DEPARTMENT OF VETERANS AFFAIRS
Medical Center
3801 Miranda Avenue
Palo Alto CA 94304

In Reply Refer To: 640/115
Lic #04-23242-01

MAY 26 1994

U.S. Nuclear Regulatory Commission
Attention: Document Control Desk
Washington, D.C. 20555

SUBJECT: Reply To Notice Of Violation
(NRC Inspection Report No. 030-20404/94-01)

We are herein responding to the "Notice of Violation" that was issued after the inspection conducted by Mr. Troy Pruett of the NRC's Walnut Creek Field Office.

The response below was prepared by John Holmes, Radiation Safety Officer, under contract with Stanford University. The numbers used refer to the items cited in the "Notice of Violation."

1. **Security of Radioactive Materials:**

The laboratory (Building 2, Room A10) where the violation occurred was located in the basement of a building where several other labs are located. During a safety inspection by the Subcommittee on Safety for the Medical Research Laboratories (Subcommittee) in February 1993 it was found and stated in the minutes of the Subcommittee that the Lab could not be locked without violating fire codes. The Research and Development Adminstration undertook investigations to solve a potential security problem by relocating the fire exit or by relocating the lab activities. These solutions were explored but apparently were not further documented in Subcommittee deliberations. The recollection of the committee members and as described in the Memorandum from the Administrative Assistant for Research and Development to the Radiation Safety Officer (RSO), dated March 30, 1994, indicated that a long term solution to the problem, i.e. moving the labs to a new annex to be constructed in the future) was selected to be pursued. The RSO had seen a copy of the February 1993 minutes and was briefed by a member of the Health Physics staff, who serves as an informal liaison member of the Subcommittee, and was aware of the potential problem and the fact that a solution was being pursued. Subsequent Subcommittee minutes did not, to the RSO's knowledge, discuss the issue. The issue was not entered into the RSO's formal documentation system, nor was it referred to the Radiation Safety Committee (RSC). Hence there was no follow-up by the radiation safety staff to verify that a satisfactory solution was implemented. During announced site visits and unannounced laboratory surveys

94-1155

performed during 1993 and 1994 (until the date of the NRC inspection) the lab was not found by the Health Physics staff to have been unlocked and unattended. (Such a finding would have brought the issue into focus for action. In short the circumstances described in the "Details" of the NRC Inspection Report are accurate.

Immediately upon the finding by the NRC of the security violation, the Research and Development Administration reconsidered possible corrective recourses. The basement access door and elevator control were provided with locks, such that one requires a key to enter the basement which is now a restricted area. Ancillary workers who may enter the area were given radiation safety instruction. The long term solution of relocating the laboratory to a new annex (still to be constructed) has also been given a high priority.

The RSO has advised the Radiation Safety Committee (RSC) about this incident and has been admonished by the RSC that he should in the future inform it of any problems that could lead to noncompliance. The staff of the RSO have been informed to be especially vigilant concerning security of radioactive materials. Users of materials have been given a reminder to maintain proper security within labs in a bulletin entitled "Radiation Safety Notices," dated May 1994 that will be sent to all users of radioactivity via the Project Directors.

We are in full compliance at the present time. We believe that the actions taken will avoid further violations.

2. **Failure of Users of Radioactive Materials to Perform Monthly Surveys:**

Several projects failed to perform a documented radiation survey during each calendar month. In the case of the Foothill Research Laboratory rooms 103 and 104, the research project staff had performed surveys the last week of January 1994 and in the first week of March 1994 missing the month of February. A similar scenario occurred in Building 2, Room A-010 during the month of November where a staff member who was in the practice of performing surveys on the last day of the month mistook November as having 31 days and was a day late for completing the surveys. A similar situation occurred in Building 1, Room E312. The room was surveyed on March 31, April 30 and June 1, 1993. We discussed the finding with the NRC inspector. We agree that performing the survey was a technical violation of the license; however, we note no safety issue was involved, since it is possible for a project to perform surveys at the beginning of a month and at the end of the next (with as much as 60 days between surveys) and remain in compliance, while missing the interval by one day (with as little as a 32 day interval) and be in non-compliance.

We have established an interim policy requesting projects to perform surveys within the first week of each month. Health Physics will check the status of the completion of surveys well before the end of the month to permit follow-up with projects before surveys become delinquent. When no materials have been used since the previous survey, the project staff will note that fact on the User Survey Log in lieu of performing a survey. The required frequency of surveys for areas where there is only storage of radioactive materials is quarterly. All projects were informed of the new interim policy on the need to perform surveys during the first week of each month early in April.

Since the date of the NRC inspection, a similar deficiency to those cited was discovered in the laboratories in Building 2 (the same Project as A10). The "March survey" was performed in the first week of April, but there was a second "April survey" performed later that month. This was found during the first Health Physics mid-month audit of all user surveys. The interim policy memo had not arrived before the end of March. The Project Director was informed by the RSO and by the RSC that in the future the user surveys must be performed during each calendar month, without exception. The RSC formally adopted the new policy at its Meeting on April 26, 1994.

