U. S. NUCLEAR REGULATORY COMMISSION

REGION V

Report No. 90-01

Docket No. 030-18926 License No. 46-19584-01

Materials Group Priority 3 Category 2120

Licensee: V. A. Medical Center
American Lake
Tacoma, Washington 98493

Facility Name: Same

Inspection at: Same

Inspection Conducted: August 7-10, 1990

Inspector: David D. Skov 8/31/90
David D. Skov, Sr. Radiation Specialist Date Signed

Approved by: James L. Montgomery for 8/31/90
Robert J. Pate, Chief, Nuclear Date Signed
Materials and Fuel Fabrication Branch

Summary:

Inspection of August 7-10, 1990 (Report No 030-18926/90-01)

Areas Inspected: This was a routine unannounced inspection to examine and assess the overall effectiveness of the radiation safety program. The areas examined included: organization; radiation safety committee; training; internal audits; material receipt and transfer; use and storage of materials; radiation surveys; bioassays; personnel monitoring; leak tests and physical inventories; waste disposal; instrument calibration; notification and reporting; transportation; independent measurements; and posting and labeling. The review period for the inspection was from December 8, 1987 to August 10, 1990.

Results: Nine apparent violations were identified during the inspection and are summarized as follows:

A. Annual radiation safety training was not provided to janitorial and receiving warehouse personnel during 1989. (Section 5). This is a repetitive violation.

B. Meetings of the Radiation Safety Committee (RSC) were not held during the first and third calendar quarters of 1989. (Section 3).

C. The RSC membership does not include an authorized user for each type of use permitted by the license. (Section 3).

D. Portable instrument and wipe radiation surveys were not always conducted at the required monthly frequency in research laboratories. (Section 10).

E. Research workers' thyroids were not always monitored for internal radiation exposure within 72 hours and once each month following their use of iodine-125. (Section 11).

F. Licensed material was not secured against unauthorized removal from a research laboratory. (Section 9).

G. The RSC failed to conduct quarterly reviews of occupational radiation exposures during the first and third quarters of 1989. The RSO also did not conduct required quarterly reviews of the occupational radiation exposure to the Nuclear Medicine Technologist during various periods in 1988, 1989, and 1990. (Sections 3 and 12).

H. Quantities of licensed material disposed of to the sanitary sewer, the results of wipe test surveys for measuring contamination levels in research laboratories, and the results of bioassays for measuring internal radiation exposure to the thyroids of research personnel, were not recorded in disintegrations per minute or in microcuries. (Sections 10, 11, and 15).

I. Records of sealed source inventories did not include the location of sealed sources. (See Section 7).

The NRC licensed program has not been properly implemented in several areas, as demonstrated by the numerous apparent violations and other problems that were identified during the inspection. These deficiencies appear to represent a lack of management control of the radiation safety program. A concern and root cause of the violations appears to be the RSO's inattention to the licensed program to ensure compliance with NRC requirements.

## DETAILS

1. Persons Contacted

Medical Center Personnel:

*F. Taylor, Medical Center Director
*S. Risse, M.D., Acting Chief of Staff and Associate Chief of Staff for Research
*T. Noel Allan, M.D., Chief, Radiology Service
*S. Glasse, Acting Associate Director
*R. Birnbaum, Ph.D., Research Chemist and RSO
S. Galt, Research Health Science Specialist
R. Perry, Biological Laboratory Technician
M. Styner, Health Science Specialist
V. Balthis, Nuclear Medicine Technologist

Other Personnel:

W. Tuttle, III, Ph.D., V.A. Medical Center - Portland, OR
D. Sutton, Manager and Consultant, Syncor, Seattle, WA

*Persons present at exit conference

2. Organization

The licensed program is organized into two separate areas: nuclear medicine and research. Nuclear medicine activities are administered by the Chief of Radiology, T.N Allan, M.D. Dr. Allan does not directly work with or supervise the use of licensed material, and he is not an authorized user under the license. VAMC-Tacoma is searching for a full-time person qualified in nuclear medicine to replace the previous staff physician and authorized user, Dr. Gary B. Robnett, who retired in June 1989. Until a staff replacement is hired, the licensee has contracted with Diagnostic Imaging Northwest (DIN), Seattle, Washington to provide part-time physician related nuclear medicine services. The contracting physicians review and authorize all requests for nuclear medicine tests, as required by the license.

