20 May 1994

License No.: 11-27384-01
Docket No.: 030-32325

The United States Nuclear Regulatory Commission
Washington, D.C. 20555

Subject: **Reply to a Notice of Violation**, NRC Inspection Report 030-32325/94-01

The administration of The Bannock Regional Medical Center (BRMC) replies as follows to the three severity level IV violations listed in the NRC Inspection Report 030–32325/94–01:

A. On January 27, 1992, BRMC submitted to the NRC a copy of the Quality Management (QM) program to be carried out in accordance with 10 CFR 35.32. This included a copy of the Written Directive form to be used in the QM program. The presumption was made that like the byproduct materials licensing process, acceptance by the NRC of this QM program description and written directive form constituted endorsement of the same.

Additionally, we note that the dose specification was in all cases clearly indicated in the patient chart, signed and dated by the authorized user, and by a second person who checked the dose calculations. This in itself fulfills the requirements of the written directive, although the information did not appear on our formal "Written Directive" form.

BRMC does not dispute that having all of the information specified for the written directive on a single form will enhance the quality of patient care, and steps are being taken to see that this is carried out. A redesigned "Written Directive" form which includes all information outlined in the definition in 10 CFR 35.2 will be put into use starting on 1 June, 1994. The NRC Region IV office will be notified in writing of these changes within thirty days of that date.

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B. Quarterly linearity measurements are routinely performed for the dose calibrator using activities ranging from a nominal maximum of 100 mCi down to 10 microCi. This is more than adequate to cover the range of all diagnostic procedures and those therapeutic administrations limited to outpatients (30mCi maximum). Dosages exceeding 100 mCi are rare, but have been administered twice in the last three years.

It is not practical to alter the routine linearity checks for the infrequent administrations which exceed 100 mCi. For this reason a policy has been instated which requires a linearity check be performed immediately before the calibration of any dosage exceeding 80 mCi. The linearity check shall be performed using the shielding method, so does not require more than a few minutes of measurements and establishes linearity from the microcurie range up to the activity of the actual dosage.

C. Only a lack of redundancy can account for the fact that the dose calibrator linearity test was carried out almost three weeks past the period of one quarter year. Two actions have been taken to see that this is not repeated in the future. New scheduling software has been installed by the RSO which provides reminders (alarms) when such periodic requirements are eminent. This change is effective immediately. Upon being alarmed, the RSO will check to see that the Nuclear Medicine Technician has made the linearity measurement, and if it has not been made, see that it is carried out immediately.

The changes in policy required for the above actions have been supported by the Radiation Safety Committee during the May 19, 1994 meeting and the Radiation Safety Officer has been duly charged with implementing the necessary changes.

Respectfully,

Bob Endo
Associate Administrator

BE/mwd

CC: Fred Eaton, Administrator, Bannock Regional Medical Center
NRC Regional Administrator, Region IV

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