

**Veterans
Administration**

July 12, 1983

In Reply Refer To: 662/00

Ross A. Scarano, Director
Division of Radiological Safety
and Safeguards Program
Nuclear Regulatory Commission, Region V
1450 Maria Lane, Suite 210
Walnut Creek, CA 94596

Dear Mr. Scarano:

We are submitting herewith our response to your letter of June 16, 1983, which was accompanied by a Notice of Violation detailing items of non-compliance found during the inspection of our facility on April 20-22, 1983.

In this reply we have described those actions taken and planned to improve the overall effectiveness of our management control system and those steps taken to correct and prevent specific violations.

We are giving these measures our highest priority and view the matter of Radiation Safety with the utmost seriousness.

Sincerely,

LAURANCE V. FOYE, JR., M.D.
Medical Center Director

Enclosure

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I. Actions Taken or Planned to Improve the Effectiveness of our Overall Management Control System

A. On April 28, 1983, the Radiation Safety Committee (RSC) met to discuss the results of the NRC inspection of April 20-22, 1983, especially the violations enumerated verbally in the exit interview between the inspectors and the Medical Center management. The Chiefs of the laboratories in which violations or potential violations were found were present at the same meeting of the RSC. After considerable discussion, the RSC adopted (unanimously) the following policy, effective immediately:

1. The RSO is directed to conduct more frequent inspections of all laboratories, including unannounced inspections.

2. Upon finding a deficiency or violation, the RSO issues a written citation, requiring the laboratory chief to correct the deficiency and respond in writing to the Chairman, RSC, within a stated period of time describing actions taken to correct the problem and to prevent future violations.

3. The RSO re-inspects the laboratory at the end of the stated period in order to ascertain compliance.

4. In the case of a laboratory in which repeat offenses occur or violations remain uncorrected, the RSO and the Chairman, RSC, will take positive enforcement action depending upon the nature of the violation. Actions will include a graded series of steps from restricting the quantity of isotopes ordered and used, to withholding all privileges in procuring radioisotopes, to closing the laboratory as the ultimate action.

The Chief of Staff will be notified of each such action and the justification upon which it is based.

B. Involvement of Top Management in the Radiation Safety Program. The following procedures have been instituted:

1. A monthly written report is submitted by the Chairman, RSC, to the Chief of Staff describing the current status of the Program and discussing problems encountered by the RSO or the Chairman in their day-to-day administration of the Program. In addition to these reports, any urgent matters requiring enforcement action will be brought immediately to the attention of the Chief of Staff, as described above (A. 4). The first of the monthly reports was submitted in June 1983.

2. The RSO is required to report directly to the Chief of Staff and ultimately to the Center Director any problems or issues of concern which in his opinion, are not being adequately dealt with by the RSC or its Chairman.

C. Proposed Changes in the Radiation Safety Committee

1. On June 14, 1983, we requested approval from the Licensing Branch of the NRC to include Dr. John Ziegler as a member of the RSC. Dr. Ziegler, who will

replace Dr. Thomas Bradley on the Committee, is an eminent hematologist-oncologist. In addition to providing the Committee with his professional expertise, Dr. Ziegler will provide an additional link between the Committee and Medical Center Management as Associate Chief of Staff for Education.

2. In August, 1983, we plan to establish a special watch-dog committee which will be charged with the active review of the Radiation Safety Program and the effectiveness of the RSO. The unofficial group will be responsible directly to the Chief of Staff and will also report to the RSC, thus helping the latter committee in its audit function.

D. Staffing of Radiation Safety Office

1. An assistant to the RSO will be appointed by September 15, 1983, after successful completion of the Radiation Safety Course given by the University of California, San Francisco.

2. The Radiation Safety Office will be placed under the Chief of Staff, thereby making it a more centralized function. This move, to be accomplished by October 1, 1983, will provide more effective administrative control and will foster better coordination of radiation safety with other safety functions at this Center.

3. Based on unsatisfactory performance, the present RSO has been given a written notice of intended removal, which he may or may not appeal. If and when he is removed from his position, a qualified individual, acceptable to the NRC, will be appointed RSO. If any delay in the appointment is expected, then a suitable substitute will be contracted for so that we are at no time without a full-time RSO.

II. Corrective Actions Taken or Planned to remedy Specific Violations Cited in Appendix A of NRC Report of June 16, 1983.

A. Contaminated glove in non-radioactive trash in the Endocrine Research Laboratory.

Corrective Actions Taken and Planned

1. The Chief of the Endocrine Research Laboratory has taken positive action, as described in his Memorandum dated April 28, 1983, in order to prevent future violations of this type in his laboratory.

