



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V

SUITE 202, WALNUT CREEK PLAZA
1990 N. CALIFORNIA BOULEVARD
WALNUT CREEK, CALIFORNIA 94596

INSPECTION REPORT NO. _____

Veterans Administration Hospital
W. Ingle and Sawtelle Blvds
Los Angeles, CA 90073

Telephone No: _____

Attached

- ☐ Appendix A
☐ Appendix B
☒ Appendix C
☐ Memo

License No. 04-00181-04 Last amendment & date: #69, Nov 8, 1976

Category: G-1 & Priority: 3, as of last amendment.

Inspection date(s): 26 April 1978 Type of inspection: unannounced

SUMMARY OF FINDINGS AND ACTION

- | | |
|---|---|
| <input checked="" type="checkbox"/> No noncompliance, clear 591 | <input type="checkbox"/> Noncompliance, 591 issued |
| <input type="checkbox"/> Noncompliance, Appendix A | <input type="checkbox"/> Regional action <input type="checkbox"/> HQ action |
| <input type="checkbox"/> Action on previous n/c, App B | <input type="checkbox"/> Supplemental info, App C |

RECOMMENDATIONS

See basis in Appendix C or attached memo.

- ☐ Change Category to: — ☐ Change Priority to: —
☐ Next inspection date: April 1980

PERSONS CONTACTED

L.W. Wetherov, RSO, Medical Physicist
W.H. Bland, Chief Nuclear Medicine Service
Peggy Joe, PhD, Radiopharmist
Jeff Stone, Physical Science Technician

Inspector: Paul R. Zimkowski

Approved: Steve Book

30 May 1978

6/6/78

Plan approved: _____ Date: _____

Licensee: VA Hospital, LALicense no: 04-00181-04

Inspection Items	Scheduled for inspection	Post-inspection status	Module no.	766 Time Info
Management meeting - Entrance and Exit Interviews [REQUIRED]	✓		30703B	1
Initial Management Meeting				
Program requirements, MC 28 [REQUIRED]	✓		78710B	5
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
Inspector Dispatched to Site			93700B	
Followup on Significant Event Occurring During Inspection			93701B	

AREAS INSPECTED AND FINDINGS

Licensee: V.A. Hagg + 1, L.A. License no: 07-0181-04 Amendment no: 69

INSPECTION ITEMS	CRITERIA	FINDING
1. <u>Organization</u>		<u>OK</u>
Structure of organization as described in requirements?	Lic Cond _____	
NOTES & REMARKS: The organizational structure remains essentially as described in the last inspection report. A Physical Science Technician has been hired to help the RSO. A Radiation Protection Technician also works for the RSO part time. Dr. W.H. Blahd remains Chief of Nuclear Medicine. Dr. M.H. Winston has been named Assistant Chief of Nuclear Medicine.		
2. <u>Licensee internal audits</u>	Lic Cond _____	<u>OK</u>
Scope and frequency of audits as required?	yes	
Conducted by appropriate persons? Records maintained? Reviewed by management?	yes	
Deficiencies identified & corrected?	yes	
NOTES & REMARKS: Now that the RSO has been given significant help to implement his program, he has much more time to get personally involved in an internal audit program.		
3. <u>Training and qualification of personnel</u>	Lic Cond _____	<u>OK</u>
Training & retraining conducted as required?	yes	
Written & oral exams conducted? Examination results reviewed by management?	yes	
Instructions to workers per 19.12?	yes	19.12
NOTES & REMARKS: The Hospital has an outstanding training program for Residents in Nuclear Medicine, Radiation Protection & Technologists. The RSO has become a very skilled instructor in the area of Health Physics and his services are in great demand at other VA Hospitals as a consultant.		
4. <u>Radiation protection procedures</u>	Lic Cond _____	<u>OK</u>
Procedures available and implemented? Identify radiopharmaceutical and dose(s)? Cover handling of patients receiving therapeutic doses? Cover handling of cadavers?	yes	
Emergency procedures for spills, etc? Personnel understand procedures?	yes	
NOTES & REMARKS: The RSO stated that the Radiation Protection Procedures authorized by the current license is issued to all qualified users of licensed material.		