We are presently in compliance with this license condition. We believe the actions taken will avoid further violations.

3. **Availability of Suitable Radiation Survey Instruments:**

We note the survey instrument used by a lab person to check for contamination that was observed by the NRC Inspector was a standard thin-end-window GM tube commonly used in research labs to survey for contamination. The lab staff member had in fact made a survey of the item prior to disposal. The NRC Inspector used a Pancake GM detector which is clearly more sensitive than the end window type. The Inspector noted to the RSO at the time (and repeats in the "Details" appended to the Notice of Violation) he found 2000 dpm in the trash receptacle, but the instrument used by the Project was not able to distinguish the material from background.

We reviewed our license conditions and note the following: In communications with the NRC regarding the renewal in 1991 of the License, namely, correspondence dated September 12, 1991 and October 21, 1991, we proposed an increase in the permissible levels of contamination by a factor of 5. We noted in the "Justification" section of our October 21 submission the following:

> "To justify our proposal, the reason we have requested the change is we have observed in our calibrations of instruments that most

> standard GM survey meters are incapable of detecting contamination at the levels noted in the Regulatory Guide for restricted areas. Nonetheless, we are promoting a routine survey program in the labs which are for the most part equipped with such instrumentation."

The NRC accepted this proposal and included the referenced letters in the License renewal issued December 12, 1991. In view of the approved increase in the contamination limits, the sensitivity of the instrument in the lab was in compliance with the conditions of the license (superseding Table 4.6 in the Radiation Protection Manual which was taken from the Regulatory Guide).

We, therefore, respectfully request that the violation be rescinded and restated as a "concern." Though we do not believe that this is a violation, we, nonetheless, plan to address the problem by requesting the Projects to be equipped with instruments with "pancake" types of GM detectors, or with scintillation types of probes where radioiodine is used. Because this will require additional expenditures for equipment, we will require all Projects to meet this requirement by May 1, 1995. Projects will still be permitted to borrow or to share instruments with other Projects provided that the proper instrument is in the laboratory whenever radioactive materials are being used.

We believe that we are presently in compliance; but the actions that are specified above should improve safety in the labs. The process will be completed by May 1995.

4. **Exceeding Project Possession Limits:**

The Controlled Radiation Authorizations (CRA) are given both per item (per order) and possession limits. In some cases the Project Directors (PD) have requested the same quantities for both limits and discussions with the PD indicated that activity purchased would be much less than the "per order" limit. The Health Physicist failed to increase the possession limit to allow for instances when the amounts purchased actually equaled the per order limit. This meant that since the two limits were equal, the Project would be in non-compliance if there was any residual activity in the lab. We have identified all of the projects which have equal "per order" and possession limits. These will be reviewed and the limits adjusted on a case by case basis so that the possession limits are at least twice the " per order" limits.

The process of review and adjustment is underway by Health Physics and will be completed by June 15, 1994, at which time we will be in full compliance.

Further questions may be directed to John Holmes, Radiation Safety Officer at phone number (415) 725-1413.

Please direct all replies through Francis K. Herbig, Deputy Director, Department of Veterans Affairs Health Physics Program (115HP), 915 North Grand Boulevard, St Louis, Missouri, 63106.

Sincerely yours,

James A. Goff, FACHE
Medical Center Director

enclosure:

cc: U.S. Nuclear Regulatory Commission
Regional Administrator, Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, Texas 76011-8064

U.S. Nuclear Regulatory Commission
Walnut Creek Field Office Director
1450 Maria Lane, Suite 210
Walnut Creek, CA 94596

E. Leidholdt, Jr., Ph.D.
Radiation Safety Program Manager (134RAD)
Department of Veterans Affairs
VHA, Western Region
301 Howard Street, Suite 700
San Francisco CA 94105-2241

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

MAY

Docket No. 030-20404
License No. 04-23242-01
EA No. 94-073

Department of Veterans Affairs
Medical Center
3801 Miranda Avenue
Palo Alto, California 94304

Attention: James A. Goff,
Medical Center Director

SUBJECT: NOTICE OF VIOLATION (NRC INSPECTION REPORT No. 030-20404/94-01)

This refers to the inspection conducted by Troy W. Pruett of this office on March 15-17, 1994. The inspection included a review of activities authorized for Veterans Affairs Medical Center, Palo Alto, California. The initial findings were discussed with you and other members of your staff on March 17, 1994. Additional discussions relevant to the inspection were held with members of your staff between March 28-31, and April 1-6, 1994 and during a meeting between the NRC (Acting Materials Branch Chief and Inspector) and Licensee management on April 28, 1994.

