☆ U.S. GOVERNMENT PRINTING OFFICE — 1982

NRC Form 591
(12-81)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION

1. LICENSEE	2. REGIONAL OFFICE
V. A. Medical Center 3350 La Jolla Village Drive San Diego, CA 92161	U. S. Nuclear Regulatory Commission Region V 1450 Maria Lane, Suite 210 Walnut Creek, CA 94596

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE OF INSPECTION
	04-15030-01	May 18-19, 1988

Licensee:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission's (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews, with personnel, and observations by the inspector. The findings as a result of this inspection are as follows:

☐ 1. Within the scope of this inspection, no violations were observed.

☐ 2. The inspector also verified the steps you have taken to correct the violations identified during the last inspection. We have no further questions on those actions at this time.

☑ 3. During this inspection certain of your activities, as checked below, were in violation of NRC requirements. THIS IS A NOTICE OF VIOLATION which is required to be posted in accordance with 10 CFR 19.11.

☐ A. _____ was not properly posted to indicate the presence of a _____. 10 CFR 20.203(b), (c), (d), (e) or 34.42.

☐ B. Containers located in _____ were not properly labeled to indicate the presence of radioactive material. 10 CFR 20.203(f)(1), or (f)(2).

☐ C. _____ of sealed sources were not performed at the proper frequencies. 10 CFR _____ License Condition Number _____.

☑ D. Records of a room release survey conducted on Nov. 5, 1986 were not properly maintained. 10 CFR 20.201(b), or License Condition Number _____.

☐ E. Documents were not properly posted or otherwise made available. 10 CFR 19.11.

☐ F. Reports or notifications of _____ were not made in accordance with 10 CFR _____ or License Condition Number _____.

☑ H. Weekly wipe surveys of the injection areas had not been conducted as required.

☑ I. The Radiation Safety Committee did not conduct an annual review of the radiation safety program in 1987.

☐ J. _____

9102190140 901220
PDR FOIA
CLARK90-509 PDR

☐ K. _____

AHH

I hereby state that within 30 days the actions described by me to the Inspector will be taken to correct the violations identified in the items checked above. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201. No further response will be submitted unless required by the NRC.

John W. Vaeth Radiation Safety Officer 6/2/88

FORM NRC-591
(3-77)

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT

INSPECTION FINDINGS AND LICENSEE ACKNOWLEDGMENT

1. LICENSEE	2. REGIONAL OFFICE
Veterans Administration Hospital 3350 La Jolla Village Drive San Diego, California 92161	U.S. Nuclear Regulatory Commission 1990 No. California Blvd., Suite 202 Walnut Creek, CA 94596

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE OF INSPECTION
30-08456	04-15030-01	

6. INSPECTION FINDINGS

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The findings as a result of this inspection are as follows:

☒ No items of noncompliance or unsafe conditions were found.

The following items of noncompliance related to records, signs, and labels were found:

☐ A. Rooms or areas were not properly posted to indicate the presence of a RADIATION AREA. 10 CFR 20.203(b) or 34.42

☐ B. Rooms or areas were not properly posted to indicate the presence of a HIGH RADIATION AREA. 10 CFR 20.203(c) (1) or 34.42

☐ C. Rooms or areas were not properly posted to indicate the presence of an AIRBORNE RADIOACTIVITY AREA. 10 CFR 20.203(d)

☐ D. Rooms or areas were not properly posted to indicate the presence of RADIOACTIVE MATERIAL. 10 CFR 20.203(e)

☐ E. Containers were not properly labeled to indicate the presence of RADIOACTIVE MATERIAL. 10 CFR 20.203(f) (1) or (f) (2)

☐ F. A current copy of 10 CFR 20, a copy of the license, or a copy of the operating procedures was not properly posted or made available. 10 CFR 20.206(b)

☐ G. Form NRC-3 was not properly posted. 10 CFR 20.206(c)

☐ H. Records of the radiation exposure of individuals were not properly maintained. 10 CFR 20.401(a) or 34.33(b)

☐ I. Records of surveys or disposals were not properly maintained. 10 CFR 20.401(b) or 34.43(d)

☐ J. Records of receipt, transfer, disposal, export or inventory of licensed material were not properly maintained. 10 CFR 30.51, 40.61 or 70.51

☐ K. Records of leak tests were not maintained as prescribed in your license, or 10 CFR 34.25(c)

☐ L. Records of inventories were not maintained. 10 CFR 34.26

☐ M. Utilization logs were not maintained. 10 CFR 34.27

☐ N. Records of radiation survey instrument calibration were not maintained. 10 CFR 34.24

☐ O. Records of teletherapy electrical interlock tests were not maintained as prescribed in your license.

☐ P. Other _____

_____
(NRC Inspector)

7. The NRC Inspector has explained and I understand the items of noncompliance listed above. The items of noncompliance will be corrected within the next 30 days.

_____ _____
(Date) (Licensee Representative - Title or Position)

ORIGINAL TO LICENSEE

Licensee V. A Hospital - San Diego License No. 04-15030-01

INSPECTION ITEMS	MODULE NUMBER	766 TIME INFO
Management Meeting - Entrance and Exit Interviews (REQUIRED)	30703B	1
Initial Management Meeting	30800B	
Program Requirements MC 28 60 (REQUIRED)	78710B	4
Transportation Activities (REQUIRED)	86740B	1
In-office Review of Event Reports	90712B	
Licensee Event Followup	92700B	
Followup on Inspector Identified Problems	92701B	
Followup on Noncompliance and Deviations	92702B	
IE Bulletin/Immediate Action Letter Followup	92703B	
Followup on Headquarters Requests	92704B	
Followup on Regional Requests	92705B	
Independent Inspection Effort (REQUIRED)	92706B	1
Review of Part 21 Reports	92715B	
Inspector Dispatched to Site	93700B	
Followup on Significant Event Occurred During an Inspection	93701B	
		All

AREAS INSPECTED AND FINDINGS

Licensee: V.A. Hosp. Tal - San Diego License no: 04-15030-01 Amendment no: 21

INSPECTION ITEMS	CRITERIA	FINDING
1. Organization		OK ?

Structure of organization as described in requirements? yes? Lic Cond ____

NOTES & REMARKS: The full-time RSO Dr. John W. Verba has gone on sabbatical starting ≈ 4 weeks before the inspection. Dr. Samuel Halpern was named by the Radiation Safety Committee to act as RSO until Dr. Verba returned. At the time of the inspection Dr. Verba had not been gone long enough to have things go sour. The Chief Tech has done an outstanding job of keeping things on an even keel. However an early reinspection may be warranted

Next inspection note!

2. Licensee internal audits	Lic Cond ____	OK

Scope and frequency of audits as required? yes

Conducted by appropriate persons? yes Records maintained? yes Reviewed by management? yes

Deficiencies identified & corrected? yes

NOTES & REMARKS: Quarterly audits are conducted by the RSO. Informal audits and contact with the users are held once or twice daily sometimes. Dr. Halpern may have trouble acting as Chief of Nuc Med and doing all of his audits?

3. Training and qualification of personnel	Lic Cond ____	OK ?

Training & retraining conducted as required? OK

Written & oral exam conducted? yes Examination results reviewed by management? yes

Instructions to workers per 19.12? OK 19.12

NOTES & REMARKS: All Nuc Med Techs are registered except two. The nurses involved in therapy appear to need more training. They sometimes show an abnormal concern about treating care of an implant patient. This was mentioned at the last interview. Dr. Helpern said they would be given more trng.

4. Radiation protection procedures	Lic Cond ____	OK

Procedures available and implemented? yes Identify radiopharmaceutical and dose(s)? yes Cover handling of patients receiving therapeutic doses? yes Cover handling of cadavers? yes

Emergency procedures for spills, etc? yes

Personnel understand procedures? yes?

NOTES & REMARKS: The procedures need are the same as in support of the current license application. Some of the nurses involved in taking care of therapy patients seem to be showing abnormal concern about radiation. It appears that they may need some additional training.

787103 - Medical

AREAS INSPECTED AND FINDINGS

Licensee: VA Hospital - San Diego License no: 04-15630-01 Amendment no: 21

INSPECTION ITEM	CRITERIA	FINDING
5. Use of materials	Lic Cond ____	OK

Procurement and use as required? yes
Special tests (moly breakthrough, leak tests, etc) required? yes
Dose calibration checks performed? yes
Posting & labeling as required? yes 20.203

NOTES & REMARKS: Moly. breakthrough tests are conducted by the Rad. pharmacist Leak tests are conducted by Mr. Aman in a timely manner and records are maintained; all storage areas appeared to be secure and posted/labeled correctly.

6. Storage of materials — OK

Material secured in both restricted and unrestricted areas? Adequately? 20.207

NOTES & REMARKS: All areas where radioactive materials are stored are locked during off duty hrs. The roof is a restricted area because the vent stacks for the hoods used on iodination studies. The door to the roof is kept locked and maintenance personnel must check with the Chief Tech before going up there

7. Facilities — Lic Cond ____ — OK

As described in lic cond or application? The greater use of macroaggregates
Any changes made? Adequacy? is being discussed with licensing.

NOTES & REMARKS: The new licenses is being held up because of the changes that are requested by this licensee.

8. Instruments — Lic Cond ____ — OK

Survey meters & instruments adequate for program? yes
Instruments & meters operable? yes Calibrated? yes
Calibration adequate? yes

NOTES & REMARKS: The portable GM & Scintillation counter instruments (calibrated by Tech. Assoc.) are calibrated yearly by Don Collins of Glendale or by John Handlozer of Santa Barbara.

AREAS INSPECTED AND FINDINGS

Licensee: VA Hospital - San Diego License no: 04-15830-01 Amendment no: 21

INSPECTION ITEMS	CRITERIA	FINDING
9. Receipt and transfer of material		OK
Written procedures for pickup, receiving, opening packages? yes	20.205	
Survey of packages when received? yes	20.205(c)(1)	
Records of survey of packages? yes	20.401(b)	
Transfer of materials proper? yes Transfer records maintained? yes	30.41, 30.51	
Authorized containers used? Shipping papers & package labels proper for packages on hand? yes	71.5	

NOTES & REMARKS: They are now using a special "Transfer of Radioactive Material" for in house Transfers between the VA Hospital and University are made. It is included with appendix "C".

10. Personnel protection - external		OK
Personnel monitoring controls adequate? yes Exposures minimized? yes	20.101, 20.202	
Exposure records (NRC-4 or 5) maintained? yes Available for employee review?	20.102(b), 20.401(a)	
Surveys conducted? Adequate? yes	20.201	
Records of monitoring, surveys? yes	20.401	
Levels in unrestricted areas within limits? OK	20.1, 20.105	

NOTES & REMARKS: A monthly film badge service from Radiation Detection Co is utilized. All high quantity whole body exposure for the Radiopharmacist of 350 mrem was noted. All Nuc Med Techs were lower.

11. Personnel protection - internal		OK
Airborne concentrations in restricted areas? OK	20.103	
Exposures to minors? none	20.104	
Posting of airborne radioactivity areas? N/A	20.203(d)	
Survey, monitoring adequate for airborne radioactivity, surface contamination? Records maintained? OK	20.201 20.401	

NOTES & REMARKS: The licensee utilizes an extra gamma camera exclusively for thyroid cants on people involved in sedimation studies. Max body burden detected so far has been $\approx$ 3 nCi. A phantom is used to calibrate the machine.

AREAS INSPECTED AND FINDINGS

Licensee: V.A Hospital - San Diego License no: 04-15030-01 Amendment no: 21

INSPECTION ITEM	CRITERIA	FINDING
12. Effluent controls, waste disposal		OK
Release of effluents controlled? YES	20.106, 20.303	
Waste disposals controlled? YES	20.301, 20.303, 20.304, 20.305	
Procedures, records maintained? YES	20.401, Lic Cond ____	
Surveys made? Adequate? YES	20.401	

NOTES & REMARKS: The licensee is incinerating liquid scintillation solvent containing small amounts of H-3 & C-14. They use to incinerate most of their experimental animals. They are discussing this w/ the Licensing.

13. Notifications and reports		OK
To individuals. OK	19.13	
Overexposures, excessive levels & concentrations, incidents.	20.403, 20.405	
Personnel exposures and monitoring, termination reports. OK	20.407; 20.408	
Theft or loss of licensed material. none	20.402	

NOTES & REMARKS: The Acting RSO stated that they have had no theft or loss of licensed material.

14. Posting of notices		OK
Part 20, license & documents, procedures, notice of violations posted? OK	19.11(a)	
NRC-3 posted? YES	19.11(c)	

NOTES & REMARKS: Form NRC-3 and Part 19 posting requirements were noted to be posted.

15. Other license conditions	Lic	OK

see last regint

AREAS INSPECTED AND FINDINGS

Licensee: V.A. Hospital - San Diego License no: 04-15830-01 Amendment no: 21

INSPECTION ITEMS	CRITERIA	FINDING

16. Confirmatory measurements — OK

All storage & waste storage areas were surveyed with an NRC 2929 (S/N 008355) due for calibration 10/10/81. No unusually high radiation areas were found. A high of 30 mr/hr was found in the Radiopharmacy in a storage area behind lead bricks. Waste storage drums were either at background or read a few mr/hr.

17. Independent inspection effort — OK

A tour of the facilities was made and discussions held with many Radiation Workers encountered during the tour. They all seemed to know what was required of them particularly in the waste disposal area. No violations of good health physics practices or NRC Regs were noted during the tour. The Inspector was particularly impressed with the Chief Techs efforts to reduce radioactive waste volume using concentration, decay, incineration, and compaction.

18. Incidents and events — OK

Any incidents of misadministrations, contamination, etc, not otherwise covered by reports?

The misadministration reported in the licensee's letter of Dec 29, 1980 was discussed with Dr. Halpern. It appears that the incident was thoroughly investigated by the Radiation Safety Committee. Documentation also appeared to be complete. Special training was given to the Nuc Med Techs so that the incident would not happen again. It is the Dr's opinion that the patients was not harmed by the misadministration.

APPENDIX B - LICENSEE ACTION ON PREVIOUS INSPECTION FINDINGS

Licensee: V A Hospital - San Diego License no: 04-15030-01

Identification and summary of action taken	Status
Report no: 79-01 Type n/c: infract. Describe: possessed two 1 ci Am-241 sources without authorization. Action taken: The license was amended to authorized possession of the two Am-241 sources.	OPEN CLOSED
Report no: 79-01 Type n/c: infract. Describe: Dose Calibrator was not calibrated since it was received Action taken: Dose calibrator now calibrated at least yearly.	OPEN CLOSED
Report no: 79-01 Type n/c: infract. Describe: Wipe tests not done at monthly intervals Action taken: Wipe tests are now performed at least monthly	OPEN CLOSED
Report no: Type n/c: Describe: Action taken:	OPEN CLOSED
Report no: Type n/c: Describe: Action taken:	OPEN CLOSED

APPENDIX C - SUPPLEMENTARY INFO

Licensee: VA Hospital - San Diego License no: 09-15030-01

[ ] Uncorrected/repeated noncompliance [ ] Unresolved items
[ ] Unusual occurrence, conditions, etc [X] Inspector's comments
[ ] Basis for change of Category or Priority

The licensee's radiation safety related organizational structure is included below. Also the new transfer form is included as page two. It appears to be a good way for a large institution to handle transfers, especially when it is associated with a university

Dr. D. Tyler, MD
Hospital Director

Dr. Sy Dayton
Chief of Staff

Dr. Samuel Helpern
Acting Chief of Nuclear Medicine

Mr. Phillip Hagan
Nuclear pharmacist

Dr. T. Nelson
Consultant Physicist

Dr. John Verba
RSO

Mrs Francis Bagley
Secretary

Dr. Paul Carver
Physician

Dr. Corey Wagstaff
physician

Mr. Russal Cain
Chief Nuc. Med Tech

Dr. John Byfield
Consultant in Therapy

1. Mr. Ronald Burks
2. Miss Ann Schleif
3. Miss Carolyn Danger
4. Miss Malinda Johnson
5. Mr. Calvin Cherry
6. Mr. William Burt
(not yet certified)

Mr. James Wing
Radiation Tech

Mr. Robert Aman
Chief Tech (Research)

Miss Marie Platt
Film Badge Tech & Secretary

Dr. Samuel Helpern, Chairman
Radiation Safety Committee

1. Mr. Phil Hagan
2. Dr. John Verba
3. Dr. Sy Dayton
4. Dr. William Ashburn
5. Dr. Herbert Wohn
6. Mr. Robert Amen (Sits on no vote)
7. Mrs. Francis Bagley - Secretary

Radiation Safety Officer
VETERANS ADMINISTRATION HOSPITAL
3350 La Jolla Village Drive
San Diego, CA 92161
Tel.: (714) 453-7500 x3239

TRANSFER OF RADIOACTIVE MATERIAL

Date: _____ No. 0509

Radionuclide: _____ Quantity: _____ mCi Supplier: _____

Chemical Form: _____ EXEMPT label / WHITE I / YELLOW II / YELLOW III (circle one)

Calibration of Lot: _____ mCi/cc. at _____ (time) on _____ (date)

Amount Transferred: _____ mCi at _____ (time) on _____ (date)

Verified by: _____

Inner Container: _____ (no. of vials) _____ (no. of ampoules) _____ (no. of other (state kind))

Outer Package: _____ (type) _____ (surface mR/hr) _____ (mR/hr at 3 ft)

Check one: Water Ice ☐ Dry Ice ☐ Refrigerate on arrival ☐ None ☐

Contaminated Animal: _____ (species) Live ☐ Dead ☐ _____ (carcass part)

Inner Container
Wipe Test
_____ cpm
Initials: _____

Outer Package
Wipe Test
_____ cpm
Initials: _____

TRANSFERRED FROM: _____ Institution/Bldg./Room

Radioactive Material License No. _____ Expiration Date: _____

Principal Investigator _____

AUTHORIZED RELEASE
Date: _____ Time: _____

Signature: _____
Printed Name & Title: _____

Telephone No. ( ) _____

Courier Signature: (if applicable) _____

TRANSFERRED TO: _____ Institution/Bldg./Room

Radioactive Material License No. _____ Expiration Date: _____

Principal Investigator _____

AUTHORIZED RECEIPT
Date: _____ Time: _____

Signature _____
Printed Name & Title: _____

Telephone No. ( ) _____

Ultimate Recipient Signature: _____

Completed WHITE COPY Send to RSO. Address at top of form.

Suspense GREEN COPY Held by RSO at point of origin.

CANARY COPY Pulled by Courier after signature.

Completed PINK COPY Retained by Ultimate Recipient in Receiving Institution.

Completed GOLDENROD COPY Retained by Receiving RSO

NRC FORM 218 (4-76) NRCM 0240

U.S. NUCLEAR REGULATORY COMMISSION

TELEPHONE OR VERBAL CONVERSATION RECORD

DATE: 1/3/84

TIME: 2:20 ☐ A.M. ☒ P.M.

☒ INCOMING CALL ☐ OUTGOING CALL ☐ VISIT

PERSON CALLING	OFFICE/ADDRESS	PHONE NUMBER / EXTENSION
Dr. Verba	V.A. San Diego, CA	
PERSON CALLED	**OFFICE/ADDRESS**	**PHONE NUMBER / EXTENSION**
R Thomas		

CONVERSATION

SUBJECT: Extension of reply time to NOV.

