

APPENDIX G

MEDICAL BROAD-SCOPE INSPECTION FIELD NOTES
Region I

NOTE: All areas indicated in field notes are not required to be addressed during each inspection. Any reference to patient is intended to include human research subject

Inspection Report No. 030-01317/95-001

Licensee (Name & Address):

Department of the Army
Walter Reed Army Medical Center
Washington, D.C.

License No. 08-01738-02
Docket No. 030-01317

Licensee Contact: Col. William Johnson, RPO

Telephone No. (301) 427 5161

Last Amendment No. 67

Date of Amendment: July, 1995

Program Code: 2110

Priority: 1

Category: G1

Date of This Inspection: August 22 - 24, 1995

Date of Last Inspection: September, 1994

Type of Inspection:

Announced
 Special

Unannounced
 Initial

Routine
 Reinspection

Next Inspection Date: March, 1997

Normal Reduced Extended

Summary of Findings and Action:

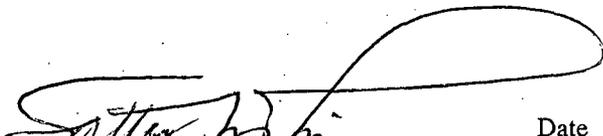
- No violations, Regional Letter issued
- Violation(s), 591 issued
- Violations, Regional letter issued
- Follow up on Previous violations

Were non-cited violations identified during this inspection?

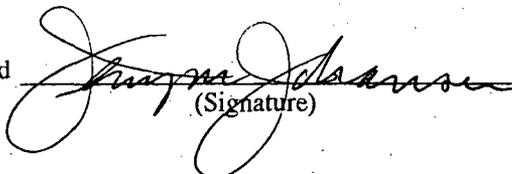
Y N

Was proprietary information reviewed by or received by the inspector?

Y N

Inspector 
(Signature)

Date 9-5-95

Approved 
(Signature)

Date 9/13/95

2/68

1. INSPECTION HISTORY

() N/A - Initial inspection

- A. Violations were identified during the last two inspections or two years, whichever is longer () Y (X) N
B. Response letters or 591(s) dated October 31, 1994
C. Open violations from previous inspections:

NO VIOLATIONS WERE IDENTIFIED DURING THE PRIOR TWO INSPECTIONS

2. ORGANIZATION AND SCOPE OF PROGRAM

A. Organizational Structure:

This facility is a part of the larger organization of the U.S. Army. Head of this organization is a general, but this facility is in effect supervised by Col. Brown (Deputy Chief of Clinical Services). Col. Tomlinson (Deputy for Preventive Medicine Services) is next in command. The RSO (Radiation Protection Officer) reports to Col. Brown or Col. Tomlinson. Licensed activities are supervised by the Health Physicists who are headed by Col. William Johnson, Chief of Physics Office (who is also the RSO). Captain Donavant, and Mr. Burton are his assistant. Licensed activities are conducted in the Departments of Nuclear Medicine, Radiation Oncology, and Research. Main research activities are mainly in two separate institutes: Armed Forces Institute of Pathology (AFIP) and Walter Reed Army Institute of Research (WRAIR). Both of these facilities are located in the main complex (Georgia Avenue). Other research labs are in Forest Glenn facility, but according to the RPO, there is a very limited use of radioisotopes at this facility and most of the research using radioisotopes is conducted at AFIP and WRAIR.

Individuals contacted during the inspection included: *Col. Johnson (RSO), *Col. Tomlinson (Second in Command), Capt. Donnavant (HP Branch Chief), *Mr. Burton (HP Branch Chief), Capt. Watkins (Nuclear Pharmacist), Col. Berndt (Nuclear Pharmacist), Ms. Yvette Sayer (CNMT), Dr. Choi (Medical Physicist), Anthony Moore (NMT), Dr. Cindy Wright (Research), Dr. Stephen Rothwell (Research), Dr. Richard Gordon (Research), Dr. John Newland (Research).

* Individuals present at exit meeting

1. Meets license requirements [L/C] (X) Y () N
2. Multiple authorized locations of use (X) Y () N

Medical & research facilities located at the main complex (on Georgia Avenue) were inspected. The facility at Forrest Glenn (that houses the radioactive waste storage) was inspected. The RSO stated that most of the use of licensed material is at these facilities.

3. Briefly describe scope of activities, including types and quantities of use involving byproduct material, frequency of use, staff size, etc.

Licensed activities are conducted in three areas, namely, Nuclear Medicine, Radiation Oncology, and Research. During the current inspection, only Nuclear Medicine and Radiation Oncology areas were inspected.

Nuclear Medicine (hot lab) is headed by a nuclear pharmacist (Captain Watkins). Sargent Dunkel is the Chief Administrative Technologist. There is a civilian CNMT (Yvett Sayer) to whom the NMTs report. There are 14 staff NMTs. There are 9 cameras, each located in a separate room. Although more than one NMT may be working in a scanning room, there is one NMT who is assigned to ensure the radiation safety aspects (QC and surveys, etc.) in that room. There is a one year Radiopharmacy Residency program that trains personnel as radiopharmacists and Col. Berndt (himself a radiopharmacist) is the head of this program. In addition to this, there is also a training program for the NMTs. Trainee-NMTs are assigned to work in the hot lab under direct supervision of CNMT or staff NMT. Only three persons (Watkins, Sayer, and Dunkel) are authorized to order radiopharmaceuticals. There are four physicians that are involved in the NM activities. Dr. Rodriguez is the chief of NM. The department operates from 6:30 a.m. to 4:30 p.m. on weekdays. One of the NMTs is on call during other hours.

