Vitality for life

Muskogee Regional
Medical Center
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918/682-5501

February 8, 1991

A. Bill Beach, Director
Division of Radiation Safety and Safeguards
Nuclear Regulatory Commission, Region IV
611 Ryan Plaza Drive, Suite 1000
Arlington, TX 76011

RE: License 35-13157-02
Docket 30-11571/90-02
EA 90-212

Supplemental response to letter dated 1/15/91 in response to NRC letter dated 2/4/91 and received 2/6/91.

Dear Mr. Beach:

Please find the following supplement(s) to our response dated January 15, 1991:

(1) Failure to follow instructions of authorized user (10 CFR 35.25 (a)) - Admitted.
Reason: Failure by staff to follow established policies and procedures and lack of oversight and enforcement that those policies and procedures were being followed.
Status:
(a) Current flow checklist has worked well and has been effective in preventing recurrence - completed.
(b) Chart redesign has been effective in allowing clear visibility and use of prescription verification - completed.
(c) Currently one (1) new position has been approved for a radiation therapist addition to staff. Actively recruiting a therapist for position and hiring of one candidate appears imminent. Should candidate accept position, position should be filled in late February. One additional position has been authorized for a full time R.T.T. and as applicants are found (either through ads or placement agencies) this position will be filled - status in progress.
(d) Policies and Procedures were amended, reviewed and approved by Radiation Safety Committee at its January 1991 meeting. Signatures of Radiation Safety Officer, Radiation Oncologist, Program Director and Chief Operating Officer are current and manual distributed - completed.
(e) Personnel have been informed of consequences of willfully disobeying policies and procedures and the employment ramifications and/or impacts on employee evaluations. No apparent violation of existing policies and procedures have been reported regarding this issue since its occurrence - completed.
(f) Radiation Safety Committee reports are now being delivered by Administrative Representative (Chief Operating Officer) at Hospital QA meetings - completed.
(g) Administrative Director has been on site and given control of department since July 1990. As a result, more immediate problem resolution and presence has been available - completed.

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(h) An additional Radiation Oncologist is due to start MRMC sometime in July or August 1991. Prior to acquiring privileges on our staff, a letter to the NRC for license amendment regarding this user will be forwarded - in progress anticipated completion third quarter 1991.

(2) Failure of Radiaton Safety Officer to ensure radiation safety activities (10 CFR 35.21 (a)) - Admitted

Reason: RSO may have over-delegated responsibilities to Radiation Oncologist on a day-to-day basis relating to radiation safety and Nuclear Regulatory Commission compliance. Radiation Oncologist relied on the Radiation Physicist who was an RSO at another facility for radiation safety and NRC standard interpretation. Since the new cancer center has been built, the Radiation Safety Officer is located a significant distance from the treatment areas causing logistical problems in day-to-day oversight.

Status: Regarding the issue in your February 4, 1991 letter with respect to the actual change in Radiation Safety Officers, at this writing, a letter to the NRC is forthcoming designating the RSO change from George H. Ladd, M.D. to Robin E. Acker, M.D. Actual responsibilities will not be changed until NRC has approved that change - letter completed, anticipated receipt by NRC is February 12, 1991. (RSO change estimated 3/15/91)

MRMC is continuing to examine the potential alternatives to add a Radiation Safety Officer specifically to handle radiation therapy issues. Alternatives include training an employee currently employed or hiring and training someone to assume that role - in progress. Completion of this action is contingent upon the availability of personnel and appropriate educational opportunities and completion of such by qualified candidate.

(3) Failure to report misadministration within twenty-four (24) hours of discovery (10 CFR 35.33 (a)). Partially admitted with reservation.

Reason: As stated in our January 15 letter and in our December 1990 hearing, it is the position of MRMC that contact was made to the NRC within twenty-four (24) hours of the discovery of the misadministration. However, it can be reasonably assumed that such misadministration would never have happened if policies and procedures were followed. In addition, if our current mechanisms and safeguards were in place in January 1990, the misadministration may have been discovered sooner (or avoided entirely) and contact could have been made to NRC within twenty-four (24) hours of the actual act.

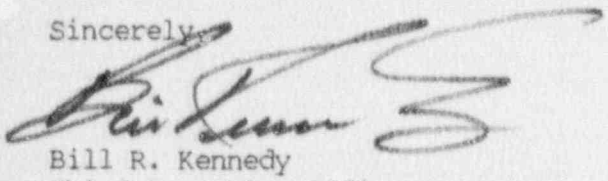
Status: "Reporting Misadministration to NRC Policy and Procedure" was written and approved by Radiation Safety Committee - completed. Checklists on flow charts, Hospital Quality Assurance activities, chart redesign, departmental meetings and other corrective actions have provided adequate safety measures to minimize the probability that such an event can recur - completed - ongoing.

Most improvements and safeguards detailed to the NRC in our presentation and correspondence have been completed and are currently working to assure patient safety. As a result, no recurrence of misadministration has occurred. Long-term actions such as the Radiation Therapy RSO may require more time due to educational opportunities and personnel resources, but MRMC is committed to complete this action at the earliest possible time.

In summation, many safeguards and improvements have been made in our program and it is apparent from ongoing chart reviews that the misadministration was an isolated event. We will continue to endeavor to complete the plan of correction

we have filed with you, however, those actions already completed have made a marked improvement in patient safety.

Sincerely,



Bill R. Kennedy
Chief Executive Officer

BRK/psj