SUMMARY

Dr. Verba will be out of town for three weeks and would like an extension on his answer to the NOV.

REFERRED TO: file

ACTION REQUESTED

10 days extension

☐ ADVISE ME OF ACTION TAKEN.

INITIALS: RThomas

DATE: 1/3/84

ACTION TAKEN

10 days extension was granted

INITIALS:

DATE:

NRC FORM 218 (4-76)

8117

3.

U.S. NUCLEAR REGULATORY COMMISSION

REGION V

Report No. 86-01

Docket No. 03008456 License No. 04-15030-01

Safeguards Group _____ Priority 2 Category 5

Licensee: Veterans Administration Medical Center

3350 La Jolla Village Drive

San Diego, CA 92161

Facility Name: Same

Inspection at: Same

Inspection conducted: Sept 4-5, 1986

Inspectors: I Francis Pong 9-10-86
Date

_____ Date

Approved by: R Bishop

12/4/86
Date

Summary:

One item of non-compliance was identified during the inspection. Radioactive contaminated trash was not controlled.

718

NUCLEAR MEDICAL INSPECTION FIELD NOTES

Inspection Report No. 86-01

License No. 04-15038-01
Docket No. 030-05456

Licensee (name and address)
Veterans Administration Medical Center
3350 La Jolla Village Drive
San Diego, CA 92161

Licensee Contact Dr. John Verba

Telephone No. 619-453-7500 X 3239

Last Amendment No. 2

Date of Amendment Nov. 6, 1986

Priority

Program Codes:

(✓) 02110 - Broad	( ) 02120 - Group		
( ) 02121 - Non Group	( ) 02200 - Private Practice		
( ) Eye Applicator	( ) 02201 - Private Practice		
( ) 02210 - VAN	( ) 02500 - Pharmacy	( ) Other	

Date of Inspection Sept 4-5, 1986

Type of Inspection.

( ) Announced	(✓) Unannounced	( ) Normal
( ) Initial	( ) Special	(✓) Reinspection

Next Inspection Date Sept, 1988

(✓) Normal ( ) Reduced ( ) Extended

Summary of Findings and Action:

( ) No Noncompliance, Clear 591 issued	( ) Action on Previous N/C
(✓) Noncompliance, 591 issued	( ) Regional Action
	( ) Headquarters Action

b. Persons contacted.
* Barbara A. Small, Medical Center Director
* Dr. D. Halpern, Chairman, RSC, Chief of Nuclear Medicine

* Those present at exit interview.
* Dr. John Verba, RSO
* Melinda Johnson, Asst. RSO

Inspector J. Frank Pond (Signature) Sept. 10, 1986 (Date Signed)

Approved (Signature) 12/4/86 (Date Signed)

Item 2 C

It appears that the nuclear physicist conducts his surveys too quickly to permit the survey instrument to respond

1. ORGANIZATION

a. Organizational structure meets license requirements. (✓) Yes ( ) No [L/C]
Remarks.

b. Use by authorized individuals. (✓) Yes ( ) No [L/C]
Remarks.

c. Radiation Safety Committee meets at required intervals. (✓) Yes ( ) No
Membership in accordance with 35.11(b) L/C ( ) Yes ( ) No
Remarks.

d. Record of Committee meetings. ( ) Yes (✓) No [L/C]
Remarks.

2. INSPECTION HISTORY

a. Item(s) of noncompliance or deviations noted during last inspection conducted on May 15-16, July 1-3 (✓) Yes ( ) No.
Response letter dated Sept 8, 1985

b.

Requirement	Type of N/C	Corrective Action Taken ( ) Yes	( ) No	Status Open	Closed
✓ Timely notification not received	S & IV				✓
✓ Annual audits	S & IV				✓
✓ Existing Deviation	S & IV				✓

(continue b. paragraph 21, if needed)

c. If any item(s) of noncompliance or deviations noted during last inspection were not corrected, explain.
The corrective action taken on the finding of contaminated tools in the non-radioactive tools containers was not effective (See opposite pg.

3. SCOPE OF PROGRAM The program consists of an extensive research, nuclear medicine, & R&D operations under a broad license.
The licensee has discontinued use of sealed sources under a Group VI to date.

4. INTERNAL AUDITS OR INSPECTIONS

a. Required by license condition. (✓) Yes ( ) No

b. Audits or inspections conducted. (✓) Yes ( ) No [L/C]
Remarks.

c. Records maintained. (✓) Yes ( ) No [L/C]
Remarks.

5. TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS

a. Training program required by license condition. (✓) Yes ( ) No

b. Training program implemented. (✓) Yes ( ) No [L/C]
Remarks.

c. Retraining program required by license condition. (✓) Yes ( ) No

d. Retraining program implemented. (✓) Yes ( ) No [L/C]
Remarks.

e. Instruction to workers in accordance with 10 CFR 19.12. (✓) Yes ( ) No [19.12]
Remarks.
Refresher training for ancillary personnel is not a requirement under this license.

6. RADIOLOGICAL PROTECTION PROCEDURES

a. Procedure referenced in license condition. (✓) Yes ( ) No

b. Used in accordance with referenced procedure. (✓) Yes ( ) No
Remarks.

c. Individuals understanding of procedures adequate. (✓) Yes ( ) No
Remarks.

d. Examples of key procedures:

(1) ordering and accepting packages of RAM
(2) general rules for safe use of RAM
(3) emergency procedures
(4) survey procedures
(5) handling of volatile RAM (e.g., Xe-133, I-131)
(6) precautions for use of RAM (sealed and unsealed) for therapy

7. MATERIALS, FACILITIES AND INSTRUMENTS

a. Facilities as described in license application. (✓) Yes ( ) No [L/C]
Remarks.

Item 7 a (cont')

eg.	1st security violation	Warning
	2nd " "	lab closed one day
	3rd " "	" " two days
	4th " "	" " three "

- The RSO said that even if the room is empty and the investigator is standing outside the door, he will cite that as a violation. Surveillance is not considered to be a valid reason according to the RSO. He states that the reason why they use this guideline is that it is easy to apply.

b. Isotope, chemical form, quantity and use as authorized.
(✓) Yes ( ) No [L/C]
Remarks.

c. Tests required by license condition or regulations.

(1) molybdenum-99 breakthrough. (✓) Yes ( ) No
(2) performed as required. (✓) Yes ( ) No
[L/C and/or 35.14(b)(4)(iii)]
(3) records maintained. (✓) Yes ( ) No [35.14(b)(4)(iv)]
Remarks.

(3) Leak tests. (✓) Yes ( ) No

(4) Leak tests performed as required. (✓) Yes ( ) No
[L/C] [35.14(b)(5)(i) or 35.14(e)(1)(i)]
Remarks.

(5) Other tests required (e.g., physical inventories; surveys to ensure that patients contain 30 millicuries of Au-198, I-131 before leaving hospital) [[/C].

Quarterly inventories and patient surveys had been conducted as required.

d. Inventory of sealed sources.
(1) Inventory of Group VI sources. (✓) Yes ( ) No
[35.14(b)(5)(v)]

(2) Inventory of calibration sources. (✓) Yes ( ) No
[35.14(f)(2)]

e. Areas for storage and use of radioactive materials.

(1) Method used to prevent an unauthorized individual from entering a restricted area is adequate. (✓) Yes ( ) No

(2) Radioactive material secured to prevent unauthorized removal from an unrestricted area. (✓) Yes ( ) No [20.207]
Remarks.
The licensee is very strict. There is a guard system to close a laboratory down depending on the number of violations incurred.

f. Instrumentation.

see opposite page

(1) Operable survey instruments are as described or equivalent to those described in license application. (✓) Yes ( ) No
[L/C]
Remarks.

(2) Capability of radiation survey instruments is adequate for program. (✓) Yes ( ) No
Remarks.

(3) Calibration of survey instruments required. (✓) Yes ( ) No

(4) Performed as required. (✓) Yes ( ) No [L/C]
Remarks.

(5) Dose calibrator checks required. (✓) Yes ( ) No

(6) Performed as required. (✓) Yes ( ) No [L/C]
accuracy tests are done on a daily basis

8. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL
Receipt of incoming packages during "off-duty" hours by whom? Where stored? Security? [L/C]

a. Survey of incoming packages. (✓) Yes ( ) No [20.205(b)(1) - L/C]
Remarks.

b. Record of survey. (✓) Yes ( ) No [20.401(b)]
Remarks.

c. Procedure for opening packages. (✓) Yes ( ) No [L/C; 20.205(d)]
Remarks.

d. BPM transferred in accordance with 10 CFR 30.41. (✓) Yes ( ) No [30.41]
Remarks.

e. Records of receipt and transfer maintained. (✓) Yes ( ) No [30.51]
Remarks.

9. PERSONNEL RADIATION PROTECTION - EXTERNAL
(Obtain information regarding whole body and extremity monitors)

a. Film or TLD badge supplier _____ Frequency Monthly

b. Reports reviewed by RSO Frequency Monthly
(Are badges assigned to personnel as per licensee's correspondence with NRC?)

c. NRC inspector reviewed personnel monitoring records for period 1984 to 1986 to date

d. NRC forms or equivalent.

(1) NRC-4: ( ) Yes (✓) No Complete: ( ) Yes ( ) No

(2) NRC-5: (✓) Yes ( ) No Complete: (✓) Yes ( ) No
[20.401(a)]
Remarks.

e. Maximum ~~quarterly~~ annual whole-body exposure. 1030 mr

f. Maximum ~~quarterly~~ annual extremity exposure. 1370 mr

g. Licensee has implemented an ALARA program. (✓) Yes ( ) No
Remarks.

h. Radiation survey of unrestricted areas. (✓) Yes ( ) No
[20.201(b) to show compliance with 20.105(b)]
Remarks.

i. Record of surveys maintained. (✓) Yes ( ) No
[20.401(b) to show compliance with 20.105(b)]
Remarks.

j. Radiation survey of use areas (hot lab, therapy treatment area, patient's room, etc.). (✓) Yes ( ) No [L/C]
Remarks.

k. Record of survey maintained. (✓) Yes ( ) No [L/C]
Remarks.

10. PERSONNEL RADIATION PROTECTION - INTERNAL

a. Potential for exposure of individuals to airborne radioactive material exists. (✓) Yes ( ) No
Remarks.

b. Monitoring for airborne radioactivity conducted. (✓) Yes ( ) No
[20.201(b) to show compliance with all sections of 20.103 - L/C]
Remarks.
Use of bioassays for iodine.

item 10C

The RSO stated that he thought that's what the inspector had recommended on his last visit. It was suggested to the RSO that he should discontinue this documentation since it is not required nor recommended. He stated that he had misinterpreted the requirement for documentation of surveys to include this also

c. Records of monitoring maintained. (✓) Yes ( ) No
[20.401(b) or L/C]
Remarks.
- The RSO also requires that individuals document daily
surveys of the hands at the end of the day. When asked why, (see opp sheet)

d. Bioassay program implemented as described in correspondence with NRC. (✓) Yes ( ) No

11. RADIOACTIVE EFFLUENT AND WASTE DISPOSAL

a. Radioactivity in effluents to unrestricted areas. (✓) Yes ( ) No

b. Release in accordance with regulatory limits. (✓) Yes ( ) No
[20.106(a)]
Remarks.

c. State solid waste disposal method.
Held for decay and also by shipment to burial site.

d. State liquid waste disposal method.
Solidification & disposal as solid waste

e. Disposal of solid and liquid waste in accordance with regulatory requirements (decay in storage). (✓) Yes ( ) No [L/C]
Remarks.

f. Records of disposal. (✓) Yes ( ) No [30.51]
Remarks.

g. Survey of waste prior to disposal. (✓) Yes ( ) No
[20.201(b) to show compliance with 20.301]
Remarks.

h. Records of surveys maintained. (✓) Yes ( ) No [20.401(b)]
Remarks.

12. NOTIFICATIONS AND REPORTS

a. Licensee in compliance with 10 CFR 19.13 (reports to individuals). ( ) Yes ( ) No [19.13]
Remarks.
N.A

item 14 The non-radioactive trash container in the Nuclear Medicine Pharmacy.

b. Licensee in compliance with 10 CFR 20.405 (overexposures).
( ) Yes ( ) No [20.405(a)]
Remarks.
N.A.

c. Licensee in compliance with 10 CFR 20.403 (incidents).
( ) Yes ( ) No [20.403]
Remarks.
N.A

d. Licensee in compliance with 10 CFR 20.402 (theft or loss).
( ) Yes ( ) No [20.402(a) or 20.402(b)]
Remarks.
N.A

e. Licensee in compliance with 10 CFR 35.42 or 10 CFR 35.43 and 35.44 (misadministration). ( ) Yes ( ) No [35.42, 35.43 and 35.44]
Remarks. N/A

There has been no incidents involving licensed material during the period since the last inspection.

13. POSTING OF NOTICES

Notices to workers posted. (✓) Yes ( ) No [19.11(a) or (b)] [19.11(c)]
Remarks.

14. CONFIRMATORY MEASUREMENTS

a. Measurements made by inspector. (✓) Yes ( ) No

b. Survey instrument ~~Xetex 308B~~ Eberline E-520 NRC Serial No. 5172 2776

c. Describe type and results of measurements and compare with licensee's measurements.

* Selected laboratory areas were surveyed for radiation & contamination & contaminated gauge measuring approx 140,000 dpm was found in see opposite page

15. INDEPENDENT MEASUREMENTS

a. Measurements made by inspector. (✓) Yes ( ) No

b. Survey instrument same NRC Serial No. same

c. Describe type and results of measurements.

Random areas in the restricted areas were surveyed for radiation and contamination. No significant radiation/contamination levels were found.

16. POSTING AND LABELING

Posting and labeling in accordance with 10 CFR 20.203. (✓) Yes
( ) No [20.203]
Remarks.

17. LICENSE CONDITIONS

a. All license conditions reviewed during inspection. (✓) Yes
( ) No

b. Activities were conducted in accordance with license conditions, except as noted elsewhere in this report. ( ) Yes ( ) No

18. BULLETINS AND INFORMATION NOTICES

a. Bulletins and Information Notices issued during current year.

b. Bulletins and Information Notices received by licensee. (✓) Yes
( ) No
Remarks.

c. Licensee took appropriate action in response to Bulletins and Information Notices. (✓) Yes ( ) No
Remarks.

19. TRANSPORTATION (10 CFR 71.5a and 49 CFR 171-178)

	Yes	Violation
a. License makes shipments of RAM? If "Yes," complete the following items.	(✓)	( )

b. Such shipments consisted of:
(✓) radwaste
(✓) sources/products
( ) other _____

c. For radwaste, shipments are:
(✓) by licensee, using common carrier
(✓) through Radwaste Broker
name of Broker _____

d. Licensee is aware of 10 CFR 61: Radwaste requirements for generators?	(✓)	( )
Licensee has classified and characterized its radwaste? (20.311(d))	( )	( )

The licensee ships the waste via a commercial waste disposal firm who also prepares the shipping papers and ensures that DOT regulations are followed

22 Additional Comments

It appears that the relationship between the radiation safety staff and the users may be a strained relationship. The Chairman of the Radiation Safety Committee stated that he had been threatened to be "punched out" by two of the users.

The RSO could probably profit from visiting VAMC-SF which is almost an identical situation to his. The RSO at VAMC-SF has much more experience in administering radiation safety programs. The strained relationships that the VAMC-SD RSO is experiencing appears to be due to his methods of enforcing compliance. The SF RSO has had no experience with radiation safety programs outside of his own so he could probably benefit greatly to see how a program similar to his own is run without encountering strained relationships. The idea of having the RSO visit VAMC-SF was brought to him and he was very enthusiastic about it and he stated that he would contact his Administrator to make the same suggestion.

(cont. on reverse of next page)

e. For shipments:

Licensee uses authorized packages? [(173.415-16)]	(✓)	( )
Package type used. 55 gal drums (17H)		
For DOT-7A, licensee has performance test records on file? (173.415(a))]	( )	( )
For special form sources, licensee has performance tests records on file for each source design? [(173.476(a))]	( ) N.A	( )
Packages are properly labeled? [(172.403)] [(173.441)]	(✓)	( )
Packages are properly marked? [(172.200)]	(✓)	( )
Proper shipping papers are prepared for each shipment? [(172.203(d))]	(✓)	( )

Remarks.

Shipping papers & package labeling, marking are attended to by the waste disposal contractor

20. ITEMS OF NONCOMPLIANCE

A contaminated gauge was found in the non-radioactive trash container in the Nuclear medical pharmacy. This is a repetative violation

21. CONTINUATION OF REPORT ITEMS - USE BACK OF PAGE IF NECESSARY

Item #	Corrective Action Yes	No	Status open	closed
Eating & drinking in labs	✓			✓
Cont. mail in regular trash	✓		✓	
Sewage discard in NRC labs	✓			✓
Sensitive ctl instituted in use of GM meter	✓			✓
RSO not maintaining records of receipt/disposal	✓			✓
Security of licensed material	✓			✓

Note

22. Ms Barbara Small, the Hospital Administrator, voiced appreciation for the suggestion & stated that she would make the necessary arrangements to carry it out. The WRMC-IF RSO was also contacted by the inspector to get prior approval for the visit.

INSPECTION REPORT NUMBE 86-01 Page ___ of ___

APPENDIX A - DOCUMENTATION of NONCOMPLIANCE

Licensee: VAMC, San Diego License no: 04-15230-01

Reference	Basis for noncompliance
Report item 14 10 CFR ✓ Lic Cond Type n/c Sh. IV	A contaminated gauge was found in the non-radioactive trash container in the Nuclear Medical pharmacy.
Report item 10 CFR Lic Cond Type n/c	
Report item 10 CFR Lic Cond Type n/c	
Report item 10 CFR Lic Cond Type n/c	
Report item 10 CFR Lic Cond Type n/c	

NRC Form 591
(12-81)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION

1. LICENSEE	2. REGIONAL OFFICE
Veterans Administration Medical Center 3350 LaJolla Village Drive San Diego, CA 92161	U. S. Nuclear Regulatory Commission Region V 1450 Maria Lane, Suite 210 Walnut Creek, CA 94596

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE OF INSPECTION
	04-15030-01	

Licensee:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission's (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews, with personnel, and observations by the inspector. The findings as a result of this inspection are as follows:

☐ 1. Within the scope of this inspection, no violations were observed.

☐ 2. The inspector also verified the steps you have taken to correct the violations identified during the last inspection. We have no further questions on those actions at this time.

☑ 3. During this inspection certain of your activities, as checked below, were in violation of NRC requirements. THIS IS A NOTICE OF VIOLATION which is required to be posted in accordance with 10 CFR 19.11.

☐ A. _____ was not properly posted to indicate the presence of a _____. 10 CFR 20.203(b), (c), (d), (e) or 34.42.

☐ B. Containers located _____ were not properly labeled to indicate the presence of radioactive material. 10 CFR 20.203(f)(1), or (f)(2).

☐ C. _____ of sealed sources were not performed at the proper frequencies. 10 CFR _____ License Condition Number _____.

☐ D. Records of _____ were not properly maintained. 10 CFR _____ or License Condition Number _____.

