NRC FORM 464 Part I (6-1998)

U.S. NUCLEAR REGULATORY COMMISSION

RESPONSE TO FREEDOM OF INFORMATION ACT (FOIA) / PRIVACY ACT (PA) REQUEST

FOIA/PA	RESPONSE NUMBER
2000-0054	1

RESPONSE TYPE ☑ FINAL ☐ PARTIAL

REQUESTER	DATE
Frank Vera	DEC 15 1999

PART I. -- INFORMATION RELEASED

☐ No additional agency records subject to the request have been located.

☐ Requested records are available through another public distribution program. See Comments section.

☐ APPENDICES ____ Agency records subject to the request that are identified in the listed appendices are already available for public inspection and copying at the NRC Public Document Room.

☑ APPENDICES A Agency records subject to the request that are identified in the listed appendices are being made available for public inspection and copying at the NRC Public Document Room.

☐ Enclosed is information on how you may obtain access to and the charges for copying records located at the NRC Public Document Room, 2120 L Street, NW, Washington, DC.

☑ APPENDICES A Agency records subject to the request are enclosed.

☐ Records subject to the request that contain information originated by or of interest to another Federal agency have been referred to that agency (see comments section) for a disclosure determination and direct response to you.

☐ We are continuing to process your request.

☐ See Comments.

PART I.A -- FEES

AMOUNT *

$

* See comments for details

☐ You will be billed by NRC for the amount listed.

☐ You will receive a refund for the amount listed.

☑ None. Minimum fee threshold not met.

☐ Fees waived.

PART I.B -- INFORMATION NOT LOCATED OR WITHHELD FROM DISCLOSURE

☐ No agency records subject to the request have been located.

☐ Certain information in the requested records is being withheld from disclosure pursuant to the exemptions described in and for the reasons stated in Part II.

☐ This determination may be appealed within 30 days by writing to the FOIA/PA Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Clearly state on the envelope and in the letter that it is a "FOIA/PA Appeal."

PART I.C COMMENTS (Use attached Comments continuation page if required)

SIGNATURE - FREEDOM OF INFORMATION ACT AND PRIVACY ACT OFFICER

Carol Ann Reed Carol Ann Reed

APPENDIX A
RECORDS BEING RELEASED IN THEIR ENTIRETY

NO.	DATE	DESCRIPTION/(PAGE COUNT)
1.	3/1/99	Appendix A Medical Broad-Scope Inspection Record (11 pages)
2.	3/16/99	Letter to D Stordahl, Jerry Pettis Memorial Hospital from E Collins, NRC (1 page)

APPENDIX A
MEDICAL BROAD-SCOPE INSPECTION RECORD
Region IV

Inspection record No. **99-01**
Licensee (Name and Address):

License No. **04-17862-01**
Docket No. **030-13550**

DVAMC Jerry Pettis Memorial Hospital
11201 Benton Street
Loma Linda, California 92357

Licensee Contact: **Moussa Raiszadeh, Ph. D. RSO** Telephone No. **(909)825-7084 x2701**

Priority: **1** Program Code: **02110**

Date of Last Inspection: **July 31 - August 4, 1995**
Date of This Inspection: **January 12-13, 1999**

Type of Inspection: ( ) Announced (X) Unannounced
(X) Routine ( ) Special
( ) Initial

Next Inspection Date **January 2004** ( ) Normal ( ) Reduced (X) Extended

Justification for change in normal inspection frequency:

No cited violations identified during this or the previous inspection. Per MC 2800 the inspection frequency should be extended to five years. The next inspection should be scheduled for January 2004.

Summary of Findings and Actions:

(X) No violations cited, clear NRC Form 591 or regional letter issued
( ) Non-cited violations
( ) Violation(s), Form 591 issued
( ) Violation(s), regional letter issued
( ) Followup on previous violations

Inspector(s) Emilio M. Garcia Date March 1, 1999
(Sign Name)

Emilio M. Garcia
(Print Name)

Approved Elmo E Collins Date 3/22/99
(Sign Name)

Elmo E. Collins
(Print Name)

A11

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:
[License amendments issued since last inspection; program changes (including major changes in facilities, activities, procedures, or personnel) noted in the license]

#	DATE	SUBJECT
25	August 10, 1995	Adds Room 1B-44 as P-32 waste storage area.
26	May 5, 1997	Releases room 4C-20 for unrestricted use. Previously used with less than 1 millicuries I-125 and 5 millicuries Ca-45.
27	July 8, 1998	Releases room 4F-19 for unrestricted used. Previously used for radioimmunoassays with less than 0.2 millicuries of I-125 or Co-57.