The licensee also has a moderately small research program employing approximately 15 persons who work with unsealed radioactive sources. The material is handled by or under the supervision of a small number of individuals who are authorized by name on the license. One of the authorized users is also the RSO, Roger Birnbaum, Ph.D. The RSO stated that he spends an estimated 20 percent of his time on radiation safety matters. He reports directly to the Associate Chief of Staff for Research, Dr. S. Risse.

No apparent violations or deviations were identified.

3. Radiation Safety Committee (RSC)

The RSC consists of the RSO, a Safety Officer from Engineering Service, the Chief of Supply Service who represents management, and a representive of Nursing Service. Dr. Birnbaum also serves as Chairman of the RSC and is the sole member representing research. However, none of the three nuclear medicine authorized users named on the license are members of the RSC. Although Dr. T. Allan, and in his absence, Ms. V. Balthis, routinely attend RSC meetings, they only participate as guests and are not licensed authorized users. Therefore, the membership of the RSC appears to be in noncompliance with 10 CFR 35.22(a)(1) which requires that the RSC include an authorized user for each type of use permitted by the license.

Appendix B of Regulatory Guide 10.8 (January 1979), incorporated by reference into License Condition No. 17.A., commits the licensee to hold RSC meetings as often as necessary to conduct its business but not less than once in each calendar quarter. However, no meetings of the RSC were held during the first and third calendar quarters of 1989. The RSO told the inspector that he did not schedule any RSC meetings because of a "lack of business" and because RSC members and staff were not available to attend meetings. The finding that RSC meetings were not held at least once in each calendar quarter is considered an apparent violation.

Two apparent violations and no deviations were identified.

4. Internal Audits

The RSC conducted annual radiation safety program audits since the last NRC inspection in 1987, as required by the license. The audits were conducted by the RSO and RSC Chairman, Dr. Birnbaum. Reports of audit findings were sent to the Chief of Staff and to the Medical Center Director for review. Because of management concerns about compliance with "new" 10 CFR Part 35 as applied to the nuclear medicine program, the licensee also had arranged for an outside consultant (Dr. W. Tuttle) to routinely audit the licensed program. The first scheduled consultant audit took place on August 7-8, 1990. The consultant's audit findings, which included several deficiencies and possible violations, were documented in a report submitted to the Medical Center Director.

No apparent violations or deviations were identified.

5. Personnel Training

The inspector reviewed the licensee's program for training of employees either using or exposed to radioactive material. Item 12 of the application dated October 24, 1980 and attachment 6 to the letter dated May 19, 1986, incorporated by reference into License Condition No. 17.A., requires annual training for all licensee personnel who work with radioactive materials, and for housekeeping, supply, and other licensee personnel who are exposed while working in the vicinity of or while transporting radioactive materials.

Records were maintained by the RSO documenting completion of required training for supply and housekeeping personnel employed by the licensee in January 1988, and of training for approximately fifteen research workers in May 1988 and during 1989. The RSO-conducted training courses included either a film presentation or use of handout materials, supplemented by a question and answer session. However, the licensee had no records showing the training of supply and housekeeping staff since 1988. The RSO indicated that he neglected to provide annual training in 1989 for these workers because he was too busy with research related duties. The absence of required annual training represents an apparent violation of License Condition No. 17.A. A similar violation was also identified during the last NRC inspection conducted on December 7-8, 1987.

One apparent violation and no deviations were identified.

6. Use of Materials

The licensee's nuclear medicine facility is a single laboratory room containing one imaging device, a hot laboratory area for preparing radiopharmaceuticals, and a patient injection area. The laboratory receives routine shipments of 150 millicuries of technetium-99m and other radiopharmaceuticals. Nuclear medicine diagnostic procedures are routinely performed on approximately 28 patients per month. The licensee neither uses, nor does the license authorize, molybdenum-technetium generators, therapeutic radiopharmaceuticals, or brachytherapy sources. Sealed sources containing up to 200 millicuries of iodine-125 are used in a Norland bone mineral analyzer (BMA). Unsealed material including carbon-14, hydrogen-3, iodine-125, phosphorus-32, calcium-45, and sulfur-35 are also used for laboratory research in Buildings 18 and 85.