☐ E. Documents were not properly posted or otherwise made available. 10 CFR 19.11.

☐ F. Reports or notifications of _____ were not made in accordance with 10 CFR _____ or License Condition Number _____.

☑ H. _____

☐ I. _____

☐ J. _____

☐ K. _____

I hereby state that within 30 days the actions described by me to the inspector will be taken to correct the violations identified in the items checked above. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201. No further response will be submitted unless required by the NRC.

SIGNATURE – LICENSEE	DATE	SIGNATURE – NRC INSPECTOR	DATE
			A19

U.S. NUCLEAR REGULATORY COMMISSION

REGION V

Report No. 8801

Docket No. 030-05456 License No. 04-15030-01

Safeguards Group _____ Priority 2 Category _____

Licensee: VA Medical Center

3350 La Jolla Village Drive

San Diego, CA 92161

Facility Name: Same

Inspection at: _____

Inspection conducted: May 18-19, 1988

Inspectors: T. Farid Pong 6-18-88
Date

_____ Date

Approved by: R.A. Ballinger for R.D. Thomas

7/18/88
Date

Summary:

Three items of non-compliance were identified during the inspection.

A/10

10.

ATTACHMENT B
NUCLEAR MEDICAL INSPECTION FIELD NOTES
Region ____

Inspection Report No. 88-01 License No. 04-15030-01
Docket No. 030-05456

Licensee (name and address)
V.A. Medical Center
3350 La Jolla Village Drive
San Diego, CA 92161

Licensee Contact Dr. John Vanbo Telephone No. 619-453-7500, X 3237

Last Amendment No. 23 Date of Amendment Oct. 1, 1986

Priority 2 Last Inspection Sept 4-5, 1986

Program Codes:
(✓) 02110 - Broad ( ) 02120 - Group
( ) 02121 - Non Group ( ) 02200 - Private Practice
( ) Eye Applicator ( ) 02201 - Private Practice
( ) 02220 - VAN ( ) 02500 - Pharmacy ( ) Other

Date of Inspection May 18-19, 1988

Type of Inspection: ( ) Announced (✓) Unannounced ( ) Normal
( ) Initial ( ) Special

Next Inspection Date May, 1990

(✓) Normal ( ) Reduced ( ) Extended

Summary of Findings and Action:
( ) No Violations, Clear 591 issued ( ) Action on Previous Violations
(✓) Violations, 591 or regional letter issued

Inspector J. Frank Pong (Signature) 6-13-88 (Date Signed)

Approved B.A. Riedlinger for R.D. Walker (Signature) 7/18/88 (Date Signed)

1. ORGANIZATION

a. Organizational structure meets license requirements. (✓) Yes ( ) No [L/C]
Remarks.

b. Use by authorized individuals. (✓) Yes ( ) No [35.22(b)(2)]
Remarks.

c. Radiation Safety Committee meets at quarterly intervals.
(✓) Yes ( ) No

(1) Membership in accordance with 35.22(a)(1)] (✓) Yes ( ) No
Remarks.

(2) Record of Committee meetings. (✓) Yes ( ) No [35.22(a)(4)]
Remarks.

(3) Consultants. ( ) Yes (✓) No
Remarks.

e. Licensee uses the services of a visiting authorized user.
( ) Yes (✓) No [35.27(a)]

(1) Licensee has a copy of visiting authorized user license.
( ) Yes ( ) No [35.27(a)(2)] N/A
(2) License has records (maintained for 2 years) of visiting authorized users last visit. ( ) Yes ( ) No [35.37(c)]
N/A

f. License utilizes mobile nuclear medicine services.
( ) Yes (✓) No [35.29]

g. Licensee provides RSO sufficient authority, organizational freedom, and management prerogative. (✓) Yes ( ) No

h. Appropriate review by Committee in accordance with 35.22(b).
(✓) Yes ( ) No

2. INSPECTION HISTORY

a. Violations or deviations noted during last inspection conducted on Sept 4-5, 1986 (✓) Yes ( ) No.
Form 591 - Response letter dated _____

(1) History of Compliance. Requirement	Type of N/C	Corrective Action Taken ( ) Yes ( ) No	Status ( )Open ( ) Closed
Containers gauge in New Jersey Testing Trailer		✓	✓
		See Item 15.C.	

(2) If any item(s) of noncompliance or deviations noted during last inspection were not corrected, explain.

3. SCOPE OF PROGRAM

Briefly list radioisotopes and their application.

Radioisotope	Application
Beam source	

4. INTERNAL AUDITS OR INSPECTIONS

a. Required by license condition. (✓) Yes ( ) No ( ) N/A

b. Investigations or inspections conducted. (✓) Yes ( ) No [35.21(a) and (b)(2)]
Remarks.

N/C: X The Radiation Safety Committee did not conduct an annual review of the Radiation Safety program in 1987.

c. Records maintained. (✓) Yes ( ) No [35.21(b)(2)(xi)]
Remarks.

5. TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS

a. Training program required. [35.900 - 35.950 and 35.961 - 35.972]

(1) Training program implemented. (✓) Yes ( ) No
Remarks.

(2) Retraining program required. (✓) Yes ( ) No [35.972]

(3) Retraining program implemented. (✓) Yes ( ) No
Remarks.

b. Instruction to workers in accordance with 10 CFR 19.12.
(✓) Yes ( ) No
Remarks.

*c. Describe the QA program to mitigate therapeutic misadministrations.

(1) Have secondary checks of the dose calculations been done?
(✓) Yes ( ) No

(2) Do the second party checks of the dose calculations provide assurance that the final treatment plan will provide the dose prescribed on the patient chart? (✓) Yes ( ) No

(3) Do technologist consult with the doctor if the prescription or other orders are unclear? (✓) Yes ( ) No
Remarks.

*d. Followup on therapy or serious diagnostic misadministrations N.A.

(1) 10 CFR 35.43 properly implemented? ( ) Yes ( ) No

(2) Was proper medical care given for the patient pursuant to the NRC medical consultant recommendations?
( ) Yes ( ) No

(3) Were appropriate actions implemented to prevent recurrence?
( ) Yes ( ) No

* Inspect when QA rule becomes final.

(4) Were the technologist and dosimetrist made aware of these actions? ( ) Yes ( ) No

(5) Does the licensee's QA/QC procedures address these actions to prevent recurrence? ( ) Yes ( ) No
Remarks.

6. RADIOLOGICAL PROTECTION PROCEDURES

a. Radiation safety program changes reviewed. (Exception to changes without license amendment may be found in 35.13 and 35.606.)
( ) Yes ( ) No N.A.

b. Records of changes in procedures reviewed. ( ) Yes ( ) No [35.31(b)]
Remarks.

c. Radioactive materials used in accordance with current procedures.
(✓) Yes ( ) No [35.31(a)]
Remarks.

(1) Individuals understanding of current procedures adequate.
(✓) Yes ( ) No
Remarks.

(2) Examples of key procedures:
(a) ordering and accepting packages of RAM
(b) general rules for safe use of RAM
(c) emergency procedures
(d) survey procedures
(e) handling of volatile RAM (e.g., Xe-133, I-131)
(f) precautions for use of RAM (sealed and unsealed) for therapy
(g) emergency procedures posted?
(h) do licensee personnel understand emergency procedures?
(i) safety procedures for patient therapy in accordance with 35.315 and 35.415

7. MATERIALS, FACILITIES AND INSTRUMENTS

a. Facilities as described in license application. (✓) Yes ( ) No
Remarks.

b. Isotope, chemical form, quantity and use as authorized.
(✓) Yes ( ) No [L/C]
Remarks.

c. Syringes containing radioactive material properly labeled and shielded unless contraindicated. (✓) Yes ( ) No [35.60(a)(b)(c)]

d. Vials containing radioactive material properly labeled and shielded.
(✓) Yes ( ) No [35.61(a)(b)]

e. Tests required by regulations.

(1) molybdenum-99 breakthrough. (✓) Yes ( ) No [35.204(b)]
(2) performed as required. (✓) Yes ( ) No [35.204(a)]
(3) records maintained. (✓) Yes ( ) No [35.204(c)]
Remarks.

(4) Leak tests. (✓) Yes ( ) No

(5) Leak tests performed as required. (✓) Yes ( ) No [35.59(b)]
Remarks.

f. Inventory of sealed sources.

(1) Inventory of Group VI sources. (✓) Yes ( ) No [35.59(g)]

(2) Inventory of calibration sources. (✓) Yes ( ) No [35.59(g)]

g. Areas for storage and use of radioactive materials.

(1) Method used to prevent an unauthorized individual from entering a restricted area is adequate. (✓) Yes ( ) No

(2) Radioactive material secured to prevent unauthorized removal from an unrestricted area. (✓) Yes ( ) No [20.207]
Remarks.

(3) Area wipe tested? (✓) Yes ( ) No
Remarks.

h. Instrumentation.

(1) Operable survey instruments are as described or equivalent to those described in license application. (✓) Yes ( ) No [35.120, 220, 320, 420]
Remarks.

(2) Capability of radiation survey instruments is adequate for program. (✓) Yes ( ) No
Remarks.

(3) Calibration of survey instruments required. (✓) Yes ( ) No

(a) Performed as required. ( ) Yes ( ) No [35.50]
Remarks.

(5) Records of calibration maintained for 2 years. [35.50(e)]
(✓) Yes ( ) No

8. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

Receipt of incoming packages during "off-duty" hours by whom?

(a) Where stored? Security? [L/C]

(b) Survey of incoming packages. (✓ Yes ( ) No [20.205(b)(1)]
Remarks.

(1) Record of survey. (✓ Yes ( ) No [20.401(b)]
Remarks.

c. Procedure for opening packages. (✓ Yes ( ) No [20.205(d)]
Remarks.

d. BPM transferred in accordance with 10 CFR 30.41. (✓ Yes ( ) No [30.41]
Remarks.

e. Records of receipt and transfer maintained. (✓ Yes ( ) No [30.51]
Remarks.

9. PERSONNEL RADIATION PROTECTION - EXTERNAL
(Obtain information regarding whole body and extremity monitors)

a. Film or TLD badge supplier _____ Frequency Monthly

b. Reports reviewed by RSD Frequency Monthly
(Are badges assigned to personnel as per licensee's correspondence with NRC?)

c. NRC inspector reviewed personnel monitoring records for period 1986 to April, 1988

d. NRC forms or equivalent.

(1) NRC-4: ( ) Yes (✓) No Complete: ( ) Yes ( ) No

(2) NRC-5: (✓) Yes ( ) No Complete: (✓) Yes ( ) No
[20.401(a)]
Remarks.

e. Maximum quarterly whole-body exposure. _____

f. Maximum quarterly extremity exposure. _____

g. Licensee has implemented an ALARA program. (✓) Yes ( ) No
[35.50] [see Procedure No. 83822, "Radiation Protection]
Remarks.

h. Radiation survey of unrestricted areas. (✓) Yes ( ) No
(20.201(b) to show compliance with 20.105(b)) [35.315(a)(4)];
[35.415(a)(4)]
Remarks.

(1) Record of surveys maintained. (✓) Yes ( ) No
[20.401(b) to show compliance with 20.105(b)]
Remarks.

i. Radiation survey of storage and use areas:

(1) Quarterly survey brachytherapy source storage. (✓) Yes
( ) No [35.59(h)]

(2) Temporary implant patient release survey. (✓) Yes ( ) No
[35.404(a)]

(3) Radiopharmaceutical and permanent implant patient release
survey. (✓) Yes ( ) No [35.75]

N/C: ✗ Records of a room release survey conducted on Nov. 5, 1986 were not maintained

(4) Radiopharmaceutical therapy room contamination survey. (✓) Yes ( ) No [35.315(a)(5) and (7)]

(5) Patient survey upon implant. (✓) Yes ( ) No [35.406(c)]

(6) Radiopharmaceutical storage and laboratory use areas. (✓) Yes ( ) No [35.70]
Remarks.

N/C: ✗ Weekly wipe surveys of the injection areas had not been conducted as required.

j. Record of survey maintained. (✓) Yes ( ) No [35.70(h)]
Remarks.

k. Inventory of brachytherapy sources after use. (✓) Yes ( ) No [35.406]
Remarks.

l. Records maintained. (✓) Yes ( ) No [35.59(g)]; [35.406]

m. Dose calibrator calibration and checks performed as follows:
Constancy (✓) Yes ( ) No Accuracy (✓) Yes ( ) No
Linearity (✓) Yes ( ) No Geometric dependence (✓) Yes ( ) No
[35.50]

10. PERSONNEL RADIATION PROTECTION - INTERNAL

a. Potential for exposure of individuals to airborne radioactive material exists. (✓) Yes ( ) No
Remarks.
Only for use of Xe-133 & I-131, 125.

b. Monitoring for airborne radioactivity conducted. (✓) Yes ( ) No [20.201(b) to show compliance with all sections of 20.103 and 35.90]
Remarks. Biosassays are used to monitor use of Iodine isotopes.

(1) Records of monitoring maintained. (✓) Yes ( ) No [20.401(b) or L/C]
Remarks.

c. Bioassay program implemented as described in correspondence with NRC. (✓) Yes ( ) No [35.315(a)(8)]

d. Control of airborne radioactivity in accordance with 35.205. (✓) Yes ( ) No

11. RADIOACTIVE EFFLUENT AND WASTE DISPOSAL

a. Radioactivity in effluents to unrestricted areas. (✓) Yes ( ) No

b. Release in accordance with regulatory limits. (✓) Yes ( ) No [20.106(a)]
Remarks.

c. State solid waste disposal method.
Hold for decay & also shipment to burial site.

d. State liquid waste disposal method.
Sink disposal

e. Disposal of solid and liquid waste in accordance with regulatory requirements (decay in storage). (✓) Yes ( ) No [35.92(a)]
Remarks.

(1) Records of disposal. (✓) Yes ( ) No [35.92(b)]
Remarks.

f. Survey of waste prior to disposal. (✓) Yes ( ) No [20.201(b) to show compliance with 20.301 - 35.92(a)(2)]
Remarks.

(1) Records of surveys maintained. (✓) Yes ( ) No [20.401(b)]
Remarks.

12. NOTIFICATIONS AND REPORTS

a. Licensee in compliance with 10 CFR 19.13 (reports to individuals). ( ) Yes ( ) No [19.13]
Remarks.

N.A

b. Licensee in compliance with 10 CFR 20.405 (overexposures).
( ) Yes ( ) No [20.405(a)]
Remarks.

N.A

c. Licensee in compliance with 10 CFR 20.403 (incidents).
( ) Yes ( ) No [20.403]
Remarks.

N.A

d. Licensee in compliance with 10 CFR 20.402 (theft or loss).
( ) Yes ( ) No [20.402(a) or (b)]
Remarks.

N.A

e. Licensee in compliance with reporting therapeutic misadministrations and taking corrective action. ( ) Yes ( ) No [35.33(a)(b)(d)]
Remarks.

N.A

f. License in compliance with reporting diagnostic misadministrations and taking corrective action as needed under conditions set forth in 10 CFR 35.33(c). ( ) Yes ( ) No
Remarks.

N.A

13. POSTING OF NOTICES

Notices to workers posted. (✓ Yes ( ) No [19.11(a), (b), or (c)]
Remarks.

14. CONFIRMATORY MEASUREMENTS

a. Measurements made by inspector. (✓ Yes ( ) No

b. Survey instrument Ludlum Mod 3 Xetex 305B NRC Serial No. 020367 8289

c. Describe type and results of measurements and compare with licensee's measurements. Contamination & radiation surveys were conducted of randomly selected laboratory areas. No significant contamination / radiation levels were noted

15. INDEPENDENT MEASUREMENTS

a. Measurements made by inspector. (✓ Yes ( ) No

b. Survey instrument none or above NRC Serial No. _____

c. Describe type and results of measurements.
Non-radioactive waste containers were randomly selected & surveyed No radioactive contamination levels were found

16. POSTING AND LABELING

Posting and labeling in accordance with 10 CFR 20.203. (✓ Yes ( ) No [20.203]
Remarks.

17. LICENSE CONDITIONS

a. All license conditions reviewed during inspection. (✓ Yes ( ) No

b. Activities were conducted in accordance with license conditions, except as noted elsewhere in this report. ( ) Yes ( ) No

18. BULLETINS AND INFORMATION NOTICES

a. Bulletins and Information Notices issued during current year.

b. Bulletins and Information Notices received by licensee. (✓ Yes ( ) No
Remarks.

c. Licensee took appropriate action in response to Bulletins and Information Notices. (✓) Yes ( ) No
Remarks.

19. TRANSPORTATION (10 CFR 71.5a and 49 CFR 171-178)

		Yes	Violation
a.	License makes shipments of RAM? If "Yes," complete the following items.	(✓)	( )
b.	Such shipments consisted of: (✓) radwaste ( ) sources/products ( ) other _____		
c.	For radwaste, shipments are: ( ) by licensee, using common carrier (✓) through Radwaste Broker name of Broker _____		
d.	Licensee is aware of 10 CFR 61: Radwaste requirements for generators?	(✓)	( )
	Licensee has classified and characterized its radwaste? (20.311(d))	(✓)	( )
e.	For shipments: Licensee uses authorized packages? [(173.415-16)]	(✓)	( )
	Package type used. _____ For DOT-7A, licensee has performance test records on file? [(173.415(a))]	( )	N.A.( )
	For special form sources, licensee has performance tests records on file for each source design? [(173.476(a))]	✗ N.A.( )	( )
	Packages are properly labeled? [(172.403)] [(173.441)]	(✓)	( )
	Packages are properly marked? [(172.200)]	(✓)	( )
	Proper shipping papers are prepared for each shipment? [(172.203(d))]	(✓)	( )

Remarks.

* Sources are returned to U.C.S.D. without having to use public highways since U.C.S.D. is adjacent to VAMC, S.D.

f. Does licensee make return shipments of radiopharmacy doses? ( ) N.A. (.)
(If Yes, does licensee assume responsibility for all shipper requirements?)
(If No, what arrangements/understanding have been made between licensee and radiopharmacy as to performance of shipper responsibilities?) (Describe)
Remarks.

20. ITEMS OF NONCOMPLIANCE

see Appendix B

21. CONTINUATION OF REPORT ITEMS - USE BACK OF PAGE IF NECESSARY

INSPECTION REPORT NUMBER 88-01 Page ___ of ___

APPENDIX A - DOCUMENTATION of NONCOMPLIANCE

Licensee: VAMC, SLD License no: 04-15030-01

Reference	Basis for noncompliance
Report item 9.c.(3) 10 CFR 20.201(b) Lic Cond ___ Type n/c SL V	Records of a room release survey conducted on Nov 7, 1986 had not been maintained.
Report item 9.c.(6) 10 CFR ___ Lic Cond 28 Type n/c S.L. IV	Weekly wipe surveys of the injection areas had not been conducted as required.
Report item 4 10 CFR ___ Lic Cond 28 Type n/c S.L. IV	The Radiation Safety Committee did not conduct an annual review of the radiation safety program in 1987.
Report item ___ 10 CFR ___ Lic Cond ___ Type n/c ___	
Report item ___ 10 CFR ___ Lic Cond ___ Type n/c ___	

I . NUCLEAR REGULATORY COMMISSIC

REGION V

Report No. 90-01

Docket No. 030-08456 License No. 04-15030-01

Safeguards Group _____ Priority 1 Category 211C

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

Facility Name: same

Inspection at: same

Inspection conducted: April 12-13, 1990

Inspectors: James F. Montgomery 4/16/90
Date

_____ _____
Date

Approved by: H Query

4/23/90
Date

Summary:

This was a routine unannounced inspection. The licensee was inspected 10 months ago with one violation identified (recording surveys in CPM instead of DPM). The current inspection revealed one violation associated with inadequate record keeping for a contamination survey.