Routine diagnostic procedures are performed using Tc-99m, Tl-201, Ga-67, In-111, Cr-51, I-123, I-131, and Xe-133. Therapeutic dosages of I-131 (liquid as well as in capsule form), P-32, and Sr-89 are also administered. Approximately 40 patients are scanned each day. The majority of scans consist of bone scans, and cardiac studies. Approximately seven therapeutic dosages of I-131 are administered each month of which one is a large dosage that requires hospitalization. Some of the I-131 therapy dosages are as high as 502 mCi. The use of P-32 is very infrequent (only 1 a year), Sr-89 is administered approximately twice a month. All therapy dosages are administered by a physician. QMP reviews of administrations are conducted by the nuclear pharmacist and the results are submitted to the RSC. The department also has an internal audit program, where the chief of NM (Dr. Rodriguez) or a designee (also a physician) reviews the therapy administrations, and a written report of this audit is prepared and a QA committee reviews this report. If item/items of non-compliance are noted in this audit, RSC is notified of the findings and corrective actions are discussed and approved by the RSC. Currently the record keeping is not computerized. However, Capt. Watkins stated that once the dose calibrator is connected to the computer, it is planned that an appropriate software will be acquired to make the record keeping computerized.

Radiation Oncology is a relatively small area of the use of licensed material. There are 3 linear accelerators, and brachytherapy is performed using Cs-137, and Ir-192 sources. No permanent implants are performed. There is a Sr-90 Eye-Applicator but is not being used and is in storage. There are 5 staff physicians but only two are actively involved in the brachytherapy. Brachytherapy is performed once or twice each month. There is one physicist (Dr. Choi) and a second physicist (Arnold Abel), who is a consultant. The position of head of Medical Physics is vacant and the institution is looking to fill that position soon.

Research activities are conducted at various sites and the main isotopes used are P-32, S-35, H-3, I-125, C-14 and Cr-51. There are currently approximately 70 authorized users. However, very few of these are active users of licensed material. No iodinations are being performed at any site.

- B. Licensee does limited distribution of pharmaceuticals¹ under Part 35 license () Y (X) N
- C. Research involving human subjects (X) N/A

Currently there are no active research protocols. The RSO stated that two protocols are being reviewed and they are scheduled to get under way in the near future.

- D. Radiation Safety Committee [33.13, 14, 15] () N/A
1. Membership as specified [35.22(a)(1)] (X) Y () N
 2. Meetings held quarterly [35.22(a)(2)] (X) Y () N
 3. Quorums established [35.22(a)(3)] (X) Y () N
 4. Has sufficient authority [35.23] (X) Y () N
 5. Record of Committee meetings [35.22(a)(4)] (X) Y () N
 6. Approve/disapprove credentials of individuals prior to allowing them to work as an authorized user or authorized nuclear pharmacist [35.22(b)(2)(ii)] (X) Y () N
 7. Approve/disapprove applications for use [L/C] (X) Y () N

The RSC meetings are held regularly and are well attended. Management is represented by Col. Brown (alternate is Col. Tomlinson) at these meetings. The RSC chairman was replaced in February, 1995. The new chairman is Col. Brown. NRC was informed and the license was amended to reflect this change. The latest meeting of RSC was held on June 6, 1995. The RSO stated that it is common in the army for personnel to be transferred and Col. Brown may be transferred to an other position thereby necessitating another request for an amendment. Inspector suggested that they pursue this matter with the NRC and may be they could get an exemption from listing an individual as the RSC chairman on the license.

- E. Radiation Safety Officer
1. Appointed & on license [33.13, 35.21(a), L/C] (X) Y () N
 2. Fulfills duties per [35.21(b)] (X) Y () N
 3. Has sufficient authority per [35.23] (X) Y () N

Col William Johnson is the RSO. He is also the Chief of Health Physics Office.

- F. Radiation Safety Program
1. Minor changes pursuant to [35.31] (X) Y () N
 2. Records of changes maintained [35.31(b)] (X) Y () N
 3. Content and implementation reviewed annually by the licensee [20.1101(c), 35.22(b)(6)] (X) Y () N
 4. Records of reviews maintained [20.2102] (X) Y () N

Radiation Safety Program is supervised by the Health Physics Office. Col. Johnson is the chief of this office. The Office is divided into three branches: Operations branch, Technical Services branch, and Radioactive Materials Control branch.

¹If licensee distributes radiopharmaceuticals to several facilities, the inspector should consider the need to complete the radiopharmacy fieldnotes.

- G. Use by authorized individuals [L/C] (X) Y () N
- H. Mobile Nuclear Medicine Service (X) N/A
- I. Any Amendments or Notifications since last inspection [35.13, 14] (X) Y () N

Licensee has notified NRC within 30 days after RSO stopped work or changed name, or mailing address changed [35.14(b)] (X) N/A

The Chairman of RSC was transferred to another position. The licensee replaced the chairman (currently Col. Brown).

3. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

- A. Instructions to workers/students per [10 CFR 19.12] (X) Y () N
- B. Individual's understanding of current procedures and regulations is adequate (X) Y () N
- C. Training program required [L/C] (X) Y () N

1. If so, briefly describe training program:

The training program for the workers appears to be is effective. This is observation is based on the responses of NMTs, research associates, etc. during the inspection. NMTs are trained by the nuclear pharmacist or CNMT. Research workers are provided initial training by the authorized user (supervisor). Nursing personnel are provided training by the Radiation Safety Office. Nursing personnel in each shift are provided the training by the Radiation Safety Office Personnel.

- 2. Training program implemented (X) Y () N
- 3. Periodic training program required (X) Y () N
- 4. Periodic training program implemented (X) Y () N
- 5. Records maintained (X) Y () N

D. Supervision of individuals

- 1. Supervised individuals² are instructed in preparation of material, principles and procedures for radiation safety and QM Program as appropriate [35.25(a)(1), 35.25(b)(1)] (X) Y () N
- 2. Licensee periodically reviews supervised individuals use of material and records kept to reflect use [35.25(a)(3)] (X) Y () N
- 3. Authorized nuclear pharmacist or user periodically review work and records of work of supervised individuals as it pertains to preparing byproduct material [35.25(b)(3)] (X) Y () N

E. Therapy training

- 1. Safety instruction [35.310, 410, L/C]
 - a. Control of patient and visitors (X) Y () N

²Applies to individuals that receive, possess, use, transfer, or prepare byproduct material for medical use under supervision of authorized nuclear pharmacist or user.

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|----|---|-------------|
| b. | Contamination and waste | (X) Y () N |
| c. | Size/appearance of sources | (X) Y () N |
| d. | Handling/shielding of sources | (X) Y () N |
| e. | RSO notification in emergency or death | (X) N/A |
| f. | Records maintained [35.310(b), 410(b)] | (X) Y () N |
| 2. | Manufacturer's instructions available and followed [35.59(a), 400] | (X) Y () N |
| 3. | Training for operating and emergency procedures for HDR Remote Afterloaders | (X) N/A |

F. Revised Part 20

Workers cognizant of requirements for:

- | | | |
|----|--|-------------|
| 1. | Radiation Safety Program [20.1101] | (X) Y () N |
| 2. | Annual dose limits [20.1301, 1302] | (X) Y () N |
| 3. | New forms 4 and 5 | (X) Y () N |
| 4. | 10% monitoring threshold [20.1502] | (X) Y () N |
| 5. | Dose limits to embryo/fetus and declared pregnant worker [20.1208] | (X) Y () N |
| 6. | Grave Danger Posting [20.1902] | (X) N/A |
| 7. | Procedures for opening packages [20.1906] | (X) Y () N |
| 8. | Sewer disposal limits [20.2003] | (X) Y () N |

Disposal of radioactive waste by the laboratories is limited to rinsed material. The laboratories are required to collect all liquid waste for disposal by the RSO.

NOTE: Deficiencies in Section 3.F, while not always a violation, should be brought to the attention of licensee management at the exit meeting and in the cover letter transmitting the inspection report or NOV.

4. FACILITIES

- | | | |
|----|--|-------------|
| A. | Facilities as described in license application | (X) Y () N |
| B. | Storage areas | |
| 1. | Materials secured from unauthorized removal or access [20.1801] | (X) Y () N |
| 2. | Licensee controls and maintains constant surveillance of licensed material not in storage [20.1802] | (X) Y () N |
| 3. | Licensee uses process or other engineering controls for airborne concentrations, internal exposures in restricted areas, and volatiles/gases in storage [20.1701, 1702, 35.90] | (X) Y () N |
| 4. | Maintenance program implemented for engineering controls (negative pressure, ventilation rates, filter changes, etc.) [35.205(e), L/C] | (X) Y () N |

Ventilation studies are performed in the room 7C06 of the nuclear medicine using xenon-133. The ventilation rates were measured on April 21 & 22, 1994. There was no record of checks of negative pressures in this rooms after that date. The RSO stated that he remembers (but could not be sure) that these measurements were made after that date. However, no records were available to verify that these measurements were made after that date. The inspector verified that the room was maintained at negative pressure with respect to the hall way by a crude method of observing the movements of tissue paper placed near the door. (A NON-CITED VIOLATION OF 35.205(e)).

- C. Describe any Self-contained dry-source-storage irradiators [Part 36] and/or survey instrument calibrators (model, radionuclide, activity, use, etc) (X) N/A

The licensee has a separate license for irradiator. Irradiator was inspected earlier by an other inspector.

5. EQUIPMENT

A. Dose calibrator - Photon-emitting radionuclides

There are two dose calibrators (a CRC-35R and a CRC 30BC) in the hot lab. CRC-35R is used routinely and CRC-30BC is the back up unit. Both dose calibrators are tested periodically as required except that the constancy checks for the back up unit are not made unless it is used on a day.

