UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

JAN 20 1994

Specific License: 42-01368-01
Docket: 030-03258
General License pursuant to 10 CFR 31.5

Department of the Army
Brooke Army Medical Center
ATTN: Col. David A. Marfarling, M.D.
Deputy Commander for Clinical Services
Fort Sam Houston, Texas 78234

SUBJECT: NRC INSPECTION REPORT 030-03258/93-02 (NOTICE OF VIOLATION)

This refers to the routine, unannounced inspection conducted by Ms. M. Linda McLean of this office on November 30 and December 1-3, 1993. The inspection included a review of activities authorized by Byproduct Materials License 42-01368-01. Additionally, on December 20, 1993, a followup inspection regarding the loss of a generally licensed source was conducted. At the conclusion of the inspection on site, the findings were discussed with members of your staff. Also, a final briefing was held telephonically with Major J. Tucker, Radiation Safety Officer, on January 7, 1994, to discuss the results of the December 20, 1993, inspection.

The inspection was an examination of activities conducted under the license as they relate to radiation safety and to compliance with the Commission's rules and regulations and the conditions of the license. The inspection consisted of selective examinations of procedures and representative records, interviews of personnel, independent measurements, and observation of activities in progress.

Based on the results of this inspection, certain of your activities appeared to be in violation of NRC requirements, as specified in the enclosed Notices of Violation (Notices).

You are required to respond to this letter and should follow the instructions specified in the enclosed Notices when preparing your response. In your response, you should document the specific actions taken thus far and any additional actions you plan to prevent recurrence. After reviewing your response to these Notices, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

The inspector noted that the health physics department had developed and implemented comprehensive audits of its radiation safety program at Brooke Army Medical Center (BAMC) to verify compliance with NRC requirements. It was also noted that the Radiation Safety Committee (RSC) at BAMC was active in

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program management. The RSC agenda covered audit reviews, reviews prepared by the RSO, NRC correspondence, discussions of self-identified violations discovered during the audit process, corrective actions, and followup on the implementation of corrective actions in order to review their effectiveness. These efforts appeared to have been effective in identifying and correcting program deficiencies.

The inspector reviewed the report of the loss of a generally licensed sealed source. The licensee notified the NRC of the loss of the 5-millicurie nickel-63 (Ni-63) source on September 29, 1993. The source had been used in a gas chromatograph (GC) that was sold to a medical equipment company in San Antonio, Texas. Two sources had been part of the GC; however, the second source, a tritium source, was recovered along with the GC unit. The licensee conducted a thorough search, but was unsuccessful in recovering the Ni-63 source.

The circumstances relating to this loss was identified as a violation of 10 CFR 31.5(c)(8) which requires that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to a general license shall 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. The device was transferred to an unlicensed recipient.

In regard to their specific license, the licensee had identified their failure to perform leak tests within 6 months on two sealed sources during 1993. Upon discovery, the health physics staff promptly performed the tests, identified the reason for the oversight, and established comprehensive corrective actions to avoid further violations.

Normally this failure would be cited as a violation of 10 CFR 35.59; however, because the failure was an isolated occurrence and was identified by BAMC, who instituted timely corrective actions in order to prevent future occurrences, in accordance with Section VII.B(2) of Appendix C, 10 CFR Part 2, of NRC's Enforcement Policy, no citation is being issued for this violation.

Also reviewed during this inspection was your implementation of the Quality Management (QM) program submitted to NRC by letter dated January 24, 1992. Based on our review of activities conducted at your facility which were subject to the provisions of your QM program and 10 CFR 35.32, a violation of the QM program was identified. The violation involved a failure to perform a review of your QM program at 12-month intervals as specified in 10 CFR 35.32(b). Although you had reviewed all teletherapy patient charts to determine compliance with the applicable written directive in accordance with your QM program, a 12-month review with subsequent evaluation of the QM program's effectiveness had not been conducted since the implementation of the program on January 24, 1992. A QM program audit had been completed during November 1993, a date which resulted in a review interval greater than 12 months.

Also reviewed were the actions you had taken with respect to the violation observed during our previous inspection conducted on January 4-6, 1993. The inspection verified that the corrective actions for this violation had been implemented as stated in your reply dated February 16, 1993, and that these actions were effective.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notices are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96.511.

Should you have any questions concerning this letter, please contact the inspector identified above at (817) 860-8100.

Sincerely,

James W. Chamberlain

Dwight D. Chamberlain, Acting Director
Division of Radiation Safety
and Safeguards

Enclosures:
1. Appendix A - Notice of Violation
(License 42-01368-01)
2. Appendix B - Notice of Violation
(General License)

cc:
Texas Radiation Control Program Director

bcc:
DMB - Original (IE-07)
JLMilhoan
DDChamberlain
LWCamper
RAScarano, RV
MMessier, OC/LFDCB (4503)
*WLFisher
*CLCain
*MLMcLean
*NMIS
*MIS System
*RIV Files (2)
SLMerchant, NMSS/IMAB (6 H3)

*W/IFS Form

*RIV:NMIS	*C:NMIS	ADD:DRSS	AD:DRSS	
MLMcLean	CLCain	LWCamper	DDChamberlain	
01/ /94	01/ /94	01/19/94	01/19/94	

*previously concurred

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bcc:
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01/ /94	01/ /94	01/19/94	01/19/94	

*previously concurred