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October 3, 1968

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INSPECTOR'S EVALUATION AS PER MM 900-15 VETERANS ADMINISTRATION CENTER, WADSWORTH HOSPITAL LOS ANGELES, CALIFORNIA - LICENSE NO. 4-181-4

The licensee's program (inspected September 20, 1968) remains essentially unchanged since the last previous inspection. The most significant changes consist of the transfer of the 1.15-curie strontium-90 extracorporeal blood irradiator to UCLA and the acquisition of an Anger camera. The licensee is also utilizing fluorine-18 (with a half life of 111 minutes) in conjunction with the Anger camera in the performance of bone scans. Fluorine-18 is produced by irradiation in the UCLA reactor. The material is analyzed for assay sterility and pyrogenicity.

It is the inspector's opinion that the licensee's activities do not constitute a threat to the health and safety of the licensee's patients, employees, or the general public.

H. S. North Radiation Specialist

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Inspector 1000 Reviewer

Veterans Administration Center Wadsworth Hospital Los Angeles, California

License No. 4-181-4

Summary

 An announced reinspection of the subject licensed program was conducted on September 20, 1968, by H. S. North, Radiation Specialist, Region V, Division of Compliance. The inspector was unaccompanied.

Inspection Findings and Exit Interview

2. As a result of the inspection, no items of noncompliance were noted and a Form AEC-591 reflecting this finding was issued at the conclusion of the inspection. The results of the inspection were discussed were discussed with Dr. William H. Blahd, M.D., Chairman of the Radioisotope Committee, and Chief of the Radioisotope Service; Mr. L. W. Wetterau, Physicist and Radiation Safety Officer.

Persons Interviewed

3. During the course of the inspection, the following persons were either interviewed or met by the inspector. Mr. L. W. Wetterau, Physicist and Radiation Safety Officer, whose responsibilities are Center-wide in connection with the licensed programs with the exclusion of the Radiology Department. He is responsible for the control of receipt and disposal of radioactive materials, the use of licensed materials as authorized by individual user authorizations approved by the committee, and radiation safety training. Dr. W. H. Blahd, M.D., Chief of the Radioisotope Service and Radioisotope Committee Chairman. His responsibilities include use and supervision of use of isotopes in humans. Dr. <u>A. Yuwiler</u>, Head of the Neurobiochemistry Research Section. Mr. <u>K. Shoaf</u>, Research Technician, Wadsworth Hospital, is responsible for operation of the Scanning Laboratory. <u>Mary Ann Lederer</u>, Technician, <u>David Maryn</u>, Technician, operate the whole body counter facility at the Veterans Administration Center.

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Organization

- 4. The VA Center is divided into two organizations research and hospital. Dr. Blahd holds positions in both organizations as the Chief of the Radioisotope Service under the hospital and the Chief of the Radioisotope Research Service under the research organization. Mr. Wetterau is the RSO for the VA Center. The licensee's administrative and operating organization is as shown in paragraph 4 of the notes of the last previous inspection with exception of the following changes. The Assistant Hospital Medical Director, B. Mandelstam, has been added to the staff. He reports to the Hospital Medical Director. Dr. Seymor Dayton has replaced Dr. L. Fred as Head of Hospital Medical Services. Dr. E. Weiss is now Dr. Blahd's assistant. Dr. J. M. Koplowitz, M.D., is now a conultant to the Radioisotope Service. Other portions of the organization remain unchanged.
- 5. The licensee's isotopes and research committees include approximately 12 members, among them the Chiefs of all services and medical and research investigators. The Research Committee meets weekly as a committee and on occasion Isotope Committee business is included in the Research Committee meetings. Formal Isotope Committee meetings are rare in that

they revolve primarily around policy and there have been few policy changes. Most normal committee business (i.e., review and approval of research protocols) is conducted by mail. A description of the procedure and samples of the forms used by the committee are a part of paragraph 5 of the notes of the last previous inspection.

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Radiation Safety

 Mr. Watterau's status as the RSO remains unchanged from that described in paragraph 6 of the previous inspection notes.

Instruction of Personnel

7. Written procedures are required by the license. Copies of the procedures are provided to all persons who require them in the performance of their work. Mr. Wetterau provided a copy of the licensee's <u>Radiation Safety Program Manual</u>, revised July 1968. Mr. Wetterau stated that this revision was a republication of the existing document with minor changes to correct grammatical and typing errors. This manual is attached to the inspection notes as Appendix A.