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|----|---------------------------------|-------------|
| 1. | Possessed and used [35.50(a)] | (X) Y () N |
| 2. | Constancy [35.50(b)(1)] | |
| | a. Performed daily prior to use | (X) Y () N |
| | b. Dedicated check source used | (X) Y () N |

On two occasions, namely, August 18, and 21, 1995, the records indicated that the constancy checks were not performed. Captain Watkins stated that it is possible that the checks were made and that the individual neglected to record the results. The individual who was supposed to have performed these checks was not available on the days of inspection. Records of several prior months in 1995 were reviewed and the inspector noted that the constancy checks were performed regularly and these two dates appeared to be isolated incidences (Capt. Watkins explained that the individual responsible for performing these tests was scheduled to take his board examination in days, and may have neglected to record these tests because of nervousness). Based on the circumstances, the licensee was not cited.

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|----|---|---------------------|
| 3. | Accuracy [35.50(b)(2)] | |
| | a. Performed at installation and annually | (X) Y () N |
| | b. At least 2 sealed sources used | (X) Y () N |
| 4. | Linearity [35.50(b)(3)] | |
| | a. Performed at installation and quarterly thereafter | (X) Y () N |
| | b. Includes range between 30 uCi and the highest dosage administered | (X) Y () N |
| 5. | Geometric Dependence [35.50(b)(4)] | |
| | a. Performed at installation or relocation | (X) Y () N |
| | b. Includes range of volumes and volume configurations used | (X) Y () N |
| 6. | Dosage readings over 10 uCi mathematically corrected for geometry or linearity errors greater than + or - 10% | (X) N/A () Y () N |
| 7. | Repaired or replaced when constancy or accuracy errors exceeded + or - 10% | (X) N/A () Y () N |
| 8. | Approved procedures followed [35.22, 25, L/C] | (X) Y () N |
| 9. | Records maintained and include identity of the individual performing the test [35.50(e)(2)] | (X) Y () N |

- B. Instrumentation - Alpha- or beta-emitting radionuclides () N/A
1. List type of equipment used to assay alpha and beta particles:
- The licensee administers Sr-89 and P-32 dosages. The licensee uses the same dose calibrator as described above for assaying these dosages.
- C. Licensee uses generators (X) Y () N
- Two 2.7 Ci Mo/Tc generators are on order from Dupont each week. One of them is delivered on Monday mornings and the other is delivered on Thursday mornings. Each generator is kept for 2 weeks and is then shipped back to the vendor in its original carton.
1. Each eluate/extract used for radiopharmaceuticals tested for Mo-99 breakthrough (X) Y () N
2. No radiopharmaceuticals administered with Mo-99 concentrations over 0.15 uCi per mCi of Tc-99m (X) Y () N
3. Records maintained [35.204(c)] (X) Y () N
- D. Syringes properly labeled and shielded [35.60] (X) Y () N
- E. Vials kept in a shield [35.61(a)] (X) Y () N
- F. Vial shields labeled [35.61(b)] (X) Y () N

6. MATERIALS

- A. Licensee measures activity of each dosage of photon-emitting radionuclide prior to use [35.53(a)] (X) Y () N
- B. Licensee administers alpha- or beta-emitting radionuclides (X) Y () N
- If yes,
1. Licensee receives unit doses and relies on assay data supplied by manufacturer or properly licensed organization [35.53(b)] (X) Y () N
2. Licensee measures by direct measurements or combination of measurement and calculation each dosage of alpha or beta-emitting radionuclide prior to medical use [35.53(b)] (X) Y () N
- C. Unsealed material used under 35.100, 200, or 300 are [35.100(b), 35.200(b), 35.300(b):
- (1) Obtained from manufacturer or properly licensed organization (X) Y () N
- AND/OR
- (2) Prepared by authorized nuclear pharmacist or physician user or individual under the supervision of an authorized nuclear pharmacist or physician user (X) Y () N
- D. Isotope, chemical form, quantity and use as authorized [31.11, 35.400,500, L/C] (X) Y () N

- E. Use of RAM [L/C]
- | | | |
|----|---|-------------|
| 1. | Protective clothing worn | (X) Y () N |
| 2. | Personnel routinely monitor their hands | (X) Y () N |
| 3. | No eating/drinking in use/storage areas | (X) Y () N |
| 4. | No food, drink, or personal effects kept in use/storage areas | (X) Y () N |
| 5. | Proper dosimetry worn | (X) Y () N |
| 6. | Radwaste disposed in proper receptacles | (X) Y () N |
| 7. | No pipetting by mouth | (X) Y () N |
- F. Radioisotopes are used in research in accordance with current procedures [L/C] (X) Y () N
- G. Leak tests and Inventories
- | | | |
|----|---|-------------|
| 1. | Leak test performed on sealed sources and brachytherapy sources [35.59(b)] | (X) Y () N |
| 2. | Leak test records in microcuries | (X) Y () N |
| 3. | Inventory of sealed sources and brachytherapy sources performed quarterly [35.59(g)] | (X) Y () N |
| 4. | Inventory performed promptly at the storage area after removing sources from a patient to ensure all sources taken from the storage area are returned [35.406(a)] | (X) Y () N |
| 5. | Records maintained and signed by RSO [35.59, 406] | (X) Y () N |