Although radioactive material possessed appears to conform to the license in amount, chemical/physical form, and use, the RSO was unable to provide the inspector with a current and comprehensive inventory of all unsealed sources in use by Research Service and in waste storage. Although the licensee appeared to maintain all required records of receipt, use, transfer, and disposal of sealed and unsealed material, the absence of a record keeping system that accounts for the current quantity and disposition of these materials made it difficult for the inspector to audit for compliance with license possession limits.

No apparent violations or deviations were identified.

7. Leak Tests and Physical Inventories

The inspector examined the licensee's inventory and leak test program for sealed sources. The licensee's sealed source inventory includes barium-133, cesium-137, and cobalt-57 nuclear medicine calibration sources, and BMA sources containing iodine-125. The inspector's review of records maintained by Nuclear Medicine personnel indicated that sealed sources were generally inventoried quarterly and leak tested semi-annually, as required. However, sealed sources were not clearly identified on inventory records, which created confusion and difficulty in establishing licensee compliance with inventory requirements. In addition, the

location of sealed sources were not noted on records of physical inventories conducted since the last inspection, as required by 10 CFR 35.59(g). This violation was identified by the consultant's audit and was corrected during the NRC inspection.

One apparent violation and no deviations were identified.

8. Material Receipt and Transfer

The Nuclear Medicine technologist orders and receives routine shipments of technetium-99m and other radiopharmaceuticals directly from the manufacturer. By contrast, orders placed by authorized users for unsealed licensed material used in Research Service require specific RSO approval. Radioactive packages sent to research users are received by supply service personnel which notify the RSO. The package contents are checked, surveyed, and opened by the RSO or other research personnel upon receipt in accordance with a written procedure established by the RSO, as required by the license and by 10 CFR 20.205(d). Incoming packages received by Nuclear Medicine personnel are handled under a similar written procedure.

The only radioactive material in non-waste form transferred by the licensee are sealed iodine-125 BMA sources that are returned to the manufacturer approximately once every five months. Records were maintained showing receipts and transfers of licensed material for compliance with 10 CFR 30.51.

No apparent violations or deviations were identified.

9. Storage of Licensed Material

During a walk-through inspection of Room 110 (Iodination Room) in Building 18, licensed material, including approximately 3 millicuries of iodine-125 and 25 millicuries of hydrogen-3 labeled compounds was not secured against unauthorized removal. The material was stored in an unlocked refrigerator in the room which was unattended and not under surveillance by licensee personnel and therefore the material was not under immediate control of the licensee. The finding that licensed material was not secured against unauthorized removal is considered an apparent violation of 10 CFR 20.207.

One apparent violation and no deviations were identified.

10. Radiation Surveys

The inspector reviewed the licensee's radiation survey program as applied to nuclear medicine and research laboratories. Daily and weekly radiation surveys were conducted as required by the Nuclear Medicine technologist. However, the inspector identified noncompliance with survey requirements in the Research Service. Item 22 of the application dated October 24, 1980, referenced in License Condition No. 17.A., requires monthly wipe surveys for contamination in research laboratories using or storing radionuclides. Additional monitoring with a survey

meter is required monthly. The licensee is also required to maintain records showing the results of the surveys conducted.

Research personnel conduct and record their own radiation surveys following radioiodination procedures with iodine-125. These surveys are supplemented by monthly wipe surveys of radioisotope laboratory use areas which are the responsibility of the RSO. However, the RSO stated that neither he nor his technologist conducted monthly wipe surveys for the period of April through July of 1990, in ten different radioisotope laboratories inside Building 18 as follows: Room 109 (Equipment); Room 109A; Room 110 (Iodination Laboratory); Room 107 (Tissue Culture); Room 101 (Front Laboratory); Room 3B; Room 3E (Tissue Culture); Room 4 (Equipment); and Room 6 (Molecular Biology). The RSO indicated that the surveys were omitted because he and his technologist were busy with research projects which had higher priority. In addition, monthly instrument surveys were not routinely conducted since the last NRC inspection. The RSO appeared to be unaware of the monthly meter survey requirement. The finding that monthly instrument and wipe surveys were not conducted is considered an apparent violation of License Condition No. 17.A.