The inspector verified the implementation of these amendments.

2. INSPECTION AND ENFORCEMENT HISTORY:
(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders)

No cited violations were identified during the previous inspection. Three non-cited violations were noted:

Requirement	Non Cited Violation	Status
10 CFR 35.22(b)	During quarterly meetings held on 1/4/95 & 5/30/95, the licensee's RSC had not reviewed summary of occupational dose records of all personnel working with licensed material.	CLOSED
LC 23.C Enc. B to ltr 11/15/89	Licensee failed to provide annual refresher training in 1994 for all personnel using byproduct material in research laboratories.	CLOSED
10 CFR 35.22(a)(2)	Licensee failed to hold a RD\SC meeting during the last calender quarter of 1994	CLOSED

3. INCIDENT/EVENT HISTORY:
(List any incidents, recordable events, or misadministrations reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

On September 29, 1998, Thermal Combustion Innovators (TCI), received a barrel of medical waste shipped from the licensee's facility and the barrel had a radiation reading of 288 microrems above background.

The licensee collected the drum on September 30, 1998, and conducted their independent measurements. The licensee's measurements did detect any radiation above background. Although the licensee could not identified a problem with their control of the licensed material they none the less initiated additional corrective actions. These actions were:

(1) Lowering the alarm level on their portal monitor and (2) surveying each drum of medical waste individually prior to shipment to TCI.

PART II - INSPECTION DOCUMENTATION

* References that correspond to each inspection documentation topic are in Inspection Procedure 87119, Appendix B, "Medical Broad-Scope Inspection References."

The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that all areas indicated in this part are not required to be addressed during each inspection. However, for those areas not covered during the inspection, a notation ("Not Reviewed" or "Not Applicable") should be made in each section where applicable.

All areas covered during the inspection should be documented in sufficient detail to describe what activities and procedures were observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the licensee demonstrated any practices at your request, describe those demonstrations. The observations and demonstrations you describe in this report, along with measurements and some records review, should substantiate your inspection findings. Attach copies of all

1. ORGANIZATION AND SCOPE OF PROGRAM:
(Management organization; authorities and responsibilities; Radiation Safety Officer (RSO), Radiation Safety Committee (RSC) chairman and members; administrative controls, procedures, and management policies; authorized locations of use; type, quantity and frequency of byproduct material use; staff size; mobile nuclear medicine service; limited distribution of pharmaceuticals; and research involving human subjects)

There were 27 authorized user (AU in the list maintained by the licensee. These include three in nuclear medicine, the radiation safety officer (RSO). The rest of the AU were researchers. The RSO stated that this number would be reduced by four as a result of some individuals leaving the hospital.

The staff in nuclear medicine consisted of three AU physicians, three technologist, a health safety specialist, and an a clerical assistant. For 1997, the last year that data had been compiled the licensee had a patient load of 4653 diagnostic procedures and 18 therapies. The licensee was not operating a mobile nuclear medicine service, nor distributing pharmaceuticals. At the time of the inspection there was no research involving human subjects being conducted.

2. MANAGEMENT OVERSIGHT:
[Management support to radiation safety; RSC, RSO; and program audits, including as low as is reasonably achievable (ALARA) reviews]

The RSC had been meeting at least quarterly, the last meeting was on December 16, 1998. The inspector noted that the not half of the members of the RSC were present during the meeting of September 30, 1998. This was the second meeting during this quarter of the RSC. The minutes of the September 30, 1998, meeting were approved during the December 16, 1998 meeting without objections. The RSO indicated that this had been an oversight on their part and their intention was to always have a quorum during RSC meetings. No violation was cited. The minutes of the RSC and interviews with the RSO and the Chairman of the RSC

indicate an active and involved RSC.