7. RADIATION SURVEYS () N/A

- A. Survey instruments
- | | | |
|----|---|-------------|
| 1. | Appropriate operable survey instrumentation possessed [35.120, 220, 320, 420, L/C] or available [35.520, L/C] | (X) Y () N |
| 2. | Calibrations [35.51(a), (b)] | |
| | a. Before first use, annually & after repairs | (X) Y () N |
| | b. Approved calibration procedure followed to include check source reading determination [35.51(a)(3), L/C] | (X) Y () N |
| | c. Within 20% in each scale or decade of interest [L/C] | (X) Y () N |
| 3. | Records maintained [35.51(d)] | (X) Y () N |
| 4. | Source-checked each day of use [35.51(c)] | (X) Y () N |

There are two survey instruments that are kept in the hot lab. One of them did not have the check source reading posted in it. Because the second survey instrument was in calibration and had the check source reading posted on it, the licensee is not being cited against 35.51 (A NON-CITED VIOLATION). Similarly, in two research laboratories, the survey instruments were out of calibration (about a month or two late). The records of use of licensed materials indicated that these labs had not used radioactive materials during these times. The health physicist accompanying the inspector promptly replaced these instruments with appropriately calibrated instruments. (Because these survey instruments were not used after their calibration expired, the licensee was not cited)

- B. Radiation surveys performed
- | | | |
|----|---|--|
| 1. | Daily in all areas where radiopharmaceuticals | |
|----|---|--|

- are prepared or administered [35.70(a)] (X) Y () N
 - 2. Weekly in all areas where radiopharmaceuticals or waste is stored [35.70(b)] (X) Y () N
 - 3. Weekly wipes in all areas where radiopharmaceuticals are prepared for use, administered or stored [35.70(e)] (X) Y () N
 - 4. Quarterly in brachytherapy source storage area (X) Y () N
- C. Trigger levels [35.70(d), (g)]
- 1. Established (X) Y () N
 - 2. Exceeded (X) Y () N
 - 3. Corrective action taken and documented (X) Y () N
- D. Techniques can detect 0.1 mR/hr, 2000dpm [35.70] (X) Y () N
- E. Records maintained [35.70(h), L/C] (X) Y () N
- F. Protection of members of the public

Note: See IN 94-09 for updated guidance on conflicts between Parts 20 and 35.

- 1. Licensee made adequate surveys to demonstrate either (1) that the TEDE to the individual likely to receive the highest dose does not exceed 100 mrem in a year, or (2) that if an individual were continuously present in an unrestricted area, the external dose would not exceed 2 mrem in any hour and 50 mrem in a year [20.1301(a)(1), 1302(b)] (X) Y () N
 - 2. Unrestricted area radiation levels do not exceed 2 mrem in any one hour [20.1301(a)(2)] (X) Y () N
 - 3. Records maintained [20.2103, 2107] (X) Y () N
- G. Describe licensee's survey requirements for research areas () N/A
- Laboratories that use C-14, H-3 etc., in > 200 microcurie quantities are required to perform wipe tests of the areas of use after the use. Other users like P-32 etc., are required to perform radiation surveys and wipe tests for removable contamination (on the day of use) of the areas of use at the end of the day. Additionally, these labs are also required to perform monthly surveys of the areas of use. A health physics technician (staff member of Health Physics Office) also audits the laboratories periodically (interval depends upon the frequency and type of isotopes used).
- H. Research areas surveyed as required [20.1501(a), L/C] (X) Y () N
- I. Research area survey records maintained [20.2103, L/C] (X) Y () N

8. RADIOPHARMACEUTICAL THERAPY () N/A

- A. Safety precautions implemented to include patient facilities, posting, stay times, patient safety guidance, release and contamination controls [35.315(a), L/C] (X) Y () N
- B. Area dose rate surveys and room contamination surveys [35.315(a)(4), (7)] (X) Y () N
- C. Release of patients containing radiopharmaceuticals meets <5 mR/hr @ 1m or <30 mCi [35.75] (X) Y () N
- D. RSO promptly notified if patient died or had a medical emergency [35.315(b)] (X) N/A

Occasionally very high dosages (as high as 502 mCi) of I-131 are administered to patients. There is a dedicated room for these patients (Room 7438). The licensee does not use this room to house any other patients. Because of this the licensee was granted exemption from requirement that the room be decontaminated to less than 200 dpm/100 cm.sq. Before this room, an other room (room 7437) was being used for this purpose with the same conditions. The inspector verified that this room (7437) was released for general use on 5-25-95 and was surveyed and decontaminated to less than 200 dpm/100 sq.cm., before being released for use by other patients.

9. BRACHYTHERAPY () N/A
- A. Safety precautions implemented to include patient facilities, room posting, stay times, and area radiation level surveys [35.415, L/C] (X) Y () N
 - B. Patients surveyed immediately after implant [35.406] (X) Y () N
 - C. Release of patients with permanent implants meets <5 mR/hr @ 1m [35.75] (X) N/A
 - D. Patients surveyed immediately after removing the last temporary implant source (required for all manual, LDR, MDR, and HDR therapies) [35.404(a)] (X) Y () N
 - E. Records maintained [35.404(b), 406(d), 415(a)(4)] (X) Y () N

Required surveys of the rooms, and adjoining areas are made following the implant procedure. The patient and the rooms are surveyed after implant procedure is completed and the sources are removed from the patient. However, the records of patient surveys did not meet the regulatory requirements. After the removal of the sources, the patient and the room were being surveyed. However, the records indicated that all readings were being recorded as "background". One two occasions, the survey meter used was not identified, and on one occasion, the individual performing the surveys did not include his initials in the records. (A **NON-CITED VIOLATION OF 35.404**). The RSO was reminded of the requirement for the records of patient surveys and what is required to be included in these records. He agreed with inspector's observations and immediately instructed the individuals responsible to perform surveys to ensure that this was done. He also modified the survey record form, that reminds the surveyors to record the dose rates in mR/hr on these forms.

