



DEPARTMENT OF THE ARMY
BROOKE ARMY MEDICAL CENTER
FORT SAM HOUSTON, TEXAS 78234 6200



February 17, 1994

REPLY TO
ATTENTION OF

Health Physics Office


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

Dear Sir or Madam:

Reference your letter dated January 20, 1994, subject: NRC Inspection Report 030-03258/93-02 (Notice of Violation), regarding the inspection of activities authorized by Byproduct Material License No. 42-01368-01, conducted November 30 through December 3, 1993 by Ms. M. Linda McLean, your office.

Our response to the Notices of Violation stemming from referenced inspection is enclosed.

Our point of contact is Major Jonathan E. Tucker, Chief, Health Physics Office, (210) 916-7181/7494.


David A. McFarling
Colonel, Medical Corps
Deputy Commander

Enclosure

Copy Furnished:

Regional Administrator, NRC Region IV

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Reply to a Notice of Violation
Department of the Army
Brooke Army Medical Center
Fort Sam Houston, Texas 78234-6200
General License pursuant to 10 CFR 31.5

FINDING

10 CFR 31.5(c)(8) requires, in part, that any person who acquires, possesses, uses or transfers byproduct material in a device pursuant to a general license shall, except as provided in 10 CFR 31.5(c)(9), transfer or dispose of the device containing byproduct material only by transfer to persons holding a specific license pursuant to 10 CFR Parts 30 and 32 or from an Agreement State to receive the device.

Contrary to the above, on September 9, 1993, the licensee transferred a VALCO Model AL011, Serial Number N119, sealed source containing a 5-millicurie nickel-63 sealed source, and this transfer was not made to a person holding a specific license pursuant to 10 CFR Parts 30 and 32 or from an Agreement State to receive the device, and the exceptions in 10 CFR 31.5(c)(9) did not apply. Specifically, the device was transferred to an unlicensed recipient.

RESPONSE

REASON FOR THE VIOLATION: Generally licensed items have not been subject to the same stringent controls placed upon licensed material. We believe this led to the violation.

CORRECTIVE STEPS TAKEN AND RESULTS ACHIEVED: All individuals in the activity from which the generally licensed item was transferred, specifically those who use or work around generally licensed items, were given remedial training which stressed authorized procedures for transferring generally licensed items.

CORRECTIVE STEPS TO AVOID FURTHER VIOLATIONS: The radiation protection program will be formally revised to apply the same controls to generally licensed items as are applied to licensed material. Specifically, no one will be authorized to possess or use a generally licensed item until written authorization is provided by the Radiation Control Committee (RCC). Each written authorization to possess or use a generally licensed item will list specific controls and procedures to be strictly followed by the authorized user with regard to the item. Further, the authorized user will receive appropriate training which will be documented and available for review by NRC inspectors.

DATE WHEN FULL COMPLIANCE WILL BE ACHIEVED: We feel that interim actions already accomplished will prevent a recurrence of this problem. Full compliance, to include RCC review and approval of the necessary authorizations, will be achieved by 30 April 1994.

Reply to a Notice of Violation
Department of the Army
Brooke Army Medical Center
Fort Sam Houston, Texas 78234-6200
Docket No. 030-03258 License No. 42-01368-01

FINDING

10 CFR 35.32(b) requires, in part, that the licensee develop procedures for and conduct a review to verify compliance with all aspects of the Quality Management (QM) program at intervals no greater than 12 months.

Contrary to the above, the licensee did not conduct a review to verify compliance with the quality management program between January 1992 and October 1993, an interval greater than 12 months. The licensee had conducted a review during November 1993 before the inspection.

RESPONSE

REASON FOR THE VIOLATION: We have concluded that the violation resulted from unclear wording of our quality management program (QMP) dated January 23, 1992. At present, the QMP document is both unclear and contradictory regarding responsibility for conducting the annual review.

CORRECTIVE STEPS TAKEN AND RESULTS ACHIEVED: The Chief, Health Physics, finished his review of the QMP for calendar year 1993 on 14 January 1994, i.e., within the 12-month interval required by 10 CFR 35.32(b).

CORRECTIVE STEPS TO AVOID FURTHER VIOLATIONS: The QMP document will be revised to clarify responsibilities for periodic and annual reviews of the QMP. Specifically, the Chief, Health Physics, will be designated as the individual responsible for conducting the annual review, to be completed no later than one month following the end of the calendar year.

DATE WHEN FULL COMPLIANCE WILL BE ACHIEVED: Full compliance will be achieved no later than April 30, 1994. We will submit our revised QMP document to NRC Region IV by that date.