Areas examined during the inspection are identified in the enclosed report. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations of activities in progress. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements.

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). Two of the violations were repeated from inspections performed in May 1992 and April 1993. The repetitive violations involved the failure to maintain security of licensed material and perform monthly surveys as required by your NRC license. The repetitive violations are of particular concern because they demonstrate the need to ensure that management implements effective and long lasting corrective actions for identified deficiencies in the Radiation Safety Program. Additionally, the violation involving the security of licensed materials in Research Laboratory A-10 indicates that management may not have clearly identified the actions that a non-radiation oversight committee should take when confronted with issues involving radiation safety, and that licensee personnel may not be fully aware of license requirements for securing radioactive materials.

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. Your reply should specifically describe management's actions to preclude the occurrence of repetitive violations. 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.

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 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.

Sincerely,

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

Enclosures:

1. Appendix A - Notice of Violation
2. Appendix B - NRC Inspection Report
   030-20404/94-01

APPENDIX A

NOTICE OF VIOLATION

Veterans Affairs Medical Center
Palo Alto, California

Docket No. 030-20404
License No. 04-23242-01
EA No. 94-073

During an NRC inspection conducted on March 15-17 and 28-31, and April 1-6, and 28, 1994, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

A. License Condition 23 requires in part that the Licensee possess and use licensed material in accordance with the statements, representations, and procedures contained in the application dated July 22, 1991, including the 1989 edition of the Radiation Protection Manual, and the letter dated September 12, 1991.

1. Radiation Protection Manual, Section 1, Page 7, "Security of Radioactive Materials", states in part, that radioactive materials will be secured against unauthorized removal from places of storage and that controlled areas will be secured (locked) when unoccupied. The Licensee's Radiation Protection Manual defines a **controlled area** as an area access to which is controlled by the user for purposes of radiation safety and that the area must be secured when it is not occupied by responsible personnel.

   Contrary to the above, on March 15, 1994, the Licensee did not secure from unauthorized removal or limit access to approximately 1.5 millicuries of iodine-125, 0.1 millicuries of phosphorus-32, and 0.5 millicuries of tritium located in Building 2, Room A-010, a controlled area.

   This is a Severity Level IV repeat violation, second occurrence. (Supplement VI). (94-01-02)

2. Item 5 of the letter dated September 12, 1991, states that monthly surveys will be performed in laboratories which handle or store "B" or "C" levels of radioactive materials. Monthly surveys are performed each calendar month and "B" or "C" levels of radioactive materials refer to the quantity of material possessed with "A" being the greatest and "C" the least.

   Contrary to the above, the Licensee failed to perform monthly surveys in areas where "B" or "C" levels of radionuclides were handled or stored. Specifically, the following laboratories were not surveyed:

Lab Number	Month Not Performed
Foothills Research Center 103	02/94
Foothills Research Center 104	02/94
Building Two A-010	11/93
Building One B-312	05/93

This is a Severity Level IV repeat violation, second occurrence (Supplement VI). (94-01-04)

3. Radiation Protection Manual, Section 4, Page 47, "Requirements for Survey Instruments," requires each Project that routinely utilizes millicurie quantities of radioactive material to possess a suitable survey meter for detecting contamination.

   Contrary to the above, on March 16, 1994, the Licensee's end window GM probe survey instrument (Serial Number A552M) used by Project VMN-361, which is authorized to possess and use millicurie quantities of licensed materials, was not suitable for detecting phosphorus-32 contamination.

   This is a Severity Level IV violation (Supplement VI). (94-01-03)

4. Radiation Protection Manual, Section 2, Page 12, "Controlled Radiation Authorization to Use Radioactive Materials", states that each Controlled Radiation Authorization will specify the maximum quantity to be possessed at any time by a Principle Investigator. Controlled Radiation Authorization VMN-287 states that the maximum possession limit for iodine-125 is five millicuries.

   Contrary to the above, records of quarterly inventories dated July 30 and October 28, 1993 and January 26, 1994, indicated that the Principle Investigator for Controlled Radiation Authorization VMN-287 exceeded the maximum possession limit for iodine-125.

   This is a Severity Level IV violation (Supplement VI). (94-01-01)

Pursuant to the provisions of 10 CFR 2.201, Veterans Affairs Medical Center, Palo Alto, California, is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region IV, and a copy to the Walnut Creek Field Office Director, 1450 Maria Lane, Walnut Creek, California, 94596, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Arlington, Texas
this 9th day of May 1994

APPENDIX B

U.S. NUCLEAR REGULATORY COMMISSION
RIV
(WALNUT CREEK FIELD OFFICE)

Report No. 94-01

License No. 04-23242-01

Docket No. 030-20404

EA No. 94-073

Licensee: Veterans Affairs Medical Center
Palo Alto, California

Inspection Conducted: March 15-17 and 28-31, 1994
and April 1-6 and 28, 1994

Inspector: Troy W. Pruett, Radiation Specialist, Materials Branch

Approved: Frank Wenslawski 5/4/94
Frank Wenslawski, Chief, Date Signed
Materials Branch

Areas Inspected: This was a routine unannounced inspection to examine Veterans Affairs Medical Center (VAMC) Palo Alto's Radiation Safety Program for the period of April 23, 1993, to March 17, 1994. The areas examined included: organization; use and storage of licensed materials; internal audits; material receipt and transfer; dose calibrator measurements; survey instruments and calibration; training; radiation and contamination surveys; personnel monitoring; waste disposal; sealed source leak testing and inventory; posting and labeling; Quality Management Program; and independent measurements.