A/15

15

ATTACHMENT B
NUCLEAR MEDICAL INSPECTION FIELD NOTES
Region V

Inspection Report No. 90-01 License No. 04-15030-01
Docket No. 030-08456

Licensee (name and address)

Veterans Administration Medical Center
San Diego, CA

Licensee Contact John Vieira Telephone No. 415-552-7511

Last Amendment No. 24 Date of Amendment 11/16/89

Priority 1 Last Inspection 6/19-21/89

Program Codes:
(4) 02110 - Broad ( ) 02120 - Group
( ) 02121 - Non Group ( ) 02200 - Private Practice
( ) Eye Applicator ( ) 02201 - Private Practice
( ) 01220 - VAN ( ) 02500 - Pharmacy ( ) Other

Date of Inspection 4/12-13/90

Type of Inspection: ( ) Announced (4) Unannounced (4) Normal
( ) Initial ( ) Special

Next Inspection Date 1/91

(X) Normal ( ) Reduced ( ) Extended

Summary of Findings and Action:
( ) No Violations, Clear 591 issued ( ) Action on Previous Violations
(4) Violations, 591 ~~or regional letter~~ issued

Inspector James J. Montgomery (Signature) 4/17/90 (Date Signed)

Approved H Chen (Signature) 9/23/90 (Date Signed)

1. ORGANIZATION

a. Organizational structure meets license requirements. (✓) Yes ( ) No [L/C]
Remarks. With one exception no changes have occurred in the licensee's organization since the last inspection. One new nuclear medicine physician has been added.

b. Use by authorized individuals. (✓) Yes ( ) No [35.22(b)(2)]
Remarks. An associate RSO will be recruited to assist the RSO with his duties. A physical handicap has hampered the conduct of radiation safety work making the selection of an associate RSO necessary.

c. Radiation Safety Committee meets at quarterly intervals.
(✓) Yes ( ) No

(1) Membership in accordance with 35.22(a)(1)] (✓) Yes ( ) No
Remarks.
membership remains the same as noted during last inspection.

(2) Record of Committee meetings. (✓) Yes ( ) No [35.22(a)(4)]
Remarks.

(3) Consultants. (✓) Yes ( ) No
Remarks.
Occupational Services, Inc. is now used to calibrate licensee's survey instruments. UCSD no longer provides the service.

e. Licensee uses the services of a visiting authorized user.
( ) Yes (✓) No [35.27(a)]

(1) Licensee has a copy of visiting authorized user license.
( ) Yes ( ) No [35.27(a)(2)]
(2) License has records (maintained for 2 years) of visiting authorized users last visit. ( ) Yes ( ) No [35.37(c)]

f. License utilizes mobile nuclear medicine services.
( ) Yes (✓) No [35.29]

g. Licensee provides RSO sufficient authority, organizational freedom, and management prerogative. (✓) Yes ( ) No

h. Appropriate review by Committee in accordance with 35.22(b).
(✓) Yes ( ) No

2. INSPECTION HISTORY

a. Violations or deviations noted during last inspection conducted on 6/19-21/89 (✓) Yes ( ) No.
Response letter dated 8/14/89

(1) History of Compliance.

Requirement	Type of N/C	Corrective Action Taken (✓) Yes ( ) No	Status ( )Open (✓) Closed
Record surveys in DPM units	S.L. V		

(2) If any item(s) of noncompliance or deviations noted during last inspection were not corrected, explain.

3. SCOPE OF PROGRAM

Briefly list radioisotopes and their application.

Radioisotope	Application
3-83 Broad Scope Type A	Medical/human use, basic & research w/animals

4. INTERNAL AUDITS OR INSPECTIONS

a. Required by license condition. ( ) Yes (✓) No ( ) N/A

b. Investigations or inspections conducted. (✓) Yes ( ) No [35.21(a) and (b)(2)]
Remarks.
Internal audits conducted by the RSO & reported quarterly to the Radiation Safety Committee

c. Records maintained. (✓) Yes ( ) No [35.21(b)(2)(x1)]
Remarks.

5. TRAINING RETRAINING, AND INSTRUCTION TO WORKERS

a. Training program required. [35.900 - 35.950 and 35.961 - 35.972]

(1) Training program implemented. (✓) Yes ( ) No
Remarks.

Training remains the same as noted during last inspection.

(2) Retraining program required. (✓) Yes ( ) No [35.972]

(3) Retraining program implemented. (✓) Yes ( ) No
Remarks.

b. Instruction to workers in accordance with 10 CFR 19.12.
(✓) Yes ( ) No licensee has written & distributed a "Guide
Remarks. for Radioactive Material Users In the Research Service"
to aid in Training & to help insure uniformity
in following procedures & maintaining records.

*c. Describe the QA program to mitigate therapeutic misadministrations.

(1) Have secondary checks of the dose calculations been done?
(✓) Yes ( ) No

(2) Do the second party checks of the dose calculations provide assurance that the final treatment plan will provide the dose prescribed on the patient chart? (✓) Yes ( ) No
only ^{131}I thyroid therapy is performed.

(3) Do technologist consult with the doctor if the prescription or other orders are unclear? (✓) Yes ( ) No
Remarks.

*d. Followup on therapy or serious diagnostic misadministrations N/A.

(1) 10 CFR 35.43 properly implemented? ( ) Yes ( ) No No misadministrations have occurred since last inspection

(2) Was proper medical care given for the patient pursuant to the NRC medical consultant recommendations?
( ) Yes ( ) No

(3) Were appropriate actions implemented to prevent recurrence?
( ) Yes ( ) No

* Inspect when QA rule becomes final.

(4) Were the technologist and dosimetrist made aware of these actions? ( ) Yes ( ) No N/A

(5) Does the licensee's QA/QC procedures address these actions to prevent recurrence? ( ) Yes ( ) No N/A
Remarks.

6. RADIOLOGICAL PROTECTION PROCEDURES

a. Radiation safety program changes reviewed. (Exception to changes without license amendment may be found in 35.13 and 35.606.)
(✓) Yes ( ) No

b. Records of changes in procedures reviewed. (✓) Yes ( ) No [35.31(b)]
Remarks.

c. Radioactive materials used in accordance with current procedures. (✓) Yes ( ) No [35.31(a)]
Remarks.

(1) Individuals understanding of current procedures adequate.
(✓) Yes ( ) No
Remarks.

(2) Examples of key procedures:
(a) ordering and accepting packages of RAM
(b) general rules for safe use of RAM
(c) emergency procedures
(d) survey procedures
(e) handling of volatile RAM (e.g., Xe-133, I-131)
(f) precautions for use of RAM (sealed and unsealed) for therapy
(g) emergency procedures posted?
(h) do licensee personnel understand emergency procedures?
(i) safety procedures for patient therapy in accordance with 35.315 and 35.415

7. MATERIALS, FACILITIES AND INSTRUMENTS

a. Facilities as described in license application. (✓) Yes ( ) No
Remarks.
no facility changes have occurred since the last inspection, however, the licensee is constructing a special therapy patient room which will be exclusively for this use. It is being built for easy decontamination & may also be used for mono-clonal antibody patients.

b. Isotope, chemical form, quantity and use as authorized. (✓) Yes ( ) No [L/C]
Remarks.

c. Syringes containing radioactive material properly labeled and shielded unless contraindicated. (✓) Yes ( ) No [35.60(a)(b)(c)]

d. Vials containing radioactive material properly labeled and shielded. (✓) Yes ( ) No [35.61(a)(b)]

e. Tests required by regulations.

(1) molybdenum-99 breakthrough. (✓) Yes ( ) No [35.204(b)]
(2) performed as required. (✓) Yes ( ) No [35.204(a)]
(3) records maintained. (✓) Yes ( ) No [35.204(c)]
Remarks.
all of the above tests & records are maintained by the radiopharmacist.

(4) Leak tests. (✓) Yes ( ) No

(5) Leak tests performed as required. (✓) Yes ( ) No [35.59(b)]
Remarks.

f. Inventory of sealed sources.

(1) Inventory of Group VI sources. ( ) Yes ( ) No [35.59(g)] N/A
no brachytherapy sources are possessed.
(2) Inventory of calibration sources. (✓) Yes ( ) No [35.59(g)]

g. Areas for storage and use of radioactive materials.

(1) Method used to prevent an unauthorized individual from entering a restricted area is adequate. (✓) Yes ( ) No

(2) Radioactive material secured to prevent unauthorized removal from an unrestricted area. (✓) Yes ( ) No [20.207]
Remarks.

(3) Area wipe tested? (✓) Yes ( ) No
Remarks.

h. Instrumentation.

(1) Operable survey instruments are as described or equivalent to those described in license application. (✓) Yes ( ) No [35.120, 220, 320, 420]
Remarks.
Survey instrumentation remains the same as described in last inspection report.

(2) Capability of radiation survey instruments is adequate for program (✓) Yes ( ) No
Remarks.

(3) Calibration of survey instruments required. (✓) Yes ( ) No

(a) Performed as required. (✓) Yes ( ) No [35.50]
Remarks.
Outside consultant (Occupational Services Inc.) performs calibrations.

(5) Records of calibration maintained for 2 years. [35.50(e)]
(✓) Yes ( ) No

8. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

Receipt of incoming packages during "off-duty" hours by whom? Security Station, Main Entrance.

(a) Where stored? Security? [L/C]
Security delivers package to nuclear medicine Hot Lab if no damage is evident.
If damage suspected, the radiopharmacist 4/67 R50 counter

(b) Survey of incoming packages. (✓) Yes ( ) No [20.205(b)(1)]
Remarks. Nuclear Medicine surveys their own shipments all research shipments are ~~de~~ inspected & surveyed by the Radiation Safety Office personnel

(1) Record of survey. (✓) Yes ( ) No [20.401(b)]
Remarks.

c. Procedure for opening packages. (✓) Yes ( ) No [20.205(d)]
Remarks.

d. BPM transferred in accordance with 10 CFR 30.41. (✓) Yes ( ) No [30.41]
Remarks.

e. Records of receipt and transfer maintained. (✓) Yes ( ) No [30.51]
Remarks.

9. PERSONNEL RADIATION PROTECTION - EXTERNAL
(Obtain information regarding whole body and extremity monitors)

a. Film or TLD badge supplier Radiation Detection Co. Frequency monthly

b. Reports reviewed by RSO Frequency monthly
(Are badges assigned to personnel as per licensee's correspondence with NRC?)

c. NRC inspector reviewed personnel monitoring records for period June 1989 to March 1990

d. NRC forms or equivalent.

(1) NRC-4: (✓) Yes ( ) No Complete: ( ) Yes ( ) No

(2) NRC-5: (✓) Yes ( ) No Complete: ( ) Yes ( ) No
[20.401(a)]
Remarks.

e. Maximum quarterly whole-body exposure. 80 mrem, NMT

f. Maximum quarterly extremity exposure. 320 mrem (ring badge)

g. Licensee has implemented an ALARA program. (✓) Yes ( ) No
[35.50] [see Procedure No. 83822, "Radiation Protection]
Remarks.

h. Radiation survey of unrestricted areas. (✓) Yes ( ) No
(20.201(b) to show compliance with 20.105(b)) [35.315(a)(4)];
[35.415(a)(4)]
Remarks.
Surveys were performed during 10/6/89 ^{131}I thyroid therapy.

(1) Record of surveys maintained. (✓) Yes ( ) No
[20.401(b) to show compliance with 20.105(b)]
Remarks. However records were not in compliance with 10 CFR 35.70(h). Survey instrument, DPM units, surveyors identity, & area survey plan not recorded for the 10/6/89 contamination swipe survey noted above.

i. Radiation survey of storage and use areas:

(1) Quarterly survey brachytherapy source storage. ( ) Yes N/A
( ) No [35.59(h)]

(2) Temporary implant patient release survey. ( ) Yes ( ) No N/A
[35.404(a)]

(3) Radiopharmaceutical and permanent implant patient release survey. (✓) Yes ( ) No [35.75]
Survey was adequate but not in record keeping as noted above.

(4) Radiopharmaceutical therapy room contamination survey. (✓) Yes ( ) No [35.315(a)(5) and (7)]
Inadequate record keeping.

(5) Patient survey upon implant. ( ) Yes ( ) No [35.406(c)] N/A

(6) Radiopharmaceutical storage and laboratory use areas. (✓) Yes ( ) No [35.70]
Remarks.

j. Record of survey maintained. ( ) Yes (✓) No [35.70(h)]
Remarks.
This was a violation (see pg. B-9).

k. Inventory of brachytherapy sources after use. ( ) Yes ( ) No [35.406] N/A
Remarks.

l. Records maintained. ( ) Yes ( ) No [35.59(g)]; [35.406] N/A

m. Dose calibrator calibration and checks performed as follows:
Constancy (✓) Yes ( ) No Accuracy (✓) Yes ( ) No
Linearity (✓) Yes ( ) No Geometric dependence (✓) Yes ( ) No
[35.50] all performed by the radiopharmacist.

10. PERSONNEL RADIATION PROTECTION - INTERNAL

a. Potential for exposure of individuals to airborne radioactive material exists. (✓) Yes ( ) No
Remarks.
Occasional iodination w/ ^{125}I is performed in special research hood.

b. Monitoring for airborne radioactivity conducted. (✓) Yes (✓) No [20.201(b) to show compliance with all sections of 20.103 and 35.90]
Remarks.
Weekly contamination surveys are conducted in the iodination room.

(1) Records of monitoring maintained. (✓) Yes ( ) No [20.401(b) or L/C]
Remarks.

c. Bioassay program implemented as described in correspondance with NRC. (✓) Yes ( ) No [35.315(a)(8)] (See Item 21 on pg. B-15)

d. Control of airborne radioactivity in accordance with 35.205. (✓) Yes ( ) No

11. RADIOACTIVE EFFLUENT AND WASTE DISPOSAL

a. Radioactivity in effluents to unrestricted areas. (✓) Yes ( ) No

b. Release in accordance with regulatory limits. (✓) Yes ( ) No [20.106(a)]
Remarks. Liquids are held for decay & then disposed of via sewage system when surveys do not exceed natural background

c. State solid waste disposal method. Occasional shipments (55 gal drums) are made through waste brokers. No change since the last inspection.

d. State liquid waste disposal method.

e. Disposal of solid and liquid waste in accordance with regulatory requirements (decay in storage). (✓) Yes ( ) No [35.92(a)]
Remarks.

(1) Records of disposal. (✓) Yes ( ) No [35.92(b)]
Remarks.

f. Survey of waste prior to disposal. (✓) Yes ( ) No [20.201(b) to show compliance with 20.301 - 35.92(a)(2)]
Remarks.

(1) Records of surveys maintained. (✓) Yes ( ) No [20.401(b)]
Remarks.

12. NOTIFICATIONS AND REPORTS

a. Licensee in compliance with 10 CFR 19.13 (reports to individuals). (✓) Yes ( ) No [19.13]
Remarks.

b. Licensee in compliance with 10 CFR 20.405 (overexposures).
( ) Yes ( ) No [20.405(a)] N/A none have occurred since the last inspection
Remarks.

c. Licensee in compliance with 10 CFR 20.403 (incidents).
( ) Yes ( ) No [20.403] N/A none have occurred since last inspection.
Remarks.

d. Licensee in compliance with 10 CFR 20.402 (theft or loss).
( ) Yes ( ) No [20.402(a) or (b)] N/A none have occurred.
Remarks.

e. Licensee in compliance with reporting therapeutic misadministrations and taking corrective action. ( ) Yes ( ) No [35.33(a)(b)(d)] N/A
Remarks.

f. License in compliance with reporting diagnostic misadministrations and taking corrective action as needed under conditions set forth in 10 CFR 35.33(c). ( ) Yes ( ) No N/A
Remarks.

13. POSTING OF NOTICES

Notices to workers posted. (✓) Yes ( ) No [19.11(a), (b), or (c)]
Remarks.

14. CONFIRMATORY MEASUREMENTS

c. Measurements made by inspector. (✓) Yes ( ) No

b. Survey instrument Eberline E-520 w/ PC probe NRC Serial No. _____

c. Describe type and results of measurements and compare with licensee's measurements.

15. INDEPENDENT MEASUREMENTS

a. Measurements made by inspector. (✓) Yes ( ) No

b. Survey instrument same as above NRC Serial No. _____

c. Describe type and results of measurements. Nuclear medicine & research labs using P-32 & I-125 were surveyed. No unexpected results were detected above normal background.

16. POSTING AND LABELING

Posting and labeling in accordance with 10 CFR 20.203. (✓) Yes ( ) No [20.203]
Remarks.

17. LICENSE CONDITIONS

a. All license conditions reviewed during inspection. (✓) Yes ( ) No

b. Activities were conducted in accordance with license conditions, except as noted elsewhere in this report. (✓) Yes ( ) No

18. BULLETINS AND INFORMATION NOTICES

a. Bulletins and Information Notices issued during current year.

b. Bulletins and Information Notices received by licensee. (✓) Yes ( ) No
Remarks.

c. Licensee took appropriate action in response to Bulletins and Information Notices. (✓) Yes ( ) No
Remarks.

19. TRANSPORTATION (10 CFR 71.5& and 49 CFR 171-178)

		Yes	Violation
a.	License makes shipments of RAM? If "Yes," complete the following items.	(✓)	( )
b.	Such shipments consisted of: (✓) radwaste ( ) sources/products ( ) other _____		
c.	For radwaste, shipments are: ( ) by licensee, using common carrier (✓) through Radwaste Broker name of Broker Pacific West Nuclear & Thomas Gray Assoc.		
d.	Licensee is aware of 10 CFR 61: Radwaste requirements for generators?	(✓)	( )
	Licensee has classified and characterized its radwaste? (20.311(d))	(✓)	( )
e.	For shipments: Licensee uses authorized packages? [(173.415-16)]	(✓)	( )
	Package type used. DOT 7A		
	For DOT-7A, licensee has performance test records on file? [(173.415(a))]	(✓)	( )
	For special form sources, licensee has performance tests records on file for each source design? [(173.476(a))]	N/A ( )	( )
	Packages are properly labeled? [(172.403)] [(173.441)]	(✓)	( )
	Packages are properly marked? [(172.200)]	(✓)	( )
	Proper shipping papers are prepared for each shipment? [(172.203(d))]	(✓)	( )
	Remarks.		

f. Does licensee make return shipments of radiopharmacy doses? NO ( ) ( )
(If Yes, does licensee assume responsibility for all shipper requirements?)
(If No, what arrangements/understanding have been made between licensee and radiopharmacy as to performance of shipper responsibilities?) (Describe)
Remarks.

