U.S. NUCLEAR REGULATORY COMMISSION

REGION V

Report No. 90-02

Docket No. 030-08456

License No. 04-15030-01

Licensee: Veterans Administration Medical Center
3350 La Jolla Village Drive
San Diego, California 92161

Inspection at: same as above

Inspector: James L. Montgomery 10/23/90
James L. Montgomery Date Signed
Senior Materials Specialist

Approved by: Robert J. Pate 10/31/90
Robert J. Pate, Chief Date Signed
Nuclear Materials and Fuel
Fabrication Branch

Inspection Summary:

Inspection on September 26-28, 1990 (Report No. 030-08456/90-02)

Areas Inspected: This was a special reactive announced inspection of the licensee's activities related to the investigation of alleged unauthorized use and transfer of licensed material on March 9, 1989. The purpose of the inspection was to determine the scope and adequacy of the licensee's investigation. The inspection included an examination of the licensee's organization; receipt, use and transfer of licensed material; training; licensee's internal investigation; Radiation Safety Committee meetings; and corrective actions.

Results: Four violations were identified. All four were initially identified by the licensee and are either a Severity Level IV or V violation. The violations have not been cited because the enforcement discretion criteria in paragraph V.G. of 10 CFR Part 2, Appendix C, "General Statement of Policy and Procedure for NRC Enforcement Actions", were satisfied.

DETAILS

1. Persons Contacted

Licensee

T. Trujillo, Medical Center Director
J. Parthmore, M.D., Chief of Staff
J. Verba, Ph.D., Radiation Safety Officer
R. Engler, M.D., Associate Chief of Staff, Research Service
D. Hill, Chief, Storage and Distribution
J. Mathews, Radiation Safety Technician

Non-Licensee

M. Malter, Director, Environmental Health and Safety, UCSD
K. Helm, Radiation Safety Officer, UCSD
F. Bold, Senior Health Physicist, San Diego County
Department of Health Services

2. Licensee's Organization

The Veteran's Administration Medical Center, San Diego (VAMC/SD), is headed by a Medical Center Director and Chief of Staff. The Radiation Safety Officer (RSO) reports to the Medical Center Director and also receives direction from the Chief of Staff. The RSO's staff consists of a radiation safety technician and a secretary. The licensee is currently recruiting to fill an Assistant RSO position. The RSO and the Chief of Nuclear Medicine co-chair the Radiation Safety Committee (RSC). The recommendations of the RSC are made to the Medical Center Director. Personnel actions related to radiation safety are reviewed by the Research Committee and the Clinical Executive Board. The RSO has radiation safety responsibilities and authority over all uses of radioactive material at the Medical Center in the areas of nuclear medicine, radiation therapy and research. The University of California at San Diego (UCSD) is adjacent to the VAMC/SD. Researchers and physicians frequently use and transfer radioactive material between both institutions.

No apparent violations or deviations were identified.

3. UCSD Dean's Committee

In June 1989, a post doctoral researcher (PDR) working at UCSD and VAMC/SD filed a complaint with the UCSD Academic Senate alleging that a diabetes researcher (DR), who also worked at both institutions, had used the PDR's research discoveries for his personal gain and credit. The UCSD Dean appointed a "Dean's Committee" to investigate the allegation. During this investigation, the committee discovered a possible conflict of interest related to the unauthorized transfer and use of licensed radioactive material between private companies, the VAMC/SD and UCSD. Following an interview with the PDR, the Dean's Committee notified the VAMC/SD RSO and Chief of Staff of the unauthorized use and transfer

allegations. Allegedly, the PDR and a non-VAMC/SD employee from the Amylin Corporation entered the VAMC/SD iodination laboratory on the evening of March 9, 1989 and proceeded to use licensed material. The iodination laboratory is a restricted area reserved for use by authorized VAMC/SD researchers only. Following the use of the licensed material (approximately 5 millicuries of iodine 125) the radioactive compound (a peptide) was transferred to a private company located in the City of San Diego.

On July 23, 1990, the VAMC/SD Chief of Staff appointed a three person committee, headed by the RSO, to investigate the allegations relative to the use and transfer practices at the VAMC/SD.

