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 (X) Unannounced (X) Routine
( ) Special ( ) Initial ( ) Reinspection

Next Inspection Date: March, 1997 ( ) Normal ( ) Reduced (X) Extended

Summary of Findings and Action:

(X) 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? (X) Y ( ) N

Was proprietary information reviewed by or received by the inspector? (X) Y ( ) N

Inspector _____ Date 9-5-95
(Signature)

Approved _____ Date 9/13/95
(Signature)

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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 organisation 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 who 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 appromixately 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 pharmaceuticals[1] 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.

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[1]If 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 individuals[2] 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

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

	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 respective 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.

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.

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 administerd 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 wasbeing held to be sent to burial site. There were two additional drums containing animal carcasses (< 0.05microcuries/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 (inservice 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)
_X_(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] (X) Y ( ) N

3. Readily accessible during transport [177.817(e)] ( ) 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 couselling 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.	Survey instrument	Serial No.	Last calibration
	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	( ) Y (X) N
B.	RSO too busy with other assignments	( ) Y (X) N
C.	Insufficient staffing	( ) Y (X) N
D.	Radiation Safety Committee fails to meet or functions inadequately	( ) Y (X) N
E.	Inadequate consulting services or inadequate audits	( ) Y (X) N
F.	Financial Instability	( ) Y (X) N

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

The lincesed 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

APPENDIX G

NOTE: All areas indicated in field notes are not required to be addressed during each inspection

NOTE: Any reference to patient is intended to include human research subject

MEDICAL BROAD-SCOPE INSPECTION FIELD NOTES
Region I

Inspection Report No. 96-001 License No. 08-01738-02

Licensee (Name & Address): Docket No. 030-01317
Department of the Army
Walter Reed Army Medical Center
Washington, D.C. 20307-5001

Licensee Contact Col. William S. Johnson - RSO Telephone No. (301) 295-7572/7573

Last Amendment No. 68 Date of Amendment 5/28/96

Priority: 1
Program Code 02110

Date of Last Inspection 11/2/95
Date of This Inspection 9/5-6/96, 9/16/96, 10/1/96

Type of Inspection:
(X) Announced ( ) Unannounced
( ) Routine (X) Special
( ) Initial ( ) Reinspection

Summary of Findings and Action:

( ) No violations, Clear 591 issued
( ) Violation(s), 591 issued
(X) Violation(s), Regional letter issued
( ) Followup on Previous violations

Were non-cited violations identified during this inspection? ( ) Y (X) N

Was proprietary information reviewed by or received by the inspector? ( ) Y (X) N

Inspector Richard D. McKinley (Signature) Date 10/17/96

Approved M. S. Lesser (Signature) Date 10/17/96

2/73

1. INSPECTION HISTORY ( ) N/A - Initial inspection

A. Violations were identified during the last two inspections or two years, whichever is longer (X) Y ( ) N

B. Response letter(s) or 591(s) dated _____

C. Open violations from previous inspections:

Requirement	Violation	Corrective Action Taken (Y/N)	Status Open/Closed

N I

D. Explain any previous violations not corrected or repeated ( ) N/A

2. ORGANIZATION AND SCOPE OF PROGRAM

A. Organizational Structure

Surgeon General + WRAMC Regional Commander → Deputy Commander for Clinical Services → RSO (RSO + 3 HP's + 5-10 techs)

* Col. John Pierce - DCCS
* Col. Martin Crumrine - Dep. Dir. of WRAIR
* Lt. Col. Jeffrey Davies - Exec. officer
+ Col. Wm. B. Johnson - RSO, WRAIR
* David Burton - HP

+ Lt. Col. Thomas [illegible] - Chief, DHVB
Jayasree Nath, Ph.D. - Permit Holder
Steve Rathunel, Ph.D. - Researcher, DHVB
Michael Koenig, Ph.D. - RPO, WRAIR
Col. Barbara Alving - Retiring Chief, DHVB
Chitra Krishnamurti, Ph.D. - researcher DHVB

Gary Matyas, Ph.D. - Permit Holder
Sergeant [illegible] - Biochemist
Vanessa Cox - H.A. Tech
S.S. Wm Donald - NCO in charge of [illegible]
Mary Cutting - Contract employee DHVB
Specialist Peter [illegible] - [illegible]
" Gerard Catalan, DHV
+ Col. Mildred Kressman - CO, WRA (By phone

+ Individuals contacted during inspection
* Individuals present at exit meeting

1. Meets license requirements [L/C] (X) Y ( ) N
2. Multiple authorized locations of use (X) Y ( ) N
   If yes, may use **ATTACHMENT A** as a guide for location(s) or lab(s) inspected and note lab numbers where violations are found. ( ) N/A
3. Briefly describe scope of activities, including types and quantities of use involving byproduct material, frequency of use, staff size, etc.

Inspection restricted to WRAIR and loss of vials of RAM incident reported by the RSO on 9/4/96. There are ~55 active researchers in WRAIR using ~200 labs. Only 6-10 labs are in Bldg. 40. Most use is C-14 & H-3.

On 9/4/96 the RSO reported 8 vials containing 1.13 mCi of C-14 and 3 vials containing 1.34 mCi of H-3 were missing from a locked refrigerator/freezer in Bldg 40 just outside Rm 1073. The researcher had discovered them missing during a ~~check~~ clean ~ 7/3/96 prior to transferring them to another authorization. She reported the loss to the Dept. of Parasitology & Vascular Biology (DHVB) at a meeting on 7/8/96. A search of 2 weeks was conducted and the researcher was instructed twice by her superior to report the loss to the RSO, but she did not do so until ~ 8/30/96. Interviews with the above personnel found no one who was aware of the vials having been removed from the freezer for transfer or disposal. No one had ever found the freezer unlocked.

B. Licensee does limited distribution of pharmaceuticals[1] under Part 35 license ( ) Y ( ) N

1. Indicate type of operation:

___a. Registered or licensed with FDA as a drug manufacturer
___b. Registered or licensed with State Agency as a drug manufacturer
___c. Licensed as a pharmacy by State Board of Pharmacy
___d. Operating as a nuclear pharmacy within a Federal medical institution

2. Licensee distributes
* sealed sources ( ) Y ( ) N
* alpha and beta emitters ( ) Y ( ) N
* generators ( ) Y ( ) N
* photon emitters ( ) Y ( ) N

Remarks:

C. Research involving human subjects ( ) N/A

1. Research is conducted, funded, supported, or regulated by another Federal Agency which has implemented Federal Policy for Protection of Human Subjects[2]? [35.6] ( ) Y ( ) N

If no, does licensee have license amendment authorizing human research? [35.6] ( ) Y ( ) N

2. Licensee obtains informed consent from human subjects? [35.6] ( ) Y ( ) N

3. Licensee obtains approval of research activities from an Institutional Review Board? [35.6] ( ) Y ( ) N

Remarks:

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

[2] Agencies: USDA, DOE, NASA, HUD, DOJ, DOD, VA, EPA, HHS, DOT, Dept. of Commerce, Consumer Product Safety Commission, International Development Cooperation Agency, Agency for International Development, Dept. of Education, National Science Foundation

D. Radiation Safety Committee [33.13, 14, 15] NA ( ) N/A

1.	Membership as specified [35.22(a)(1)]	( ) Y ( ) N
2.	Meetings held quarterly [35.22(a)(2)]	( ) Y ( ) N
3.	Quorums established [35.22(a)(3)]	( ) Y ( ) N
4.	Has sufficient authority [35.23]	( ) Y ( ) N
5.	Record of Committee meetings [35.22(a)(4)]	( ) 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)]	( ) Y ( ) N
7.	Approve/disapprove applications for use [L/C]	( ) Y ( ) N

Remarks:

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

F. Radiation Safety Program

1.	Minor changes pursuant to [35.31] NA ( ) N/A	( ) Y ( ) N
2.	Records of changes maintained [35.31(b)]	( ) Y ( ) N
3.	Content and implementation reviewed annually by the licensee [20.1101(c), 35.22(b)(6)]	( ) Y ( ) N
4.	Records of reviews maintained [20.2102]	( ) Y ( ) N

G. Use by authorized individuals [L/C] ( ) Y ( ) N
If no, list name/position of individual

H. Mobile Nuclear Medicine Service ( ) N/A

1.	Licensee operates services per [35.29, 80]	( ) Y ( ) N
2.	Compliance with 20.1301 evaluated and met	( ) Y ( ) N

I. Any Amendments or Notifications since last inspection [35.13, 14] ( ) Y ( ) N

Licensee has notified NRC within 30 days after RSO stops work or changes name, or mailing address changes [35.14(b)] NA ( ) N/A ( ) Y ( ) N

Remarks:

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: RSO & HP's conduct annual training, permit holders also conduct training, All workers interviewed were aware of the requirement to notify the RSO in case of missing RAM.