During the September 8, 1998, meeting of the RSC the licensee reviewed the radiation safety practices in two human research projects that had been suspended in 1995. These projects involved the study of radioimmunoguided surgery (RIGS). These projects had first been suspended by the Hospital's Human Studies Subcommittee (HSS) and shortly there after by the RSO. In a June 5, 1998, memorandum from the RSO to the Chief Executive Officer, the RSO raised some concerns regarding the radiation safety aspects of these studies. The Chairman of the RSC conducted a review of the records available and interviewed a few individuals that were still around. The results of this review were presented to the RSC during a special meeting conducted on September 8, 1998.

This study protocol was performed at 24 other hospitals in the United States and Europe, besides the Loma Linda VA. The review found that there were 8 human research subjects involved in these studies at the Loma Linda VA, one of these individuals was also a renal dialysis patient. Each individual was administered 2 millicuries of I-125 labeled in CC49 monoclonal antibody. Prior to administration patients were administered a thyroid blocking agent. The administrations occurred at Loma Linda University Medical Center, a State of California licensee, not under the auspices of this license. The research subjects were scheduled for surgery at Loma Linda VA 19 to 29 days after the administration, by that time most the activity would have been excreted from the body and only that bound to tumor would remain.

The RSC Chairman's review of these studies identified three violation of the licensee's radiation safety program. The RSC concluded that these items were violations. These violations were: (1) handling of radioisotopes by an individual who was not authorized to use nor trained in radiation safety policy and procedures of the licensee (License Condition 23.D, Item 8.1 Training Program); (2) two research projects involving licensed material were conducted without receiving final approval from the RSC (License Condition 23.D, Item 10.1, Radiation Safety Committee/Radiation Safety Officer, Appendix F of Regulatory Guide 10.8 Rev. 2, Responsibilities, step 3); (3) licensed material contained in dialysis fluid was shipped from the licensee's facility to another licensee without proper authorization or labeling of the packages (49 CFR Part 172, Subpart D, Marking and Labeling). Since these violations had occurred several years in the past, the projects had been terminated by the licensee, and many of the individuals involved were no longer employed by the licensee, the RSC concluded that corrective actions should focus on ways to prevent recurrence. The corrective actions were to add specific reminders in the Annual Refresher Training that: (1) radiation safety training and authorization are absolutely required before participation in an approved study, and that (2) any and all shipments of radioactive materials must have prior approval and authorization from the RSO. The RSC also reaffirmed the requirement that a signed, approved copy of the application for the use of radioactive materials be received by the RSO before a project is initiated, this topic was to be included in the Annual Refresher Training for Research Service personnel. The inspector concluded that these items were non-cited violations since they had been identified and corrected by

the licensee and met the other criteria of Section VII.B.1 of the NRC Enforcement Policy.

The licensee had been conducting annual reviews of the radiation safety program and had requested special audits of the VA national health physics program.

3. FACILITIES:
[Facilities as described; uses; control of access; engineering controls,(e.g., ventilation, hoods, filters, etc); irradiators and survey instrument calibrators; maintenance by authorized persons]

Facilities were as described in the license. The licensee had a Amersham 145.5 millicurie Cs-137 survey instrument calibrator SN 5-817. This source was securely stored in room 1B-43. Iodinations with I-125 were performed in room 1-B-49. In 1998 11 I-125 iodinations ranging from 22.5 microcuries to 5 millicuries were performed. No violations were identified in this area.

4. EQUIPMENT AND INSTRUMENTATION:
(Dose calibrator; instrumentation for assaying alpha- and beta- radionuclides; generators; syringes and vials; survey instruments; 10 CFR Part 21 procedures; and special equipment and instrumentation)

NM had a Capintec model CRC-35R dose calibrator, SN 350191. The software for this instrument was revision 2.16. According the manufacturer's web page, this revision of the software will not perform a next day or future dose measurement going from December 31, 1999 to January 1, 2000. All other dates function normally. The licensee was informed of this problem by the inspector and they committed to have it resolved by either a change in the software version or by administrative controls.

The licensee was conducting routine quality control tests on this dose calibrator. The last geometry test had been conducted on December 13, 1996. The next accuracy test was due on June 16, 1999, and the next linearity was due on January 30, 1999. Constancy tests were performed each day the dose calibrator was used. The licensee had a backup dose calibrator a CRC 10 SN 10253. This instrument was not subject to the Y2K bug.