Results:

* The Licensee's overall radiation safety program was adequate.

* Two violations were repeated from inspections performed in May 1992 and April 1993. The repetitive violations involved the failure to maintain security of licensed material and perform monthly surveys as required by the NRC license. The repetitive violations indicated that Licensee management had not been fully effective in correcting identified violations of regulatory requirements.

* The violation involving the security of licensed materials in Research Laboratory A-10 indicated that management may not have clearly identified the actions that a non-radiation oversight committee should take when confronted with issues involving radiation safety, that management had not developed a mechanism for tracking potential items of non-compliance, and that licensee personnel may not have been fully aware of license requirements for securing radioactive materials.

Summary of Inspection Findings:

* (Open) Violation 94-01-01: Failure to maintain iodine-125 inventories below the maximum allowable inventory as required by CRA Number VMN-287. (Section 2)

* (Open) Violation 94-01-02: Failure to secure radioactive material from unauthorized removal or lock a controlled area when unattended as required by RPM Page 7. This is a repeat violation, second occurrence, last cited May 1992. (Section 3)

* (Open) Violation 94-01-03: Failure of Project CRA VMN-361 to possess a suitable survey instrument for detecting contamination in Research Laboratory 242, as required by RPM Section 4, Page 47. (Section 7)

* (Open) Violation 94-01-04: Failure to perform monthly surveys as required by RPM Page 45, and the letter to NRC dated September 12, 1991. This is a repeat violation, second occurrence, last cited April 1993. (Section 9)

* (Closed) Violation 93-01-01: Failure to monitor hands prior to leaving the restricted area. (Section 2.1)

* (Closed) Violation 93-01-02: Failure to wear assigned dosimetry while working with or around licensed materials. (Section 10.1)

* (Closed) Violation 93-01-03: Failure to perform monthly surveys as required by RPM Page 45, and the letter to NRC dated September 12, 1991. This item will continued to be monitored under violation 94-01-04. (Section 9.1)

Attachments:

* Attachment 1 - Persons Contacted and Exit Meeting

DETAILS

1. Organization

The Stanford University Health Physics staff is under contract with the Medical Center to provide oversight of the radiation safety program. Radioisotope committee memberships include Licensee management representatives from the Medical Center, Stanford University, and the Health Physics staff. The use of the Stanford Health Physics staff to provide oversight of both facilities allows the Medical Center to have additional health physics resources not typically available to other Veterans Affairs Medical Centers and provides for a non-disruptive transition of personnel between Stanford and the Medical Center.

1.1 Research

There are approximately 35 Project Managers/Principle Investigators (PI) who perform research at the Medical Center or the Foothills Research Center. PIs are approved to use licensed material by the Local Control Committee, the Administrative Panel on Radiological Hazards, and the RSO. The most common isotopes used by the PIs are phosphorus-32, iodine-125, tritium, sulfur-35, and carbon-14. The Licensee has three approved human research protocols (one inactive, two active) involving approximately thirteen individuals. PIs performing human research have been authorized by the licensee's School of Medicine Isotope Committee and the Committee on the Use of Human Subjects in Research.

1.2 Nuclear Medicine

The Licensee performs approximately 200 diagnostic studies per month primarily using technetium-99m and iodohippurate. The Licensee administered greater than 30 microcuries of iodine-131 on three occasions and administered strontium-89 (metastron) on five occasions. The Licensee uses unit doses received from a local radiopharmacy.

No apparent violations or deviations were identified during the inspection of this program area.

2. Use of Licensed Material

Observations of procedures performed in Nuclear Medicine and Research indicated that personnel were knowledgeable of the requirements for safe use of radioactive materials.

License Condition 23 requires in part that the Licensee possess and use licensed material in accordance with the statements, representations, and procedures contained in the application dated July 22, 1991 (including the Radiation Protection Manual, 1989 Edition). Page 12 of the Radiation Protection Manual (RPM), Section "Controlled Radiation Authorization (CRA) to Use Radioactive Materials", states that each CRA will specify the maximum quantity to be possessed at any time by a PI. The CRA for Project VMN-287 stated that the maximum possession limit for Iodine-125 was five millicuries.