10. RADIOACTIVE WASTE () N/A
- A. Disposal
 - 1. Decay-in-storage () N/A
 - a. Approved [20.2001, 35.92, L/C] (X) Y () N
 - b. Procedures followed [35.92, L/C] (X) Y () N
 - c. Labels removed or defaced [20.1904, 35.92] (X) Y () N
 - 2. Special procedures performed as required [L/C] (X) Y () N
 - 3. Liquid scintillation (LS) media and animal carcasses per [20.2005] (X) Y () N

The licensee has a large storage area for radioactive waste collected from various areas of use. The waste is kept in metallic drums that are labeled and code numbers on these drums identify these as short half-life waste (decay in storage) or

long half-life (for burial/incineration). The licensee had a drum that contained approximately 45 lbs of animal carcasses. The records indicated that this drum was closed in June 1990, and contained H-3 (0.38 microcuries/gm). This drum was being held to be sent to burial site. There were two additional drums containing animal carcasses (< 0.05 microcuries/gm of H-3 or C-14). These two drums were to be incinerated. In April 1993 (specific date unknown), a health physics technician erroneously assumed that he could average the radioactivity/gm by dividing total activity in these drums by the total weight of animal carcasses, and because the result was < 0.05 microcuries/gm, he sent the three drums for incineration. The licensee identified this error on December 8, 1994, when a shipment for burial was being prepared and the drum that was supposed to be shipped for burial could not be located. The individual who had disposed this drum had left the licensee. The licensee conducted an investigation and prepared a written report of the incident. The matter was discussed by the radiation safety committee. According to licensee's calculations, there was a release of 5.04E-8 microcuries/ml into the effluents because of incineration. This was in violation of 20.2005. However, because the violation was identified by the licensee and appropriate corrective actions were instituted (in service to health physics staff, and separate locations for drums that do not meet the requirement for disposal by incineration) this is considered as **A NON-CITED VIOLATION OF 20.2005**. The licensee stated that currently all radioactive waste is either being decayed in storage (if it meets the criteria), or is held for shipment for burial. No radioactive waste is being incinerated.

- | | | |
|----|--|-------------|
| 4. | Improper/unauthorized disposals [20.2001] | () Y (X) N |
| 5. | Records maintained [20.2103(a), 2108, L/C] | (X) Y () N |

B. Effluents

- | | | |
|----|--|-------------|
| | | () N/A |
| 1. | Release into sanitary sewer [20.2003] | (X) Y () N |
| | a. Material is readily soluble or readily dispersible [20.2003(a)(1)] | (X) Y () N |
| | b. Monthly average release concentrations do not exceed App B, Table 2 values | (X) Y () N |
| | c. No more than 5 Ci of H-3, 1 Ci of C-14 and 1 Ci of all other radionuclides combined released in a year [20.2003(a)] | (X) Y () N |
| | d. Procedures to ensure representative sampling and analysis implemented [20.1501, L/C] | (X) Y () N |
| 2. | Release into septic tank [20.2003] | (X) N/A |
| 3. | Waste incinerated | (X) N/A |

SEE REMARKS IN ITEM 10.A ABOVE

- | | | |
|----|--|-------------|
| 4. | Control of air effluents and ashes [20.1201, 1301, 1501, 2001, L/C] {See also IP 87102, RG 8.37} | () Y () N |
| | a. Compliance with air emissions requirements in Part 20: | |
| | Licensee has demonstrated compliance with air emission requirements in 10 CFR Part 20 | (X) Y () N |

Basis for compliance determination (check one or more; provide basis below)

- (1) Measured concentrations of radionuclides in air effluents are below Appendix B, Table 2 concentrations (and external dose < 50 mrem/yr)
- (2) Bounding calculations show that air effluents could not exceed Appendix B, Table 2 concentrations (and external dose < 50 mrem/yr)
- (3) Dose modeling shows that dose equivalent to the individual likely to receive the highest dose does not exceed 10 mrem/yr
- (4) Licensee does not possess sufficient radioactive material to exceed Part 20 requirements

Basis for Determination:

The licensee monitors the releases in the sewer and the amount of total activity released in sewer system via sinks is averaged over the volume of water used. The RSO stated that the released amounts are well below part 20 limits. Currently there is no activity in research that involves the use of volatile materials (free radioiodine). Currently there is no incineration of radioactive waste.

b. Description of effluent program

- 1. Monitoring system hardware adequate (X) Y () N
- 2. Equipment calibrated as appropriate (X) Y () N
- 3. Air samples/sampling technique (i.e. charcoal, HEPA, etc.) analyzed with appropriate instrumentation (X) Y () N

C. Waste Management () N/A

- 1. Waste compacted () Y () N

Glass vials containing LS materials are crushed. Liquids are drained for disposal.