The licensee did not use a Mo-Tc generator, all materials used were unit doses. The inspector observed the NM technologist using syringe shields, and each dose was appropriately labeled. The licensee had and used calibrated survey instruments.

No violations were identified.

5. MATERIAL RECEIPT, USE, CONTROL, AND TRANSFER:
(Materials and uses authorized; use of radiopharmaceuticals; security and control of licensed materials; and procedures for receipt and transfer of licensed material)

In NM the licensee used unit doses. Nuclides administered included Tc-99m, I-131, Sr-90, Tl-201, I-123, Co-58, Co-57, Cr-51, and In-111. According to the RSO

the licensee had not conducted brachytherapies in the last 10 years nor used Xe-133 in the last 5 years. Materials used in research included H-3, C-14, P-32, P-33, S-35, Ca-45, and I-125.

Materials used in NM were received and surveyed in NM. Materials used in research were received and surveyed by the radiation safety office staff.

The inspector observed a NM technologist performed a package receipt survey. The procedure demonstrated included additional surveys not required by 10 CFR 20.1906.

No violations were identified.

6. THERAPIES:
(Safety precautions; postings; contamination control; stay times; surveys; release criteria of patients and rooms)

The licensee had been conducting I-131 and Sr-89 therapies, but no P-32. All Sr-89 therapies were treated as outpatients unless the patient was hospitalized for other reasons. Records reviewed and interviews with the RSO indicate that appropriate safety precautions were taken for inpatient therapies. The licensee had not used the new released criteria in 35.75 for early patient releases. Therapies of greater than 30 millicuries of I-131 were hospitalized. The licensee maintained records of patient and room surveys.

No violations were identified.

7: QUALITY MANAGEMENT PROGRAM (GMP) AND MISADMINISTRATIONS:
(QMP - written directives, implementation, reviews, and records; misadministrations - identification, notifications, reports, and records)

The licensee maintained required QMP records. The table below list the numbers and types of procedures requiring QMP records that were performed since the year of the last inspection. All Sr-89 were prescribed at 4.0 millicuries.

YEAR	I-131	Range of administered I-131 doses in millicuries	Sr-89
1999	1	15.46	0
1998	22	5.0-150.2	3
1997	16	13.05-152.5	2
1996	20	5.31-154.8	1
1995	10	5.17-152.9	1

Annual reviews of the implementation of the QMP were performed by the Chief of Nuclear Medicine on January 10, 1996, for 1995, January 15, 1997 for 1996, and February 3, 1998 for 1997. The review for 1998, had not been performed at the

time of the inspection. These reviews had not identified any recordable events or misadministrations or need for changes in the QMP. The inspector reviewed selected QMP records and did not identified any problems.

No violations or weaknesses were identified in this area.

8. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL:
(Radiation and contamination surveys; air sampling; leak tests; inventories; handling of radioactive materials; protective clothing; dosimetry; records; and public doses)

The inspector observed the daily survey conducted by the NM staff. This procedure exceeded the requirements of 10 CFR 35.70(c) in that the survey could identify contamination at levels well below 0.1 millirem/hour. The technologist found a gauze with a small amount of contamination. The technologist stated that it was not unusual to find similar small amounts of contamination. A survey that just met the requirements of 10 CFR 35.70(c) would not have identified such contamination. Records of the daily radiation survey and the weekly swipe survey were maintained by the licensee.

The inspector reviewed the therapy room surveys for three therapies performed in 1998. No deficiencies were identified.

Review of records of surveys conducted in selected research laboratories indicate that surveys were conducted as required.

The licensee had performed inventories every three months and leak tests every six months on ten sealed sources, three of which were under the NRC license. The last inventory and leak tests were performed on November 19, 1998.

The inspector noted that personnel using radioactive material wore protective clothing including gloves, and if assigned wore their extremity and whole body dosimetry badges.

No violations were identified.