AREAS INSPECTED AND FINDINGS

Licensee: V.A. Hospital, L.A.License no: OK-00181-04 Amendment no: 69

INSPECTION ITEM	CRITERIA	FINDING
5. <u>Use of materials</u>	Lic Cond _____	<u>OK</u>
Procurement and use as required? <u>yes</u>		
Special tests (moly breakthrough, leak tests, etc) required? <u>yes</u>		
Dose calibration checks performed? <u>yes</u>		
Posting & labeling as required? <u>yes</u>	20.203	
NOTES & REMARKS: All purchases of licensed material must be authorized by either the chief of Nuclear Medicine or by the RSC. A full time Nuclear Pharmacist (Ph.D.) was available in new facility with the most modern equipment. She performs all required test which includes opening and checking all incoming radionuclides.		
6. <u>Storage of materials</u>		<u>OK</u>
Material secured in both restricted and unrestricted areas? Adequately? <u>yes</u>	20.207	
NOTES & REMARKS: Most incoming radionuclides are stored in the Radio-pharmacy under lock and key until needed. The storage facilities are among the most modern available.		
7. <u>Facilities</u>	Lic Cond _____	<u>OK</u>
As described in lic cond or application? <u>yes</u>		
Any changes made? Adequacy? <u>yes</u>		
NOTES & REMARKS: The licensee has moved into a new facility since the last inspection. The facilities are among the finest and best equipped in the country. One of the fine equipment, the licensee possesses a whole body counter shielded with pre World War II Battleship steel.		
8. <u>Instruments</u>	Lic Cond _____	<u>OK</u>
Survey meters & instruments adequate for program? <u>yes</u>		
Instruments & meters operable? Calibrated? <u>yes</u>		
Calibration adequate? <u>yes</u>		
NOTES & REMARKS: Calibration is performed yearly by Technical Associates. The hospital has a remote area monitoring system with four detectors in one patient waiting room. The monitor is in the RSO's office.		

AREAS INSPECTED AND FINDINGS

Licensee: V.A. Hospital, L.A. License no: 04-10181-04 Amendment no: 69

INSPECTION ITEMS	CRITERIA	FINDING
<u>9. Receipt and transfer of material</u>		<u>OK</u>
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? 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: The material is received by the Hospital's nuclear pharmacist. The nuclear pharmacist stated that she had not received a leaking package since the last inspection. She also stated that the measurements received were the quantities indicated during this same time interval.		
<u>10. Personnel protection - external</u>		<u>OK</u>
Personnel monitoring controls adequate?	yes 20.101, 20.202	
Exposures minimized?	yes	
Exposure records (NRC-4 or 5) maintained?	yes 20.102(b), 20.401(a)	
Available for employee review?	yes	
Surveys conducted? Adequate?	yes 20.201	
Records of monitoring, surveys?	yes 20.401	
Levels in unrestricted areas within limits?	yes 20.1, 20.105	
NOTES & REMARKS: The licensee utilizes a monthly film badge program from Radiation Detection Company of Sunnyvale, Ca. The exposures were quite low. The nuclear pharmacist had the high quarterly exposure of 110 mrem.		
<u>11. Personnel protection - internal</u>		<u>OK</u>
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?	yes 20.201 yes 20.401	
NOTES & REMARKS: The licensee possesses a Xe Monitor made by Technical Associates. The licensee has had no problems with their Xe equipment. Bioassays for H-3, C-14 and I-125 are performed monthly on high risk researches (at 15-25 µm month). Exposures were very low.		

AREAS INSPECTED AND FINDINGS

Licensee: V. A. Hospital - L.A. License no: 04-00181-04 Amendment no: 69

INSPECTION ITEM	CRITERIA	FINDING
12. Effluent controls, waste disposal		<u>OK</u>
Release of effluents controlled?	yes 20.105, 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 has a storage building used only for the storage of radioactive waste. The services of Industrial Trucking, Inc. (providing Cool Salvage) are utilized for waste disposal. Approximately 115-20 55 gallon drums are shipped per quarter.

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

NOTES & REMARKS: The RSO stated that there has been no theft or loss of licensed material since the last inspection.

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

NOTES & REMARKS: All Part 19 posting requirements were noted to be posted in several areas in the Hospital.

15. Other license conditions	Lic	<u>OK</u>
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Condition 18 requires bioassay for H-3 when quantities greater than 100 mCi are handled. The RSO performs and evaluates these and other bioassays (C-14 & I-125). No overexposures were noted during a review of the bioassay records.

AREAS INSPECTED AND FINDINGS

Licensee: _____ License no: _____ Amendment no: _____

INSPECTION ITEMS	CRITERIA	FINDING
16. <u>Confirmatory measurements</u>		<u>—</u>

none

17. Independent inspection effortOK

A two hour tour of the facilities was made. The Radiopharmacist and several technicians were questioned about the safety aspects of their jobs. They all appeared quite knowledgeable in this area. No violations of good health physics practices were noted during this tour.

18. Incidents and eventsOK

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

The RSO and Radiopharmacist both stated that they have had no problems of this nature since the last inspection.