No apparent violations or deviations were identified.

4. Receipt of Licensed Material

Licensed material normally arrives at the VAMC/SD receiving dock. Regardless of who the package is addressed to, the receiving supervisor notifies the RSO that a package marked with radioactive labels has arrived. The RSO retrieves the package and performs the required radiation surveys and record keeping. The RSO then personally delivers the package to the laboratory researcher or physician who ordered it.

The RSO had identified problems concerning the receipt of some licensed material by individual researchers without the knowledge of the RSO. Shipments were identified as arriving from the Eli Lilly Company without the usual licensee's purchase order. The RSOs at VAMC/SD and UCSD were aware of the shipment problems and have reminded authorized users of the requirement for all shipments of licensed material to be routed through the Radiation Safety Office.

No apparent violations of deviations were identified.

5. Use and Transfer of Licensed Material

Frequently, one researcher will use licensed material at laboratories located at both UCSD and VAMC/SD. Licensed material procured under one institution may be transferred and used at the other institution provided applicable institution procedures, license conditions and regulations are followed. Occasionally licensed material is transferred between UCSD or VAMC/SD and a private company. Again, this is authorized if applicable requirements are followed. The transfer of the iodinated compound from the VAMC/SD on or about March 9, 1989 was not authorized and was in violation of VAMC/SD radiation safety procedures.

One apparent violation was identified.

6. Use and Transfer Records

The VAMC/SD has established written procedures and record forms for the use and transfer of licensed material. Whenever a transfer is contemplated, the researcher or his designee must complete a

"Interinstitutional Transfer Form" which the VAMC/SD designated as VARSO 1005. All such forms must go through the RSO's office for approval. The transfer of radioactive material following the unauthorized use on March 9, 1989 was made without completing the required VAMC/SD documentation. This is described in more detail in Sections 8 and 9 of this report.

One apparent violation was identified.

7. Training

All personnel at the VAMC/SD who use licensed material or frequent areas where licensed material is used or stored receive initial and annual refresher training given by the RSO or other qualified personnel such as principal investigators. During annual audits of each investigator's laboratory, refresher training is conducted with the laboratory personnel. The RSO noted that the DR has not attended these audits and has missed his refresher training on several occasions. The PDR had received initial and refresher training in accordance with VAMC/SD procedures. The employee from the Amylin Corporation who was present with the PDR in the iodination room on March 9, 1989 had not received any VAMC/SD training. This was identified by the RSO as a violation of the VAMC/SD radiation safety procedures.

One apparent violation was identified.

8. Iodination Room Use and Logs

Combining iodine 125 with various chemical compounds is routinely done by several VAMC/SD personnel through a process known as iodination. Volatile, liquid iodine 125 in usually millicurie quantities is bound to a molecule and later used in experiments involving radioimmunoassay. The iodination must be done in a properly operating laboratory fume hood to minimize the potential for airborne contamination. The VAMC/SD requires all iodinations to be done in a fume hood located in one laboratory on the sixth floor of the research wing. Personnel doing the iodination must demonstrate adequate training and experience for the procedure and be authorized by the RSO. A log to record all iodinations is required to be completed by each user. The log and the required radiation surveys were completed by the PDR who used the iodination room on the evening of March 9, 1989. Also present in the iodination room on March 9, 1989 was an employee of the Amylin Corporation. The Amylin individual was not authorized to be in the restricted area of this room. The presence of unauthorized persons in restricted areas is a violation of the VAMC/SD radiation safety procedures.

One apparent violation was identified.

9. VAMC/SD Investigation

On July 23, 1990 the three member VAMC/SD committee appointed by the Chief of Staff began its investigation. The committee, consisting of the RSO and two research physicians, conducted an extensive search of the DR's radiation safety records and interviewed the DR and his staff. From

these records and interviews the committee discovered that several transfers of radioactive tagged blood samples had occurred between the VAMC/SD and UCSD without the required transfer documentation. An interview by the committee with the PDR revealed that an employee of the Amylin Corporation and the PDR iodinated a peptide molecule at the VAMC/SD on March 9, 1989. The PDR stated that the Amylin employee performed the iodination. However, the PDR signed and made entries in to the iodination log. In a letter dated September 4, 1990 to the San Diego County Department of Health Services, the Amylin employee stated he observed and assisted the PDR with the iodination.