- 2. Storage area(s) () N/A
 - a. Protection from elements and fire [L/C] (X) Y () N
 - b. Control of waste maintained [20.1801] (X) Y () N
 - c. Containers properly labeled and area properly posted [20.1902, 1904] (X) Y () N
 - d. Package integrity maintained [L/C] (X) Y () N

- 3. Packaging, Control and Tracking [App. F.III] [20.2006(d)]

All long-lived waste is being stored. Licensee occasionally sends the waste for burial. The records of these shipment are kept that include the date of shipment, approximate radioactivity in the contents, etc.

- 4. Transfers to land disposal facilities () N/A

D. Records of surveys and material accountability are maintained [20.2103, 2108] (X) Y () N

11. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

- A. Describe how packages are received and by whom [33.13, L/C] () N/A
- Packages containing radioactive materials are delivered to the health physics office (RSO). The health physics personnel take the packages to the delivery points at the main facility and the intended recipients are contacted to pick up the packages. Radiopharmaceuticals for human use (in nuclear medicine) are delivered directly to the hot lab.
- B. Written package opening procedures established and followed [20.1906(e)] (X) Y () N
- C. All incoming packages with a DOT label wiped, unless exempted (gases and special form) [20.1906(b)(1)] (X) Y () N
- D. Incoming packages surveyed [20.1906(b)(2), L/C] (X) Y () N
- E. Monitoring in (C) and (D) above performed within time specified [20.1906(c)] (X) Y () N
- F. Transfer(s) between licensees performed per [30.41] (X) Y () N
- G. All sources surveyed before shipment and transfer [20.1501(a), 49 CFR 173.475(i), L/C] (X) Y () N
- H. Records of surveys and receipt/transfer maintained [20.2103(a), 30.51] (X) Y () N
- I. Transfers within licensee's authorized users or locations performed as required [L/C] (X) Y () N
- J. Arrangements made for packages containing quantities of radioactive material in excess of Type A quantity [20.1906(a)] (X) Y () N
- K. Package receipt/distribution activities evaluated for compliance with 20.1301 [20.1302] (X) Y () N

12. TRANSPORTATION (10 CFR 71.5(a) and 49 CFR 171-189) () N/A

- A. Licensee shipments are:
(X) delivered to common carriers
- B. Licensee returns radiopharmacy doses () Y (X) N
- C. Packages
1. Authorized packages used [173.415, 416] (X) Y () N
 2. Performance test records on file () N/A
 - a. DOT-7A packages [173.415(a)] (X) Y () N
 - b. Special form sources [173.476(a)] () Y (X) N
 3. Two labels (White-I, Yellow-II, Yellow-III) with TI, Nuclide, Activity, and Hazard Class [172.403, 173.441] (X) Y () N
 4. Properly marked (Shipping Name, UN Number, Package Type, RQ, "This End Up" (liquids), Name and Address of consignee) [172.301,306,310,312,324] (X) Y () N
 5. Closed and sealed during transport [173.475(f)] (X) Y () N
- D. Shipping Papers () N/A
1. Prepared and used [172.200(a)] (X) Y () N
 2. Proper {Shipping Name, Hazard Class, UN Number, Quantity,

Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, Category of label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, "Limited Quantity" (if applicable), "Cargo Aircraft Only" (if applicable)} [172.200-204]

3. Readily accessible during transport [177.817(e)] (X) Y () N
() Y () N

13. PERSONNEL RADIATION PROTECTION

A. Licensee performed exposure evaluation [20.1501] (X) Y () N

B. Licensee incorporated ALARA considerations in the Radiation Protection Program [35.20, 20.1101(b)] (X) Y () N

C. External Dosimetry () N/A

1. Licensee monitors workers [20.1502(a), L/C] (X) Y () N

2. External exposures account for contributions from airborne activity [20.1203] (X) Y () N

3. Supplier Landauer Frequency Monthly/Quarterly

4. Supplier is NVLAP-approved [20.1501(c)] (X) Y () N

5. Dosimeters exchanged at required frequency [L/C] (X) Y () N

The licensee monitors more than 800 workers for exposure to radiation. According to the records for all of 1994, a large majority of these workers (over 600) received minimal radiation exposures, and the average whole body dose was 39 mrem.

D. Internal Dosimetry () N/A

1. Licensee monitors workers [20.1502, L/C] (X) Y () N

2. Briefly describe licensee's program for monitoring and controlling internal exposures [20.1701, 1702, L/C]:

Personnel involved in the administration of I-131 therapy dosages are monitored within 72 hours of the administration. Researchers are also monitored to any thyroid uptake if they perform iodinations.

3. Aerosols and gases sampled [20.1204, 35.205] (X) Y () N

4. Monitoring/controlling program implemented (includes bioassays) [35.205(d), 315(a)(8), L/C] (X) Y () N

5. Respiratory protection equipment [20.1703] () Y (X) N

E. Reports

1. Reviewed by Assistant RSO Frequency Monthly/quarterly

2. Inspector reviewed personnel monitoring records for period 1994 to June 1995

3. Prior dose determined for individuals likely to receive doses [20.2104] (X) Y () N

4. Maximum exposures TEDE 470 mrem Other: extremity dose 1170 mrem

5. Maximum CDEs _____ Organ(s) _____

6. Maximum CEDE _____

7. Licensee sums internal and external [20.1202] (X) Y () N

8. TEDEs and TODEs within 20.1201 limits (X) Y () N

9. NRC forms or equivalent [20.2104(d), 2106(c)]

- a. NRC-4 (X) Y () N Complete: (X) Y () N
- b. NRC-5 (X) Y () N Complete: (X) Y () N

- 10. Worker declared her pregnancy in writing during inspection period (review records) (X) Y () N
- If yes, licensee in compliance with [20.1208] (X) Y () N
- and records maintained (X) Y () N

Currently there are 8 declared pregnant workers. All of them are provided counselling and a fetal monitoring badge.