APPENDIX C - SUPPLEMENTARY INFO

Licensee: VA Hospital - LALicense no: 07-00151-04☐ Uncorrected/repeated noncompliance☐ Unresolved items☐ Unusual occurrence, conditions, etc☒ Inspector's comments☐ Basis for change of Category or Priority

The licensee material on hand at the time of the inspection was:

<u>Radioisotope</u>		<u>Millicuries</u>
^3H - as labeled compounds	-	177.477
^{14}C - as labeled compounds	-	21.179
^{22}Na - as labeled compounds	-	0.410
^{32}P - as labeled compounds	-	13.000
^{36}Cl - as labeled compounds	-	0.200
^{45}Ca - as labeled compounds	-	4.000
^{51}Cr - as labeled compounds	-	5.875
^{54}Mn - as labeled compounds	-	0.300
^{57}Co - as labeled compounds	-	0.006
^{63}Ni - as labeled compounds	-	11.0
$^{99\text{m}}\text{Tc}$ - as labeled compounds	-	150.000
^{125}I - as labeled compounds	-	10.205
^{131}I - as labeled compounds	-	17.000
^{111}In - as labeled compounds	-	1.000
^{113}In - as labeled compounds	-	25.000
^{35}S - as labeled compounds	-	0.2

(over)

Rad. isotopeM. H. curies

^{67}Ga - as labeled compounds	-	4.000
^{201}Tl - as labeled compounds	-	1.600
^{75}Se - as labeled compounds	-	2.000
^{133}Xe - as gas	-	10.000
^{125}I - Norland sealed source	-	200.000
^{63}Ni - Hewlett Packard G.C. sources	-	2 X 15.000
^{90}Sr - Radiochem. Center M-SLC-7 Source	-	10.000
^{90}Sr - Ophthalmic Eye Therapy source	-	24.000
^3H - Varian G.C. source	-	150.000

APPENDIX C - SUPPLEMENTARY INFO

Licensee: _____

License no: _____

☐ Uncorrected/repeated noncompliance☐ Unresolved items☐ Unusual occurrence, conditions, etc☒ Inspector's comments

☐ Basis for change of Category or Priority *The procedures carried out in FY 1977 are as follows:*

<u>Radiopharmaceutical</u>	<u>3.1</u> No. of Patients	<u>3.2</u> No. of Tests or Images
131-Iodine Iodide	368	1394
IHSA	10	10
Rose Bengal	5	15
Hippurate	640	1280
123-Iodine	342	1026
99m-Technetium Pertechnetate	12	29
Sulphur Colloid	1082	9608
MAA	734	2936
DTPA	4231	16,035
Pyrophosphate	933	10,193
DMSA	32	48
HIDA	36	174
51-Chromium Sodium Chromate	16	16
Albumin	5	5
111-Indium Bleomycin	13	48
DTPA	342	684
57-Cobalt Vitamin B12	67	134
133-Xenon	191	1528
75-Selenomethionine	3	6
67-Gallium	803	2766
201-Thallium	160	1244

3.3 Number of in vitro tests done for each radiopharmaceutical used:

<u>Radiopharmaceutical</u>	<u>No. of tests</u>
125-Iodine	18,235
57-Cobalt	1,172

(over)

II. THERAPY

131-Iodine Iodide: 13 patients treated for hyperthyroidism

4 patients treated for thyroid CA

SCOPE OF SERVICES

1. Number of hours per week of Nuclear Medicine Service: 40 hours
2. After hours, weekend, and emergency services: No regular standby or on-call service. Weekend and holiday services not provided.
3. Sites: 35 different locations
Personnel: 160 persons using radionuclides
4. Radiation Safety Officer is L. W. Wetterau, Jr.
He reports to the Chief, Nuclear Medicine Service
5. No. of ambulatory (OPD) patients who have had nuclear medicine services:
4207 ambulatory patients
6. Of the patient load, 38 % is outpatient.
7. Radiopharmaceutical uses covered by an FDA IND application are:
 - a. IND 12,989, as of Nov. 26, 1976, issued to Medi-Physics, Inc., for MPI Hepato-Biliary Reagent
 - b. IND 12,784, as of Sept. 17, 1976, issued to Manuel Tubis, Ph.D., Nuclear Medicine Service, for I 131-Labeled 1-Bromometronidazole. A copy of this IND, the subsequent correspondence regarding additional data requested, copies of the "Protocols for the Use of 1 131 Labeled Bromometronidazole for Visualizing Amebic Hepatic Abscesses," and for the "Preparation etc.," are herewith furnished - see enclosure.
 - c. Indium 111-DTPA, Medi-Physics, Inc., Phase 3, for intrathecal use in cisternography.
 - d. Livercolloid ReagentTM (Stannous chloride), Medi-Physics, Inc., for lymphoscintigraphy.
 - e. Kidney Scintigraphin, (DMSA). Medi-Physics, Inc., "for evaluation of kidney parenchymal morphology."
 - f. Thallium chloride Tl 201, New England Nuclear, for myocardial perfusion imaging.

