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

REGION V

Report No. 80-02

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: December 8-11, 1980

Inspectors: B. G. Riedlinger — 2/20/81
B. Riedlinger, Radiation Specialist — Date Signed

J. F. Pang — 2-20-81
J. F. Pang, Radiation Specialist — Date Signed

P. V. Joukoff — 2/23/81
P. V. Joukoff, Investigator — Date Signed

O. C. Shackleton Jr. — 2/23/81
O. C. Shackleton, Jr., Senior Investigator — Date Signed

R. D. Thomas — 2/23/81
R. D. Thomas, Chief, Materials Radiological Protection Section — Date Signed

Approved by: R. D. Thomas — 2/23/81
R. D. Thomas, Chief, Materials Radiological Protection Section — Date Signed

Approved by: H. E. Book — 2/23/81
H. E. Book, Chief, Fuel Facility and Materials Safety Branch — Date Signed

Summary:

Inspection on December 8-11, 1980 (Report No. 80-02) and
Investigation on December 8-11, 1980 and on December 17-18, 1980

Areas Inspected: Organization, Training and Qualification of Personnel, Area and Patient Surveys, Inventory of Radioactive Material, Personnel Monitoring, Source Storage, Instrumentation, Receipt and Transfer of

Radioactive Material and independent inspection effort. This was a special safety inspection conducted in conjunction with an investigation regarding the allegation by a former employee about the use of sealed sources at the V.A. Wadsworth Hospital. A copy of the allegation is included as Appendix D. This inspection addressed only those portions of Appendix D which are under NRC jurisdiction. This inspection involved 67 inspector hours onsite by two inspectors.

In addition, the supporting investigation involved 61 hours onsite by two investigators and 8 hours onsite by a third inspector.

Results: Of the nine areas inspected, four items of noncompliance and two deviations were identified.

The first item was found to be in noncompliance with 10 CFR 20.401(b) and concerned a record of a personnel exposure evaluation which was not maintained. This item is described in section 5 of this report.

The second item was found to be in noncompliance with License Condition 23, which requires the licensee to possess and use licensed material in accordance with statements, representations, and procedures contained in the license application and in supporting documents. There were three sub-parts to this item. They are described in sections 1, 6, and 8 of this report.

The third item was found to be in noncompliance with License Condition 15, which requires that records of patient surveys be maintained. This item is described in section 3 of this report.

The fourth item was found to be in noncompliance with 10 CFR 35.14(b)(5)(v), which requires a quarterly physical inventory to account for all sources received and possessed. This item is described in section 4 of this report.

The first deviation involved missing survey results for incoming packages. This deviation is described in section 8 of this report.

The second deviation concerned the fact that a copy of 49 CFR was not available in the Nuclear Medicine Department. This deviation is described in section 9 of this report.

DETAILS

1. Persons Contacted

*William K. Anderson, Director
Ben Cantler, Administrative Assistant to the Chief of Staff
Eleanora Cepoi, Dosimetrist
Teresita Chua, R.N.
Forrest Craig, Acting Laundry Plant Manager
*Dr. H. Earl Gordon, Chief of Staff
Sarah Hammond, Chief of Building Maintenance
Dr. Eugene F. Holly, Interim RSO and current Associate Professor at U.C.L.A.
Dr. Leopold Jose, Radiation Therapist
*Dr. Ralph E. Mackintosh, Medical Physicist and RSO
Faith Meggs, L.V.N.
*Dr. Zbigniew Petrovich, Chief, Radiation Therapy Service
*Jesse Raymond, Acting Asst. Director
Dr. John Thomas, Former Resident and current Resident Supervisor at U.S.C. Medical Center
*Leonard W. Wetterau, Jr., Physicist and RSO
Marilyn C. Wexler, Interim RSO and current Radiation Physicist Cedars - Sinai Hospital

*Denotes those attending the exit interview.

Alleger

Dr. Neal Tobochnik, Former Medical Physicist and RSO

Background

This was a special safety inspection conducted in conjunction with an investigation regarding the allegations by a former employee about the use of sealed sources at the V.A. Wadsworth Hospital. This inspection pertaining to the use of implant sources focused primarily on the radiation safety program as well as the specific areas mentioned in the allegation which were under NRC jurisdiction. A copy of the allegation is included as Appendix D.

The inspection was conducted by Ms. B. Riedlinger and Mr. J. F. Pang during the period of December 8-11, 1980. The supporting investigation was conducted by Mr. P. Joukoff during the period of December 8-10, 1980 by Messrs. O. Shackleton, R. D. Thomas, and P. Joukoff during the period of December 17-18, 1980.