2. On July 11 and 20, the Chief of Staff and the Chairman, RSC will hold meetings at which all laboratory personnel are required to attend in order to discuss this and other violations, to announce the new efforts being made to improve management controls and to enlist the active cooperation of all concerned in implementing these efforts.

3. In the course of conducting unannounced inspections of all laboratories, the RSO will pay particular attention to this aspect of the regulations.

4. The new duties of the RSO and assistant to the RSO will include the collection and removal of radiowaste from individual laboratories. In the course of this activity, they will survey non-radioactive trash containers in the same laboratories in order to ascertain compliance.

B. Daily surveys of the dose preparation and patient injection laboratory in Nuclear Medicine were not conducted on June 7, August 23, and October 6, 7, 8, 11, 1982. (N.B.: October 11, 1982 was an official holiday and no doses were given on that day)

Corrective Actions Taken and Planned

1. Daily radiation surveys and regular wipe tests of the laboratory work areas in the Nuclear Medicine dose preparation and administration room have been assigned to the Senior Imaging Technologist. In his absence, these duties will be performed by another technologist who has been specifically trained in these tasks. A third technologist has been appointed as additional back-up. In addition, these duties have been included as critical elements in the Performance Standards of each of these technologists.

2. The records of such laboratory surveys and wipe tests are reviewed and initialed at the end of each week by the Chief, Nuclear Medicine Service, as of May 6, 1983. (See attached Memorandum of May 17, 1983 to the Radiation Safety Committee)

C. The dose calibrator was not checked for linearity of response during the fourth quarter of 1982 and daily constancy checks were not performed on September 7-10, 23-24, November 4 and 9-10, 1982.

Corrective Actions Taken and Planned

1. Daily constancy checks are performed by the senior Imaging Technologist (Nuclear Medicine) and back-up support is provided by the same two technologists as described in B.1., above. The Chief, Nuclear Medicine Service, reviews and initials the records of the constancy check results. (Date begun: May 6, 1983)

2. The RSO is specifically assigned the responsibility for performing the linearity checks at least once per quarter. These records are also reviewed and signed by the Chief, Nuclear Medicine Service.

D. All survey meters were not calibrated semi-annually, as required by the License.

Corrective Action Taken and Planned

1. All survey meters are now being calibrated by the Radiation Detection Co. (Sunnyvale). As of July 1, 1983, eight of the G-M meters in use were calibrated, and the remaining eight meters will be calibrated by August 1, 1983.

2. In order to facilitate timely calibrations in the future, a Cesium-137 sealed source will be procured from a commercial supplier. This source is housed in a shielded, locked container from which the source cannot be completely removed. This calibrator will be procured by October 1, 1983.

E. Door to the Iodination Laboratory, Room 3B43, Building 203, was unlocked and the Laboratory was unattended at the time of the inspection.

Corrective Action Taken and Planned

1. All personnel using this Laboratory have been instructed to keep the door locked. (See Memorandum dated May 16, 1983, from the Chief of this Laboratory to the RSC)

2. The importance of security of areas where radioactive materials are stored or used will be emphasized at the general meetings on July 11 and 20, 1983, at which all laboratories will be represented.

3. Repeated visits to this laboratory have revealed no recurrence of this violation.

4. Future violations of this type in any laboratory will be dealt with by severe measures, according to the policy outlined in I. A. above.

5. We are seriously considering having the lock on every laboratory of this type changed to an automatic spring lock in order to help insure complete security.

F. Failure to record disposals of less than one microcurie amounts of iodine-125 released to the sanitary sewerage system in the Iodination Laboratory, Room 3343, Bldg. 203.

Corrective Action Taken and Planned

1. All laboratory personnel are being instructed in the necessity of maintaining complete records of disposal of activity via the sanitary sewerage system, at the general meetings already referred to and during regular instructional sessions held by the RSO.

2. Inspection of this laboratory on June 29, 1983, revealed complete compliance to this rule.

G. Records of leak tests performed on sealed sources were kept in units of counts per minute rather than in units of microcuries.

Corrective Action Taken and Planned

1. Records of leak tests have been corrected to show results in microcuries as of July 15, 1983.

2. The performance of leak tests and the maintenance of proper records of leak tests of sealed sources are incorporated as a critical element of the Performance Standards of the RSO.

H. Neither documents required to be posted or notices stating where they could be found were posted at the time of the inspection.

Corrective Actions Taken and Planned

1. Notices stating where copies of the license and other pertinent documents could be found have been posted in all laboratories where radioactive materials are used as of June 27, 1983.