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

Remarks:

D. Supervision of individuals

NT

1. Supervised individuals[3] 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)] ( ) Y ( ) N

2. Licensee periodically reviews supervised individuals use of material and records kept to reflect use [35.25(a)(3)] ( ) 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) N/A ( ) Y ( ) N

Remarks:

E. Therapy training

1. Safety instruction [35.310, 410, L/C]

a. Control of patient and visitors ( ) Y ( ) N
b. Contamination and waste ( ) Y ( ) N
c. Size/appearance of sources ( ) N/A ( ) Y ( ) N
d. Handling/shielding of sources ( ) N/A ( ) Y ( ) N
e. RSO notification in emergency or death ( ) Y ( ) N
f. Records maintained [35.310(b), 410(b)] ( ) Y ( ) N

2. Manufacturer's instructions available and followed [35.59(a), 400] ( ) Y ( ) N

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

3. Training for operating and emergency procedures for HDR Remote Afterloaders ( ) N/A ( ) Y ( ) N

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) N/A ( ) Y ( ) N
4. 10% monitoring threshold [20.1502] ( ) Y ( ) N
5. Dose limits to embryo/fetus and declared pregnant worker [20.1208] ( ) N/A ( ) Y ( ) N
6. Grave Danger Posting [20.1902] ( ) N/A ( ) Y ( ) N
7. Procedures for opening packages [20.1906] ( ) N/A ( ) Y ( ) N
8. Sewer disposal limits [20.2003] (X) N/A ( ) Y ( ) N

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.

Remarks:

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) N/A ( ) Y ( ) N
4. Maintenance program implemented for engineering controls (negative pressure, ventilation rates, filter changes, etc.) [35.205(e), L/C] (X) ( ) Y ( ) N

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

1. Maintenance of safety-related components performed by authorized persons [L/C] ( ) Y ( ) N
2. Access to keys and/or material controlled [20.1801, 1802, L/C] ( ) Y ( ) N
3. Access to high/very high radiation areas controlled [20.1601, 1602, L/C] ( ) Y ( ) N
4. Adequate protection of shield integrity, fire protection [L/C] ( ) Y ( ) N

Remarks:

5. EQUIPMENT

A. Dose calibrator - Photon-emitting radionuclides NT

1. Possessed and used [35.50(a)] ( ) Y ( ) N
2. Constancy [35.50(b)(1)]

   a. Performed daily prior to use ( ) Y ( ) N
   b. Dedicated check source used ( ) Y ( ) N

3. Accuracy [35.50(b)(2)]

   a. Performed at installation and annually ( ) Y ( ) N
   b. At least 2 sealed sources used ( ) Y ( ) N

4. Linearity [35.50(b)(3)]

   a. Performed at installation and quarterly thereafter ( ) Y ( ) N
   b. Includes range between 30 uCi and the highest dosage administered ( ) Y ( ) N

5. Geometric Dependence [35.50(b)(4)]

   a. Performed at installation or relocation ( ) Y ( ) N
   b. Includes range of volumes and volume configurations used ( ) Y ( ) N

6. Dosage readings over 10 uCi mathematically corrected for geometry or linearity errors greater than + or - 10% ( ) N/A ( ) Y ( ) N

7. Repaired or replaced when constancy or accuracy errors exceeded + or - 10% ( ) N/A ( ) Y ( ) N

8. Approved procedures followed [35.22, 25, L/C] ( ) Y ( ) N

9. Records maintained and include identity of the individual performing the test. [35.50(e)(2)] ( ) Y ( ) N

Remarks:

B. Instrumentation - Alpha- or beta-emitting radionuclides ( ) N/A

1. List type of equipment used to assay alpha and beta particles:

2. Licensee has procedures for use of instrumentation [35.52(b)] ( ) Y ( ) N

3. Accuracy, linearity and geometric dependence tests are performed prior to initial use, periodically, and following repair, if applicable[4] [35.52(b)(1), L/C] ( ) Y ( ) N

4. Instruments are checked for constancy and proper operation at the beginning of each day of use [35.52(b)(2), L/C] ( ) Y ( ) N

5. Appropriate action taken when calibration errors in excess of limits are identified [L/C] ( ) Y ( ) N

6. Records maintained [L/C] ( ) Y ( ) N

Remarks:

C. Licensee uses generators ( ) Y ( ) N

1. Each eluate/extract used for radiopharmaceuticals tested for Mo-99 breakthrough ( ) Y ( ) N
2. No radiopharmaceuticals <u>administered</u> with Mo-99 concentrations over 0.15 uCi per mCi of Tc-99m ( ) Y ( ) N
3. Records maintained [35.204(c)] ( ) Y ( ) N

D. Syringes properly labeled and shielded [35.60] ( ) Y ( ) N
E. Vials kept in a shield [35.61(a)] ( ) Y ( ) N
F. Vial shields labeled [35.61(b)] ( ) Y ( ) N

Remarks:

6. <u>MATERIALS</u>

A. Licensee measures activity of each dosage of photon-emitting radionuclide prior to use [35.53(a)] ( ) Y ( ) N

B. Licensee administers alpha- or beta-emitting radionuclides ( ) Y ( ) N
If yes,
1. Licensee receives unit doses and relies on assay data supplied by manufacturer or properly licensed organization [35.53(b)] ( ) Y ( ) N

[4]Linearity and geometric dependence tests are not applicable if liquid scintillation is used. Linearity is ~~not~~ applicable if sodium iodide is used.

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)] ( ) 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 AND/OR ( ) Y ( ) N
(2) Prepared by authorized nuclear pharmacist or physician user or individual under the supervision of a authorized nuclear pharmacist or physician user ( ) Y ( ) N

D. Isotope, chemical form, quantity and use as authorized [31.11, 35.400,500, L/C] ( ) Y ( ) N

Remarks:

E. Use of RAM [L/C]

1. Protective clothing worn ( ) Y ( ) N
2. Personnel routinely monitor their hands ( ) Y ( ) N
3. No eating/drinking in use/storage areas ( ) Y ( ) N
4. No food, drink, or personal effects kept in use/storage areas ( ) Y ( ) N
5. Proper dosimetry worn ( ) Y ( ) N
6. Radwaste disposed in proper receptacles ( ) Y ( ) N
7. No pipetting by mouth ( ) 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)] ( ) Y ( ) N
2. Leak test records in microcuries ( ) Y ( ) N
3. Inventory of sealed sources and brachytherapy sources performed quarterly [35.59(g)] ( ) 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)] ( ) Y ( ) N
5. Records maintained and signed by RSO [35.59, 406] ( ) Y ( ) N

Remarks:

7. RADIATION SURVEYS NF ( ) N/A

A. Survey instruments

1. Appropriate operable survey instrumentation possessed [35.120, 220, 320, 420, L/C] or available [35.520, L/C] ( ) N/A ( ) Y ( ) N
2. Calibrations [35.51(a), (b)]

   a. Before first use, annually & after repairs ( ) Y ( ) N
   b. Approved calibration procedure followed to include check source reading determination [35.51(a)(3), L/C] ( ) Y ( ) N
   c. Within 20% in each scale or decade of interest [L/C] ( ) Y ( ) N

3. Records maintained [35.51(d)] ( ) Y ( ) N
4. Source-checked each day of use [35.51(c)] ( ) Y ( ) N

B. Radiation surveys performed

1. Daily in all areas where radiopharmaceuticals are prepared or administered [35.70(a)] ( ) Y ( ) N
2. Weekly in all areas where radiopharmaceuticals or waste is stored [35.70(b)] ( ) Y ( ) N
3. Weekly wipes in all areas where radiopharmaceuticals are prepared for use, administered or stored [35.70(e)] ( ) Y ( ) N
4. Quarterly in brachytherapy source storage area ( ) Y ( ) N