Records of quarterly inventories dated July 30 and October 28, 1993 and January 26, 1994, indicated that the PI for VMN-287 exceeded the maximum possession limit for iodine-125 on at least three occasions. The RSO stated that the possession limit was exceeded because orders for iodine-125 equalled the maximum authorized limit. Therefore, the CRA limit was exceeded whenever a shipment of iodine-125 was received and iodine-125 remained in the laboratory from prior shipments or as radioactive waste. The RSO stated that the PI's CRA would be amended to increase the allowable possession limit and that a review of other CRA's would be performed to ensure that there were no similar unidentified violations.

The following violation was identified during the review of this program area.

1. The failure to maintain iodine-125 inventories below the maximum allowable inventory as required by CRA Number VMN-287. (94-01-01)

2.1 Use of Licensed Materials Follow-up

(Closed) Violation 93-01-01: Radiation Protection Manual, Page 2, "Individuals", Item 9, required individuals to survey their hands prior to leaving the laboratory. Based on observations of individuals working with or around licensed materials, monitoring of hands was performed prior to an individual leaving the restricted area.

3. Storage of Licensed Materials

Radiation Protection Manual, Section 1, Page 7, "Security of Radioactive Materials", states in part, that radioactive materials will be secured against unauthorized removal from places of storage and that any controlled area will be secured (locked) when unoccupied. The Licensee's Radiation Protection Manual defines a **controlled area** as an area access to which is controlled by the user for purposes of radiation safety and that the area must be secured when it is not occupied by responsible personnel.

On March 15, 1994 the inspector observed that Research Laboratory A-10, a controlled area, was unlocked and unattended. Inventory records for Research Laboratory A-10 dated March 2, 1994 indicated that the maximum allowable amount of radioactive material which could be stored in the labeled "Caution Radioactive Materials" unlocked refrigerator was 0.1 millicuries of iodine-125, 0.1 millicuries of phosphorus-32, and 0.5 millicuries of tritium, and that approximately 1.4 millicuries of iodine-125 and 0.1 millicuries of tritium was stored as radioactive waste. During the May 1992 NRC inspection an NRC Form 591 was issued to the Licensee for failure to maintain control or surveillance of licensed material in the Foothills Research Center. The Licensee's corrective actions for the May 1992 violation included key locking the entrances to the Foothills Research Center, training individuals who required access, and ensuring that other Research Laboratories did not have a similar problem during audits performed by the Health Physics staff.

The PI for Research Laboratory A-10 stated that although he could not provide an exact quantity, that microcurie amounts of radioactive materials were stored as cultures in the unlocked refrigerator and that laboratory

technicians had been working in a Dark Room adjacent to the laboratory when the inspector observed the space unlocked and unattended. Additionally, the PI and the Health Physics staff stated that as a result of a non-radiological safety inspection performed in February 1993, that the Subcommittee on Safety for Medical Research Laboratories (Subcommittee) decided to leave the door to Research Laboratory A-10 open during normal working hours to allow access to a secondary emergency exit located inside the laboratory. The inspector requested that the licensee develop a corrective action plan for security of radioactive materials within the laboratory by March 17, 1994.

On March 16, 1994 the Licensee stated that it would key lock the elevator and door leading to the basement area and that all personnel who required access to the basement would be provided a key and radiation safety training. Additionally, the door to Research Laboratory A-10 would be locked when unoccupied until the entrances to the Building Two Basement were key locked. On April 4, 1994 the Licensee notified the inspector that the entrances to the Building Two Basement had been locked or disabled.

During February 1993 members of the Subcommittee toured the Building Two Basement area and noted several items of non-compliance with the National Fire Protection Association Life Safety Code (NFPA 101). Based on discussions with Licensee personnel assigned to the Subcommittee and the Health Physics staff, it appears that on February 10 and March 9, 1993, the Subcommittee discussed problems associated with having an emergency exit located inside Research Laboratory A-10. As framed by licensee personnel at the time, the issue was:

(1) whether the laboratory should remain unlocked when unattended to facilitate emergency egress from the basement area located outside laboratory A-10; even though this would:

   (a) allow for potential unauthorized access to the laboratory by hospital patients, guests, and staff, and

   (b) potentially conflict with NRC requirements that require a space containing radioactive materials to be locked or under surveillance of Licensee personnel, or

(2) whether to lock the laboratory when unattended to maintain compliance with NRC regulations, but prevent ready access to the basement emergency exit thus violating the National Fire Protection Association Life Safety Code (NFPA 101) which requires that two approved exits be accessible without passing through intervening rooms or spaces other than corridors.