The inspectors participated in interviews of witnesses conducted by the investigators.

The instrument used for radiation surveys by the inspectors was a Technical Associates Model PUG-IAB, NRC No. 004279. Probes used with this instrument were the Technical Associate's P-7 GM probe, Serial No. 12982; the P-11 Pancake probe, Serial No. 10743; and the PGS-3 Scintillation probe, Serial No. 10746. The instrument was last calibrated on November 12, 1980.

Investigation Details

A. Receipt of Allegations by NRC

On November 14, 1980, the Region V office received a letter from Gregory C. Gottlieb, attorney for Dr. Neal Tobochnik. Dr. Tobochnik is the former Medical Physicist and RSO at V.A. Wadsworth Hospital. This letter included the sworn affidavit of allegations which is attached as Appendix D. The letter requested an investigation of possible violations of NRC regulations at the hospital. These violations involved the use of radioisotope implant sources. On December 8, 1980, Dr. Tobochnik was interviewed in Los Angeles, California by the investigation team in the presence of Mr. Gottlieb. During the course of this interview, Dr. Tobochnik made allegations which pertained to personnel practices, staff personality conflicts, medical practices, and items of noncompliance with NRC regulations and/or license conditions.

The investigation team had previously received information from the U. S. Department of Labor that the personnel practices of the V.A. Wadsworth Hospital with respect to Dr. Tobochnik had been adjudicated. This Labor Department finding had already been appealed by Dr. Tobochnik to the Office of the Special Council of the Merit System Protection Board. Consequently, Dr. Tobochnik was advised by the investigation team that this investigation would center upon the radiation safety practices of the hospital as required by 10 CFR and the license conditions. Additionally, the personnel and personality issues at the hospital could only be evaluated if it was determined that they were impacting health and safety issues under the jurisdiction of NRC.

On December 9, 1980, Dr. Tobochnik reviewed and signed a sworn statement which itemized his safety concerns. The specific allegations were:

I. Contrary to License Condition 23 of NRC License No. 04-00181-04, licensed material was not possessed and used as described in application dated November 25, 1977 and letters dated July 27, 1978 and October 6, 1978. Noncompliance with accepted procedures are indicated below.

   a. Contrary to commitments made in the letter dated October 6, 1978, packages of radioactive material were not surveyed on receipt to determine surface radiation levels.

b. Contrary to commitments made in the letter dated July 27, 1978, the log describing the receipt, quantity, implant activities, transfer, and disposition of implant sources was not properly maintained.

c. Contrary to commitments made in the letter dated July 27, 1978, and 10 CFR 35.14(b)(vii), patients who received implants of sealed radioactive sources were not monitored with a suitable survey meter before discharge from the hospital.

II. Contrary to 10 CFR 20.201(b), surveys were not made to assure that radiation levels in unrestricted areas were as required by Part 20.

III. Contrary to 10 CFR 20.207, licensed materials (implant sources) were in unrestricted areas, were not in storage, and were not maintained under the constant surveillance and immediate control of the licensee.

IV. Contrary to 10 CFR 30.51(i)(3), records of transfer of byproduct material were not maintained by the licensee.

In addition to the signed sworn statement, Dr. Tobochnik made available to the investigation team five color polaroid pictures which depicted improper implant source storage conditions. Dr. Tobochnik alleged that these pictures indicated the improper storage conditions which occurred while he was on leave.

From these allegations the special safety inspection/investigation was initiated although it was not limited to the specific allegations.

B. Staff Interview Results

During the course of this investigation a total of eight current, former, and interim V.A. Wadsworth Hospital staff members were interviewed under oath. Additionally, numerous other staff members were contacted and/or interviewed informally. The interviews substantiated two instances of improper seed accountability and storage (see Section 6 of this report). The specific conditions shown in the polaroid pictures of Dr. Tobochnik could not, however, be substantiated.

During the course of the interviews, it was determined that certain supervising staff members of the hospital did feel that maintaining compliance with NRC regulations and license conditions was primarily the concern of the RSO. It was stressed by the investigation team that these areas were the concern not only of the RSO, but of all members of the staff involved in the source implant program; especially the source users named on the NRC license.

Other areas of technical concern developed during interviews were provided to the NRC inspectors for evaluation and incorporation in the special safety inspection.