20. ITEMS OF NONCOMPLIANCE

Failure to record ^{131}I therapy patient room survey instrument, surveyor's identity, DPM units and survey diagram was a violation of 10 CFR 35.70(h). Form 591 issued to licensee during exit briefing on 4/13/

21. CONTINUATION OF REPORT ITEMS - USE BACK OF PAGE IF NECESSARY

10.C - Bioassay Program:

A laboratory researcher using iodine 125 in iodination procedures accumulated elevated iodine 125 in the thyroid gland as evidenced by bioassay.

Details:

Mid April 1989, iodination room 6198, researcher handled 125 I vial that was apparently leaking. Unknown to the researcher at the time, the iodine was internally deposited. The deposition was detected during a routine bioassay conducted on 4/25/89. The 4/25 reading was 82.4 nCi of I-125 calculated to be in the thyroid. Following discovery of this level, the RSO suspended all iodination activity by the researcher until the thyroid activity dropped below 10 nCi. This occurred with the August 10, 1989 bioassay which read 8.38 nCi (i.e. it took from 4/25/89 to 8/10/89 for the activity to decrease from 82.9 to 8.38 nCi). The researcher has now resumed iodination & no thyroid levels above natural background have been observed.

(OVER

The licensee's corrective action was considered appropriate & conformed to NRC Regulatory Guide 8.20.

Future inspectors should continue to closely monitor the coloration process in Room 6198 & the bioassay program conducted by the RSO.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CALIFORNIA 94596

DEC 27 1983

License No. 04-15030-01

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

Attention: John W. Ditzler, M.D.
Medical Center Director

Gentlemen:

Subject: NRC Inspection

This refers to the routine inspection conducted by Mr. David D. Skov of this office on December 7-9, 1983, of activities authorized by NRC License No. 04-15030-01 and to the discussion of our findings held by Mr. Skov with you and other members of your staff at the conclusion of the inspection.

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector.

Based on the results of this inspection, it appears that certain of your activities were not conducted in full compliance with NRC requirements, as set forth in the Notice of Violation enclosed as Appendix A to this letter. These items have been categorized into severity levels as described in the NRC Enforcement Policy, 10 CFR Part 2, Appendix C.

In addition to the need for corrective action regarding the specific violations included in Appendix A, we are concerned about the implementation of your management control system that permitted the violations to occur. Of particular concern was the occurrence of excessively high levels of radioactive contamination of a radioisotope laboratory (Room 6223), and the contamination of an individual who was working in the same laboratory which were detected by the NRC inspector during a visit to your sixth floor research facility.

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It is especially significant when it is noted that this individual as well as other persons working with licensed material in other research and nuclear medicine laboratories, as a matter of practice, have failed to conduct frequent and routine (daily and weekly) laboratory and personnel surveys to verify the absence of radioactive contamination. Based upon discussions by the NRC inspector with the Radiation Safety Officer and other licensee representatives, it appears that the absence of surveys by authorized users is considered to be an acceptable policy and the only surveys required are those conducted monthly by the Radiation Safety Office. The lack of more frequent surveys is significant in light of the additional findings that the results of monthly surveys, extending over a period of several months, indicate the presence of significant levels of surface contamination in a number of nuclear medicine and research laboratories.

Although radioactive contamination of the laboratory (Room 6223) and the individual observed during the inspection involved only materials which are not licensed by the NRC (yittrium-88, indium-111), this incident appears to be symptomatic of the failure of this particular aspect of the radiation safety program to properly exercise adequate control over the safe use of byproduct material. Consequently, in your reply you should describe those actions taken or planned to improve the effectiveness of your radiation safety program and the overall management control system, particularly with reference to your radiation monitoring program.

Your response to this Notice is to be submitted in accordance with the provisions of 10 CFR 2.201 as stated in Appendix A, Notice of Violation.

The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

If you have any questions on this matter or concerning this inspection, please telephone Mr. Skov on 415-943-3850.

Sincerely,

Ross A. Scarano, Director
Division of Radiological Safety
and Safeguards Program

Enclosure:
Notice of Violation

APPENDIX A

NOTICE OF VIOLATION

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

License No. 04-15030-01

As a result of the inspection conducted December 7-9, 1983, and in accordance with the NRC Enforcement Policy, 10 CFR Part 2, Appendix C, the following violations were identified:

A. 10 CFR 20.207(a) states that licensed materials stored in an unrestricted area shall be secured from unauthorized removal from the place of storage.

Contrary to the above requirement, licensed materials (2 millicuries, hydrogen-3; approximately 100 microcuries, iodine-125) contained in Laboratory Room 6078, were not secured from unauthorized removal from its place of storage. During a walk-through inspection of the sixth floor research laboratory facility at approximately 12:40 p.m., on December 9, 1983, the door to Room 6078 was observed by the inspector to be open and the room unattended. Under these conditions, the laboratory would be considered as an unrestricted area.

This is a Severity Level IV Violation (Supplement IV).

B. License Condition 20 states that the licensee shall possess and use licensed material in accordance with statements, representations, and procedures contained in application dated July 25, 1980; and letters dated March 26, 1975, and March 3, 1983. Also, 10 CFR 20.201(b) states, in part, that each licensee shall make or cause to be made such surveys as are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present.

1. Section 6.51 of the Radiation Safety Manual (REV. 7/80), which was submitted as an attachment to the application dated July 25, 1980, states that whenever unsealed quantities of radioactivity exceeding 100 times those listed in Appendix VI are used in a single procedure, a survey of the work area shall be made by the user immediately after the completion of the procedure and the results recorded. Appendix VI of the Radiation Safety Manual (REV. 7/80) specifies for technetium-99m an activity of 100 microcuries.

Contrary to the above requirements, surveys of the Nuclear Medicine Radiopharmacy (Room 4520) and Dispensing Laboratory (Room 4504) have not been conducted following the use of unsealed technetium-99m exceeding 10 millicuries for the period between August 1981, and the date of the inspection December 7-9, 1983.

2. Item 6, Section 3.40 of the Radiation Safety Manual (REV. 7/80), which was submitted as an attachment to the application dated July 25, 1980, states that each person who has contact with sources of ionizing radiation is responsible for checking working areas for

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contamination after each open radioisotope procedure. Item 3, Section 3.40 also states that each individual user has a responsibility to survey hands, shoes, body and clothing for radioactivity before leaving the laboratory following the use of open radioisotope sources.

Contrary to the above requirements, licensee representatives stated at the time of the inspection that radiation surveys of working areas and personnel have not been conducted following open radioisotope procedures with licensed material (iodine-125, iodine-131, hydrogen-3) which are used in several research laboratories (Rooms 6056, 6078, and 6141).

These items constitute a Severity Level IV Violation (Supplement VI).

C. 10 CFR 30.51(a) states that each person who receives byproduct material pursuant to a license issued pursuant to the regulations in this part and Parts 31-35 shall keep records showing the receipt, transfer and disposal of such byproduct material.

Contrary to the above requirement, at the time of the inspection, records had not been maintained showing the receipt and transfer of up to 125 millicuries of iridium-192 as seeds in nylon ribbons for interstitial treatments of cancer in patients who were treated on September 2, 1981, April 25, 1983 and June 15, 1983.

This is a Severity Level V Violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Veterans Administration Medical Center, San Diego, California is hereby required to submit to this office within thirty days of the date of this Notice, a written statement of explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

DEC 27 1983
Dated

R. D. Thomas, Chief,
Materials Radiation Protection
Inspection and Licensing Section

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CALIFORNIA 94596

AUG 09 1985

Docket No. 030-08456
License No. 04-15030-01
EA 85-82

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

DELIVERED THROUGH
Certified By Dot Mack

Attention: Norman E. Hensley
Medical Center Director (Acting)

Gentlemen:

Subject: Notice of Violation (NRC Inspection Report No. 30-08456/85-01)

This refers to the inspection conducted on May 15-16 and July 1-3, 1985 at the Veterans Administration Medical Center, San Diego, California, by Mr. F. Pang of this office. The inspection was conducted to investigate the circumstances associated with the loss of iridium-192 seeds at the Medical Center around the April 24-25, 1985 timeframe. The missing seeds were reported to NRC Region V by your Radiation Safety Officer on May 1, 1985. During the inspection eight violations of NRC requirements were identified. On May 31 and July 10, 1985, we held an enforcement conference and telephone conference, respectively, with you and members of your staff during which these violations, their causes, and your corrective actions were discussed.

The violations described in the Notice of Violation include: (1) the loss of radioactive materials; (2) failure to survey areas in which radioactive materials are located or handled; (3) failure to conduct annual audits, (4) failure to maintain adequate records; (5) inadequate training, and (6) several examples of failing to comply with the requirements of the Radiation Safety Manual. Collectively, these violations represent a breakdown in the management oversight and control of the radiation safety program. Two of the eight violations were repeat violations.

The violations have been categorized in the aggregate as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1985). Civil penalties are normally considered for Severity Level III violations. However, the NRC Enforcement Policy allows for reduction of a civil penalty under certain circumstances. In this case, because of your prompt identification and reporting, and your unusually prompt and extensive corrective actions, I have decided, after consultation with the Director, Office of Inspection and Enforcement, not to propose a civil penalty in this case.

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. After reviewing your response to this Notice, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

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In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and its enclosure 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, PL 96-511.

Sincerely,

John B. Martin
Regional Administrator

Enclosure:
Notice of V[illegible]

cc:
State of California

APPENDIX A

NOTICE OF VIOLATION

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

Docket No. 030-08456
License No. 04-15030-01
EA 85-82

During an NRC inspection conducted on May 15-16 and July 1-3, 1985, violations of NRC requirements were identified. The violations include: (1) the loss of radioactive materials; (2) failure to survey areas in which radioactive materials are located or handled; (3) failure to conduct annual audits; (4) failure to maintain adequate records; (5) inadequate training; and (6) several examples of failing to comply with the requirements of the Radiation Safety Manual. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1985), the violations are listed below:

A. License Condition 20 states that the licensee shall possess and use licensed material in accordance with statements, representations, and procedures contained in the application dated July 25, 1980; and letters dated March 26, 1975 and March 3, 1983.

1. Section 6.61 of the Radiation Safety Manual states, in part, that radioisotopes requiring labels must be stored in areas under control of the Radiation Safety Officer (RSO) and secured against unauthorized removal.

   Contrary to the above requirement, on three separate occasions, licensed material requiring labels was not under the control of the RSO and secured from unauthorized removal as evidenced by the following:

   a. A shielded container containing iridium-192 sources totaling approximately 47 millicuries was left unattended in the patient's room overnight on April 24, 1985.

   b. A ribbon/catheter containing five iridium-192 seeds of approximately 0.76 millicuries each was found by the Assistant RSO underneath the patient's bed on April 25, 1985.

   c. A ribbon containing four iridium-192 seeds was confirmed to be lost on May 1, 1985.

2. In the application dated July 25, 1980 the licensee committed to an ALARA program which requires that management and the Radiation Safety Officer independently conduct annual audits of the radiation safety program.

   Contrary to the above requirement, at the time of the inspection, the annual audits had not been conducted since 1980.

3. Section 3.40.5(a) of the Radiation Safety Manual states that smoking, eating, or drinking in radioisotope laboratories is prohibited.

   Contrary to the above requirement, on July 1, 1985, the inspector observed individuals drinking or evidence of drinking in Rooms 6022, 6058, 6069, 6122, 6124, 6197, and 6202. Food was also observed in Room 6122.

4. Section 6.61.1 of the Radiation Safety Manual states, in part, that radioactive waste requiring a "Radioactive Materials" label must be secured against unauthorized removal. Section 3.30.8 of the Radiation Safety Manual establishes 11,000 dpm as the criterion for determining whether an item is considered to be radioactively contaminated and thus requires disposal in a properly labeled and secured container.

   Contrary to the above requirements, at the time of the inspection, a contaminated gauze and bottle were found in the non-radioactive trash container in the Nuclear Medicine imaging room which was not labelled or secured against unauthorized removal. The contaminated gauze and bottle each measured approximately 150,000 dpm.

5. Section 6.51 of the Radiation Safety Manual states that when unsealed quantities of activity exceeding 100 times those listed in Appendix VI of the manual (e.g. ted from 10 CFR 30.71, Schedule B) are used in a single procedure, survey shall be made by the user and the results recorded.

   Contrary to the above requirement, the Nuclear Medicine Laboratory, containing unsealed quantities of activity greater than 100 times the quantities specified in 10 CFR 30.71, Schedule B, had not been surveyed on the following representative dates in 1985: April 22, 23, 26 and 29, May 6, 7, 14 and 20, and June 3, 7.

   This a repeat violation.

6. In the letter dated March 26, 1975, the licensee stated that the janitors on the research floor (6th) of the hospital will be instructed in the proper use of a G.M. survey meter to check bagged non-radioactive waste before transferring it to the hospital's central disposal area.

   Contrary to the above requirement, at the time of the inspection, the janitors on the sixth floor had not been instructed in the proper use of a G. M. survey meter to check bagged non-radioactive waste.

7. Section 6.62 of the Radiation Safety Manual and 10 CFR 20.401(c)(3) requires that records be maintained of all liquid radioactive waste disposed of into the sanitary sewer.

   Contrary to the above requirement, at the time of the inspection, the Radioimmunoassay Laboratory had not maintained records of sanitary sewer disposals.

B. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured from unauthorized removal from the place of storage.

Contrary to the above requirement, during the walkthrough inspection conducted on July 1, 1985, Rooms 6122 and 6158, each containing licensed material, were found unlocked and unattended during the lunch hour.

This a repeat violation.

Collectively, the above violations constitute a Severity Level III problem (Supplements IV and VI).

Pursuant to the provisions of 10 CFR 2.201, the Veterans Administration Medical Center, San Diego is hereby required to submit to this Office within 30 days of the date of this Notice, a written statement or explanation including for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, (3) the corrective steps which have been taken and the results achieved, (4) corrective steps which will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, the Director, Office of Inspection and Enforcement, may issue an order 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. Consideration may be given to extending the response time for good cause shown.

AUG 09 1985

Dated

U. S. NUCLEAR REGULATORY COMMISSION

REGION V

Report No. 85-01

Docket No. 030-08456 License No. 04-15030-01

Materials Group Priority: 2 Category: G1

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

Facility Name: (Same as above)

Inspection at: (Same as above)

Inspection conducted: May 15-16 and July 1-3, 1985

Inspector: J. Frank Pang, Radiation Specialist — Date Signed 8/2/85

Approved By: R. D. Thomas, Chief
Nuclear Materials Safety Section — Date Signed 8/2/85

Summary:

Inspection of May 15-16 and July 1-3, 1985 (Report No. 85-01)

This special inspection was conducted as a result of a notification by the licensee on May 1, 1985 that a ribbon of four (4) iridium-192 seeds of approximately 0.76 millicuries each was missing and also because the licensee was due for a routine inspection.

The areas examined included organization; internal audits; training and qualifications of personnel; radiation protection procedures; use of materials; storage of materials; facilities; instruments; receipt and transfer of materials; personnel protection-external and internal; effluent controls and waste disposal; and required postings. The actions taken to correct the previous violations as stated by the licensee in correspondence to the NRC after the last inspection were also examined during this inspection.

This inspection also focused on the verification of the licensee's surveys which had been conducted to locate the missing seeds and the determination of the cause of the breakdown in controls which resulted in the missing seeds.

This inspection involved 34 inspector hours onsite by one inspector.

Results

Eight violations were identified during the inspection. The violations have been categorized in the aggregate as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C '1985). The violations are summarized as follows:

A. The loss of four iridium-192 seeds was the result of the licensee not following acceptable procedures. The following items constituted one violation.

1. A shielded container containing Ir-192 sources totaling approximately 47 millicuries, was left unattended in the patient's room overnight on April 24, 1985.

2. A ribbon/catheter containing five iridium seeds of approximately 0.76 millicuries each was found by the Assistant Radiation Safety Officer (RSO) underneath the patient's bed on April 25, 1985, indicating a survey was not adequately conducted.

3. A ribbon containing four iridium-192 seeds was confirmed to be lost on May 1, 1985. (Items 8 and 11.b.)

B. Two laboratories containing licensed material were found unlocked and unattended. This is a repetitive violation. (Item 8)

C. Management and the RSO have not conducted annual audits of the radiation safety program. (Item 4)

D. Evidences of eating/drinking was observed in several laboratories. (Item 12.c)

E. Contaminated material was found in the non-radioactive trash container in the Nuclear Medicine Laboratory. (Item 15)

F. Daily surveys of the Nuclear Medicine Laboratory had not been conducted on occasions. This is a repetitive violation. (Item 11.2.a)

G. Janitors on the sixth floor had not been trained to monitor non-radioactive trash. (Item 5)

H. The Radioimmunoassay (RIA) Laboratory did not maintain records of disposals of liquid waste into the sanitary sewer. (Item 13)

DETAILS

1. Persons Contacted

Norman Hensley, Acting Director
Fred Marciano, Acting Director
Jean Parthmore, Chief of Staff
Todd Yates, Assistant Administrator
John Yerba, RSO
Melinda Johnson, Assistant RSO
Gordon Perkins, Development Engineer
Lee Henderson, Assistant Chief of Staff
Richard Horn, Radiation Physicist, University of California at San Diego (UCSD)

2. Background

This special inspection was conducted as a result of a notification by the licensee on May 1, 1985, that a ribbon of four (4) iridium-192 seeds of approximately 0.76 millicuries each was missing and also because the licensee was due for a routine inspection. The eight violations identified have been categorized in the aggregate as a Severity Level III problem.

A synopsis of the activities by the licensee relating to the incident is as follows:

April 22, 1985	A patient was implanted with 69 iridium-192 seeds of approximately 0.76 millicuries each.
April 24, 1985	The seeds were removed from the patient and kept in a container in the patient's room. A survey meter had been left in the patient's room for use by the attending physician.
April 25, 1985	A survey of the patient's room was conducted by the Assistant RSO. A ribbon of five seeds was found under the patient's bed.
April 30, 1985	The seeds which had been removed from the patient were returned to the UCSD.
May 1, 1985	The licensee was notified by UCSD that a ribbon of four seeds was missing from the shipment. The licensee conducted radiation surveys in the various areas using GM survey meters. However upon the recommendation of Region V, the licensee subsequently repeated the surveys of the various areas using the much more sensitive Eberline Micro R Meters.
May 2, 1985	Radiation surveys were completed by the licensee. These surveys included a commercial biological waste handing facility and the appropriate areas at the San Diego sanitary landfill.

The surveys conducted by the licensee did not reveal the whereabouts of the missing seeds.

The instruments used during the inspection were an Eberline PRM-7 Micro R, SN 510; an Eberline E-520, SN 1939; with a HP 260 pancake probe; and a Xetex 305B, SN 8194, due for calibration on September 5, September 12 and August 22, 1985 respectively.

3. Organization

The licensee conducts a large nuclear medicine and research program under a broad scope license and has a Radiation Safety Committee (RSC) which oversees the radiation safety program in the Medical Center, which includes a large number of research laboratories. The Co-Chairpersons of the Radiation Safety Committee are Dr. J. Verba and Dr. S. Halpern.

The radiation safety program is implemented by the radiation safety office which consists of Dr. J. Verba, RSO; Melinda Johnson, Assistant RSO; and Sally Witherby, Secretary. Dr. Verba is a physicist in the Nuclear Medicine Department, who also is assigned the collateral duties of RSO. Ms. Melinda Johnson is the Assistant RSO and is currently being trained on-the-job in that capacity by Dr. Verba.