C. Trigger levels [35.70(d), (g)]

1. Established ( ) Y ( ) N
2. Exceeded ( ) Y ( ) N
3. Corrective action taken and documented ( ) Y ( ) N

D. Techniques can detect 0.1 mR/hr, 2000dpm [35.70] ( ) Y ( ) N
E. Records maintained [35.70(h), L/C] ( ) 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)] ( ) Y ( ) N
2. Unrestricted area radiation levels do not exceed 2 mrem in any one hour [20.1301(a)(2)] ( ) Y ( ) N
3. Records maintained [20.2103, 2107] ( ) Y ( ) N

G. Describe licensee's survey requirements for research areas ( ) N/A

H. Research areas surveyed as required [20.1501(a), L/C] ( ) Y ( ) N
I. Research area survey records maintained [20.2103, L/C] ( ) Y ( ) N

Remarks:

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] ( ) Y ( ) N
B. Area dose rate surveys and room contamination surveys [35.315(a)(4), (7)] ( ) Y ( ) N
C. Release of patients containing radiopharmaceuticals meets <5 mR/hr @ 1m or <30 mCi [35.75] ( ) Y ( ) N
D. RSO promptly notified if patient died or had a medical emergency [35.315(b)] ( ) N/A ( ) Y ( ) N

Remarks:

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] ( ) Y ( ) N
B. Patients surveyed immediately after implant [35.406] ( ) Y ( ) N
C. Release of patients with permanent implants meets <5 mR/hr @ 1m [35.75] ( ) N/A ( ) Y ( ) N

D. Patients surveyed immediately after removing the last temporary implant source (required for all manual, LDR, MDR, and HDR therapies) [35.404(a)] ( ) N/A ( ) Y ( ) N
E. Records maintained [35.404(b), 406(d), 415(a)(4)] ( ) Y ( ) N

Remarks:

10. RADIOACTIVE WASTE ( ) N/A

A. Disposal

1. Decay-in-storage ( ) N/A

a. Approved [20.2001, 35.92, L/C] ( ) Y ( ) N
b. Procedures followed [35.92, L/C] ( ) Y ( ) N
c. Labels removed or defaced [20.1904, 35.92] ( ) Y ( ) N

2. Special procedures performed as required [L/C] ( ) Y ( ) N
3. Liquid scintillation (LS) media and animal carcasses per [20.2005] ( ) N/A ( ) Y ( ) N
4. Improper/unauthorized disposals [20.2001] ( ) Y ( ) N
5. Records maintained [20.2103(a), 2108, L/C] ( ) Y ( ) N

B. Effluents ( ) N/A

1. Release into sanitary sewer [20.2003] ( ) N/A ( ) Y ( ) N

a. Material is readily soluble or readily dispersible [20.2003(a)(1)] ( ) Y ( ) N
b. Monthly average release concentrations do not exceed App B, Table 2 values ( ) 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)] ( ) Y ( ) N
d. Procedures to ensure representative sampling and analysis implemented [20.1501, L/C] ( ) Y ( ) N

2. Release into septic tank [20.2003] ( ) N/A ( ) Y ( ) N

a. Within unrestricted limits [App B,Table 2] ( ) Y ( ) N

3. Waste incinerated ( ) N/A

a. License authorizes [20.2004(a)(3)] ( ) Y ( ) N
b. Licensee directly monitors exhaust ( ) Y ( ) N
c. Airborne releases evaluated and controlled [20.1501, 1701] ( ) Y ( ) N

Remarks:

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 ( ) 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: _____

_____

_____

b. Description of effluent program

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

Remarks:

C. Waste Management ( ) N/A

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

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

Note: The licensee's waste is likely to be Class A.

a.	Not packaged for disposal in cardboard or fiberboard boxes [61.56(a)]	( ) Y ( ) N
b.	Liquid wastes solidified, i.e., less than 1% freestanding liquid, and void spaces minimized [61.56(a), (b)]	( ) Y ( ) N

c. Does not generate harmful vapors [61.56] ( ) Y ( ) N

d. Structurally stable (will maintain its physical dimensions and form under *expected disposal conditions*) [61.56(b)] ( ) Y ( ) N

e. Packages properly labeled [App. F.III.A.2] ( ) Y ( ) N

f. Licensee conducts a QC program to ensure compliance with [61.55, 56] and includes management evaluation of audits [App. F.III.A.3] ( ) Y ( ) N

g. Shipments not acknowledged within 20 days after transfer are investigated and reported [App. F.III.A.8] ( ) N/A ( ) Y ( ) N

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

a. Transferred to person specifically licensed to <u>receive waste</u> [30.41, 20.2001(b)] ( ) Y ( ) N

b. Each shipment accompanied by a manifest prepared as specified in Section I of Appendix F [20.2006(b) and App. F.III.A.4] ( ) Y ( ) N

c. Manifests certified as specified in Section II of Appendix F [20.2006(c)] ( ) Y ( ) N

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

Remarks:

11. <u>RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL</u>

A. Describe how packages are received and by whom [33.13, L/C] ( ) N/A

B. Written package opening procedures established and followed [20.1906(e)] ( ) Y ( ) N

C. All incoming packages with a DOT label <u>wiped</u>, unless exempted (gases and special form) [20.1906(b)(1)] ( ) Y ( ) N

D. Incoming packages surveyed [20.1906(b)(2), L/C] ( ) Y ( ) N

E. Monitoring in (C) and (D) above performed within time specified [20.1906(c)] ( ) Y ( ) N

F. Transfer(s) between licensees performed per [30.41] ( ) Y ( ) N

G. All sources surveyed before shipment and transfer [20.1501(a), 49 CFR 173.475(i), L/C] ( ) Y ( ) N

H. Records of surveys and receipt/transfer maintained [20.2103(a), 30.51] ( ) Y ( ) N

I. Transfers within licensee's authorized users or locations performed as required [L/C] ( ) N/A ( ) Y ( ) N

J. Arrangements made for packages containing quantities of radioactive material in excess of Type A quantity [20.1906(a)] ( ) Y ( ) N

K. Package receipt/distribution activities evaluated for compliance with 20.1301 [20.1302] ( ) Y ( ) N

Remarks:

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

A. Licensee shipments are:

( ) delivered to common carriers
( ) transported in licensee's own private vehicle
( ) both
( ) no shipments since last inspection

B. Licensee returns radiopharmacy doses ( ) N/A ( ) Y ( ) N

1. Licensee assumes shipping responsibility ( ) Y ( ) N
2. If NO, describe arrangements made between licensee and radiopharmacy for shipping responsibilities:

C. Packages

1. Authorized packages used [173.415, 416] ( ) N/A ( ) Y ( ) N
2. Performance test records on file ( ) N/A

a. DOT-7A packages [173.415(a)] ( ) Y ( ) N
b. Special form sources [173.476(a)] ( ) Y ( ) N

3. Two labels (White-I, Yellow-II, Yellow-III) with TI, Nuclide, Activity, and Hazard Class [172.403, 173.441] ( ) 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] ( ) Y ( ) N
5. Closed and sealed during transport [173.475(f)] ( ) Y ( ) N

D. Shipping Papers ( ) N/A

1. Prepared and used [172.200(a)] ( ) 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] ( ) Y ( ) N
3. Readily accessible during transport [177.817(e)] ( ) Y ( ) N

Remarks:

13. PERSONNEL RADIATION PROTECTION

A. Licensee performed exposure evaluation [20.1501] ( ) Y ( ) N
B. Licensee incorporated ALARA considerations in the Radiation Protection Program [35.20, 20.1101(b)] ( ) Y ( ) N

C. External Dosimetry ( ) N/A

1. Licensee monitors workers [20.1502(a), L/C] ( ) Y ( ) N
2. External exposures account for contributions from airborne activity [20.1203] ( ) N/A ( ) Y ( ) N
3. Supplier _____ Frequency _____
4. Supplier is NVLAP-approved [20.1501(c)] ( ) Y ( ) N
5. Dosimeters exchanged at required frequency [L/C] ( ) Y ( ) N