9. TRAINING AND INSTRUCTIONS TO WORKERS:
(Interviews and observations of routine work; staff knowledge of all routine activities; 10 CFR Part 20 requirements; therapy training and postulated emergency situations; supervision by authorized users; retraining and periodic training programs; training of ancillary personnel such as housekeeping, security, and maintenance; adequacy of training and instruction)

The licensee had provided radiation protection training to new employees and annual refresher training to all employees. Refresher training was provided to each service as a group. The inspector reviewed selected records of the most recent refresher training sessions, these included Warehouse, 7 people on December 15, 1998, Nuclear Medicine, 8 people on July 8, 1998, Facility Management 14 people on June 24, 1998. The nursing service completed their most recent refresher training on January 9, 1998. The training summaries reviewed indicate that the subject covered were appropriate for the work

functions.

QMP records of inpatient therapies indicate that the licensee verified that the nursing staff was appropriately trained. Review of QMP was included on the NM annual refresher training.

No violations were identified in this area.

10. RADIATION PROTECTION:
[Radiation protection program with ALARA provisions (worker and general public external and internal exposure control; effluent control); external and internal dosimetry program; exposure evaluations; dose records and reports; and patient release]

The license was using ICN as their dosimetry supplier, a NVLAP certified laboratory. Prior to February 1996, they had used Radiation Detection Co., also NVLAP certified. The inspector reviewed the records maintained. A summary of the maximum recorded exposures is listed below.

YEAR	TEDE in millirem	SDE in millirem
1998 to 11/30/98	194	1858
1997	220	1540
1996	110	1290
1995	660	5683

The licensee conducted bioassays of individuals involved in the administrations of I-131 and in iodinations. All results were less than 0.02 of an ALI.

The chairman of the RSC and another individual conducted annual reviews of the content and implementation of radiation protection program. The last review was completed and reported to the RSC during the December 1998, RSC meeting.

No violations were identified in this area.

11. RADIOACTIVE WASTE MANAGEMENT:
(Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment incinerators, hoods, vents, and compactors; and records)

The licensee used decay-in-storage for the disposal of short lived radioactive waste. Materials were stored in a secure area protected from the elements in labeled containers. The labels included the required information, the date placed in storage, and the nuclides contained.

The licensee was storing longer lived material that could not be disposed by decay-in-storage. The license had not made any transfer of waste since the last inspection. The licensee had a waste compactor.

No disposal of radioactive waste to the sanitary sewer, or septic tanks were done

nor was radioactive waste incinerated.

The licensee maintained records of waste disposed.

No violations were identified in this area.

12. DECOMMISSIONING:
(Records of radiological conditions; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements)

This area was not reviewed during this inspection.

13. TRANSPORTATION:
(Quantities and types of licensed material shipped; packaging design requirements; HAZMAT communication procedures; unit dose return; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports)

The licensee did not have any records of any shipment of radioactive materials, except for the unauthorized shipment of dialysis fluid described in Section 2 above.

No violations were identified in this area.

14. NOTIFICATIONS AND REPORTS:
(Theft; loss; incidents; overexposures; change in RSO, authorized user, or nuclear pharmacist; and radiation exposure reports to individuals)

The licensee had not suffered any thefts nor losses of licensed material, radiological incidents, overexposures, nor changes in RSO or authorized users that required NRC notification or reports. Individuals were advised annually of their exposures.

No violations were identified in this area.

15. POSTING AND LABELING:
(Notices; license documents; regulations; bulletins and generic information; posting of radiation areas; and labeling of containers of licensed material)

During tours of the facilities the inspector noted that license had appropriate posting, labeling and notices.

No violations were identified in this area.

16. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:
(Areas surveyed; comparison of data with licensee's results and regulations; and instrument type and calibration date)

The inspector conducted independent and confirmatory measurements using a Ludlum Model 3 radiation survey meter, NRC 022879, calibrated on

September 14, 1998. Confirmatory measurements were conducted during a package receipt survey in NM and during the NM daily survey. The inspector conducted independent measurements in research laboratories.

No violations were identified in this area.

17. VIOLATIONS, NON-CITED VIOLATIONS (NCVs); AND OTHER SAFETY ISSUES:
(State requirement and how and when licensee violated the requirement. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

No cited violations were identified during the inspection, but three non-cited violations were recorded based on the violations identified by the licensee during the RSC meeting of September 8, 1998, see Section 2 above.