The minutes of the RSC for the meetings held since the last inspection of December 7-9, 1983 were reviewed. The RSC has met on a frequency of at least a quarterly basis.

On May 15, 1985, the licensee held a RSC meeting to determine the cause of the incident. This meeting was attended by both the radiation physicist who implanted the seeds and the physician who removed the seeds from the patient. The inspector attended this meeting as an observer.

4. Audits

The licensee does not conduct audits. This was identified as a violation. The licensee had committed to an ALARA program in the application dated July 25, 1980, which requires that management and the RSO each independently conduct annual audits of the radiation safety program. The Radiation Safety Office conducts inspections of the various laboratories on a monthly basis which basically consists of performing radiation and contamination surveys of laboratories. However, these monthly inspections cannot be construed as audits because there is no in-depth review of program requirements. The conduct of in-depth audits is basic to the implementation of a good radiation safety program.

This was identified as a violation.

5. Training

A review of the training program indicated that the licensee is in compliance with the training requirements as specified in the license condition for all groups in the program with the exception of the janitors on the sixth floor, where the research laboratories are located. According to License Condition 20, the licensee has committed to train

the janitors on the sixth floor in use of survey meters so that they could monitor the non-radioactive trash. This training commitment has never been carried out. This was identified as a violation.

It appears that the training program could be strengthened. The training program should ensure that all persons receive the appropriate retraining at a prescribed frequency. For example, the license commitment specifies, "periodic" or "special lectures" to be given on radiation safety. However, the frequency of "periodic" or "special lectures" has not been defined so that in effect it may be years before such retraining is given, if at all. For example: building and maintenance workers received a special lecture about two years ago according to the RSO. Also, a number of the research workers interviewed received only the initial training. Also, much of the training that had been given is not documented. There is no requirement in the license to maintain training records.

This was identified as a violation.

6. Radiation Protection Procedures

Each laboratory where licensed materials are used has a copy of the Veterans Administration Medical Center, San Diego, Radiation Safety Manual which is essentially a compendium of radiation protection procedures.

No violations were identified.

7. Use of Materials

Posting of restricted areas and labeling of containers of radioactive materials were observed in a number laboratories and were found to be as required.

A review of the records of leak tests and quarterly inventories indicated that leak tests and quarterly inventories were conducted as required. Leak tests are conducted on a quarterly rather than on a semiannual basis.

Since the lost seeds incident of May 1, 1985, the licensee has suspended all brachytherapy treatments until such time that a satisfactory procedure to prevent lost seeds can be developed, established, and implemented.

The following facts regarding the use of the seeds associated with the incident were established during the inspection:

a. The physician who removed the seeds from the patient stated that he did not count the seeds after removal from the patient.

b. Because the assumption was made by the UCSD physicist that the manufacturer's stated inventory on the shipping papers was correct, the physicist did not count the seeds upon receipt. However, since fewer seeds were implanted than were ordered there was a question

that the manufacturer's stated inventory could have been in error. A telephone conversation held with the manufacturer during the inspection indicated that the manufacturer's quality assurance procedure consisted of an autoradiograph of the shipment as well as independent counts by two individuals. At the inspector's request the manufacturer's representative recounted the autoradiograph of the shipment and confirmed that it was as stated in the inventory.

No violations were identified.

8. Storage of Materials

The security of licensed material was observed in the Nuclear Medicine Laboratory and in several research laboratories. Laboratories having "Caution-Radioactive Materials" signs posted on hallway doors were also checked at random during the inspection to determine if any licensed material was left unattended. During the walkthrough inspection on July 1, 1985, Room Numbers 6122 and 6158 each containing licensed material were found unlocked and unattended during the lunch hour. This was identified as a repetitive violation.

As noted in Section 2 of this report, the seeds were removed from the patient on April 24, 1985 and kept in a container in the patient's room overnight until it was removed by the Assistant RSO the following morning. This was identified as one item of the Severity Level III Violation. The Radiation Safety Manual which is incorporated into the license requires that radioactive material be under the control of the RSO at all times.

This was identified as a violation.

9. Instruments

A review of the dose calibration records indicated that the quarterly linearity tests, the annual accuracy and daily constancy checks have been conducted as required. The accuracy tests have been done on a daily rather than on an annual frequency.

The licensee's survey instruments are calibrated on an annual basis. The responsibility for the timely calibration of the survey instruments is assigned to the hospital's engineering department. All instruments were in calibration.

No violations were identified.

10. Receipt and Transfer

The RSO reviews all incoming shipments of radioactive material to the hospital except those destined for the Nuclear Medicine Department. Records of receipt since January 1984 to date were reviewed. Receipt surveys had been conducted as required.

No violations were identified.

11. Personnel Protection

A. External

(1) Radiation Exposure

Records of radiation exposures since January 1984 were reviewed. No significant radiation exposures were noted. The maximum quarterly and maximum annual whole body exposures for 1984 were 170 mrem and 1500 mrem respectively. The maximum cumulative whole body radiation exposure for 1985 through May was 520 mrem.

The RSO conducts investigations of monthly exposures of greater than 40 mrem in a month. The ALARA investigation criteria is 125 mrem in a month.

(2) Surveys

a. Facility

The Radiation Safety Manual requires surveys to be conducted when 100 times the amount of activity listed in Appendix VI of the manual (equivalent to 10 CFR 30.71, Schedule B) are used either on a daily or weekly basis. Under this requirement surveys of the research laboratories would be required only on rare occasions such as when iodinations are performed. Laboratories using tritium or carbon-14 would not be required to conduct surveys unless activities of 100 millicuries or 10 millicuries respectively were used. However, in practice the licensee conducts surveys at least on a monthly basis of all laboratories.

Records of surveys conducted by the Nuclear Medicine Laboratory, RSO, and several randomly selected research laboratories were reviewed. Daily surveys of the Nuclear Medicine Laboratory had not been conducted on the following representative dates in 1985; April 22, 23, 26, 29, May 6, 7, 14 and 20, and June 3, 7. This was identified to be a repetitive violation.

This was identified as a violation.

b. Lost Seeds

The physician who removed the seeds from the patient also stated that he performed the required surveys. He stated that he did not survey the patient in the patient's room because of the "high background", but that he conducted a survey of the patient in the Ear-Nose-Throat (ENT) Room where he removed the catheters. The attending nurse did not recall seeing a survey instrument in the ENT room. However, there is a question of whether she knows what a

survey instrument looks like or whether she was in the room if and when a survey was made. The Assistant RSO stated that she used the same survey meter to make the survey of the patient's room on April 25, 1985 and the radiation levels in the room pegged the meter on the least sensitive (highest) scale. The radiation levels in the room was subsequently found to be due to a ribbon of five (5) seeds which was under the patient's bed. The fact that the physician did not conduct a proper survey was identified to be one item of the Severity Level III Violation.

The licensee subsequently conducted surveys in an effort to locate the missing seeds, but was unsuccessful. The location of the seeds is unknown. This is identified to be one item of the Severity Level III Violation.

A review of the areas that the licensee had covered in the surveys indicated that the coverage was thorough. However, certain areas that were not surveyed by the licensee, which the inspector considered should be surveyed, were subsequently surveyed by the inspector or by the licensee at the request of the inspector. The areas not surveyed previously by the licensee were; the patient's apartment and adjacent grounds where he worked; the vehicle used for transportation of the patient from the hospital to his home; the hospital food carts which were used to carry food trays to and from the patient's room; and the hospital's sewage drainage system such as sumps and catch basins.

Surveys of the patient's apartment and adjacent grounds where he worked were made by the inspector and licensee representatives on May 16, 1985. No radioactive material was found.

During the NRC inspection, surveys were conducted of the patient's room, the entire hospital wing (5E) in which the room was located; the corridors from the room leading to the exits from the hospital; randomly selected elevators; the balcony of the hospital wing; cafeteria dishwashing areas; hospital waste facility; the commercial biological waste service facility (W. D. Bingham, Inc.); and the area of the San Diego Sanitary Landfill where the waste from the hospital for that period was identified to be buried.

The RSO was requested to determine the feasibility of conducting a survey of the sewage drainage system from the hospital, i.e., determining the existence of locations where a survey of the sewer sumps and catch basins would be appropriate and practical considering attenuation.

The surveys conducted during the NRC inspection did not indicate the presence of the missing seeds. The

whereabouts of the missing ribbon with the four iridium-192 seeds is unknown at this time. Most probably it has been removed from the hospital as part of the non-radioactive waste and buried in the sanitary landfill. However, this remains but a hypothesis since there are no facts to substantiate it.

This was identified as a violation.

12. Personnel Protection - Internal

A. Thyroid Scan

Thyroid scans are conducted by the licensee on a periodic basis as a means of monitoring personnel exposure when iodine-125 or iodine-131 is used. The licensee conducts thyroid scans whenever any major iodination procedure is carried out. Regulatory Guide criteria is followed. Records of thyroid scans conducted were reviewed. No significant exposures were noted.

No violations were identified.

B. Bioassays

The license requires that bioassays be conducted weekly when 500 times the maximum permissible body burden (MPBB) of the isotope, or if greater than 100 millicuries of tritium is used in the laboratory. The use of 500 times the MPBB of isotopes other than tritium is rather conservative. According to the RSO, these limits have not been met so that there was no need to conduct bioassays.

No violations were identified.

C. Eating and Drinking in the Laboratories

Eating/drinking in the restricted areas is specifically prohibited by the licensee's Radiation Safety Manual, which has been incorporated into the license. During the walkthrough inspection, during lunchtime, the inspector observed drinking or evidence of drinking in some of the laboratories visited. This was identified to be a violation. Drinking was observed in Rooms 6022, 6058, 6069 and 6197. A cup and a coke was observed in Room 6202 including a hot beverage heater. A coffee cup and apricots were observed in Room 6122 and a cup filled with coke in Room 6124. Apricots and a cup where also observed in Room 6122.

It was noted that in a number of the laboratories inspected, the whole laboratory was designated a restricted area where only a small portion of the laboratory was actually used for working with licensed material. The designation of uncontrolled areas in such laboratories, when appropriate, was discussed with the RSO.

This was identified as a violation.

13. Effluent Controls, Waste Disposal

A. Disposal by Release into the Sanitary Sewer System

Some laboratories dispose of small quantities of liquid radioactive waste into the sanitary sewer. It was noted that the RIA Laboratory did not maintain records of such disposals to the sanitary sewer system.

This was identified as a violation.

B. Solid Radioactive Waste

All radioactive waste having short half lives are held for ten half lives, monitored, and were disposed of if the radiation levels are background. Solid radioactive wastes having long half lives are stored in 55 gallon drums and shipped to a waste burial ground via a waste broker and consultant. The licensee averages seven shipments of about 25 drums each per year. Records of disposals made and shipping papers were reviewed and found to be acceptable.

No violations were identified.

14. Posting of Notices

Postings in accordance with 10 CFR 19.11 were observed in the laboratories visited during the inspection.

No violations were noted.

15. Independent Inspection Effort

It is noted that the criteria for contamination established by the Radiation Safety Manual which is incorporated into the license is 11,000 dpm. Levels lower than 11,000 dpm may be considered uncontaminated. This criteria for contamination is excessively high and should be revised downwards. In practice, the licensee uses a much lower criteria for determining the presence or absence of contamination.

Recommendations for the improvement of the radiation safety program were given to and discussed with the RSO. The recommendations included the establishment of a master list of persons trained together with dates of training and retraining to control the effectiveness of the training program.

Contamination and radiation surveys were conducted in some of the laboratories visited. The contents of several of the laboratories inspected were also surveyed. A contaminated gauze and bottle were found in the non-radioactive trash container in the Nuclear Medicine imaging room. The contaminated gauze and bottle each measured approximately 150,000 dpm.

This was identified as a violation.

Licensee's actions taken on violations found on the last inspection of December 7-9, 1983

A. A laboratory containing licensed material was found open and unattended. This violation was also noted on this inspection. This remains an open item.

B. Surveys of the Nuclear Medicine Laboratory and certain research laboratories had not been conducted on occasions. This violation was also noted on this inspection. This remains an open item.

C. Records of receipt and transfer had not been maintained on one occasion. The licensee maintain records of receipt and transfer as required. This item is closed.

16. Conclusions

Based on the findings of this inspection, it appears that the licensee had taken appropriate actions in a timely manner to locate the missing seeds. The seeds were lost due to a lack of adherence to proper control procedures.

Deficiencies were found in the radiation safety program. Audits which are basic to the implementation of a good radiation safety program were not being conducted. The implementation of an audit program should hopefully serve to identify and correct deficiencies in the program.

The license should be amended to reflect current practice and standards where appropriate.

Medical Center
3350 La Jolla Village Drive
San Diego CA 92161

Veterans Administration

September 5, 1985

In Reply Refer To: 664/115
Your Reference
License 04-15030-01

US Nuclear Regulatory Commission
Region V
1450 Maria lane, Suite 210
Walnut Creek, CA 94596

Gentlemen:

This is in reply to your letter of August 9, 1985 concerning the NRC inspection of the VA Medical Center, 3350 La Jolla Village Drive, San Diego, California, 92161. The inspection was conducted by Mr. J. Frank Pang on May 15-16 and July 1-3, 1985, and dealt with activities authorized by NRC License No. 04-15030-01.

We have examined the items of noncompliance detailed in Appendix A of your letter. We are including in this communication: (1) the corrective steps which have been taken; (2) the corrective steps which will be taken in the future; and (3) the date when full compliance will be achieved.

We will consider each item of noncompliance separately and in the same order as in Appendix A of your letter.

Item A(1). License condition 20 states that the licensee shall possess and use licensed material in accordance with statements, representation, and procedures contained in the application dated July 5, 1980; and letters dated March 26, 1975 and March 3, 1983.

Section 6.61 of the Radiation Safety Manual states, in part, that radioisotopes requiring labels must be stored in areas under the control of the Radiation Safety Officer (RSO) and secured against unauthorized removal.

Contrary to the above requirement, on three separate occasions, licensed material requiring labels was not under the control of the RSO and secured from unauthorized removal as evidenced by the following:

a. A shielded container containing Iridium-192 seeds totaling approximately 47 mCi, was left unattended in the patient's room overnight on April 24, 1985.

b. A ribbon/catheter containing 5 Iridium-192 seeds of approximately 0.76 mCi each, was found by the assistant RSO underneath the patient's bed on April 25, 1985.

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c. A ribbon containing 4 Iridium-192 seeds was confirmed to be lost on May 1, 1985.

This particular item of noncompliance resulted because of a breakdown in the procedure for handling therapeutic implants. The medical center has decided to discontinue all implants procedures in this hospital until such times as a complete and thorough revamping of the procedure for doing such therapy can be arrived at and approved by the radiation safety committee. When the revamp procedure is approved, it will be forwarded to the Nuclear Regulatory Commission for their concurrence. As of this date we will be in compliance in matters concerning implants since we have discontinued this procedure here at the medical center.

Item A(2). License condition 20 states that the licensee shall possess and use licensed material in accordance with statements, representations, and procedures contained in the application dated July 15, 1980; and letters dated March 26, 1975 and March 3, 1983. In the application dated July 25, 1980 the licensee committed to an ALARA program which requires that management and the Radiation Safety Officer independently conduct annual audits of the Radiation Safety Program.

Contrary to the above requirements, at the time of the inspection, the annual audit had not been conducted since 1980.

This item of noncompliance will be corrected by instituting an audit generally following the procedure laid out in Appendix E of the US Nuclear Regulatory Commission Pamphlet NUREG-0267 Revision 1, "Principals and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably Achievable". Since our Radiation Safety Program is currently being heavily scrutinized and our manual changed to reflect the current condition of our Radiation Safety Program and since we have just undergone a rather thorough audit by the Nuclear Regulatory Commission, it was felt that the Radiation Safety Officer's audit should be conducted some time in the next three months with the audit by management being conducted within the next six months. This item of noncompliance has been thoroughly discussed in our radiation safety committee meeting and it is thoroughly understood that an annual audit by the Radiation Safety Officer as well as an annual audit by management should be conducted as soon as the program stablizes. Our plan for a completely updated manual calls for a completion date of January 1, 1986.

A(3) License condition 20 states that the licensee shall possess and use licensed material in accordance with statements, respresentations, and procedures contained in the application dated July 25, 1980; and letters dated March 26, 1975 and March 3, 1983.

Section 3.4.5(a) of the Radiation Safety Manual states that smoking, eating, or drinking in radioisotope laboratories is prohibited.

Contrary to the above requirement, on July 1, 1985 the inspector observed individuals drinking or evidence of drinking in rooms 6022, 6058, 6069, 6122, 6124, 6197, and 6202. Food was observed in room 6122.

This item of noncompliance is being aggressively addressed as indicated in the two enclosed memorandums from the acting hospital director and an additional memorandum issued by the Radiation Safety Officer. These procedures for aggressively penalizing violators is currently in place and we are confident that they are strict enough to bring us into total compliance on this particular item in the very near future.

A(4). License condition 20 states that the licensee shall possess and use license material in accordance with statements, representations, and procedures contained in the application dated July 25, 1980; and letters dated March 26, 1975 and March 3, 1983.

Section 6.61.1 of Radiation Safety Manual states, in part, that radioactive waste requiring (a) "radioactive materials" label must be secured against unauthorized removal. Section 3.30.8 of the Radiation Safety Manual establishes 11,000 DPM as the criterion for determining whether an item is considered to be radioactively contaminated and thus requires disposal in a properly labeled and secured container.

Contrary to the above requirements, at the time of the inspection a contaminated gauze and bottle was found in a non-radioactive trash container in the Nuclear Medicine imaging room which was not labeled or secured against unauthorized removal. The contaminated gauze and bottle each measured approximately 150,000 DPM. This item of noncompliance has been thoroughly discussed in the department meetings of the Nuclear Medicine Service. A procedure has now been established for monitoring the non radioactive trash before it is removed from the Nuclear Medicine Service. This system is already in place and as of this date we should be in complete compliance.

A(5). License condition 20 states that the licensee shall possess and use license material in accordance with statements, representations, and procedures contained in the application dated July 25, 1980; and letters dated March 26, 1975 and March 3, 1983.

Section 6.51 of the Radiation Safety Manual states that when unsealed quantities of activity exceeds 100 times those listed in Appendix VI of the manual (extracted from 10 CFR 30.71, Schedule B) are used in a single procedure, a survey shall be made by the user and the results recorded.

Contrary to the above requirements the nuclear medicine laboratory containing unsealed quantities of activities greater than 100 times the quantity specified in 10 CFR 30.71, Schedule B, had not been surveyed on the following representative dates in 1985; April 22, 23, 26, and 29, May 6, 7, 16, and 20, and June 3, 7.

This particular item of noncompliance was also discussed thoroughly in the department meetings of the Nuclear Medicine Service. New forms have been adopted which will make it more readily apparent that surveys were not completed. In addition, a procedure for a monthly audit of the necessary surveys has been instituted. Since this new system has already been installed, we should have an immediate improvement in this particular item starting as of this date.

A(6). License Condition 20 states the licensee shall possess and use licensed material in accordance with the statements, representation, and procedures contained in the application dated July 25, 1980; and letters dated March 26, 1975 and March 3, 1983.