D. Internal Dosimetry ( ) N/A

1. Licensee monitors workers [20.1502, L/C] ( ) Y ( ) N
2. Briefly describe licensee's program for monitoring and controlling internal exposures [20.1701, 1702, L/C]:
3. Aerosols and gases sampled [20.1204, 35.205] ( ) Y ( ) N
4. Monitoring/controlling program implemented (includes bioassays) [35.205(d), 315(a)(8), L/C] ( ) Y ( ) N
5. Respiratory protection equipment [20.1703] ( ) Y ( ) N

E. Reports

1. Reviewed by _____ Frequency _____
2. Inspector reviewed personnel monitoring records for period _____ to _____
3. Prior dose determined for individuals likely to receive doses [20.2104] ( ) Y ( ) N
4. Maximum exposures TEDE _____ Other _____
5. Maximum CDEs _____ Organ(s) _____
6. Maximum CEDE _____
7. Licensee sums internal and external [20.1202] ( ) Y ( ) N
8. TEDEs and TODEs within 20.1201 limits ( ) Y ( ) N
9. NRC forms or equivalent [20.2104(d), 2106(c)]

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

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

F. Who performed any PSEs at this facility (number of people involved and doses received) [20.1206, 2104(b), 2105, 2204] ( ) N/A

G. Records of exposures, surveys, monitoring, and evaluations maintained [20.2102, 2103, 2106, 35.205(d), 315(a)(8), L/C] ( ) Y ( ) N

Remarks:

14. MISADMINISTRATIONS AND RECORDABLE EVENTS

A. If misadministrations or recordable events (defined in 35.2) have occurred since last inspection, evaluate the incident(s) and the licensee's quality management program (QMP) using the existing guidance. [Reference TI 2800/025 and IP 87103]

1. Event date _____ Information Source _____
2. Notifications

NRC Ops Center	( ) Y ( ) N	Region	( ) Y ( ) N
Referring Physician	( ) Y ( ) N	Patient	( ) Y ( ) N
In writing	( ) Y ( ) N		

If notification did not occur, why not:

3. Written Reports [35.33]

a. Submitted to Region within 15 days ( ) Y ( ) N
b. Copy to patient within 15 days ( ) Y ( ) N

B. Records maintained [35.33(b)] ( ) Y ( ) N

Remarks:

15. NRC INDEPENDENT MEASUREMENTS

A. Survey instrument Serial No. Last calibration

B. Inspector's measurements were compared to licensee's ( ) Y ( ) N
C. Describe the type, location, and results of measurements:

16. NOTIFICATION AND REPORTS

A. Licensee in compliance with [19.13] (reports to individuals, public and occupational, monitored to show compliance with Part 20) ( ) None ( ) Y ( ) N

B. Licensee in compliance with [20.2201] (theft or loss) ( ) None ( ) Y ( ) N

C. Licensee in compliance with [20.2202] (incidents) ( ) None ( ) Y ( ) N

D. Licensee in compliance with [20.2203] (overexposures and high radiation levels) ( ) None ( ) Y ( ) N

E. Licensee aware of NRC Ops Center phone number ( ) Y ( ) N

17. POSTING AND LABELING

A. NRC-3 "Notice to Workers" is posted [19.11] ( ) 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] ( ) Y ( ) N

C. Other posting and labeling per [20.1902, 1904] and the licensee is not exempted by [20.1903, 1905] ( ) Y ( ) N

Remarks:

18. RECORDKEEPING FOR DECOMMISSIONING

A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination [30.35(g)] ( ) Y ( ) N

B. Records include all information outlined in [30.35(g)] ( ) Y ( ) N

Remarks:

19. BULLETINS AND INFORMATION NOTICES

A. Bulletins, Information Notices, NMSS Newsletters, etc., received by the licensee ( ) Y ( ) N

B. Licensee took appropriate action in response to Bulletins, Generic Letters, etc. ( ) Y ( ) N

Remarks:

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

A. Special license conditions or issues to be reviewed:

B. Evaluation:

VI

21. DEBRIEF WITH LICENSING STAFF

10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

22 Contrary to the above, on July 8, 1996, the licensee did not secure from unauthorized removal or limit access to 1.13 mCi of carbon-14 and 1.34 mCi of hydrogen-3 contained in vials located in a refrigerator/freezer in the hallway of Building 40 of WRAIR outside Room 1073, an unrestricted area, nor did the licensee control and maintain constant surveillance of this licensed material. These materials were lost.

10 CFR 20.2201(a)(1)(ii) requires that each licensee shall report by telephone within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, all licensed material in a quantity greater than 10 times the quantity specified in appendix C to part 20 that is still missing at this time.

EPA referral form for all [illegible] sent to appr[illegible]
EPA regional offi[illegible]

Contrary to the above, the licensee did not report by telephone within 30 days after the occurrence of missing licensed material became known to the licensee on July 8, 1996. Specifically, upon discovery of the loss of 1.13mCi of carbon-14 and 1.34 mCi of hydrogen-3 on or about July 8, 1996, the licensee did not report this loss to the NRC until September 4, 1996, a time period greater than 30 days.

Licensee (name & location): Dept of the Army, Walter Reed Army MC, Washington, D.C

Inspector: Richard W. McKinley

Inspection Date: 7/5-6/96 & 9/16/96 & 10/1/96

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

Remarks (consider above assessment and/or other pertinent PEFs):
Licensee submission dated 10/1/96 addresses violations above. No need for a response to NOV, see attached letter 10/1/96.

Regional follow-up on above PEFs citations:

END

ATTACHMENT A

LABORATORY INSPECTION FIELD NOTES

1. Date 9/5-6/96 Authorized User(s) Lt. Col. Thomas Reid, Joyasree Nath, Ph.D., Steve Rothwell, Ph.D., Michael Koenig, Ph.D., Lt Barbara Ching, Chitra Krishnamurthi, Ph.D., Gary Matyas, PhD
2. Location(s) Building Bldg 40 & WRAIR Room(s) In and around Rm 1073
3. Person(s) Contacted ~~Dr~~ Dave Lovell and Vanessa Cox, S.S. Wm Donald, Mary Cutting, Peter MacInnes, Gerard Estebar
4. Describe scope of lab use (Nuclides, form, frequency, purpose, etc): Most use was CH/PS, especially C-14 & H-3. Occasional I-125 and ~~Exempt~~ In-111. RAM in question had not been used for at least 2 years. This was typical of research in DHVB
5. Training
   A. Frequency: annual Conducted by: RSO & Permit holder
   B. Individuals interviewed understand safety practices (X) Y ( ) N

Remarks: ~~Dr~~ all personnel interviewed the security arrangements and access to RAM.

6. Surveys
   A. Types of surveys performed (daily, ~~weekly,~~ monthly, etc.) N/I
   B. Instrumentation properly calibrated and used ( ) Y ( ) N
   C. Efficiency of counting system determined ( ) Y ( ) N
   D. Hood airflow adequate and checked as required ( ) N/A ( ) Y ( ) N
   E. Records maintained: trigger levels established, area diagram, instrument used, individual performing survey, results in proper units, decontamination performed as necessary, etc.) ( ) Y ( ) N
   F. Inspector surveyed ( ) Y ( ) N
      Results satisfactory ( ) N/A ( ) Y ( ) N

Remarks:

7. Receipt and Transfer
   A. Incoming packages properly surveyed ( ) Y ( ) N
   B. Interlaboratory transfers performed as specified in the license ( ) N/A ( ) Y ( ) N
   C. Records maintained ( ) Y ( ) N

Remarks: There was no record of any RAM having been transferred to other labs, nor could anyone recall it having been done in the recent past (~2 yrs).