Inspection Details

1. Organization

The hospital has a Medical Radioisotope Committee as required and also a Radiation Safety Committee. Although human implant sources are listed under the Nuclear Medicine License (04-00181-04), the RSO for this license does not have responsibility for these sources. The RSO for the teletherapy license (04-00181-10) has been delegated the responsibility for these sources, the rationale being that the implant sources are used by the Radiation Therapy group of which teletherapy is a part. The licenses do not reflect this assignment of responsibility.

The licensee has a requirement in Item 3 of the letter dated October 6, 1978, which was submitted as part of the license application, which states that the Medical Radioisotope Committee will meet at least on a quarterly basis. An examination of the minutes of the Medical Radioisotope Committee indicated that no meeting was held between March 26, 1980 and October 2, 1980. This item is in noncompliance with License Condition 23, which states that the licensee shall possess and use licensed material in accordance with statements, representations, and procedures contained in application dated November 25, 1977 and letters dated July 27, 1978, October 6, 1978, February 12, 1979, November 8, 1979, January 18, 1980, May 15, 1980 and July 31, 1980.

2. Training and Qualification of Personnel

Two nurses in the section where implant patients are hospitalized were interviewed on their knowledge of the care of patients who had received source implants. They were knowledgeable about the care of such patients. They also had a copy of the internal hospital procedure, "Hospital Management of Patients who have received Radioactive Implants for Therapeutic Purposes" revised 8-18-80.

Mr. Ralph Mackintosh, who has been delegated the RSO responsibility for the implant sources, joined the hospital staff in February, 1980. He holds a M.S. in Medical Physics and will be awarded a Ph.D. in the same field shortly. It could not be determined from a review of the minutes of the Medical Radioisotope Committee that Mr. Mackintosh's qualifications were evaluated prior to his appointment.

No item of noncompliance or deviation was noted.

3. Area and Patient Surveys

License Condition 15. states that patients treated with iridium-192 implants must remain hospitalized until surveys made with an appropriate radiation detection instrument indicate that all implants have been removed. License Condition 15. also requires that the results of the surveys be recorded and maintained for inspection for five years from the time the implants are removed. The records of seven source implant patients selected at random were examined to determine if such surveys had been made and if the records of these surveys exist. The survey records of two patients could not be found. Patient A was discharged on 12/21/79 and Patient B had source implants removed on 4/22/79. This is an item of noncompliance with License Condition 15.

4. Materials Inventory

An examination was made of the monthly radioisotope inventory records from 4/30/75 to 10/30/80. Only eight of the approximately 40 records had actual seed counts. One record had reference to the number of seeds for one isotope but not for another. The remaining records listed the seeds only by the total millicuries without reference to seed strength. Thus it could not be determined from an examination of these remaining records as to whether an actual physical inventory (seed count) had been conducted.

The records indicated that no physical inventory was conducted during the period between June 30, 1977 through February 28, 1978; and October 31, 1979 through March 31, 1980. 10 CFR 35.14(b)(5)(v) requires a quarterly physical inventory to account for all sources received and possessed. This section also requires that records of the inventories be maintained for inspection and shall include the quantities and kinds of byproduct material, location of sources and devices, and the date of the inventory. The lack of quarterly inventories during the period specified above is an item of noncompliance with this requirement.

In addition, a strontium-90 eye applicator (source serial number 510; source activity: 50 millicuries on 3-4-54) and a strontium-90 calibration source (source serial number 10521/22; source activity: 10 millicuries on 5-76) which are kept in the sealed sources storage area, are listed only on the monthly radioisotope inventory sheet dated June 25, 1979. There were no indications on the inventory sheets of the millicurie amounts or identifying serial numbers associated with either of the strontium sources. Since the quarterly inventory records did not account for all sources received and possessed, this was identified as an item of noncompliance with 10 CFR 35.14(b)(5)(v).

5. Personnel Monitoring Records

Radiation exposure records for Radiation Therapy and nursing personnel associated with source implant patient care were examined for the period of 1977 to October 1980. The radiation exposures received by these individuals were within the limits of 10 CFR 20.101. The highest annual radiation exposures received by the individuals are listed in the table below.