Wipe test surveys following radioiodinations conducted since the last inspection were generally documented as required. However, the wipe survey results had been recorded by laboratory personnel in counts per minute (cpm) rather than in disintegrations per unit time or activity units (microcuries), as required by 10 CFR Parts 20.5 and 20.401(b). Also, instead of entering a numerical value under the column heading "CPM" on the survey form as intended, laboratory personnel frequently entered a check mark or an "OK" to indicate the results of surveys performed. The RSO appeared to be unaware of the requirement to properly document survey results. A similar problem was noted with survey records showing the results of thyroid bioassays and with records of liquid disposal to the sanitary sewer system (see Sections 11 and 15). The findings that results of radiation surveys and disposals of licensed material were not recorded in the proper units is considered an apparent violation.

One apparent violation and no deviations were identified.

11. Bioassays

A potential internal source of radiation exposure to several research laboratory workers results from their routine use of volatile iodine-125 to label proteins in radioiodination experiments. All radioiodinations are conducted within a chemical fume hood inside Room 110, Building 18. Approximately 1 to 2 millicuries of iodine-125 are handled during each radioiodination procedure.

License Condition No. 17.I. requires the licensee to use a NaI detector counting system for monitoring individuals' thyroids within 72 hours after each radioiodination procedure, and at least once each month for all laboratory workers who are otherwise potentially exposed during the handling of iodine-125. If a thyroid scan reveals an organ burden

exceeding 10 nanocuries, the licensee is also required to investigate the cause of the exposure and to restrict further iodine-125 use.

The inspector's review of records for thyroid bioassays conducted indicated no significant exposures. Persons who perform radioiodination procedures are responsible for monitoring themselves within 24 to 72 hours following the procedure. On one occasion in May 1989, an elevated uptake of 27 nanocuries was detected following radioiodination. The RSO properly investigated the cause of the exposure, which was documented in a report, and he restricted the individual's further use of radioiodine as required.

However, the licensee failed to implement the bioassay program on multiple occasions over extended time periods since the last NRC inspection. For example, thyroid bioassays apparently have not been conducted on personnel following at least 44 radioiodination procedures between January 13, 1988 and December 22, 1989, and in February and June 1990. Also, monthly thyroid bioassays were either not performed or were not recorded on numerous occasions since December 1987. The RSO had no explanation for most of the missing thyroid bioassays but stated that some measurements were omitted because the NaI detector system had malfunctioned several times, including the four month period of June-September 1989, when the instrument was returned to the manufacturer for repair. The RSO further indicated that his previous reviews of the bioassay program and associated records were sometimes neglected because of his other research related duties. The omission of required 72 hour post radioiodination and monthly thyroid bioassays is considered an apparent violation of License Condition No. 17.I.

Records of thyroid bioassays were also deficient since the bioassay results were often documented by laboratory personnel in counts per minute (cpm) rather than in activity units (nanocuries, microcuries), as required by 10 CFR Parts 20.5 and 20.401(b). The finding that the results of thyroid bioassays were not recorded in the proper units is considered as one part of an apparent violation. See Sections 10 and 15.

One apparent violation and no deviations were identified.

12. Personnel Monitoring

The licensee utilizes whole body film and finger ring thermoluminescent (TLD) badges (dosimeters) to monitor nuclear medicine and research personnel for radiation exposure. The dosimeters are supplied by Radiation Detection Company (RDC) and are exchanged monthly. The inspector's review of vendor supplied monthly dosimeter reports indicated annual whole body and extremity exposures to personnel were a maximum of 310 mrem and 2810 millirem, respectively. Annual whole body radiation exposures averaged 0 millirem for 1989 and 1990 to date.

The inspector also evaluated the licensee's procedures for reviewing personnel dosimeter reports. Attachment 9 to the letter dated May 27, 1981, incorporated by reference into License Condition No. 17.B., requires the RSO and the RSC to conduct quarterly reviews of occupational radiation exposures to determine that personnel exposures were As Low As

Reasonably Achievable (ALARA). The inspector's review of minutes for RSC meetings held since December 8, 1987, indicated that occupational radiation exposures were evaluated by the RSC on a quarterly basis as required except for the first and third calendar quarters of 1989, when the RSC did not hold meetings.

The inspector noted similar problems involving the RSO's review of occupational radiation exposure records. Monthly dosimeter reports for badge monitored research personnel are routinely sent to and reviewed by the RSO. However, the RSO apparently had neither filed nor reviewed reports of occupational radiation exposure to the Nuclear Medicine technologist for the months of January 1988, December 1988 through September 1989, and November 19[illegible] through June 1990. The RSO appeared to be unaware of the missing reports in his files until they were brought to his attention by the inspector. The licensee does not have a centralized filing system for maintaining all dosimeter reports under the RSO's administrative control. The finding that the RSO and the RSC did not conduct quarterly reviews of occupational radiation exposures is considered an apparent violation.