The March 9, 1993 Subcommittee meeting minutes stated that the Subcommittee decided to develop a proposal for submission to the Facility Five Year Plan which would authorize funding to construct an alternate location for the Building Two Basement emergency exit. It appears, based on discussions with Subcommittee members and on the March 30, 1994 memorandum from the Administrative Assistant for Research Administration to the Radiation Safety Officer, that in April 1993, the Subcommittee decided by general consensus that:

(1) the proposal for constructing an alternate emergency exit was unworkable due to interference with existing fixtures and costs,

(2) relocation of Research Laboratory A-10 would be added to the proposed construction of the Building Two Annex,

(3) locking Research Laboratory A-10 to provide security for NRC licensed material and providing basement workers with a key to be used for egress was not an acceptable alternative,

(4) the door to Research Laboratory A-10 would be left unlocked during normal working hours until the relocation was completed (as of April 28, 1994 funding for the annex construction Project had not received final approval), and

(5) relocating Research Laboratory A-10 to the annex would correct the potential NRC security violation and several NFPA-101 violations.

On April 28, 1994 a meeting between the NRC (Acting Materials Branch Chief and Inspector) and Licensee management was held to discuss the Subcommittee's reasons for allowing Research Laboratory A-10 to remain unlocked when unattended. The following information was obtained during the meeting:

(1) The Subcommittee's Health Physics Liaison stated that the Subcommittee and the Radiation Safety Officer (RSO) had been informed that a potential NRC violation existed if licensed materials were left unlocked and unattended and that prior to the March 1994 NRC inspection the laboratory had not been cited for a security violation.

(2) The RSO stated that because the security of licensed material in the laboratory was classified only as a "potential" item of non-compliance that he did not place the item in the tracking system for monitoring nor notify the Radiation Safety Committee of a potential conflict with NRC requirements.

(3) The PI for Research Laboratory A-10 stated that he thought leaving the door to the laboratory open was acceptable for complying with NRC requirements since stock solutions of radioactive materials were stored in a locked freezer, that personnel assigned to the laboratory usually remained within the basement area outside the laboratory when the laboratory was unlocked and unattended, and that he mistakenly thought that radioactive waste and cultures containing radioactive materials did not require the same level of security as stock solutions. Stock solutions are aqueous radioactive materials received by the supplier and typically contain approximately 0.5 to 5.0 millicuries of licensed materials.

(4) The Administrative Officer for Research Administration, who has no radiation oversight responsibilities, stated that the Health Physics staff only identified the security of licensed materials as a potential violation if the laboratory was left unlocked and

unattended and that he thought the Research Laboratory was complying with NRC requirements. Therefore, he assumed that his decision to leave the laboratory unlocked during normal working hours until the Basement Area laboratories could be relocated to the Annex satisfied the immediate concerns of NFPA safety requirements while maintaining compliance with NRC requirements.

(5) The Subcommittee members stated that at no time did they decide to adhere to NFPA requirements and disregard NRC requirements.

The NRC representatives reminded the licensee of the requirements to secure all licensed materials including radioactive waste and materials used in experiments and explained the application of the NRC Enforcement Policy with respect to repetitive violations and willful or careless disregard of NRC requirements.

The security of licensed materials in Research Laboratory A-10 identified three areas of concern: (1) licensee management has not been fully effective in correcting identified violations and potential items of non-compliance, (2) licensee management has not defined the actions a non-radiation oversight committee should take when confronted with issues involving radiation safety, and (3) licensee personnel may not be fully aware of the need to secure all forms and quantities of licensed material. The following repetitive violation was identified during the review of this program area.

1. Failure to secure radioactive material from unauthorized removal or lock a controlled area when unattended as required by RPM Page 7. (94-01-02)

4. Audits

The Stanford Health Physics office performs a complete review of each PI's program during the annual renewal of the CRA. A member of the Health Physic's staff schedules a meeting with the PI to discuss modifications to the CRA and to tour the laboratory. In addition, a member of the Health Physics staff performs independent radiation and contamination surveys of each laboratory at least once per calendar quarter.

No apparent violations or deviations were identified during the review of this program area.

5. Material Receipt and Transfer

5.1 Research

Radioactive material is delivered to the Stanford University Inspection Station. A Stanford Health Physicist performs all inspections and surveys of each package shipped to VAMC Palo Alto as required by the license and 10 CFR Part 20. Quantities of material received for each PI are entered into the computer to verify that the PI will not exceed their allowable maximum possession limit and to ensure that personnel who receive radioiodine are notified of bioassay requirements. Upon delivery to the Research Laboratory,

the Laboratory Manager records the receipt of the material into the Radioisotope Journal.

5.2 Nuclear Medicine

Nuclear Medicine packages are delivered directly to the VAMC. The packages are placed in a designated storage area by the delivery person and monitored by the morning technologist as part of the daily Nuclear Medicine morning routine.

No apparent violations or deviations were identified during the inspection of this program area.

6. Dose Calibrator Measurements

Based on a review of dose calibrator test records dated between May 7 and November 22, 1993; geometry, accuracy, linearity, and constancy tests were performed as required by 10 CFR 35.50.