18. PERSONNEL CONTACTED:
[Identify licensee personnel contacted during the inspection (including those individuals contacted by telephone).]

 # Dean Stordhl, Chief Executive Officer
 # Anne Gillespie, R.N. Vice President for Patient Care
 # Larry Dressel, Associate Chief Facility Management Service
*** Dwight Evans, M.D., Vice President**
*** John Farley, Ph.D., Chairman RSC**
#* Moussa Raiszadeh, Ph.D., Radiation Safety Officer
Joseph Garcia Llaurado, M.D., Chief of Nuclear Medicine
Dean Dammer, RT CMT, Chief Nuclear Medicine Technologist
Irimie Racataian, Radiation Safety Technologist
Nancy Quach-Ang, Nuclear Medicine Technologist
Vellore Stevenson, Supervisor Chemistry Laboratory
Sumit Bahattacharya, Ph.D., Post Doctoral Fellow
Carolyn Hargrave, Technician

Use the following identification symbols:
Individual(s) present at entrance meeting
* Individual(s) present at exit meeting

19. PERFORMANCE EVALUATION FACTORS (PEFs):

A.	Lack of senior management involvement with the radiation safety program and/or RSO oversight		( ) Y (X) N
B.	RSO too busy with other assignments		( ) Y (X) N
C.	Insufficient staffing		( ) Y (X) N
D.	RSC fails to meet or functions inadequately	( ) N/A	( ) Y (X) N
E.	Inadequate consulting services or inadequate audits conducted	( ) N/A	( ) Y (X) N

Remarks (consider the above assessment and/or other pertinent PEFs with regard to the licensee's oversight of the radiation safety program):

No violations were cited and three licensee identified NCV were noted during this inspection.

21. Special Conditions or Issues:
(Special license conditions; year-2000 effects of computer software)

The software version used in the dose calibrator will not perform a next day or future dose measurement going from December 31, 1999 to January 1, 2000. All other dates function normally. The licensee was informed of this problem by the inspector and they committed to have it resolved by either a change in the software version or by administrative controls. See Section 4 above.

PART III - POST- INSPECTION ACTIVITIES

1. REGIONAL FOLLOWUP ON PEFs:

No violations identified during the last two inspections per MC 2800 extend the inspection frequency to five years. The next inspection should be scheduled for January 2004.

2. DEBRIEF WITH REGIONAL STAFF:
(Post-inspection communication with supervisor, regional licensing staff, Agreement State Officer; and/or State Liaison Officer)

The inspector's supervisor accompanied the inspector during the inspection. On February 5, 1999, the inspector debrief with the Division Director.

3. YEAR-2000 ISSUES:
(Convey, to the NMSS Year-2000 Coordinator, all year-2000 licensee-identified problems and corrective actions taken.)

No new year 2000 issues were identified.

END

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

March 16, 1999

Dean Stordahl, Chief Executive Officer
Department of Veterans Affairs Medical Center
Jerry Pettis Memorial Hospital
11201 Benton Street
Loma Linda, California 92357

SUBJECT: NRC INSPECTION REPORT 030-13550/99-01

Dear Mr. Stordahl:

On January 13, 1999, the NRC completed an inspection at your Jerry Pettis Memorial Hospital, at Loma Linda, California. The inspection included a review of activities authorized by Byproduct Materials Licenses 04-17862-01. At the conclusion of the inspection an exit briefing was conducted with Dr. Dwight Evans and other members of your staff.

Within the scope of this inspection, three violations were identified. These violations involved: (1) handling of radioisotopes by an individual who was not authorized to use nor trained in radiation safety policy and procedures of the licensee; (2) two research projects involving licensed material were conducted without receiving final approval from the radiation safety committee; (3) licensed material contained in dialysis fluid was shipped from the licensee's facility to another licensee without proper authorization or labeling of the packages. These violations are not being cited because the criteria of Section VII.B.1 of the Enforcement Policy (Non-Cited Violations) were met. No response to this letter is required.

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

Should you have any questions concerning this inspection, please contact Emilio Garcia at (530) 756-8925 or Elmo Collins, at (817) 860-8291.

Sincerely,

Elmo E. Collins, Chief
Nuclear Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No.: 030-13550
License No.: 04-17862-01

cc: California Radiation Control Program Director

A/2