In a letter dated March 26, 1975, the licensee states that the janitors on the research floor (6th) of the hospital will be instructed in the proper use of a G.M. survey meter to check bagged non-radioactive waste before transferring it to the hospital's center disposal area.

Contrary to the above requirements, at the time of the inspection, the janitors on the 6th floor had not been instructed in the proper use of a G. M. survey meter to check bagged non-radioactive waste.

This item of noncompliance is to be addressed by a procedure which will involve a designee of the Radiation Safety Officer being appointed to monitor the bagged non-radioactive waste before it will leave the 6th floor. Alternate designees will also be appointed to help with these surveys. Contrary to our letter of March 26, 1975, all the janitors on 6th floor will not be instructed in the proper use of a G. M. survey meter. The monitoring of bagged non-radioactive waste will be performed by these designees of the Radiation Safety Officer. This system of monitoring is now being put in place. It should be fully functional by the end of September.

A(7). License condition 20 states that the licensee shall possess and use licensed material in accordance with the statements, representations, and procedures contained in the application dated July 25, 1980; and letters dated March 26, 1975 and March 3, 1983.

Section 6.62 of Radiation Safety Manual and 10 CFR20.401(C)(3) requires that records be maintained of all liquid radioactive waste disposed into the sanitary sewer.

Contrary to the above requirement, at the time of the inspection the radioimmunoassay laboratory had not maintained records of sanitary sewer disposal.

A system for maintaining records of disposed radioactive waste into the sanitary sewers has now been put in place in the radioimmunoassay laboratory. As of this time we are in complete compliance with this particular item of noncompliance.

B(1). 10 CFR20.207(A) requires that licensed material stored in a non-restricted area be secured from unauthorized removal from the place of storage.

Contrary to the above requirements during a walk through inspection conducted on July 1, 1985, rooms 6122 and 6158 each contained licensed material and were found unlocked and unattended during the lunch hour.

Similar to Item A(3), this particular item of noncompliance is being aggressively addressed as indicated by the two memorandums enclosed

from the acting hospital director to investigators on the 6th floor along with a similar memorandum from the Radiation Safety Office. We feel that this aggressive treatment of these particular items should bring us into compliance within a very, very short time.

We have tried to take corrective steps on all the detailed items pointed out in Appendix A and, in addition, have accepted all the comments of the inspector in the constructive spirit that they were made, and we hope our action, as outlined above will adequately resolve the deficiencies noted. We feel that we are promptly implementing all the programs outlined above, and plan on reviewing the procedures and the results of their implementation in the near future to determine their effectiveness.

Sincerely yours,

for BARBARA A. SMALL
Medical Center Director

Enclosures: 4

cc: Director, Nuclear Medicine Service (115)
VACO
Regional Director, Western Region (10BA6)
VACO

I have read the enclosed memorandum of September 6, and have discussed it with all of my laboratory employees.

_____

Principal Investigator

Please sign this sheet and return it to the Radiation Safety Office.

Veterans Administration

Memorandum

Date: September 6, 1985
00:JP-sbw/X3911

To: All Supervisors with Responsibility for Supervising Radioactive Material

Subj:

1. The utilization of radioactive material is an integral part of the mission of this Medical Center, both from the point of view of our ongoing patient care responsibilities and in the area of medical research.

2. We are presently faced with a problem of considerable moment: the possibility that our Medical Center may no longer enjoy the privilege of utilizing radioactive material.

3. I have addressed this memorandum to a relatively small and senior group of individuals who are intimately aware of both the value of radioactive material and its potential for harm. You are similarly aware of the fact that radioactive material is carefully controlled by the Nuclear Regulatory Commission, an independent agency of the Federal government which is primarily responsible for the safe use and frequent monitoring of radioactive materials in this and other government facilities. This Medical Center is licensed by the Nuclear Regulatory Commission to possess and utilize radioactive material. The Commission uses a relatively involved series of procedures to measure our ability to safely handle this material. Briefly, irregularities, shortcomings and failures on our part to follow the rules of the Nuclear Regulatory Commission are cumulative in the sense that for each class of penalty, punishments progress from basically administrative to mandatory fines and loss of license. Since shortly after our activation we have been guilty of violations, which, if considered alone, would be relatively minor. But under the cumulative penalty system of the NRC, over the past decade we have reached the point at which any further violation, however, trivial, will lead to serious consequences, i.e., fines of up to $20,000 and/or loss of license and therefore shutdown of all activities utilizing radioactive materials.

4. In accordance with the foregoing, I must solicit, and in fact insist on, your cooperation in ensuring that appropriate local and NRC regulations are henceforth scrupulously followed. Our most recent violation pertains to the failure of several laboratories and work locations to maintain total security of radioactive materials, and also to scrupulously exclude food and drink from areas in which radioactive materials are used. Radioactive material, in any form, must be secured against unauthorized removal. Food and drink should never be found in controlled radioactive material areas. To accomplish this,

I must direct that each supervisor receiving this memorandum immediately take steps to meet with his/her staff and personally review the gravity of the situation with them. Secondly, and most importantly, each supervisor will establish failsafe procedures which address radiation safety issues for their work areas. Management is presently pursuing avenues of disciplinary and/or adverse action which can be taken against employees and their supervisors who fail to follow required precautionary procedures.

5. I would appreciate your rapid and full compliance with the foregoing instructions. In this connection, I have attached copies of a memorandum you should distribute to each employee with access to your rooms containing nuclear material. It also emphasizes the importance of this matter. Any questions concerning the above may be discussed with Dr. John Verba, Radiation Safety Officer.

C Parthemore

JACQUELINE PARTHEMORE, M.D.
Acting Medical Center Director

Veterans Administration

Memorandum

Date August 30, 1985
151:JWV-sbw/x3911

To All Investigators/Technicians Using Radioactive Material

Subj Enforcement of NRC Regulations

1. In an effort to enforce NRC regulations, random walk-through inspections of Research laboratories will be instituted. Rooms marked with radioactive material signs, found open and unattended at night, will be cited. During the day, if you are storing no radioactivity (i.e., trash, liquid waste, inventory), or if you have all your radioactive materials locked in a refrigerator, freezer or cabinet, and are not in the process of doing an open procedure, you may post a notice on your outer door stating that the lab is either free from radioactivity or that all radioactivity is secured against unauthorized removal during the daytime normal working hours only. Please sign and date this notice. A wipe test must be done prior to posting this notice. You will be required to show wipe test records. With such posting, doors may be left open and the room unattended. Without such a posting, rooms must be occupied when the door is open. This will apply only during the day. Random inspections will be made and violators cited. For the first violation, the lab will be closed and secured for one day. The second violation in a calendar quarter will result in a two-day closure. The third violation will result in a four-day closure. The fourth will result in an eight-day closure, etc.

2. Floors may be cordoned off with tape to designate controlled and non-controlled areas within your lab space. Notify Radiation Safety once your floors have been marked, so they can be checked. Specify which side of the line is controlled and which is non-controlled. Food or drink should never be found in controlled areas. Finding food or drink in controlled areas will constitute lab closure. Closure will increase in duration in the same manner as unattended lab closures.

3. Non-radioactive trash must be monitored before being removed from your lab area. Building Management will do the monitoring on the sixth floor. Labs using open radioactivity on other floors will be required to monitor their own trash. See Radiation Safety if you have any questions.

4. A log must be kept of all radioactivity that is poured down the drain. This log should include an estimate of the amount poured down the drain and a wipe test of the drain trap. This applies to wash water. Please continue to bring all other liquid waste to the centralized storage area - Room 6056. Radiation Safety will be glad to help you set up your log book.

5. Radiation Safety will begin auditing each laboratory's radiation safety compliance program. You are advised to review your records and procedures. Irregularities could constitute lab closure. See Radiation Safety personnel if you have any specific questions.

7. This memorandum will go into effect on September 6, 1985.

JOHN W. VERBA, Ph.D.
Radiation Safety Officer

Veterans Administration

Memorandum

Date: September 6, 1985
00:JP-sbw/X3911

To: Employees working in laboratories or spaces where nuclear material is
Subj: stored or utilized

1. I have recently directed a memorandum to your supervisor regarding serious deficiencies in our nuclear radiation control program at this Medical Center. I have asked your supervisor to discuss this problem with you and to explain fully the impact on this Medical Center of any future dereliction in our responsibility toward safeguarding of nuclear material. I have also directed your supervisor to establish specific procedures to be followed in insuring that nuclear material is always secure.

2. This is a matter of great concern to this Medical Center. We must insist on your full cooperation with all current regulations of the Nuclear Regulatory Commission and of this Medical Center. New procedures will be established in the days to come by your supervisor, to prevent future deficiencies. Please make certain that you are fully aware of these. Management is presently pursuing avenues of disciplinary and/or adverse action which can be taken against employees and their supervisors who fail to follow required precautionary procedures. With the Radiation Safety Committee, I plan to monitor the implementation of this program personally.

J Parthemore

JACQUELINE PARTHEMORE, M.D.
Acting Medical Center Director

VA FORM 2105
MAR 1980

APPENDIX A

NOTICE OF VIOLATION

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

Docket No. 030-08456
License No. 04-15030-01
EA 85-82

During an NRC inspection conducted on May 15-16 and July 1-3, 1985, violations of NRC requirements were identified. The violations include: (1) the loss of radioactive materials; (2) failure to survey areas in which radioactive materials are located or handled; (3) failure to conduct annual audits; (4) failure to maintain adequate records; (5) inadequate training; and (6) several examples of failing to comply with the requirements of the Radiation Safety Manual. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1985), the violations are listed below:

A. License Condition 20 states that the licensee shall possess and use licensed material in accordance with statements, representations, and procedures contained in the application dated July 25, 1980; and letters dated March 26, 1975 and March 3, 1983.

1. Section 6.61 of the Radiation Safety Manual states, in part, that radioisotopes requiring labels must be stored in areas under control of the Radiation Safety Officer (RSO) and secured against unauthorized removal.

   Contrary to the above requirement, on three separate occasions, licensed material requiring labels was not under the control of the RSO and secured from unauthorized removal as evidenced by the following:

   a. A shielded container containing iridium-192 sources totaling approximately 47 millicuries was left unattended in the patient's room overnight on April 24, 1985.

   b. A ribbon/catheter containing five iridium-192 seeds of approximately 0.76 millicuries each was found by the Assistant RSO underneath the patient's bed on April 25, 1985.

   c. A ribbon containing four iridium-192 seeds was confirmed to be lost on May 1, 1985.

2. In the application dated July 25, 1980 the licensee committed to an ALARA program which requires that management and the Radiation Safety Officer independently conduct annual audits of the radiation safety program.

   Contrary to the above requirement, at the time of the inspection, the annual audits had not been conducted since 1980.

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3. Section 3.40.5(a) of the Radiation Safety Manual states that smoking, eating, or drinking in radioisotope laboratories is prohibited.

   Contrary to the above requirement, on July 1, 1985, the inspector observed individuals drinking or evidence of drinking in Rooms 6022, 6058, 6069, 6122, 6124, 6197, and 6202. Food was also observed in Room 6122.

4. Section 6.61.1 of the Radiation Safety Manual states, in part, that radioactive waste requiring a "Radioactive Materials" label must be secured against unauthorized removal. Section 3.30.8 of the Radiation Safety Manual establishes 11,000 dpm as the criterion for determining whether an item is considered to be radioactively contaminated and thus requires disposal in a properly labeled and secured container.

   Contrary to the above requirements, at the time of the inspection, a contaminated gauze and bottle were found in the non-radioactive trash container in the Nuclear Medicine imaging room which was not labelled or secured against unauthorized removal. The contaminated gauze and bottle each measured approximately 150,000 dpm.

5. Section 6.51 of the Radiation Safety Manual states that when unsealed quantities of activity exceeding 100 times those listed in Appendix VI of the manual (extracted from 10 CFR 30.71, Schedule B) are used in a single procedure, a survey shall be made by the user and the results recorded.

   Contrary to the above requirement, the Nuclear Medicine Laboratory, containing unsealed quantities of activity greater than 100 times the quantities specified in 10 CFR 30.71, Schedule B, had not been surveyed on the following representative dates in 1985: April 22, 23, 26 and 29, May 6, 7, 14 and 20, and June 3, 7.

   This a repeat violation.

6. In the letter dated March 26, 1975, the licensee stated that the janitors on the research floor (6th) of the hospital will be instructed in the proper use of a G.M. survey meter to check bagged non-radioactive waste before transferring it to the hospital's central disposal area.

   Contrary to the above requirement, at the time of the inspection, the janitors on the sixth floor had not been instructed in the proper use of a G. M. survey meter to check bagged non-radioactive waste.

7. Section 6.62 of the Radiation Safety Manual and 10 CFR 20.401(c)(3) requires that records be maintained of all liquid radioactive waste disposed of into the sanitary sewer.

   Contrary to the above requirement, at the time of the inspection, the Radioimmunoassay Laboratory had not maintained records of sanitary sewer disposals.

B. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured from unauthorized removal from the place of storage.

Contrary to the above requirement, during the walkthrough inspection conducted on July 1, 1985, Rooms 6122 and 6158, each containing licensed material, were found unlocked and unattended during the lunch hour.

This a repeat violation.

Collectively, the above violations constitute a Severity Level III problem (Supplements IV and VI).

Pursuant to the provisions of 10 CFR 2.201, the Veterans Administration Medical Center, San Diego is hereby required to submit to this Office within 30 days of the date of this Notice, a written statement or explanation including for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, (3) the corrective steps which have been taken and the results achieved, (4) corrective steps which will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, the Director, Office of Inspection and Enforcement, may issue an order 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. Consideration may be given to extending the response time for good cause shown.

AUG 09 1985

Dated

AUG 05 1985

RSB

30-05456

License No. 04-15030-01

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

Attention: Norman E. Hensley
Medical Center Director (Acting)

Gentlemen:

This refers to the enforcement conference held with Mr. N. Hensley and his staff at the Veterans Administration Medical Center, San Diego, California on May 31, 1985. The conference was related to activities authorized by the NRC license listed above. Subjects discussed during that meeting are described in the report which is enclosed for your information.

No response to this letter is required. If you have questions concerning this report, please contact Mr. R. D. Thomas at 415-943-3700.

Sincerely,

/s/

Ross A. Scarano, Director
Division of Radiation Safety
and Safeguards

Enclosure:
Report No. 85-02

cc:
State of CA

bcc: RSB/Document Control Desk (RIDS)
Mr. J. Martin
LFMB

RV
RThomas
7/15/85

JMontgomery
7/15/85

for RScarano
7/15/85

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04-15030-01 PDR

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U. S. NUCLEAR REGULATORY COMMISSION

REGION V

Report No. 85-02

License No. 04-15030-01 Priority: 2 Category: G1

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

Facility Name: Same as above

Conference at: Same as above

Conference conducted: May 31, 1985

Participants: J. L. Montgomery 7/15/85
J. L. Montgomery, Chief Date Signed
Nuclear Materials Safety and Safeguards Branch

J. L. Montgomery for 7/15/85
R. D. Thomas, Chief Date Signed
Nuclear Materials Safety Section

Approved By: Paul Scarano 7/29/85
P. A. Scarano, Director Date Signed
Division of Radiation Safety and Safeguards

Summary:

Enforcement Conference on May 31, 1985 (Report No. 85-02)

The following matters were discussed:

1. The violations involving the loss of iridium 192 seeds and loss of control over licensed radioactive material.

2. NRC enforcement options.

3. NRC Concerns.

4. Licensee Management and radiation safety committee responsibilities.

The enforcement conference involved a total of two hours, utilizing two NRC representatives.

Enforcement Conference

DETAILS

1. Enforcement Conference Participants

J. W. Hollingsworth, Chief of Medicine VAMC
R. Moder, Acting Chief of Staff, VAMC
N. E. Hensley, Acting Director, VAMC
J. W. Verba, Radiation Safety Officer, VAMC
S. E. Halpern, Acting Chief, Nuclear Medicine, VAMC
F. T. Yates, Acting Associate Director
R. D. Thomas, US NRC Region V
J. L. Montgomery, US NRC Region V

2. Enforcement Conference

On May 31, 1985, an enforcement conference was held at the VAMC, San Diego, California with the individuals listed above participating. The enforcement conference was related to the safety inspection conducted at the VAMC, San Diego, California. The activities at this location are authorized by NRC License Number 04-15030-01. The inspection was conducted on May 15-16, 1985, by an NRC Region V inspector. The enforcement conference was announced in a letter to the licensee dated May 22, 1985. A copy of that letter is attached.

Mr. J. L. Montgomery, NRC, stated that the purpose of the enforcement conference was based upon the results of the special inspection which was conducted at the VAMC by an NRC Region V inspector following the loss of four iridium-192 therapy implant seeds. The two violations identified involved the lack of control over licensed radioactive material and it's subsequent loss. The need for strong participation on the part of management and the Radiation Safety Committee to control the overall licensed program was stressed as one of the most significant requirements in maintaining an acceptable radiological safety program.

Mr. R. D. Thomas, NRC, reviewed the past enforcement history of the licensee for the period June 1979 to December 1983. The two violations which were identified during the special inspection were discussed in detail. Mr. Thomas and Mr. Montgomery stressed the need for adequate training of personnel using licensed material, and the strict adherence to written procedures, and NRC regulations.

Dr. J. Verba and Mr. N. Hensley described the incident and the steps they and their staffs had taken to locate the missing iridium sources. Mr. Hensley stated that all therapy at VAMC with iridium 192 seeds would be halted until the incident had been fully investigated and recommendations made to prevent recurrence.

Mr. J. L. Montgomery, NRC, explained the enforcement policies and procedures of the NRC as published in 10 CFR 2, Appendix C. Copies of the enforcement policy were given to the licensee. Escalated enforcement actions such as civil penalties, orders to modify, suspend, or revoke a license, and orders to cease and desist were discussed. The relative significance of the different severity levels was explained.

In summary Mr. J. L. Montgomery, NRC, stated that any information submitted by the licensee would be given due consideration regarding the violations; however, a strong management and Radiation Safety Committee commitment will be expected in the licensed program to preclude future violations.

3. Conclusions

In addition to temporarily suspending further iridium seed implant therapy, the licensee indicated a review of VAMC policies and procedures would be made. Mr. N. Hensley indicated recommendations for improvement would be made to him and appropriate action would be taken.

3008456

SEP 27 1985

License No. 04-15030-01

Veterans Administration Medical Center
3350 La Jolla Village Drive
San Diego, CA 92161

Attention: Ms. Barbara A. Small
Medical Center Director

Gentlemen:

Thank you for your letter dated September 5, 1985 informing us of the steps you have taken to correct items which we brought to your attention in our letter dated August 9, 1985. Your corrective actions will be verified during our next inspection.

Your cooperation with us is appreciated.

Sincerely,
Original signed by
R. D. Thomas
James L. Montgomery, Chief
Nuclear Materials Safety and
Safeguards Branch

bcc w/letter dated 9/5/85:
RSB/Document Control Desk (RIDS)
State of CA
Mr. Martin

PANG/dot	THOMAS	MONTGOMERY
9/25/85	9/26/85	9/26/85

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FSR

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CALIFORNIA 94596-5368

JUL 25 1989

License No. 04-15030-01

Veterans Administration
3350 La Jolla Village Drive
San Diego, California 92161

Attention: Thomas Trujillo
Medical Center Director

Gentlemen:

Subject: NRC Inspection

This letter refers to the routine safety inspection conducted by Messrs. James Montgomery and Paul Zurakowski of this office on June 19-21, 1989, of activities authorized by NRC License No. 04-15030-01 and to the discussion of our findings held by the inspectors with members of your staff following the inspection on June 21, 1989.