No apparent violations or deviations were identified during the inspection of this program area.

7. Survey Instruments and Calibration

Based on a review of survey instruments in use during the inspection and on a review of calibration records, the Licensee used instruments that were calibrated annually as required by 10 CFR 35.51 and the license.

RPM Section 4, Page 47 "Requirements for Survey Instruments", requires Projects to have a suitable survey meter for detecting contamination. The calibration record for the Licensee's end window GM probe survey instrument (Serial Number A552M) used by Project CRA VMN-361 (Research Laboratory 242) indicated that the instrument was not suitable for detecting contamination. During independent surveys the inspector found 2,000 dpm of phosphorus-32 in the unmonitored waste receptacle and the Project's survey instrument was not able to distinguish the material from background. Additional indications of the survey instrument's inability to detect contamination included several areas of phosphorus-32 contamination identified by the inspector during independent surveys including a counter top, fume hood outer surface, and laboratory equipment. The Health Physics staff stated that the Project's survey instrument did not appear to be adequate for detecting phosphorus-32 contamination.

Based on discussions with the Health Physics staff, on a review of calibration records, and on independent measurements, the inspector concluded that Project CRA VMN-361 did not possess a suitable survey meter for detecting phosphorus-32 contamination.

The following violation was identified during the review of this program area.

1. Failure of Project CRA VMN-361 to possess a suitable survey instrument for detecting contamination as required by RPM Section 4, Page 47. (94-01-03)

8. Training

Formal training is based on a statement of work experience provided to the Local Control Committee by the PI. Personnel without experience are required to attend a radiation protection course, satisfactorily complete a written examination, and receive on-the-job training. Personnel with experience are not required to attend the radiation protection course, but must satisfactorily complete the written examination and on-the-job training. Refresher training is required every two years, but is performed at least annually as part of the annual CRA renewal. Based on discussions with personnel and a review of records, it appeared that the Licensee continued to implement it's training program, and had provided specific training to personnel on the requirements of the revised 10 CFR Part 20.

No apparent violations or deviations were identified during the inspection of this program area.

9. Surveys

RPM Section IV, Page 45, and the letter to NRC dated September 12, 1991, require that surveys be performed by users monthly (once per calendar month) in areas where "B" or "C" levels of radionuclides are used or stored. The Licensee classifies the quantity of a licensed material as either A, B, C, or Low Activity Sources (LAS), with A quantities being the greatest and LAS quantities the least. Based on a review of user survey records, the following Research Laboratories using "B" or "C" quantities of radionuclides did not perform monthly surveys:

Research Laboratory	Month Not Performed
Foothills Research Center, Room 103	February 1994
Foothills Research Center, Room 104	February 1994
Building 2, Room A-10	November 1993
Building 1, Room E-312	May 1993

Based on discussions with laboratory technicians, it appears that the technicians forgot to perform the surveys at the required monthly frequency. The failure to perform monthly surveys in eight laboratories, including Rooms 103 and 104, was identified during the April 1993 NRC inspection. The Licensee's corrective actions for the April 1993 survey violation consisted of a May 19, 1993 memorandum from the "Radiation Safety Officer" to "All Users of Radioactivity, Care of Project Directors", which described the NRC violation and the requirements for performing surveys. The repetitive failure of the Licensee to perform required surveys indicates that Licensee management did not implement effective corrective actions to prevent recurrence of the survey violation. Additionally, the second occurrence of the PI responsible for Foothills Research Center Rooms 103 and 104 to not perform required surveys appears to indicate that additional management oversight is needed to ensure the PI complies with NRC and license requirements. During the Exit Meeting, Licensee management representatives stated that implementation of the survey program would be reviewed and the necessary corrective actions implemented.

The following repeat violation was identified during the review of this program area.

1. Failure to perform monthly surveys as required by RPM Page 45, and the letter to NRC dated September 12, 1991. (94-01-04)

9.1 Surveys Follow-up

(Closed) Violation 93-01-03: Failure to perform monthly surveys as required by RPM Page 45, and the letter to NRC dated September 12, 1991, involved the failure to perform surveys in several Research Laboratories. This item will continued to be monitored under violation 94-01-04.

10. Personnel Monitoring

Based on observations and discussions with personnel, it appeared that personnel monitoring devices were worn as required by the Licensee. The highest annual exposure for 1993 was whole body: 185 mrem and extremity 650 mrem. Based on discussions with the RSO, the Licensee was aware of the revised 10 CFR Part 20 limits.

RPM Section IV, Page 42, requires that any person who works with radioiodine receive a quarterly bioassay if the amount of iodine handled per experiment exceeds ten millicuries for iodine-125 or one millicurie for iodine-131. The Licensee's computerized receipt system notifies personnel that bioassays are required when greater than or equal to five millicuries of iodine-125 or iodine-131 is entered into the database. Based on a review of receipt and use records, iodine-131 was not used in amounts greater than one millicurie. The RSO stated that he would correct the database reporting system to ensure that personnel received a notification for bioassay if greater than or equal to one millicurie of iodine-131 was entered into the database.