8. Personnel Dosimetry
   A. Appropriate dosimetry assigned and worn N/E ( ) N/A ( ) Y ( ) N
   B. Results available to lab personnel ( ) Y ( ) N
   C. Bioassays performed N/A ( ) N/A ( ) Y ( ) N

Remarks:

9. Handling Waste

A.	Procedures followed		( ) Y ( ) N
B.	Proper storage (area, containers, labeling, etc.)		( ) Y ( ) N
C.	Liquid/solid waste disposal		( ) Y ( ) N
D.	Incineration	( ) N/A	( ) Y ( ) N
E.	Compaction	( ) N/A	( ) Y ( ) N
F.	Sewer discharge	( ) N/A	( ) Y ( ) N
G.	Records maintained		( ) Y ( ) N

Remarks: There was no evidence in waste disposal records that the vials in question (11 vials = 8 vials containing 1.13 mCi of C-14 and 3 vials containing 1.34 mCi of C-14) had been disposed in RAM waste. The licensee suspects that they were inadvertently disposed with other RAM & therefore weren't recorded

10. Inventory conducted ( ) N/A (X) Y ( ) N
Records Maintained (X) Y ( ) N

Remarks: Semiannual inventories conducted jointly by researchers and Rad Safety HP's though in the past they weren't usually physical inventories. A physical inventory had been done of the vials in question in 3/96 by R.S. Researcher. The latter also does quarterly inventories in-between. 3/19/96

11. Storage and use of RAM

A.	Adequate method to prevent unauthorized access	(X) Y ( ) N
B.	Condition of areas acceptable	(X) Y ( ) N
C.	Personnel wear disposable gloves and protective clothing while handling material	NI ( ) Y ( ) N
D.	Hands monitored after procedures or before leaving	( ) Y ( ) N
E.	No eating, drinking, or smoking in use/storage areas	( ) Y ( ) N
F.	No food, drink, or personal items stored in use/storage areas	( ) Y ( ) N
G.	Use of shielding/distance while using/storing material	(X) Y ( ) N
H.	RAM is under surveillance and control when not in storage in an unrestricted area	(X) Y ( ) N

Remarks: RAM locked in refrigerator/freezers when not in use. Keys are kept in labs. Saw no evidence of unattended RAM not in storage.

12. Posting and Labeling

A.	NRC-3 "Notice to Workers"	( ) Y ( ) N
B.	Parts 19, 20, 21, Section 206 of Energy Reorganization Act, procedures for Part 21, and license documents or a notice indicating where documents can be examined	( ) Y ( ) N
C.	Other posting and labeling requirements met	( ) Y ( ) N

Remarks:

13. Violations Observed

Failure to control RAM (licensed) 10CFR20.1801 and 1802.
Failure to report the loss of C-14 in excess of 10 times app C value within 30 days of discovery 10CFR20.2201(a)(1)(ii).

END

APPENDIX G

NOTE: All areas indicated in field notes are not required to be addressed during each inspection

NOTE: Any reference to patient is intended to include human research subject

MEDICAL BROAD-SCOPE INSPECTION FIELD NOTES
Region 1

Inspection Report No. 97-001 License No. 08-01738 -02

Licensee (Name & Address): Docket No. 030-01384

Dept. of the Army

Washington, DC

Licensee Contact Col. Wm. Johnson Telephone No. _____

Last Amendment No. 68 Date of Amendment 5-28-96

Priority: 1 G1
Program Code 2110

Date of Last Inspection 9/5-96/96
Date of This Inspection 2/11-21/97

Type of Inspection:

( ) Announced (✓) Unannounced
(✓) Routine ( ) Special
( ) Initial ( ) Reinspection

Summary of Findings and Action:

( ) No violations, Clear 591 issued
(✓) Violation(s), 591 issued
( ) Violation(s), Regional letter issued
( ) Followup on Previous violations

Were non-cited violations identified during this inspection? ( ) Y (✓) N

Was proprietary information reviewed by or received by the inspector? Mark Sitek, Grad Fellow ( ) Y ( ) N

Inspector Teresa Hall Darden (Signature) Date 2/14/97

Approved M. Shanbaky (Signature) Date 4/15/97

2/74

NRC Inspection

1) Nuclear Medicine

*	COL	Rodriguez	Chief Nuclear Medicine
	LTC	Berndt	Nuclear Pharmacy Instructor
*	CPT	Thomas	Nuclear Pharmacist
	CPT	Krueger	Nuclear Pharmacy Resident
	CPT	Thompson	" " "
	Ms	Marquez-Sayer	" " Technician
	Mr	French	" Medicine Imaging
	SGT	Horner	Nuclear Medicine Tech. Student

2) Radiation Oncology

*	Dr.	Choi	Medical Physicist
	Dr.	Saylor	" " (Contract)
	MAJ	Willison	Acting Chief Rad. Oncology
	MAJ	Halligan	Rad. Oncology Physician
	Mr.	Eck	" " Technician
*	Dr.	Fred Williamson	

3) WRAIR Walter Reed Army Institute of Research

*	Dr.	Mike Koenig	RSO
	SSG	Mensing	Medical lab NCO in Safety Office (alternate RPO)

Ron Suter, Site RSO / RSC AFIP

* Comdr Michael Kussman, Brig Gen
* Col John Pierce

1. INSPECTION HISTORY ( ) N/A Initial inspection

A. Violations were identified during the last two inspections or two years, whichever is longer (✓) Y ( ) N

B. Response letter(s) or 591(s) dated _____

C. Open violations from previous inspections:

Requirement	Violation	Corrective Action Taken (Y/N)	Status Open/Closed
20.1801	Security of C^{14} & H^3	Y	C
20.2201(a)(i)	Notification Failure	Y	C

D. Explain any previous violations not corrected or repeated (✓) N/A

2. ORGANIZATION AND SCOPE OF PROGRAM

A. Organizational Structure:

As described in license Backup

* See Attachment

+ Individuals contacted during inspection
* Individuals present at exit meeting

1. Meets license requirements [L/C] (✓) Y ( ) N
2. Multiple authorized locations of use (✓) Y ( ) N
   If yes, may use **ATTACHMENT A** as a guide for location(s) or lab(s) inspected and note lab numbers where violations are found. ( ) N/A
3. Briefly describe scope of activities, including types and quantities of use involving byproduct material, frequency of use, staff size, etc.

Type A medical Broadscope
1. Nuclear Pharmacy with Training for pharmacists, residents & techs.
2. 10CFR 35.100, 200, 300 & 400 procedures with relatively active therapy components
3. R+D with general use of CHIPS & small quantities some others

RS Office 19 FTE positions with 6 vacancies

B. Licensee does limited distribution of pharmaceuticals[1] under Part 35 license (✓) Y (✓) N

1. Indicate type of operation:

___a. Registered or licensed with FDA as a drug manufacturer
___b. Registered or licensed with State Agency as a drug manufacturer
___c. Licensed as a pharmacy by State Board of Pharmacy
✓d. Operating as a nuclear pharmacy within a Federal medical institution

2. Licensee distributes
* sealed sources ( ) Y ( ) N
* alpha and beta emitters ( ) Y ( ) N
* generators ( ) Y ( ) N
* photon emitters ( ) Y ( ) N

Remarks:
Licensee make & distributes only to WRAMC

C. Research involving human subjects ( ) N/A

1. Research is conducted, funded, supported, or regulated by another Federal Agency which has implemented Federal Policy for Protection of Human Subjects[2]? [35.6] ( ) Y (✓) N

If no, does licensee have license amendment authorizing human research? [35.6] (✓) Y ( ) N

2. Licensee obtains informed consent from human subjects? [35.6] (✓) Y ( ) N

3. Licensee obtains approval of research activities from an Institutional Review Board? [35.6] (✓) Y ( ) N

Remarks:

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

Agencies: USDA, DOE, NASA, HUD, DOJ, DOD, VA, EPA, HHS, DOT, Dept. of Commerce, Consumer Product Safety Commission, International Development Cooperation Agency, Agency for International Development, Dept. of Education, National Science Foundation

D. Radiation Safety Committee [33.13, 14, 15] ( ) N/A

1. Membership as specified [35.22(a)(1)] (✓) Y ( ) N
2. Meetings held quarterly [35.22(a)(2)] (✓) Y ( ) N
3. Quorums established [35.22(a)(3)] (✓) Y ( ) N
4. Has sufficient authority [35.23] (✓) Y ( ) N
5. Record of Committee meetings [35.22(a)(4)] (✓) 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)] (✓) Y ( ) N
7. Approve/disapprove applications for use [L/C] (✓) Y ( ) N

Remarks:

E. Radiation Safety Officer

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

F. Radiation Safety Program

1. Minor changes pursuant to [35.31] ( ) N/A (✓) Y ( ) N
2. Records of changes maintained [35.31(b)] (✓) Y ( ) N
3. Content and implementation reviewed annually by the licensee [20.1101(c), 35.22(b)(6)] (✓) Y ( ) N
4. Records of reviews maintained [20.2102] (✓) Y ( ) N

G. Use by authorized individuals [L/C] (✓) Y ( ) N
If no, list name/position of individual

H. Mobile Nuclear Medicine Service (✓) N/A

1. Licensee operates services per [35.29, 80] ( ) Y ( ) N
2. Compliance with 20.1301 evaluated and met ( ) Y ( ) N

I. Any Amendments or Notifications since last inspection [35.~~13, 14~~] (✓) Y ( ) N

Licensee has notified NRC within 30 days after RSO stops work or changes name, or mailing address changes [35.14(b)] (✓) N/A ( ) Y ( ) N

Remarks:

Nuc. Pharmacist was not trained in requirements for Bioassay.

5. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

NC

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

1. If so, briefly describe training program:

All's are responsible for initial 19.12 training of their workers.

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

Remarks:

* 1 individual ~~was doing~~ who handles RAM in R&D lab was unaware of the requirement to wear protective clothing when handling RAM. This individual performs simple assays & will receive required user training in April

D. Supervision of individuals

? Bioassay not performed on nuclear pharmacists

1. Supervised individuals[3] 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)] (✓) Y ( ) N

2. Licensee periodically reviews supervised individuals use of material and records kept to reflect use [35.25(a)(3)] (✓) 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)] ( ) N/A (✓) Y ( ) N

Remarks:

E. Therapy training

1. Safety instruction [35.310, 410, L/C]

a. Control of patient and visitors (✓) Y ( ) N
b. Contamination and waste (✓) Y ( ) N
c. Size/appearance of sources ( ) N/A (✓) Y ( ) N
d. Handling/shielding of sources ( ) N/A (✓) Y ( ) N
e. RSO notification in emergency or death (✓) Y ( ) N
f. Records maintained [35.310(b), 410(b)] (✓) Y ( ) N

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

2. Manufacturer's instructions available and followed [35.59(a), 400] Leak Tests etc. (✓) Y ( ) N
3. Training for operating and emergency procedures for HDR Remote Afterloaders (X) N/A ( ) Y ( ) N

F. Revised Part 20

Workers cognizant of requirements for:

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

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.

Remarks:

4. FACILITIES

A. Facilities as described in license application (✓) Y ( ) N
B. Storage areas

1. Materials secured from unauthorized removal or access [20.1801] (✓) Y ( ) N
2. Licensee controls and maintains constant surveillance of licensed material not in storage [20.1802] (✓) 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] (✓) Y ( ) N
4. Maintenance program implemented for engineering controls (negative pressure, ventilation rates, filter changes, etc.) [35.205(e), L/C] (✓) Y ( ) N

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

1. Maintenance of safety-related components performed by authorized persons [L/C] ( ) Y ( ) N
2. Access to keys and/or material controlled [20.1801, 1802, L/C] ( ) Y ( ) N
3. Access to high/very high radiation areas controlled [20.1601, 1602, L/C] ( ) Y ( ) N
4. Adequate protection of shield integrity, fire protection [L/C] ( ) Y ( ) N

Remarks:

5. EQUIPMENT

A. Dose calibrator - Photon-emitting radionuclides

1. Possessed and used [35.50(a)] (✓) Y ( ) N
2. Constancy [35.50(b)(1)]

a. Performed daily prior to use (✓) Y ( ) N
b. Dedicated check source used (✓) Y ( ) N

3. Accuracy [35.50(b)(2)]

a. Performed at installation and annually (✓) Y ( ) N
b. At least 2 sealed sources used (✓) Y ( ) N

4. Linearity [35.50(b)(3)]

a. Performed at installation and quarterly thereafter (✓) Y ( ) N
b. Includes range between 30 uCi and the highest dosage administered (✓) Y ( ) N

5. Geometric Dependence [35.50(b)(4)]

a. Performed at installation or relocation (✓) Y ( ) N
b. Includes range of volumes and volume configurations used (✓) Y ( ) N

6. Dosage readings over 10 uCi mathematically corrected for geometry or linearity errors greater than + or - 10% ( ) N/A ( ) Y (✓) N Instrumen Repaired

7. Repaired or replaced when constancy or accuracy errors exceeded + or - 10% ( ) N/A (✓) Y ( ) N

8. Approved procedures followed [35.22, 25, L/C] (✓) Y ( ) N

9. Records maintained and include identity of the individual performing the test. [35.50(e)(2)] (✓) Y ( ) N

Remarks: Licensee has 2 dose calibrators in continual use in the Nuclear Pharmacy

B. Instrumentation - Alpha- or beta-emitting radionuclides ( ) N/A HF

1. List type of equipment used to assay alpha and beta particles:

2. Licensee has procedures for use of instrumentation [35.52(b)] ( ) Y ( ) N

3. Accuracy, linearity and geometric dependence tests are performed prior to initial use, periodically, and following repair, if applicable[4] [35.52(b)(1), L/C] ( ) Y ( ) N

4. Instruments are checked for constancy and proper operation at the beginning of each day of use [35.52(b)(2), L/C] ( ) Y ( ) N

5. Appropriate action taken when calibration errors in excess of limits are identified [L/C] ( ) Y ( ) N

6. Records maintained [L/C] ( ) Y ( ) N

Remarks: No Sr 89 administered since 6/96

C. Licensee uses generators (✓) Y ( ) N

1. Each eluate/extract used for radiopharmaceuticals tested for Mo-99 breakthrough (✓) Y ( ) N

2. ~~No~~ Radiopharmaceuticals administered with Mo-99 concentrations over 0.15 uCi per mCi of Tc-99m ( ) Y (✓) N

3. Records maintained [35.204(c)] (✓) Y ( ) N

D. Syringes properly labeled and shielded [35.60] (✓) Y ( ) N

E. Vials kept in a shield [35.61(a)] (✓) Y ( ) N

F. Vial shields labeled [35.61(b)] (✓) Y ( ) N

Remarks:

6. MATERIALS

A. Licensee measures activity of each dosage of photon-emitting radionuclide prior to use [35.53(a)] (✓) Y ( ) N

B. Licensee administers alpha- or beta-emitting radionuclides ( ) Y (✓) N
Not currently, but used in the past
If yes,

1. Licensee receives unit doses and relies on assay data supplied by manufacturer or properly licensed organization [35.53(b)] ( ) Y ( ) N/A

Linearity and geometric dependence tests are not applicable if liquid scintillation is used. Linearity is not applicable if sodium iodide is used.

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)] NI ( ) 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 AND/OR (✓) Y ( ) N
(2) Prepared by authorized nuclear pharmacist or physician user or individual under the supervision of a authorized nuclear pharmacist or physician user (✓) Y ( ) N

D. Isotope, chemical form, quantity and use as authorized [31.11, 35.400,500, L/C] (✓) Y ( ) N

Remarks:

E. Use of RAM [L/C]

1. Protective clothing worn (✓) Y ( ) N
2. Personnel routinely monitor their hands (✓) Y ( ) N
3. No eating/drinking in use/storage areas (✓) Y ( ) N
4. No food, drink, or personal effects kept in use/storage areas (✓) Y ( ) N
5. Proper dosimetry worn (✓) Y ( ) N
6. Radwaste disposed in proper receptacles (✓) Y ( ) N
7. ~~No~~ pipetting by mouth ( ) Y (✓) N

F. Radioisotopes are used in research in accordance with current procedures [L/C] (✓) Y ( ) N

G. Leak tests and Inventories

1. Leak test performed on sealed sources and brachytherapy sources [35.59(b)] (✓) Y ( ) N
2. Leak test records in microcuries (✓) Y ( ) N
3. Inventory of sealed sources and brachytherapy sources performed quarterly [35.59(g)] (✓) 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)] (✓) Y ( ) N
5. Records maintained and signed by RSO [35.59, 406] (✓) Y ( ) N