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector.

Based on the results of this inspection, it appears that one of your activities was not conducted in full compliance with NRC requirements, as set forth in the Notice of Violation enclosed as Appendix A to this letter. This item has been categorized into a severity level as described in the NRC Enforcement Policy, 10 CFR Part 2, Appendix C. (1988).

Your response to this Notice is to be submitted in accordance with the provisions of 10 CFR 2.201 as stated in Appendix A, Notice of Violation.

The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL-511.

If you have any questions on this matter or concerning this inspection, we will be glad to discuss them with you.

Sincerely,

Robert J. Pate

Robert J. Pate, Chief
Nuclear Materials Safety and
Safeguards Branch

A/12

Enclosures:
1. Appendix A, Notice of Violation
2. Inspection Report No. 030-~~15030-01~~/89-01

~~8907280355~~ 890725 08456
REG5 LIC30
04-15030-01 FDC

IE05

bcc w/copy of enclosures:
Docket File
G. Cook
B. Faulkenberry
J. Martin
A. Johnson
State of California

bcc w/o copy of enclosure 2:
M. Smith
J. Zollicoffer

REGION V/joan			
PZurakowski	RThomas	AJohnson	RJPate
7/24/89	7/24/89	7/25/89	7/25/89
REQUEST COPY	REQUEST COPY	REQUEST COPY	REQUEST COPY
YES / NO	YES / NO	YES / NO	YES / NO

SEND TO PDR
YES / NO

APPENDIX A

NOTICE OF VIOLATION

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

Docket No. 030-08456
License No. 04-15030-01

During an NRC inspection on June 19-21, 1989, one violation of an NRC requirement was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1988), the violation is listed below:

A. 10 CFR 20.401(b) provides, in part, that each licensee shall maintain records in the same units used in Part 20, showing the results of surveys required by 10 CFR 20.201(b), and disposals made under 10 CFR 20.302 and 20.303. 10 CFR 20.5 provides that radioactivity levels evaluated as a result of surveys completed by licensees are to be measured in units of disintegrations per unit time or in curies.

Contrary to the above requirement, at the time of the inspection, contamination survey results had been recorded in counts per minute (CPM) rather than in disintegrations per unit time or activity units (microcuries).

This is a Severity Level V violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, V. A. Medical Center, San Diego is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region V within 30 days of the date of the letter transmitting this 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 if admitted, (2), the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be achieved. If an adequate reply is not received within the time specified in this Notice, an order 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. Consideration may be given to extending the response time for good cause shown.

FOR THE NUCLEAR REGULATORY COMMISSION

Robert J. Pate

Robert J. Pate, Chief
Nuclear Materials Safety and
Safeguards Branch

Dated at Walnut Creek, California
this 25th day of July, 1989.

U. S. NUCLEAR REGULATORY COMMISSION

REGION V

Report No. 89-01

Docket No. 030-08456

License No. 04-15030-01

Licensee: V. A. Medical Center
3350 La Jolla Village Drive
San Diego, California 92161

Inspection at: San Diego, California

Inspection Conducted: June 19-21, 1989

Inspector: P. R. Zurakowski — 7/24/89
P. R. Zurakowski, Radiation Specialist — Date Signed

Inspector: B. A. Ridlinger for — 7/24/89
J. L. Montgomery, Senior Materials Specialist — Date Signed

Approved by: B. A. Ridlinger for — 7/24/89
R. D. Thomas, Chief — Date Signed
Nuclear Materials Safety Section

Inspection of June 19-21, 1989 (Report No. 030-08456/89-01).

Areas Inspected: This was a special unannounced team inspection to examine and assess the overall effectiveness of the radiation safety program. The areas examined included: organization, audits, training, radiation protection procedures, use of licensed material, instrumentation, transportation, personnel radiation protection, waste disposal and required postings and labeling.

The period reviewed was from the date of the last inspection on May 18-19, 1988 to the date above.

Results: One apparent violations was identified during the inspection and is summarized as follows:

A. Contrary to 10 CFR 20.401(b), contamination survey results were recorded in counts per minute rather than in disintegrations per minute or activity units (microcuries).

DETAILS

1. Persons Contacted

*J. Parthemore, Chief of Staff
T. Trujillo, Medical Center Director
*F. Fiscella, AA/Chief of Staff
*J. Verba, Radiation Safety Officer (RSO)
*D. Whorley, AO/Research
J. Mathews, Radiation Safety Technologist
*T. Yates, Acting Associate Director
M. Delaney, Secretary
*S. Halpern, M.D., Chief, Nuclear Medicine
P. Hagan, Radiopharmacist
G. Greenspan, M.D., Nuclear Medicine
R. Burkes, Chief Nuclear Medicine Technologist

*Present at the exit meeting.

2. Organization

The VAMC licensed program consisted of the Nuclear Medicine Department and the Research Division. The latter had forty-six principal investigators and about 275 laboratory technologists. The Nuclear Medicine Department consisted of four physicians, one radiopharmacist and five technologists.

The Radiation Safety Office consisted of the RSO, Assistant RSO and one secretary.

3. Training

New employee orientation training in radiation safety consists of a thirty minute lecture given by the RSO. Refresher training is given annually by the RSO or principal investigator during the annual audit. Ancillary personnel training was conducted through the Building Management Office. Training records were reviewed by the inspector and found to be complete. The inspector also questioned several laboratory workers about the adequacy and timeliness of their training.

No apparent violations were identified.

4. Radiological Protection Procedures

The Inspectors reviewed the licensee's conduct of procedures for emergencies, ordering and receiving licensed material, laboratory rules, and surveys. These procedures were being adequately followed by the licensee. Staff personnel also demonstrated sufficient understanding of the procedures when interviewed by the Inspectors during a tour of the facilities.

Measurements made by the Inspector in the patient rest room adjacent to the Nuclear Medicine area disclosed that a waste basket was reading in excess of 2500 disintegrations per minute on the Inspector's GM survey instrument. The container was not marked to identify that it contained radioactive material. However, the licensee routinely surveyed nonradioactive trash prior to incineration making release to unrestricted areas unlikely. Nevertheless, in the interest of ALARA, the trash container should be labelled to preclude accidental release to unrestricted areas.

The inspector also noted a deficiency in the record keeping associated with required weekly wipe tests. It was noted by the inspectors that many records were maintained in units of counts per minute per 100 cm^2 instead of the required disintegrations per minute per 100 cm^2 or mrem/hour. This was an apparent violation of 10 CFR 20.401(b).

One apparent violation was identified.

5. Use of Licensed Material

The licensee's facilities had not changed significantly since the last inspection conducted on May 18-19, 1988. Essentially, they were the same as described in the application dated August 1, 1986. However, the licensee's program was found to be significantly improved. All violations and items of concern identified during the last inspection were adequately addressed and/or corrected. Management's knowledge and control of the licensed program as exercised through a strong Radiation Safety Committee (RSC) were found to be key elements in the improvement.

The Nuclear Medicine Department followed required procedures and regulations for the use of diagnostic materials, leak testing, syringe and vial shields and sealed source inventories. The licensee performed adequate linearity and accuracy tests as required for the dose calibrator. Daily constancy checks were also performed as required. The required molybdenum-99 breakthrough test has been performed after each milking of the generator. The Radiopharmacist performs this test. In his absence a qualified Nuclear Medicine Technologist has been trained for the task.

A nuclear medicine research laboratory survey and radiological safety program was found to be greatly improved through strong intervention of the Radiation Safety Technologist, the RSO and the RSC. No serious health physics or security problems were noted by the inspectors during a tour of the research facilities.

No apparent violations were identified.

6. Instrumentation

The licensee's radiation detection instrumentation used in the nuclear medicine program was adequate to accurately measure the kinds and amounts of radioactive material used. A review of the calibration records and an examination of the instruments encountered during a tour of the

facilities disclosed that the instruments were being calibrated in a timely manner and those examined were operational.

No apparent violations were identified.

7. Personnel Protection

A. External

The license utilizes the Radiation Detection Company for a monthly film badge program and TLD finger badge. Maximum quarterly whole body and extremity exposures were observed to be about 100 and 400 mrems respectively. No exposures exceeding 25% of the maximum permissible limit had occurred since the last inspection.

B. Internal

The licensee's procedures included, in part, that thyroid scans be conducted on medical personnel within 6-72 hours subsequent to their administering of therapeutic doses of iodine-131 or working with 10 mci or more of iodine-125 in unbound form. It was determined that thyroid scans had been conducted as required on personnel assaying and administering the therapeutic doses of iodine-131 or working with unbound iodine-125.

No apparent violations were identified.

8. Required Postings

Inspection of all the licensee laboratories, treatment rooms and storage areas revealed that radiation caution signs, notices to employees and emergency procedures were posted as required. Copies of the license, regulations and safety procedures were identified to employees as being on file and available for review upon request.

No apparent violations were identified.

9. Effluent Controls, Waste Disposal

Liquid radioactive waste having short radiological half lives was held for decay for a minimum of ten half lives and monitored and disposed of if the radiation levels were not above background. The licensee had a dedicated disposal sink on the sixth floor where liquid waste was stored prior to disposal. This area was found to be well secured against unauthorized entry. The liquid waste was found to be stored in clearly marked plastic bottles which indicated the date they were placed into storage. When the required decay period was completed, the Radiation Safety Technologist poured the liquid down the sink with an appropriate note in the log. If it was necessary to dispose of longer lived liquid waste in the sink, an entry was made in the log indicating the amount of activity disposed of in this manner. Care was taken not to dispose of more activity than the yearly regulatory limit. An examination of the records by the inspector disclosed that no regulatory limit was exceeded and that records of disposal were maintained. An independent

contamination measurement by the Inspector of a representative portion of the storage rack and floor area disclosed no significant contamination.

The solid waste storage area was also inspected. Although the 55 gallon drums were found to be stacked in a manner leaving little room to move about in the rather small storage room, no violations of good security or health physics practices were noted. Records of disposal were found to be maintained as required.

No apparent violations were identified.

10. Transportation

Several times a year a local broker is used to transport the solid waste to a licensed disposal facility. For the last several years the brokers used have been either Pacific West Nuclear or Thomas Gray and Associates. Appropriate D.O.T. packaging and labeling requirements were observed during these shipments. It was verified that proper shipping papers were prepared for each shipment since the last inspection.

No apparent violations were identified.

11. Independent Measurements

Because I-125 was widely used in research activities and iodination studies were performed frequently, independent measurements were made in the Iodination Laboratory and on the roof where discharges from the Iodination Laboratory hood occurred. The discharge stack was not filtered. A survey instrument with a sodium iodide probe specifically calibrated for I-125 was used by the Inspector. No readings above background were found in the vicinity of or on the discharge stack. One "hot spot" of approximately 350 disintegrations per minute was found by the inspector inside one of the Iodination Laboratory Hoods. The Radiation Safety Technologist commented that this small amount of contamination was probably left by the last researcher to use the laboratory on June 15, 1989, and that he would check into why the spot had not been cleaned up. Although this small amount of contamination was above the licensee's 200 CPM "cleanup limit", there was no evidence that the laboratory was used in an irresponsible manner. The log for the laboratory and the weekly surveys appeared to be properly maintained. Administrative controls on the use of the laboratory appeared to be adequate.

No apparent violations were identified.

12. Exit Meeting

The exit meeting was held on June 21, 1989. The one apparent violation was discussed. The inspectors noted significant improvements in the performance of radiation safety oversight by the Radiation Safety Committee.

Medical Center

3350 La Jolla Village Drive
San Diego CA 92161

Veterans Administration

August 14, 1989

In Reply Refer To: 664/115

United States Nuclear Regulatory
Commission
Attn: Document Control Desk
Washington, D.C. 20555

RE: Reply to a notice of violation found during a Nuclear Regulatory Commission inspection held on June 19th through June 21st, 1989 of the Broad Scope Product Materials License for the Department of Veterans Affairs Medical Center, San Diego - Docket #030-08456 - License #04-15030-01

Dear Sirs:

As was pointed out in your notice of violation to the Department of Veterans Affairs Medical Center, San Diego, 10 CFR 20.401 (b) provides, in part, that each licensee shall maintain records in the same units used in Part 20, showing the results of surveys required by 10 CFR 20.201 (b), and disposals made under 10 CFR 20.302 and 20.303. Federal law 10 CFR 20.5 provides that radioactivity levels evaluated as a result of surveys completed by the licensees are to be measured in units of disintegrations per unit time or in curies.

At the time of this inspection, we were aware of the above requirement and also aware that some investigators and some portions of our program were not in compliance. At the time of the NRC visit, we had already completed over 80% of the annual audits of the individual investigators and clinical uses. During these audits, we specifically were checking for compliance with the above requirement and instituted corrections when non-compliance was observed. Since the NRC visit, we have completed all but one of these annual audits. The one program that remains unaudited is, however, in compliance with this regulation.

At this time, all of our investigators and clinical programs have been advised of the need for expressing monitoring results in the proper units. In the very near future, we will make another pass to our investigators to assure their continuing compliance.

In addition to the above counseling of our various users, which should take care of the problem, we hope to shortly introduce standardized wipe tests forms for use throughout our medical center. These standardized forms should make auditing more convenient; and, in addition, encourage continual compliance with the above regulations.

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U.S. Nuclear Regulatory Commission
Attn: Document Control Desk

In conclusion, we were aware of some difficulties in complying with the above requirements. We were, at the time of your inspection, in the process of correcting this problem. Since your visit, we have finished the institution of what we hope will be an adequate correction. Finally, in the future, we have plans for an even more thorough sclution to the problem.

If you have any questions or concerns about our shortcomings under your notice of violation, please contact us immediately.

Sincerely,

Thomas A. Trujillo
Medical Center Director

cc: Regional Administrator
Region V, Suite 210
U.S. Nuclear Regulatory Commission
1450 Maria Lane
Walnut Creek, CA 94596

James Fletcher, M.D.
Director of Nuclear Medicine (115)
VA Central Office
Washington, D.C. 20420

SEP 12 1989

Docket No. 030-08456

Veterans Administration Medical Center
3350 La Jolla Village Drive
San Diego, CA 92161

Attention: Thomas A. Trujillo
Medical Center Director

Thank you for your letter of August 14, 1989, in response to our Notice of Violation and Inspection Report No. 89-01, dated July 25, 1989, informing us of the steps you have taken to correct the items which we brought to your attention. Your corrective actions will be verified during a future inspection.

Your cooperation with us is appreciated.

Sincerely,

Original Signed

Robert J. Pate, Chief
Nuclear Materials Safety and
Safeguards Branch

bcc w/copy of letter dated 8/14/89:
docket file
State of California
A. Johnson
G. Cook
B. Faulkenberry
J. Martin
J. Zollicoffer
M. Smith

REGION V		
~~AJohnson~~	JLMontgomery	RJPate
9/~~X~~/89	9/12/89	9/12/89

REQUEST COPY] YES / NO]	REQUEST COPY] YES / NO]	REQUEST COPY] YES / (NO)]

(SEND TO PDR] YES) / NO]

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RE35 LIC30
04-15030-01 PDC

NRC Form 591
(12-81)
10 CFR 2.201

U. S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION

1. LICENSEE	2. REGIONAL OFFICE
Veterans Administration Medical Center 3350 La Jolla Village Drive San Diego, CA 92161	RECEIVED NRC U. S. Nuclear Regulatory Commission Region V 1450 Maria Lane, Suite 210 Walnut Creek, CA 94596

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE OF INSPECTION
030-08456	04-15030-01	April 12-13, 1990

Licensee

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission's (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews, with personnel and observations by the inspector. The findings as a result of this inspection are as follows:

☐ 1. Within the scope of this inspection, no violations were observed.

☒ 2. The inspector also verified the steps you have taken to correct the violations identified during the last inspection. We have no further questions on those actions at this time.

☒ 3. During this inspection certain of your activities, as checked below, were in violation of NRC requirements. THIS IS A NOTICE OF VIOLATION which is required to be posted in accordance with 10 CFR 19.11.

☐ A. _____ was not properly posted to indicate the presence of a _____. 10 CFR 20.203(b), (c), (d), (e) or 34.42

☐ B. Containers located in _____ were not properly labeled to indicate the presence of radioactive material. 10 CFR 20.203(f)(1), or (f)(2).

☐ C. _____ of sealed sources were not performed at the proper frequencies. 10 CFR _____ License Condition Number _____

☐ D. Records of Surveys For I^{131} Contamination in Rm. 3E/A,3223, on 10/6/89 10 CFR 35.70(h) were not properly maintained or License Condition Number _____

☐ E. Documents were not properly posted or otherwise made available. 10 CFR 19.11.

☐ F. Reports or notifications of _____ were not made in accordance with 10 CFR _____ or License Condition Number _____

☐ H. _____

☐ I. _____

☐ J. ~~9005220020~~ 900412 REG5 LIC30 04-15030-01 PDC

☐ K. _____

I hereby state that within 30 days the actions described by me to the inspector will be taken to correct the violations identified in the items checked above. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201. No further response will be submitted unless required by the NRC.

SIGNATURE - LICENSEE	DATE	SIGNATURE - NRC INSPECTOR	DATE
[signature]	4/13/90	James L. Montgomery	4/13/90

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IE07011

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V
1450 MARIA LANE, SUITE 210
WALNUT CREEK CALIFORNIA 94596

NOV 1990

Report No. 90-02
Docket No. 030-08456
License No. 04-15030-01

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

Attention: Thomas Trujillo
Medical Center Director

Gentlemen:

SUBJECT: NRC INSPECTION

This letter refers to the special safety inspection conducted by Messrs. J. Montgomery of this office and G. Power of the Office of Investigation during September 26-28, 1990, of activities authorized by NRC License number 04-15030-01. The findings of this inspection were discussed with you and Dr. J. Verba during the exit briefing at your office on September 28, 1990.

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and records, interviews with personnel and observations by the inspector which related to the unauthorized use and transfer of licensed material.

During this inspection, activities related to the unauthorized use and transfer of licensed material and training were found to be in violation of NRC requirements. These violations, described in the enclosed inspection report, 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. Your internal investigation of the unauthorized use and transfer of licensed material which identified the violations was also reviewed during this inspection.

If you have any questions concerning this inspection, please contact Mr. Jim Montgomery of my staff at 415-943-3778.

Sincerely,

Robert J. Pate

Robert J. Pate, Chief,
Nuclear Materials and Fuel
Fabrication Branch

Enclosure:
Inspection Report No. 030-08456/90-02

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NOV - 6 1990

bcc w/enclosure:
docket file
inspection file
State of California
G. Cook
B. Faulkenberry
J. Martin

bcc w/o enclosure:
M. Smith
J. Zollicoffer

REGION V/dot
JIMontgomery
10/23/90

RJPate
10/26/90

REQUEST COPY] REQUEST COPY]
YES / NO] YES / NO]

SEND TO PDR]
YES / NO]

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 he 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 RSC 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.