No apparent violations or deviations were identified during the inspection of this program area.

10.1 Personal Monitoring Follow-up

(Closed) Violation 93-01-02: Radiation Protection Manual, Page 36, "Proper Use of the Film Badge", Item 5, required individuals who worked with or around licensed materials to wear their film badge. Based on observations, all individuals who were working with or around licensed materials were wearing their assigned personnel monitoring devices.

11. Waste Disposal

Solid radioactive waste is segregated within each Research Laboratory. When a waste container is filled the PI notifies the Stanford Health Physics staff to make arrangements for a transfer of radioactive material.

Liquid waste is disposed of to the sanitary sewer and solidified for disposal. Based on a review of sewer disposal records it appears that the licensee's sewer disposals were below 10 percent of the limits specified in 10 CFR Part

20, Appendix B, Table 3 for sewer releases.

No apparent violations or deviations were identified during the inspection of this program area.

12. Sealed Source Leak Testing and Inventory

Based on a review of leak test and inventory records, leak tests and inventories had been performed and documented as required by 10 CFR Part 35 and the license.

No apparent violations or deviations were identified during the inspection of this program area.

13. Posting and Labeling

Based on observations of the facility, the Licensee met the posting and labeling requirements pursuant to 10 CFR Parts 19, 20, and 35.

No apparent violations or deviations were identified during the inspection of this program area.

14. Quality Management Program.

The Licensee submitted it's Quality Management Program to NRC on February 27, 1992. Modalities of use for the facility include radiopharmaceutical therapies with iodine 131 and strontium-89. The facility is authorized to perform brachytherapy but seldom performs a procedure (last two procedures were May 10, 1992 and December 20, 1990).

Based on a review of material receipt records and all written directives, the Licensee administered greater than thirty microcuries of iodine-131 on three occasions and strontium-89 on five occasions.

No apparent violations or deviations were identified during the inspection of this program area.

15. Independent Measurements

The inspector performed surveys in Nuclear Medicine, Research, and adjacent unrestricted areas using a Ludlum Model 3, NRC Serial Number 035644, last calibrated December 8, 1993. With the exception of CRA VMN-361, no significant readings were noted (See Section 7).

No apparent violations or deviations were identified during the inspection of this program area.

ATTACHMENT 1

1 Persons Contacted

1.1 Licensee Personnel

*+James Goff, Medical Center Director
*+Susan Pendergrass, Asst. Medical Center Director
*+John Holmes, RSO
*+David Thomas, AO/ACOS
*+David Goodwin, Chief of Nuclear Medicine
*+Stuart Bailey, VA Safety Officer
*+Shiela Kronenberger, Senior Health Physicist
*Michael Murphy, Associate Director
*George Segall, Assistant Chief of Nuclear Medicine
+Shilo Herrling, Administrative Assistant
+Salman Ahzar, Principle Investigator
+Richard Maze, Chief of Staff
Janice Kirkley, Health Physicist
Anrfeh Shanjani, Health Physicist
Mimi Auns, Health Physicist
Dawn Banghart, Health Physicist
Tigran Khachatrian, Health Physics Technician
Kristina Reid, Lab Technician
Steven Lubic, Lab Technician
Isabella Lee, Lab Technician
L. Ji, Lab Technician
Vincent Dentamaro, CNMT
Woncsick Choe, Chief Resident
Chung Song, Lab Technician
Shuwen Chen, Lab Technician
Dan Stien, Lab Technician
Sarah Claus, Lab Technician
Jim Thompson, Lab Technician
Steve Dunn, Lab Technician
Juan Ludert, Lab Technician

1.2 NRC Personnel

*+Troy W. Pruett, Radiation Specialist
+Gregory P. Yuhas, Acting Materials Branch Chief

* Individuals present at March 17, 1994 exit meeting
+ Individuals Present at April 28, 1994 meeting

2 Exit Meeting

An exit meeting was held on March 17, 1994 to discuss the initial inspection findings. The inspector expressed his concerns regarding the repetitive violations involving security of licensed material and monthly surveys and explained the potential enforcement actions for continued repetition of these violations. The Licensee stated that a review of the survey program would be performed and that action was being taken to correct the security problem in Research Laboratory A-10.

A meeting between NRC (Acting Materials Branch Chief and Inspector) and Licensee management was held on April 28, 1994 to discuss the Subcommittee on Safety for Medical Research Laboratory's reasons for allowing Research Laboratory A-10 to remain unlocked when unattended. The results of the meeting are documented in Section 3 of the NRC Inspection Report.

No proprietary information was disclosed during the inspection.