Year	Maximum Dose
1977	720 millirem
1978	200 millirem
1979	960 millirem
January 1980 - October 1980	130 millirem

The radiation exposure records of E. Cepoi, a hospital employee, had a recorded exposure of 7.7 rems for the month of November 1979. Dr. Z. Petrovich, Chief of Radiation Therapy Services stated that an investigation conducted by the hospital staff indicated that the reported exposure could not be valid, due to pocket dosimeter data which did not show the abnormal exposure. Ms. E. Cepoi also stated that pocket dosimeter readings for the month of November 1979 showed no radiation exposure. In addition, she stated that she did not work in an area where she could have received an exposure during this period. See Appendix A of this report for a supporting statement. However, the licensee could not produce any documentation indicating that an investigation and evaluation had been made relative to the recorded exposure. The records of the investigation and evaluation conducted pursuant to 10 CFR 20.201(b) should have been maintained as required by 10 CFR 20.401(b). The investigation and evaluation are conducted to demonstrate compliance with 10 CFR 20.101(a). This situation was identified as an item of noncompliance with 10 CFR 20.401(b).

6. Source Storage Area

The implant source storage area is located in the room adjacent to Room 0425. The door to the room was posted with a "Caution - Radioactive Material" sign. Eleven shielded containers of implant sources were stored behind a vertical shield in one corner of the room. The strontium-90 eye applicator was stored in a locker on the floor adjacent to the implant storage location. The source storage room was surveyed using the Technical Associates survey meter and GM probe described in the "Background" section of this report. Levels generally ranged from 0.05 millirem/hour to 1.5 millirem/hour with higher dose rates in localized areas. Over the source storage area, the level was 7.5 millirem/hour. A maximum

reading of about 15 millirem/hour was found at the surface of the locker where the eye applicator was stored.

Four wipes were taken on December 9, 1980 to check for removable contamination. Wipes were taken from the floor near the locker where the eye applicator was stored, from the lead bricks and surfaces around the source storage area, on the floor by the fume hood in the storage room, and from inside the fume hood. The wipes were initially checked with the Technical Associates instrument and were later counted on the NRC Region V NMC PC-55 gas flow proportional counter. No significant removable contamination level was detected.

The proper storage of the iridium-192 and iodine-125 implant sources was a primary concern during this inspection and investigation. The "Radiation Safety Program Manual - Veterans Administration - Wadsworth Hospital Center - Nuclear Medicine Service, Revised June 1974", which was submitted as part of the application dated November 25, 1977 states that "the primary prerequisite of an effective Radiation Safety Program is the precise knowledge and distribution of all radioactive materials present within the VAH and its related structures at all times." When questioned about proper implant source storage, Dr. R. Mackintosh stated under oath that a ribbon containing five to ten iridium-192 seeds had been found on the floor of the source storage room outside of its storage container on approximately February 11, 1980. Refer to Appendix B of this report for a supporting statement.

In addition, Ms. Marilyn Wexler, who served as an RSO for Wadsworth Hospital on a part-time basis during the time interval of approximately December 1979 through January 1980, stated under oath that during this time period she found several iodine-125 seeds outside their proper storage containers but within the implant storage area. Refer to Appendix C of this report for a supporting statement.

This loss of control of implant sources constitutes an item of noncompliance with License Condition 23, which requires that the licensee adhere to statements, representations, and procedures contained in the license application.

It should be noted that although implant sources were found to be outside their storage containers within the implant storage area, there was no indication that implants had been found in unrestricted areas except for one instance on September 13, 1978, which was reported to the NRC. An investigation conducted by the hospital concluded that the cause was probably due to accidental patient implant displacement followed by removal of the patient's laundry from the room, which is contrary to written hospital procedures.

7. Instrumentation

The survey instrument used in conjunction with the licensee's implant source activities is a Technical Associates Model PUG-1, Serial No. 131. The instrument was calibrated by Technical Associates on February 12, 1980 and will be due for calibration one year from this date.

No item of noncompliance or deviation was identified.

8. Receipt and Transfer of Radioactive Material (Records)

An examination was made of the shipping papers for the period December 1976 to the date of the inspection relative to the receipt and transfer of the implant sources used by the Radiation Therapy Department. The information obtained from the shipping papers was compared with the log book entries of receipt and transfer. The logbook is an official record and includes such information as the results of instrument surveys performed on receipt as well as the current physical inventory. It should be noted that Addendum 1, "Logging Procedures for Sealed Radioactive Sources for Implants" which was submitted with the letter dated July 27, 1978, states that a log shall be maintained indicating the disposition of all sealed radioactive sources. The July 27, 1978 letter was submitted as a supplement to the license application and is referenced in License Condition 23. Examination of the log book indicated that the following receipts were not recorded:

Date	Radionuclide	Quantity
5-30-79	Iridium-192	70 seeds (0.5 mCi/seed)
10-23-79	Iodine-125	46 mCi
11-29-79	Iodine-125	32 mCi

Also, there was no record in the logbook of a transfer to Alpha-Omega on February 11, 1980, for disposal of the following: (a) 100 seeds of iridium-192 in container number 423, (b) 100 seeds of iridium-192 in container number 213. In addition, there was no record in the logbook for December 6, 1979 to document the disposal of approximately 300 iodine-125 seeds totaling about 2.4 millicuries. Also there was no indication of the disposal of approximately 3 containers of iridium-192 which were also returned to the supplier on that date. Refer to Appendix C of this report for a supporting statement.