Training

8. Mr. Wetterau conducts a training course on radiation protection and isotope handling. A description of the training program is included in paragraph 8 of the notes of the last previous inspection. Mr. Wetterau stated that since the last inspection, approximately 25 technicians and 25 physicians have attended the training course. Training consists of lectures, with no examination. No certificates are issued. Since the last inspection, the training course has been presented a total of four times.

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Records of Receipt and Transfer

9. The licensee's methods of procurement and receipt are the same as those described in paragraphs 9 and 10 of the notes of the last previous inspection. Wetterau stated that an estimate of present procurement would be approximately 50 curies per year at the maximum. The licensee is maintaining current and effective records showing the receipt of materials. Occasional transfers of materials occur between the VA Center and other Veterans Hospitals or UCLA; however, such transfers are very infrequent. Transfers are well documented. Since the last inspection, the licensee returned to UCLA an extracorporeal blood irradiation unit containing 1150 millicuries of strontium-90. This was returned to UCLA on June 19, 1967.

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- 10. The major significant change in the licensee's procurement program is the use of fluorine-18 (half life 111 minutes). This material is produced in the UCLA reactor by the irradiation of lithium-6 carbonate. The fluorine-18 is used in the performance of bone scans and results in a lower bone and whole body dose than similar scans performed with strontium-85.
- 11. The production of fluorine-18 involves the irradiation of approximately 10 grams of lithium-6 carbonate sealed in a Vicor tube contained in a screw-top teflon irradiation container. The material is irradiated for approximately four hours at a thermal flux of 5 x 10¹² or 5 x 10¹³. When the container is removed from the reactor, the surface of the teflon container reads between 600-700 mr/hr. The irradiation produces approximately four millicuries of fluorine-18. Irradiated

material is transferred to the VA Center, where the capsule is opened in a glove box, with the resulting whole body dose of approximately 25 millirad. After the capsule has been opened, the irradiated lithium carbonate is distilled with sulfuric acid into sodium hydroxide. The sodium hydroxide - sodium fluoride mixture is titrated with hydrochloric acid to produce a physicological saline solution. The distillation is performed in a closed system in a hood. Following preparation, which is designed to produce a sterile, hydrogen-free material, Wetterau determines the assay of fluorine-18, M. Tubis, Ph.D. (formerly with the USDA) checks sterility, and pyrogenicity is evaluated by Bioscience Laboratories. The short half life of the material, pyrogenicity and sterility findings are not avilable until after the material has been used. Based on calculations made by the staff of the VA Center, it appears that a one-millicurie dose of fluorine-18 results in a 250 millirad bone exposure and approximately 25 millirad whole body exposure. This may be compared to 100 microcuries strontium-85 dose which would produce approximately 1.2 rad bone exposure and 625 millirad whole body exposure.

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Inventory

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 Attached as Appendix B is a copy of the licensee's inventory prepared by Mr. Wetterau.

Use of Licensed Materials

13. The licensee operates under a broad license authorizing medical research diagnosis and therapy as well as tracer studies on laboratory animals. The license also authorizes possession of certain specific materials in greater quantities for certain specified uses. On the basis of the review of the licensee's activities and facilities, it did not appear that materials were used in any unauthorized activities. The licensee stated that materials were used only as authorized by the license.

Facilities and Equipment

- 14. The licensee's definition of a restricted area and his facilities and equipment are essentially as described in paragraphs 15, 16 and 17 of the notes of the last previous inspection.
- 15. Since the last inspection, the only new portable survey instrumentation acquired by the licensee is a Technical Associates PUG-IA alpha survey instrument.
- 16. Paragraph 17 of the notes of the last previous inspection noted that funds had been alloted for the purchase of an Anger camera. This device has now been acquired and installed in Wadsworth Hospital in a room adjoining the uptake room. The licensee also has installed at Wadsworth a Picker Magnascanner II with a three-inch crystal and a Picker Magnascanner III with a five-inch crystal. Small amounts of licensed material are stored at Wadsworth for use in conjunction with the diagnostic work performed at this facility.
- 17. A review of the facilities at Building 114, Wadsworth Hospital, and the Biochemistry Laboratories revealed that all areas were posted as required by the regulations. Materials were secured against unauthorized removal or were stored in areas where access to the facility was controlled. Individual containers were appropriately

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labelled and Forms AEC-3 were posted in restricted areas.