Remarks:

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] ( ) N/A (✓) Y ( ) N
2. Calibrations [35.51(a), (b)]

a. Before first use, annually & after repairs (✓) Y ( ) N
b. Approved calibration procedure followed to include check source reading determination [35.51(a)(3), L/C] (✓) Y ( ) N
c. Within 20% in each scale or decade of interest [L/C] (✓) Y ( ) N

3. Records maintained [35.51(d)] (✓) Y ( ) N
4. Source-checked each day of use [35.51(c)] (✓) Y ( ) N

B. Radiation surveys performed

1. Daily in all areas where radiopharmaceuticals are prepared or administered [35.70(a)] (✓) Y ( ) N
2. Weekly in all areas where radiopharmaceuticals or waste is stored [35.70(b)] (✓) Y ( ) N
3. Weekly wipes in all areas where radiopharmaceuticals are prepared for use, administered or stored [35.70(e)] (✓) Y ( ) N
4. Quarterly in brachytherapy source storage area (✓) Y ( ) N

C. Trigger levels [35.70(d), (g)]

1. Established (✓) Y ( ) N
2. Exceeded (✓) Y ( ) N
3. Corrective action taken and documented (✓) Y ( ) N

D. Techniques can detect 0.1 mR/hr, 2000dpm [35.70] (✓) Y ( ) N
E. Records maintained [35.70(h), L/C] (✓) 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)] (✓) Y ( ) N
2. Unrestricted area radiation levels do not exceed 2 mrem in any one hour [20.1301(a)(2)] (✓) Y ( ) N
3. Records maintained [20.2103, 2107] (✓) Y ( ) N

G Describe licensee's survey requirements for research areas( ) N/A

Activity Related > 200 uCi = Weekly Surveys
200 ≤ 100 monthly

H. Research areas surveyed as required [20.1501(a), L/C] (✓) Y ( ) N
I. Research area survey records maintained [20.2103, L/C](✓ Y ( ) N

Remarks: Rad. Prot. Office performs their surveys as required and IDs users with survey deficiencies

8. Patient Release (✓) N/A

THE FOLLOWING GUIDANCE IS TO BE USED AFTER THE 1997 REVISION TO 10 CFR 35.75 BECOMES EFFECTIVE. IF USING THIS SECTION, DO NOT ANSWER ITEMS 9.C AND 10.C BELOW.

A. Individuals released when TEDE less than 0.5 mrem [35.75(a)] ( ) Y ( ) N
B. Instructions on ALARA provided to individual when TEDE exceeds 0.1 rem [35.75(b)] ( ) Y ( ) N
C. Instructions to breast-feeding women included required information [35.75(b)] ( ) Y ( ) N
D. Release records mainatined if 35.75(c) criteria are not met [35.75(c)] ( ) Y ( ) N
E. Records of instructions given to breast-feeding women maintained if required [35.75(d)] ( ) Y ( ) N

9. 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] (✓) Y ( ) N
B. Area dose rate surveys and room contamination surveys [35.315(a)(4), (7)] (✓) Y ( ) N
C. Release of patients containing radiopharmaceuticals meets <5 mR/hr @ 1m or <30 mCi [35.75] (✓) Y ( ) N
D. RSO promptly notified if patient died or had a medical emergency [35.315(b)] (✓) N/A ( ) Y ( ) N

Remarks: Licensee has (license) exception for decaying I-131 pt. room that is dedicated for ≥ 30 mCi therapy doses

10. BRACHYTHERAPY ( ) N/A

A. Safety precautions implemented to include patient facilities, room posting, stay times, and area radiation level surveys [35.415, L/C] (✓) Y ( ) N
B. Patients surveyed immediately after implant [35.406] (✓) Y ( ) N
C. Release of patients with permanent implants meets <5 mR/hr @ 1m [35.75] ( ) N/A (✓) Y ( ) N

D. Patients surveyed immediately after removing the last temporary implant source (required for all manual, LDR, MDR, and HDR therapies) [35.404(a)] ( ) N/A (✓) Y ( ) N

E. Records maintained [35.404(b), 406(d), 415(a)(4)] (✓) Y ( ) N

Remarks:

II. RADIOACTIVE WASTE ( ) N/A

A. Disposal

1. Decay-in-storage ( ) N/A

a. Approved [20.2001, 35.92, L/C] (✓) Y ( ) N
b. Procedures followed [35.92, L/C] (✓) Y ( ) N
c. Labels removed or defaced [20.1904, 35.92] (✓) Y ( ) N

2. Special procedures performed as required [L/C] (✓) Y ( ) N
3. Liquid scintillation (LS) media and animal carcasses per [20.2005] ( ) N/A (✓) Y ( ) N
4. Improper/unauthorized disposals [20.2001] ( ) Y (✓) N
5. Records maintained [20.2103(a), 2108, L/C] (✓) Y ( ) N

B. Effluents ( ) N/A

1. Release into sanitary sewer [20.2003] ( ) N/A (✓) Y ( ) N

a. Material is readily soluble or readily dispersible [20.2003(a)(1)] (✓) Y ( ) N
b. Monthly average release concentrations do not exceed App B, Table 2 values ( ) 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)] ( ) Y (✓) N
d. Procedures to ensure representative sampling and analysis implemented [20.1501, L/C] (✓) Y ( ) N

2. Release into septic tank [20.2003] (✓) N/A ( ) Y ( ) N

a. Within unrestricted limits [App B,Table 2] ( ) Y ( ) N

3. Waste incinerated (✓) N/A

a. License authorizes [20.2004(a)(3)] ( ) Y ( ) N
b. Licensee directly monitors exhaust ( ) Y ( ) N
c. Airborne releases evaluated and controlled [20.1501, 1701] ( ) Y ( ) N

Remarks:

4. Control of air effluents and ashes [20.1101, 1201, 1301, 1501, 2001, L/C]
{See also IP 87102, RG 8.37} ( ) N/A

a. Air effluent less than 10 mrem constraint limit [20.1101] (√) Y ( ) N

b. If no, licensee reported appropriate information to NRC ( ) Y ( ) N
1. Corrective actions implemented and on schedule ( ) Y ( ) N

c. Description of effluent program

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

MI

Remarks:

C. Waste Management ( ) N/A

1. Waste compacted (√) Y ( ) N
2. Storage area(s) ( ) N/A

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

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

Note: The licensee's waste is likely to be Class A

a. Not packaged for disposal in cardboard or fiberboard boxes [61.56(a)] ( ) Y (√) N
b. Liquid wastes solidified, i.e., less than 1% freestanding liquid, and void spaces minimized [61.56(a), (b)] (√) Y ( ) N

c. Does not generate harmful vapors [61.56] ( ) Y (√) N

d. Structurally stable (will maintain its physical dimensions and form under expected disposal conditions) [61.56(b)] (√) Y ( ) N
e. Packages properly labeled [App. F.III.A.2] (√) Y ( ) N

f. Licensee conducts a QC program to ensure compliance with [61.55, 56] and includes management evaluation of audits [App. F.III.A.3] (√) Y ( ) N

g. Shipments not acknowledged within 20 days after transfer are investigated and reported [App. F.III.A.8] (√) N/A ( ) Y ( ) N

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

a. Transferred to person specifically licensed to receive waste [30.41, 20.2001(b)] (√) Y ( ) N

b. Each shipment accompanied by a manifest prepared as specified in Section I of Appendix F [20.2006(b) and App. F.III.A.4] (√) Y ( ) N

c. Manifests certified as specified in Section II of Appendix F [20.2006(c)] (√) Y ( ) N

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

Remarks:

12. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

A. Describe how packages are received and by whom [33.13, L/C] Packages routinely received in RPO except for nuclear medicine materials ( ) N/A