The Radiation Safety Officer (RSO) for the Radiation Therapy Section stated that he could not reconcile the logbook with the actual inventory when he started working at Wadsworth Hospital. To correct this situation the RSO disposed of all the implant sources on hand so that he could start a new and accurate inventory. The failure

to maintain an up to date logbook was identified as an item of noncompliance with License Condition 23.

The records of surveys performed on shipments received were lacking for the 5/30/79, 11/29/79, and 10/23/79 shipments. Item 1A, "Receipts of Radionuclides - Package Opening, all packages" of the letter dated October 6, 1978, which was submitted as a supplement to the license application, states that every package will be monitored to determine surface radiation level and that the results of the survey will be recorded in a log. The NRC License Management Branch, by letter dated September 21, 1978, required the licensee to perform surveys on receipt of all packages, however, they did not require that these surveys be recorded. Since the licensee made a commitment in their letter dated October 6, 1978, to record all surveys of shipments received, the failure to record them is a deviation from commitments made to the Commission rather than an item of noncompliance.

9. Additional Radiological Surveys

A. In addition to these surveys conducted by the inspectors on December 9, 1980 in the source storage area, additional surveys were conducted on December 10-11, 1980 in selected areas. The Wadsworth Hospital laundry serves as a central laundry facility for five other hospitals in the area including the V.A. Hospital at Sepulveda. A radiation survey was made of the hospital laundry area on December 10, 1980 using the Technical Associates PUG-1AB with a scintillation probe as described in the "Background" section of this report.

During the survey, it was discovered that a load of laundry received from the V.A. Hospital at Sepulveda contained radioactive trash consisting of plastic backed absorbent paper. Spots of approximately 2 mrem/hr were noted on the trash. The presence of the radioactive material in an unrestricted area appears to be in noncompliance with 10 CFR 20.207; however, since the materials identified were not applicable to the license being inspected, no citation was issued. Mr. Wetterau (RSO) was notified of the findings, and this matter was discussed at the exit interview. This matter will also be addressed during the next inspection of licensed activities at the V.A. Hospital at Sepulveda.

B. A second radiation survey was made using the Technical Associates PUG-1AB with a scintallation probe. This survey was conducted in the hospital corridors leading to the elevators in the basement and on the third floor. These corridors and elevators are used when implant sources are transported. The rooms on

the third floor where implant patients are hospitalized were also surveyed. There were no radiation levels found to be above normal background.

Due to patient scheduling, the inspectors could not perform surveys in the appropriate operating rooms; however, the hospital RSO stated that a survey would be conducted by December 12, 1980. Subsequent to the inspection, the hospital RSO conducted the surveys on December 16, 1980 and the results indicated no significant radiation levels.

C. A discussion was held with Mr. Wetterau regarding compliance with IE Bulletin 79-19. Wadsworth Hospital answered the bulletin in a letter dated September 17, 1979. Item 1 of this letter stated that the Department of Transportation (DOT) regulations had been requested; however, a copy of 49 CFR, the Department of Transportation (DOT) regulations, was not available in the Nuclear Medicine Department at the time of the inspection. Since the licensee did not have a copy of 49 CFR at the time of the inspection, this was identified as a deviation from a commitment made to the Commission.

10. Exit Interview

An exit interview was held with the persons denoted in paragraph 1 during which the inspectors summarized the scope and findings of the inspection.

A discussion was held relative to the radioactive trash found in a load of laundry from the V.A. Hospital at Sepulveda. Mr. Wetterau stated that he would contact the hospital regarding this matter. (See 9.A. for details).

A discussion was held relative to a radiation survey of the operating rooms where sources are implanted into patients. A commitment was obtained from Mr. Mackintosh to have the survey conducted. Subsequent to the inspection, a letter dated December 18, 1980 was received from Mr. Mackintosh stating that the survey was completed on December 16, 1980 and that the results were negative. (See 9B for details)