used for confinement of patients requiring radiation-related restrictions.

c. This brachytherapy patient, however, needed a mechanical ventilator post-operatively because of long standing respiratory insufficiency. Furthermore, skilled nursing care was necessary because of placement of a chest-drainage tube from a thoracotomy. These special medical needs precluded the patient from being confined in the designated brachytherapy therapy room. The patient's medical condition, especially the need for respiratory support, necessitated his confinement to the Surgical Intensive Care Unit (SICU). None of the nursing, respiratory and other support personnel had received prior instruction because of the unanticipated medical problems that arose post-operatively.

d. Our concern for the safety and well-being of our employees and visitors is paramount. We recognized that this brachytherapy procedure resulted in unusual circumstances. We instituted monitoring procedures and

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issued film badges to all SICU personnel who had direct patient care responsibilities to this patient to include, not only the nursing and respiratory care personnel, but also the laboratory and environmental workers. Subsequently, instructions to personnel mandated by 10 CFR 35.410 were given, albeit, after some delay.

2. Corrective steps taken and results achieved:

a. Corrective steps. The institution's Radiation Safety Committee (RSC) convened on August 19, 1993, and the circumstances of this violation were identified. It was noted that:

(1) There was poor coordination between RSO and Radiation Oncology Section.

(2) Notification of the brachytherapy procedure by the Radiation Oncology Department to the RSO was too short.

(3) RSO has too many other responsibilities, e.g., nuclear medicine technologist and the appointed day of the brachytherapy procedure must assume his leadership role in radiation safety matters.

b. Results. Based on this report by the RSC, amendments to the institution's clinical memoranda and operating procedures pertinent to brachytherapy were made.

(1) These amendments emphasized (a) close coordination between RSO and Radiation Oncology; (b) early notification of the RSO by the Radiation Oncology (two working days, minimum) to allow for preparation, instruction and coordination with nursing, respiratory care and other medical personnel.

(2) RSO, radiation oncologist, or their designee, must instruct all personnel involved in direct care of the brachytherapy patient regarding 10 CFR 35.410 prior to the brachytherapy procedure itself.

(3) Twenty-four hour paging system for the RSO or his designee will be in place at all times when a brachytherapy patient is admitted.

3. Corrective steps that have been taken to avoid further violations:

a. On September 3, 1993, the institution's RSC convened and approved amendments in the clinical memoranda pertinent to brachytherapy. These amendments were attached to ensure (1) close coordination between RSO and the radiation oncologist; (2) 2-day minimum notification of the RSO by the radiation oncologist; (3) prior instruction to all personnel who are in direct care of the brachytherapy patient as defined by 10 CFR 35.410; (4) provision for a 24-hour paging system of the RSO or his designee during the time of confinement of the brachytherapy patient.

b. Acquisition of new teaching materials in matters of hospital radiation safety practices. These new teaching materials will supersede our previous training tapes.

c. Purchase of dummy source seeds for brachytherapy. These dummy sources are available and more will be purchased in the future for demonstration purposes to medical personnel.

d. Brochures, photographs, and written descriptions of sources are also available for use during instruction of personnel as required by 10 CFR 35.410.

4. Date of achievement of full compliance. Upon approval by RSC of the amendments to the clinical memoranda pertinent to brachytherapy, compliance with 10 CFR 35.410 was achieved. However, additional measures have been contemplated to strengthen our radiation safety program:

a. The RSO, incumbent, at the time this violation occurred, has relinquished his post citing numerous responsibilities such as being concurrently Chief, Nuclear Medicine Technologist. V. C. Taasan, M.D., has temporarily assumed this responsibility. Joseph Syh, Ph.D., will eventually be designated as RSO. Dr. Syh has a doctorate in medical health physics, and he will be on station by the middle of December 1993.

b. We have received the film badge readings from all personnel involved in the care of this patient, and these readings were well below the prescribed limits.

c. An annual review of the institution's brachytherapy program will be made under the auspices of the RSC.

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Lastly, please note that we recognized the uniqueness of this brachytherapy situation, and we reported and consulted NRC, Region II, Atlanta, Georgia. The corrective and preventive measures enumerated above were conveyed to Mr. Pelchat in a letter dated August 25, 1993.

Sincerely,

CARL J. GERBER, M.D., Ph.D.
Medical Center Director

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