



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION IV  
611 RYAN PLAZA DRIVE, SUITE 400  
ARLINGTON, TEXAS 76011-8064

SEP 2 1994

Docket: 030-02873  
License: 35-00526-04

Department of Veterans Affairs (VAMC)  
V.A. Medical Center  
ATTN: Steven J. Gentling, Director  
921 Northeast 13th Street  
Oklahoma City, Oklahoma 73104

SUBJECT: NRC INSPECTION REPORT 030-02873/94-01 (NOTICE OF VIOLATION)

This refers to the routine, unannounced inspection conducted by Mr. Gilbert L. Guerra, Jr., of this office on August 11-12, 1994, and to the telephonic conference held with members of your staff by Ms. Linda L. Kasner and Mr. Gilbert L. Guerra, Jr., on August 17, 1994. The inspection included a review of activities authorized by Byproduct Materials License 35-00526-04. At the conclusion of the inspection, the findings were discussed with members of your staff.

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 Notice of Violation (Notice). Five violations of NRC requirements were identified; however, for reasons described below, no citation is being issued for one of the violations.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, 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.

Also reviewed during this inspection was your implementation of the Quality Management (QM) program submitted to NRC on January 8, 1992. The inspector determined that you had administered several dosages of sodium iodide I-131 in quantities greater than 30 microcuries since our last inspection on September 20, 1993. Although VAMC staff had generally complied with the provisions of the QM program and 10 CFR 35.32, two violations associated with

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the QM Rule (10 CFR 35.32) were identified by the inspector, and one recordable event was identified by VAMC.

One violation involved the failure to maintain records of the 12-month QM program reviews conducted by VAMC staff. As specified in 10 CFR 35.32(b), a licensee must retain records of the evaluations and findings of such reviews in an auditable form for 3 years. It was noted that VAMC's radiation safety officer (RSO) has conducted quarterly reviews of all written directives to determine compliance with the QM program and that the QM program had been a topic of discussion during radiation safety committee meetings. However, no records describing the evaluations and findings of the QM program reviews were maintained. This was identified as a violation of 10 CFR 35.32(b)(3).

A second violation was identified regarding the content of written directives prepared for radiopharmaceutical administrations. As defined in 10 CFR 35.2, a written directive for administration of sodium iodide I-125 or I-131 in quantities greater than 30 microcuries must contain certain information, including the dosage. The inspector identified one written directive in which the dosage to be administered to the patient was not specified. In addition, the inspector noted that the activity unit (i.e., microcurie or millicurie) had been omitted in 4 out of 26 written directives reviewed. The failure to designate the dosage to be administered in five written directives was identified as a violation of 10 CFR 35.32(a)(1).

The inspector also reviewed a recordable event which was previously investigated by the RSO involving misplacement of a written directive. On August 13, 1993, during a routine quarterly audit by the RSO, it was discovered that a written directive was missing for a procedure involving administration of 4 millicuries of sodium iodide I-131. The investigation conducted by VAMC's RSO revealed that the technologist and physician both remembered using the written directive form and filling out the applicable sections. The RSO subsequently concluded that the written directive was misplaced after the procedure was completed. Corrective actions taken in response to the investigation findings included formal discussion of the findings with the staff to ensure that written directives are properly handled in the future. The inspector verified that corrective actions were instituted in a timely manner.

Two other violations were identified regarding the use of survey instrument check sources as described in 10 CFR 35.51 and package receipt surveys required under 10 CFR 20.1906 as of January 1, 1994. These violations are described in the enclosed Notice.

One noncited violation was identified by the inspector regarding decay-in-storage waste disposal records. VAMC's records appeared to indicate that waste had been disposed of even though detectable radiation levels at the surface of waste packages were above background readings. The inspector noted that recorded background readings were 0.0 milliroentgen per hour (mR/hr) and that final waste package survey readings were recorded as less than 0.1 mR/hr,

Department of Veterans Affairs  
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giving the impression that some activity still remained. However, following discussions with the chief nuclear medicine technologist, it was determined that this was only an error in recording detected background radiation levels.

Since the violation described above would normally be categorized as a Severity Level V violation and VAMC committed to implementing corrective actions during the inspection, no citation is presently being issued because the criteria in 10 CFR Part 2, Appendix C, Section VII.B.1 have been met.

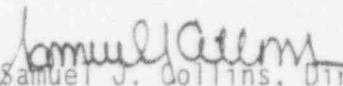
Overall, the inspection revealed that the radiation safety program, as well as implementation of the QM program, was properly managed. However, based on our inspection findings, it appears that further training on the requirements and importance of the QM program may be warranted in order to prevent future violations.

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

The responses directed by this letter and the enclosed Notice 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,

  
Samuel J. Collins, Director  
Division of Radiation Safety  
and Safeguards

Enclosure:  
Appendix - Notice of Violation

cc:  
Oklahoma Radiation Control Program Director

Department of Veterans Affairs  
Office of the Program Director  
Nuclear Medicine Service  
ATTN: Rosemary duFour  
24 Frank Loyd Wright Drive  
P.O. Box 505 Lobby M  
Ann Arbor, Michigan 48106

Department of Veterans Affairs  
V.A. Medical Center

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bcc:  
DMB - Original (IE-07)  
LJCallan  
DWeiss, OC/LFDCB (T-9E10)  
WLFisher  
LLKasner  
FAWenslawski, WCFO  
\*GLGuerra  
\*NMIB  
\*MIS System  
\*RIV Nuclear Materials File - 5th Floor (2)  
SLMerchant, NMSS/IMAB, (T-8F5) w/QMP field notes  
  
\*W/IFS Form

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*GLGuerra	LLKasner	RAScarano	SJCollins	
08/ /94	09/2/94	09/ /94	09/2/94	

\*Previously Concurred

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\*NMIB  
\*MIS System  
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SLMerchant, NMSS/IMAB, (T-875) w/QMP field notes  
  
\*W/IFS Form

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