One apparent violation and no deviations were identified.

13. Instrument Calibration

The inspector reviewed the licensee's program for calibration of portable radiation survey meters, dose calibrators, and the counting system used for monitoring workers' thyroids for iodine-125 uptake. The thyroid counting system and all survey meters are calibrated twice per year. Records of calibration performed since the last inspection were maintained and found to be acceptable.

Three portable radiation survey meters and a fixed area survey instrument are available for monitoring radiation and contamination levels in Nuclear Medicine Laboratory. Although the number and type of instruments are sufficient for Nuclear Medicine activities, only one GM survey meter is available for use in Research Service.

The licensee replaced the dose calibrator used by the Nuclear Medicine technologist with a temporary loaner (Capintec Model CRC-10R) and a new unit (Syncor Accucal Model 2001) in February 1989. Annual accuracy, quarterly linearity, daily constancy, and geometric variation tests and checks had been performed and recorded as required on all three dose calibrators.

No apparent violations or deviations were identified.

14. Posting and Labeling

The inspector observed NRC-3 ("Notice to Employees") forms and other notices posted in Nuclear Medicine and Research areas in accordance with 10 CFR 19.11. The laboratories were also posted with "Caution, Radioactive Material" signs and labels in compliance with 10 CFR 20.203.

No apparent violations or deviations were identified.

15. Waste Disposal

Solid radioactive waste from Nuclear Medicine is held for decay a minimum of ten half-lives and monitored prior to disposal as normal waste. Results of prior surveys were documented in records maintained by the Nuclear Medicine technologist.

Solid waste from research laboratories is collected and stored in 55 gallon drums and transferred to a waste broker for burial approximately once every six months. The inspector's review of the shipping manifest for the last radioactive waste shipment of four drums in April 1990, indicated compliance with NRC and Department of Transportation (DOT) requirements.

Liquid radioactive waste from non-clinical uses of licensed material have been routinely disposed of into the sanitary sewer via designated laboratory sinks. Disposal records were maintained by the RSO that included the radionuclide and date disposed. However, in most cases, the radionuclide amounts disposed of since December 1987 were recorded only in counts per minute (cpm) rather than in disintegrations per unit time (dpm) or activity units (microcuries), as required by 10 CFR 20.5 and 20.401(b). A similar problem was also identified with records of radiation surveys and thyroid bioassays (see Sections 10 and 11). An annual summary of radionuclides and amounts disposed to the sanitary sewer system would also help to assure compliance with the disposal limits in 10 CFR 20.203. The findings that disposal of licensed material and the results of radiation surveys were not recorded in the proper activity units is considered an apparent violation of 10 CFR 20.401(b).

One apparent violation and no deviations were identified.

16. Notification and Reports

According to the licensee, no misadministrations or incidents have occurred since the previous NRC inspection which would require notification of the NRC or individuals.

No apparent violations or deviations were identified.

17. Independent Measurements

Radiation and contamination surveys were conducted by the inspector in nuclear medicine and research laboratories using an Eberline Model E-520 survey instrument, calibrated on 5/31/90. No significant radiation or contamination levels were measured.

No apparent violations or deviations were identified.

18. Exit Conference

The exit conference was held with the persons noted in Section 1 of this report at the conclusion of the site inspection on August 9, 1990. The inspector discussed the scope and findings of the overall inspection. Each apparent violation identified was reviewed. The inspector also

expressed his concern with the control, conduct, and oversight of licensed activities to assure compliance with NRC regulatory requirements and license conditions.

Licensee representatives indicated that they had previously shared many of the same concerns that were raised by the inspector, resulting in an independent audit by the consultant, Dr. W. Tuttle, that was held on August 7-8, 1990. However, because of time constraints imposed when the consultant audit coincided with the NRC inspection, the audit was generally limited to nuclear medicine activities. The Medical Center Director provided a report of the consultant audit findings to the inspector. He commented that some of the audit findings were similar to those that were identified as a result of the NRC inspection.

The licensee's general plan for devoting more resources to the radiation safety program was also discussed. Under this plan, an additional staff person would be recruited to assist the RSO in conducting research, which would free up more time for the RSO to administer the radiation safety program.