U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report Nos. 030-02618/88-002
070-01331/88-002

Docket Nos. 030-02618
030-01331

License No. 31-00786-02 Priority 2 Category G1
SNM-1305 7 K

Licensee: Veterans Administration Medical Center
3495 Bailey Avenue
Buffalo, New York 14215

Facility Name: Veterans Administration Medical Center

Enforcement Conference At: Region I, King of Prussia, Pennsylvania

Enforcement Conference Conducted: May 5, 1988

Prepared by: Judith A. Joustra 5/19/88
Judith A. Joustra, Health Physicist date signed

Josephine M. Piccone 5/19/88
Josephine M. Piccone, Ph.D. date signed
Senior Health Physicist

Approved by: John E. Glenn 5/19/88
John E. Glenn, Ph.D., Chief date signed
Nuclear Materials Safety Section A

Conference Summary: The findings documented in Combined Inspection Report Nos. 030-02618/88-001 and 070-01331/88-001 were discussed. The licensee described planned corrective actions. The NRC enforcement policy was explained.

DETAILS

1. Persons Attending

Veterans Administration Medical Center

Bill Quain, Health Physicist, Joint Radioisotope Committee
Jayakumari M. Gona, M.D., Radiation Safety Officer
Stephen Spaulding, M.D., ACOS/Research and Development
John Elie, AA/ACOS/Research and Development

U.S. Nuclear Regulatory Commission

James M. Allan, Deputy Regional Administrator
Frank J. Congel, Acting Director, Division of Radiation Safety and Safeguards
James H. Joyner, Chief Nuclear Materials Safety Branch
John E. Glenn, Ph.D., Chief, Nuclear Materials Safety Section A
Daniel J. Holody, Enforcement Officer
John McGrath, Regional State Agreements Officer
Josephine Piccone, Ph.D., Senior Health Physicist
Judith A. Joustra, Health Physicist
Jeff Kant, Office of Enforcement (by phone)
Jenny Johansen, Office of Enforcement (by phone)

2. Conference Summary

a. Introductions were made and the representatives of the Veterans Administration Medical Center were welcomed to Region I by James M. Allan, Deputy Regional Administrator.

b. James H. Joyner, Chief, Nuclear Materials Safety Branch, explained the purpose and format of the Enforcement Conference.

c. Judith A. Joustra, Health Physicist, presented the findings of the April 5-7, 1988 inspection.

d. Dr. Jayakumari Gona outlined the licensee's planned actions to correct violations and provided handouts (attached) describing these actions.

(1) As a result of the exposure in excess of regulatory limits, the licensee has implemented the following corrective and preventive actions concerning the use of phosphorus-32 (P-32): revocation of the authorization to conduct collaborative studies by the VAMC Investigator primarily responsible for the laboratory in which the exposure occurred; formal reprimand of the same VAMC Investigator, including a six month probation; prohibition on the transfer of radioactivity from the State University of New York (SUNY) at Buffalo to the VAMC Investigator's laboratory; placement of an area monitor in the research hot lab; placement of plastic runners in the hot lab and adjacent hall; provision for disposable shoe covers for the hot lab and additional supplies for contamination incidents; restriction of access to the hot lab; completion of additional training on the contamination incident and the handling of P-32; development of guidance for the use of P-32; and plans to recruit an on-site Health Physicist.

(2) In connection with the apparent violation involving failure to assay a radiopharmaceutical dose prior to being administered to a patient, the requirement is now understood and has been emphasized in training given to the Nuclear Medicine Staff.

(3) In connection with the apparent violation involving failure to wipe test incoming packages of radiopharmaceuticals, the following steps have been taken to ensure that required package surveys are conducted:

(a) Increased frequency of audits;

(b) Written guidelines for required package inspections; and

(c) Periodic re-training.

e. Daniel Holody, Enforcement Officer, reviewed the enforcement options available to the NRC.

f. Mr. Allan thanked the Veterans Administration Medical Center personnel for their presentation, and stated that the information would be considered by NRC management in determining the NRC's proposed enforcement action.

NRC ENFORCEMENT CONFERENCE

May 5, 1988

P-32 CORRECTIVE ACTIONS

NRC inspection of April 5, 1988, confirmed that the following corrective actions had been implemented:

1. Revocation of the VAMC Investigator's authorization to conduct collaborative studies.

   See attached letter signed by RSO and JRC Chairman, and revised JRC Authorization VA-228;

2. Formal reprimand of the VAMC Investigator with a six month probation;

   See attached letter signed by RSO and JRC Chairman;

3. Prohibition on the transfer of radioactivity from the University to the VAMC Investigator's laboratory;

   See attached letter signed by RSO and JRC Chairman;

4. Increased audit frequency of the VAMC Investigator to maintain surveillance and track compliance:

   The laboratory was inspected by the JRC Health Physicist on the following dates; 03-24-88, 04-01-88, 04-14-88, and 05-02-88;

5. Placement of an area monitor in the research hot lab:

   An area monitor loaned from JRC Health Physics was placed in the hot lab. A new monitor, Ludlum Model 177 Ratemeter (see attached certificate) has been purchased and was received in April, 1988;

6. Placement of plastic runners in the hot lab and adjacent hall to facilitate easier decontamination;

7. Obtain disposable shoe covers for use in the hot lab and additional supplies to be maintained for use in any future contamination incidents.