Survey Program

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18. The licensee's survey program remains essentially unchanged from the last previous inspection. A new record log of surveys was begun in May 1968. This record records surveys on a laboratory-by-laboratory basis so that all records associated with any one laboratory are found in a particular portion of the logbook. The Barremises of the surveys are stated the date, identity of the surveyor, dose rates, and maximum contamination in counts per minute. One section of the record identifies whether wipes were taken or not and provides space for remarks. In the event that wipes are collected, records of the results of counting are retained in another logbook. In all cases where anything above technical contamination in laboratory areas was observed, immediate contamination was performed. The effectiveness of the decontamination was confirmed by additional wipes. The licensee collects and analyzes room air and stack samples from the isotope laboratory. Samples are collected at any time that I-125 or I-131 are used to iodinate ACTH which is used for in vitro immunio assay work in connection with the experimental program. Stack samples were observed to run over the MPC; however, the samples were collected on a spot basis only during the iodination work. The licensee had made no effort to average the results. Averaging on a weekly or yearly basis would produce results substantially below the MPC.

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Personnel Monitoring

19. The licensee uses Landauer badges which are supplied monthly. A total of approximately 52 persons are subject to personnel monitoring. Complete Forms AEC-4 and 5 are maintained. The licensee has pocket dosimeters available; however, these are not routinely used. Summary of high quarterly exposures is noted below.

	lst Quarter	2nd Quarter	3rd Quarter	4th Quarter
1967		280 mr 5	410 mr F	120 mr F
1968	220 mr J *1240 mrem D	130 mr		The me can p

*This particular badge was issued to Dr. Yuji, who is responsible for handling the I-131 in the ACTH iodination work. The results of this exposure were recorded on Dr. Yuji's record; however, a notation was made that the beta exposure was due to direct badge contamination with iodine. A Form AEC-4 had been completed for Dr. Yuji showing that he had received 0 prior exposure. It is the inspector's opinion that the licensee adequately documented that this was a badge only exposure. It is noted that, in spite of the fact that this was a badge only exposure, the licensee removed Dr. Yuji from further isotope work for that quarter.

20. A review of all exposures generally noted that most exposures are minimal at on average ranging from 30-100 mr/quarter. It is noted that the licensee conducts routine whole body counts of personnel involved in the use of radioisotopes. Wetterau stated that there had been no significant results from the whole body counting program.

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Waste Disposal

21. The licensee disposes of no waste by sewer on an intentional basis. All wastes are accumulated. Higher level wastes are stored for later transfer to California Salvage Company. Records are maintained of all such transfers of waste. The licensee also disposes of significant quantities of waste by burial on VA property. The following is specific information relating to two disposals, with general information relating to several others which have occurred since the last previous inspection. Waste was disposed by burial on the following dates: May 4, June 23, August 23, November 27, 1967; January 26, March 28, June 20 and August 15, 1968. On June 20, 1968, the following materials and quantities were disposed: tritium, 33.92 millicuries; carbon-14, 1.928 millicuries; sodium-22, 0.002 millicuries; sulfur-35, 0.2 millicuries; iron-59, 0.148 millicuries; chromium-51, 0.05 millicuries; iodine-125, 0.42 millicuries (not decay corrected); iodine-131, 0.606 millicuries; 30 cubic feet plus 162 gallons of dry and liquid waste. The August 15, 1968 disposal consisted of: tritium, 5.7 millicuries; carbon-14, 2.16 millicuries; sodium-22, 0.025 millicuries; iron-59, 1.06 millicuries; iodine-125, 0.45 millicuries; iodine-131, Canded in in 1.5 millicuries; molybdenum-99, technetium-99m, one millicurie; 41 cubic feet plus 175 gallons of dry and liquid waste. It is noted that all liquid waste is packaged in breakage-resistent containers which are packaged inside drums with dry waste.

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Leak Tests

22. The licensee is authorized to perform tests for leakage and/or contamination. Sealed sources possessed by the licensee were leak tested at the following times:

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Material	Leak Test Dates		
Cobalt-60, 5 millicuries Model # R-30	4/27/67	10/2/67	4/2/68
Strontium-90 medical applicator, Model # RA-1	4/27/67	10/2/67	4/2/68
Strontium-90 blood irradiator	4/27/67	Returned to UCL	A by transfer.

The results of the tests for leakage were recorded in units of microcuries. In all cases, removable contamination was less than 0.005 microcuries.

Incidents

23. The licensee stated that there had been no unreported incidents. In connection with unusual occurrences, the licensee stated that there had been several occasions when leaking packages (i.e., the individual container leaked into the packing material contained in a sealed metal can). These occurrences involved shipments of iodine-125 from Isoserve in Cambridge, Massachusetts. In these cases, the VA Hospital notified Isoserve, calling attention to the problem and suggesting corrective action. The licensee received prompt response from Isoserve stating that corrective action would be taken. It is noted that in connection with this type of activity, the licensee has maintained nonroutine surveys which are well documented.

24. The licensee has no AEC contracts.

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