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

REGION V

Report No. 81-01
License No. 04-00181-04 Priority 3 Category G1
Licensee: Veterans Administration Center
Wilshire and Sawtelle Blvds.
Los Angeles, California

Facility Name: _____

Inspection at: Wadsworth Hospital

Inspection Conducted: May 7, 1981

Inspectors:	<u>G. S. Spencer</u>	<u>5/15/81</u>
	G. S. Spencer, Chief, Division of Technical Inspection	Date Signed
	<u>H. E. Book</u>	<u>5/15/81</u>
	H. E. Book, Chief, Radiological Safety Branch	Date Signed
	<u>R. D. Thomas</u>	<u>5/15/81</u>
	R. D. Thomas, Chief, Materials Radiation Protection Section	Date Signed
	<u>J. L. Camper</u>	<u>5/15/81</u>
	L. Camper, Materials Licensing Branch, NRC Headquarters	Date Signed
	<u>B. A. Riedlinger</u>	<u>5/14/81</u>
	B. A. Riedlinger, Radiation Specialist	Date Signed
Approved by:	<u>R. D. Thomas</u>	<u>5/15/81</u>
	R. D. Thomas, Chief, Materials Radiation Protection Section	Date Signed
Approved by:	<u>H. E. Book</u>	<u>5/15/81</u>
	H. E. Book, Chief, Radiological Safety Branch	Date Signed

Summary:

Enforcement Conference on May 7, 1981 (Report No. 81-01)

Items discussed at enforcement conference: (1) Enforcement options available to the NRC, (2) Recent changes in NRC Enforcement Policy, (3) Items of noncompliance associated with last NRC inspection at Wadsworth Hospital, (4) Compliance history, (5) NRC actions to be taken in the present situation, and (6) Possible future actions by the NRC.

The need for increase management control of the radiation safety program was stressed, as was the need for license amendments to reflect the current program.

The enforcement conference involved a total of five hours onsite by five NRC representatives.

DETAILS

1. Persons Contacted

Mr. Lu M. Nackman, Assistant Hospital Director (Acting Director)
Dr. H. Earl Gordon, Chief of Staff
Mr. Leonard Wetterau, Nuclear Medicine Service Radiation Safety Officer
Dr. Ralph Mackintosh, Radiation Therapy, Radiation Physicist
Dr. Zbigniew Petrovich, Chief, Radiation Therapy Service
Dr. Wm. H. Bland, Chief, Nuclear Medicine Ultrasound Service
Mr. Jim Smathers, U.C.L.A.

2. Background

This enforcement conference was held between NRC and licensee management representatives to discuss the findings of a special safety inspection conducted on December 8, 1980 through December 11, 1980. The inspection had been conducted in conjunction with allegations by a former employee about the use of sealed sources at the Veterans Administration Wadsworth Hospital. During the inspection, four items of noncompliance and two deviations were identified. These items of noncompliance were described in Report 80-02 which documented the inspections conducted during December 8-11, and 17-18, 1980, and in a Notice of Violation dated February 25, 1981. The licensee responded to the Notice of Violation in a letter dated March 26, 1981. The licensee's response was discussed during the enforcement conference.

3. Items Discussed During Enforcement Conference

The enforcement options available to the NRC were discussed, and the recent changes in the NRC Enforcement Policy as stated in the Federal Register on October 7, 1980 were reviewed.

The hospital's compliance history was discussed; and the items of noncompliance noted during the special safety inspection of December 8-11, 1980 were reviewed. Several specific areas of concern were addressed: (1) The fact that a possible overexposure was not reported to the NRC, (2) the apparent lack of administrative control over the radiation safety program, and (3) the fact that the Radiation Physicist was required to function as the Radiation Safety Officer for radiation therapy implants.

Following the discussion of these areas of concern, Mr. Camper outlined changes that are necessary so that the license reflects the actual radiation safety program: (1) The responsibilities of the Radiation Physicist need to be clearly stated in a license amendment application if he is to function as an Assistant Radiation Safety Officer. (2) One person must assume overall responsibility for the radiation safety program. (3) Changes in radiation safety procedures need to be submitted to licensing for incorporation in the license.

X

The licensee was informed that their reply to the Notice of Violation will be acknowledged with the understanding that a license amendment will be submitted to document the current radiation safety program. Licensee representatives stated that the required amendment will be prepared and submitted to NRC's Licensing Branch for review.

At the end of the meeting possible future enforcement actions were discussed. The licensee was reminded that the failure to assure that the license describes the actual radiation safety program could result in more serious repetitive items of noncompliance. Repetition of items of noncompliance may result in the issuance of a civil penalty.