- F. Who performed any PSEs at this facility (number of people involved and doses received) [20.1206, 2104(b), 2105, 2204] (X) N/A
- G. Records of exposures, surveys, monitoring, and evaluations maintained [20.2102, 2103, 2106, 35.205(d), 315(a)(8), L/C] (X) Y () N

14. MISADMINISTRATIONS AND RECORDABLE EVENTS

The licensee reported no misadministrations nor any recordable events were identified by the licensee since the last inspection.

15. NRC INDEPENDENT MEASUREMENTS

- A.

<u>Survey instrument</u>	<u>Serial No.</u>	<u>Last calibration</u>
Ludlum 14C	96161	July 1995
- B. Inspector's measurements were compared to licensee's (X) Y () N
- C. Describe the type, location, and results of measurements:

Inspector verified the survey results in the hot lab. Some of the active research labs were surveyed. Sinks in these labs appeared to be free of radioactive contamination.

16. NOTIFICATION AND REPORTS

- A. Licensee in compliance with [19.13] (reports to individuals, public and occupational, monitored to show compliance with Part 20) (X) None
- B. Licensee in compliance with [20.2201] (theft or loss) (X) None
- C. Licensee in compliance with [20.2202] (incidents) (X) None
- D. Licensee in compliance with [20.2203] (overexposures and high radiation levels) (X) None
- E. Licensee aware of NRC Ops Center phone number (X) Y () N

17. POSTING AND LABELING

- A. NRC-3 "Notice to Workers" is posted [19.11] (X) Y () N
- B. Parts 19, 20, 21, Section 206 of Energy Reorganization Act, procedures adopted pursuant to Part 21, and license documents are posted or a notice indicating where documents can be examined is posted [19.11, 21.6] (X) Y () N
- C. Other posting and labeling per [20.1902, 1904] and the licensee is not exempted by [20.1903, 1905] (X) Y () N

18. RECORDKEEPING FOR DECOMMISSIONING

This item not inspected during this inspection.

19. BULLETINS AND INFORMATION NOTICES

- A. Bulletins, Information Notices, NMSS Newsletters, etc., received by the licensee (X) Y () N
B. Licensee took appropriate action in response to Bulletins, Generic Letters, etc. (X) Y () N

20. SPECIAL LICENSE CONDITIONS OR ISSUES () N/A

21. DEBRIEF WITH LICENSING STAFF

Inspection findings discussed with licensing staff (X) N/A

22. CONTINUATION OF REPORT ITEMS

23. VIOLATIONS, NCVs, AND OTHER ISSUES

Note: Briefly state (1) the requirement and (2) how and when the licensee violated the requirement. For non-cited violations, indicate why the violation was not cited.

- A. 35.51: Failure to post apparent exposure rate from a dedicated check source on the survey instrument
B. 35.50: Failure to perform constancy check of the dose calibrator on two occasions
C. 35.404: Failure to include all pertinent information in records of radiation surveys
D. 20.2005: Unauthorized disposal of radioactive waste (self-identified)
E. 20.2108: Record of radioactive waste disposal not maintained (self-identified)

24. EPA REFERRAL FORM

EPA referral form for air effluents sent to appropriate EPA regional office per IP 87102 () Y (X) N
If no, explain:

Licensee stated that the releases of radioactivity into effluents have been calculated and are well below Part 20 limits.

25. PERFORMANCE EVALUATION FACTORS

Licensee Department of the Army
Walter Reed Army Medical Center
Washington, D.C.

Inspectors: Sattar Lodhi

Inspection Dates: August 22 - 24, 1995

- | | | |
|----|---|--|
| A. | Lack of senior management involvement with the radiation safety program and/or Radiation Safety Officer (RSO) oversight | <input type="checkbox"/> Y <input checked="" type="checkbox"/> N |
| B. | RSO too busy with other assignments | <input type="checkbox"/> Y <input checked="" type="checkbox"/> N |
| C. | Insufficient staffing | <input type="checkbox"/> Y <input checked="" type="checkbox"/> N |
| D. | Radiation Safety Committee fails to meet or functions inadequately | <input type="checkbox"/> Y <input checked="" type="checkbox"/> N |
| E. | Inadequate consulting services or inadequate audits | <input type="checkbox"/> Y <input checked="" type="checkbox"/> N |
| F. | Financial Instability | <input type="checkbox"/> Y <input checked="" type="checkbox"/> N |

Remarks (consider above assessment and/or other pertinent PEFs):

The lincensed activities are supervised by the health physics office. The program is well managed. Upper management is actively involved in the program. Prior two inspections were clear. Based on these observations, it is recommended that the next inspection be advanced at least six months and be scheduled during March 1997.

Regional follow-up on above PEFs citations:

The next inspection should include visits to all sites where licensed material is being used.

END