   These supplies were purchased and received in March and April, 1988;

8. Access to the hot lab has been restricted. Investigators will need to obtain permission from ACOS/R or the Administrative Officer on each individual occasion access is required. See attached letter signed by Dr. Spaulding 02-04-88.

9. Conduct additional training relative to the contamination incident and handling of P-32.

   A training session for users of the hot lab was held on April 1, 1988. See attached attendance record.

FOLLOW-UP INFORMATION and ACTION:

The following additional corrective actions have been initiated:

10. On April 13, 1988 another training session was presented to all research workers related to the P-32 incident, general radiation safety topics, and discussion of the NRC Inspection. See attached attendance record;

11. Other recent training related to radiation safety was provided on March 16, 1988 to Building Management; March 23, April 27, and May 3, 1988 to Nuclear Medicine Technologists.

12. P-32 guidance (and other nuclides) has been formalized with preparation of a written guide, Appendix to the JRC Safety Manual, Volume I. See the attached P-32 Guide;

13. Restrictions on the individual research investigator's authorization have been added. See attached revision in Dr. Smith's authorization;

14. The Nuclear Medicine Service held a meeting on April 27, 1988 to discuss the findings of the NRC inspection and necessary corrective actions. See attached minutes of the meeting.

15. The VAMC Management recognizes the need for an on-site Health Physicist and is in the process of writing a job description to be expanded to include radioisotope coverage. Recruitment for this position will begin shortly. Responsibilities in this regard have been formalized in the document "Joint Radioisotope Committee Charter and Delegation of Authority" (attached).

16. A written report, dated 04-08-88 and 04-15-88, was submitted to Chairman of the Joint Radioisotope Committee by the JRC Health Physicist summarizing the findings of the NRC inspection and the progress in follow-up corrective actions. The findings will be formally reviewed at the next meeting of the Joint Radioisotope Committee on June 16, 1988.

NRC ENFORCEMENT CONFERENCE

May 5, 1988

WIPE TEST OF PACKAGES

NRC inspection of April 6-7, 1988 indicated that the Nuclear Medicine Service failed to wipe test packages containing greater than 100 mCi of Tc-99m.

FOLLOW-UP INFORMATION:

The VAMC purchases the Tc-99m from the Program's University based radiopharmacy. The containers are transported by a radiopharmacy employee using his private vehicle and delivered to the VAMC Nuclear Medicine Service with the containers inside of a US DOT approved shipping container (US Army Surplus Ammunition Box). DOT labels, bill of lading, and other shipping requirements are observed.

During the previous NRC inspection by M. Varela and C. Oberg, in October 1986, the VAMC was instructed to wipe test the individual inner "containers" which exceed 100 mCi, not the DOT shipping package. The current inspection report refers to wipe testing the "packages" exceeding 100 mCi. Also, it refers to the procedures described in Section V, Volume I of the Radiation Protection Manual, "Receipt of Radioactive Materials". The current NRC report continues "These procedures require that **packages** exceeding exceeding 100 millicuries of technetium-99m be wipe tested, using a dry swab, on the **outside of the package.**

FOLLOW-UP CLARIFICATION REQUESTED:

Is it appropriate to wipe test the inner containers which exceed 100 mCi? If contamination on the inner container exceeds 22,000 dpm, should the instructions outlined in Section V, Volume I of the Radiation Protection Manual, be followed. These instructions are:

"If contamination exceeds 22,000 dpm per 100 cm^2 (0.01 uCi), notify immediately:

1) the *__public carrier__ that delivered the package

2) at the VAMC, the Nuclear Regulatory Commission (by tele. 215-337-5000 or FTS488-1000, and by telegraph, mailgram, or facsimile)."

*__Note:__ Prior to the NRC inspection by M. Varela and C. Oberg, in October 1986, the VAMC did not wipe test the "packages" delivered by the University radiopharmacy driver because the delivery vehicle was a sole-use vehicle used only for this purpose and it was not considered a "public carrier".

FOLLOW-UP ACTION:

The following steps have been taken to ensure that required package surveys are conducted:

1. More frequent inspections, as necessary, are planned by the Joint Radioisotope Committee Health Physicist.

2. The inservice and staff meeting on April 27, 1988 stressed this point.

3. Guidelines regarding required package inspections have been written to assure compliance. See attached guideline dated April 1988.

4. The University radiopharmacy has revised their procedures to reduce the possibility of contamination on the containers.