The committee's findings of impropriety can be summarized as follows:

- Radioactive transfers between UCSD and VAMC/SD occurred without proper procedures being followed.

- Unauthorized iodination occurred in the presence of an unauthorized individual.

- An unauthorized and undocumented transfer of licensed material to the Amylin Corporation was made for purposes not associated with VAMC/SD research.

- Improper receipt and undocumented use of licensed material from the Eli Lilly Company.

According to the VAMC/SD RSO, the PDR also alleged that the DR and other Amylin personnel conducted a meeting where the unauthorized use of licensed material was discussed culminating in a decision to wilfully violate regulatory requirements in order to complete needed research and development of the iodinated peptide. Minutes of the Amylin Corporation meeting were reviewed by the RSC and the inspector. These minutes do not support the allegation of a willful conspiracy to violate NRC or VAMC/SD requirements.

No apparent violations or deviations were identified.

10. Radiation Safety Committee Meetings

On August 31, 1990 a special meeting of the VAMC/SD RSC was held to discuss the findings of the Chief of Staff appointed committee investigation and determine the appropriate corrective actions. At the conclusion of the meeting the RSC decided to suspend the DR's authorization to use licensed material at VAMC/SD for one month (September) and to reconvene within one or two weeks to determine what further corrective action would be appropriate. No action was taken against the PDR because be was scheduled to leave the VAMC/SD for a position with another institution.

On September 17, 1990 the RSC reconvened. Upon invitation, the DR attended the meeting. The DR was asked by the RSC Chairman to comment on the charges against him. The DR stated he thought that the usual transfer requirements for licensed material didn't apply to samples that

were only to be counted for radioactivity. The DR added that he did not wilfully violate any procedures and did not attempt to deceive anyone concerning the use or transfer of licensed material. He said he did not believe that an Amylin employee used licensed material at the VAMC/SD or transferred material to an unlicensed facility. (NOTE: The State of California is conducting an investigation to determine who received the iodinated peptide and whether a valid license to possess and use the radioactive material had been issued.) The DR then left the meeting.

The RSO reminded the RSC that as the principal investigator, the DR is responsible for all use of radioactive material in his laboratory. The RSO emphasized that punitive action was appropriate and that the RSC had the responsibility to determine what action should be taken. After some discussion, the RSC voted unanimously to close the DR's research laboratory at VAMC/SD until January 31, 1991. The RSC also unanimously voted to require the DR to personally perform monthly audits of his laboratory beginning on February 1, 1991. Additional radiation safety training for the DR and his staff was also recommended. The RSO was directed to provide the RSC findings and recommendations to the VAMC/SD Director who is responsible for the final decision on punitive and corrective actions. The RSC also sanctioned a sub-committee to review receipt, transfer and inventory control over licensed material and recommend corrective actions to avoid future unauthorized transfers, uses and inventories exceeding license limits.

No apparent violations or deviations were identified.

11. Exit Briefing

An exit briefing was held with the Medical Center Director and the RSO at the conclusion of the inspection. Four violations were identified as follows:

- Unauthorized transfer of licensed material.
- Inadequate radiation safety training.
- Unauthorized entry into a restricted area.
- Failure to maintain transfer records for licensed material.

The inspector acknowledged the licensee's identification of the above violations. These violations will not be cited because the criteria in paragraph V.G. of 10 CFR Part 2, Appendix C, "General Statement of Policy and Procedures for NRC Enforcement Actions", were satisfied.

12. Final Corrective Actions

On October 19, 1990 the inspector was informed by the VAMC/SD RSO that the RSC recommendations (see section 10 of this report for details) were concurred upon by the VAMC/SD Research Committee the Clinical Executive Board. The RSC recommendations were then formally approved by the Medical Center Director. The RSO stated that the DR was in the process of transferring all of his research activities to UCSD. His VAMC/SD laboratory and research will be inactive until February 1, 1991.