B. Written package opening procedures established and followed [20.1906(e)] (√) Y ( ) N

C. All incoming packages with a DOT label wiped, unless exempted (gases and special form) [20.1906(b)(1)] (√) Y ( ) N

D. Incoming packages surveyed [20.1906(b)(2), L/C] (√) Y ( ) N

E. Monitoring in (C) and (D) above performed within time specified [20.1906(c)] (√) Y ( ) N

F. Transfer(s) between licensees performed per [30.41] (√) Y ( ) N

G. All sources surveyed before shipment and transfer [20.1501(a), 49 CFR 173.475(i), L/C] (√) Y ( ) N

H. Records of surveys and receipt/transfer maintained [20.2103(a), 30.51] (√) Y ( ) N

I. Transfers within licensee's authorized users or locations performed as required [L/C] ( ) N/A (√) Y ( ) N

J. Arrangements made for packages containing quantities of radioactive material in excess of Type A quantity [20.1906(a)] (√) Y ( ) N

K. Package receipt/distribution activities evaluated for compliance with 20.1301 [20.1302] (√) Y ( ) N

Remarks:

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

A. Licensee shipments are:

(✓) delivered to common carriers
( ) transported in licensee's own private vehicle
(✓) both
( ) no shipments since last inspection

B. Licensee returns radiopharmacy doses (✓) N/A ( ) Y ( ) N

1. Licensee assumes shipping responsibility ( ) Y ( ) N
2. If NO, describe arrangements made between licensee and radiopharmacy for shipping responsibilities:

C. Packages

Waste only

1. Authorized packages used [173.415, 416] ( ) N/A ( ) Y ( ) N
2. Performance test records on file ( ) N/A
   a. DOT-7A packages [173.415(a)] ( ) Y ( ) N
   b. Special form sources [173.476(a)] ( ) Y ( ) N
3. Two labels (White-I, Yellow-II, Yellow-III) with TI, Nuclide, Activity, and Hazard Class [172.403, 173.441] ( ) 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] ( ) Y ( ) N
5. Closed and sealed during transport [173.475(f)] ( ) Y ( ) N

D. Shipping Papers ( ) N/A

1. Prepared and used [172.200(a)] (✓) 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] (✓) Y ( ) N
3. Readily accessible during transport [177.817(e)] (✓) Y ( ) N

Remarks:

14. PERSONNEL RADIATION PROTECTION

A. Licensee performed exposure evaluation [20.1501] (✓) Y ( ) N
B. Licensee incorporated ALARA considerations in the Radiation Protection Program [35.20, 20.1101(b)] (✓) Y ( ) N

ing Radiation Dosimetry Lab
IRDC
Redstone Arsenal, Alabama

C. External Dosimetry ( ) N/A

1. Licensee monitors workers [20.150[illegible], L/C] (✓) Y ( ) N
2. External exposures account for contributions from airborne activity [20.1203] ( ) N/A ( ) Y ( ) N
3. Supplier USARMY Ionizing / Frequency monthly
4. Supplier is NVLAP-approved [20.1501(c)] (✓) Y ( ) N
5. Dosimeters exchanged at required frequency [L/C] (✓) Y ( ) N

D. Internal Dosimetry ( ) N/A

1. Licensee monitors workers [20.1502, L/C] (✓) Y ( ) N
2. Briefly describe licensee's program for monitoring and controlling internal exposures [20.1701, 1702, L/C]: Bioassays
3. Aerosols and gases sampled [20.1204, 35.205] (✓) Y ( ) N
4. Monitoring/controlling program implemented (includes bioassays) [35.205(d), 315(a)(8), L/C] (✓) Y ( ) N
5. Respiratory protection equipment [20.1703] ( ) Y ( ) N

N/c - Nuclear Pharmacist does not have bioassays performed often

E. Reports each preparation > 30 mCi

1. Reviewed by RPD/RSC Frequency monthly/quarterly
2. Inspector reviewed personnel monitoring records for period Aug 1995 to Nov. 1996
3. Prior dose determined for individuals likely to receive doses [20.2104] (✓) Y ( ) N
4. Maximum exposures TEDE _____ Other _____
5. Maximum CDEs _____ Organ(s) _____
6. Maximum CEDE _____
7. Licensee sums internal and external [20.1202] (✓) Y ( ) N
8. TEDEs and TODEs within 20.1201 limits (✓) Y ( ) N
9. NRC forms or equivalent [20.2104(d), 2106(c)]

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

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

F. Who performed any PSEs at this facility (number of people involved and doses received) [20.1206, 2104(b), 2105, 2204] (✓) N/A

G. Records of exposures, surveys, monitoring, and evaluations maintained [20.2102, 2103, 2106, 35.205(d), 315(a)(8), L/C] (✓) Y ( ) N

Remarks:

15. MISADMINISTRATIONS AND RECORDABLE EVENTS

A. If misadministrations or recordable events (defined in 35.2) have occurred since last inspection, evaluate the incident(s) and the licensee's quality management program (QMP) using the existing guidance. [Reference TI 2800/025 and IP 87103]

Maine yankee 11/96

1. Event date _____ Information Source _____
2. Notifications

NRC Ops Center	( ) Y ( ) N	Region	( ) Y ( ) N
Referring Physician	( ) Y ( ) N	Patient	( ) Y ( ) N
In writing	( ) Y ( ) N		

If notification did not occur, why not:

3. Written Reports [35.33]

a. Submitted to Region within 15 days ( ) Y ( ) N
b. Copy to patient within 15 days ( ) Y ( ) N

B. Records maintained [35.33(b)] ( ) Y ( ) N

Remarks: 2 Special inspections
- 9/95 - misadministration I-131
- 11/96 - loss of control of QAM material

16. NRC INDEPENDENT MEASUREMENTS

A. Survey instrument Serial No. Last calibration

B. Inspector's measurements were compared to licensee's (✓) Y ( ) N
C. Describe the type, location, and results of measurements:
Ludlum 14 c - Package receipt

17. NOTIFICATION AND REPORTS

A. Licensee in compliance with [19.13] (reports to individuals, public and occupational, monitored to show compliance with Part 20) ( ) None (✓) Y ( ) N

B. Licensee in compliance with [20.2201] (theft or loss) ( ) None (✓) Y ( ) N

C. Licensee in compliance with [20.2202] (incidents) ( ) None (✓) Y ( ) N

D. Licensee in compliance with [20.2203] (overexposures and high radiation levels) (✓) None ( ) Y ( ) N

E. Licensee aware of NRC Ops Center phone number (✓) Y ( ) N

F. Licensee in compliance with [20.2203] (Constraint on air emissions) ( ) None (✓) Y ( ) N

18. POSTING AND LABELING

A. NRC-3 "Notice to Workers" is posted [19.11] (✓) 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] (✓) Y ( ) N

C. Other posting and labeling per [20.1902, 1904] and the licensee is not exempted by [20.1903, 1905] (✓) Y ( ) N

Remarks:

19. RECORDKEEPING FOR DECOMMISSIONING

A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination [30.35(g)] (✓) Y ( ) N

B. Records include all information outlined in [30.35(g)] (✓) Y ( ) N

Remarks:

20. BULLETINS AND INFORMATION NOTICES

A. Bulletins, Information Notices, NMSS Newsletters, etc., received by the licensee (✓) Y ( ) N

B. Licensee took appropriate action in response to Bulletins, Generic Letters, etc. (✓) Y ( ) N

Remarks:

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

A. Special license conditions or issues to be reviewed:

35.315 die Exception to decay pt 4 therapy rooms to 200 dpm
Room is dedicated to therapy (iodine-131)

B. Evaluation:

22. DEBRIEF WITH LICENSING STAFF

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

Items discussed:

23. CONTINUATION OF REPORT ITEMS

24. 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.

35.315 - Failure to perform bioassays on nuclear pharmacists after therapy dose preparation

19.12 - Failure to train nuclear pharmacist to have bioassays perfo

25. PERFORMANCE EVALUATION FACTORS

Licensee (name & location) Dept. of the Army

Inspector T. H. Darden

Inspection Date 2-11to14-97

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

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

Regional follow-up on above PEFs citations:

END

ATTACHMENT A
LABORATORY INSPECTION FIELD NOTES

1. Date _____ Authorized User(s) _____

2. Location(s) Building _____ Room(s) _____

3. Person(s) Contacted _____

4. Describe scope of lab use (Nuclides, form, frequency, purpose, etc):

5. Training — Critical by HPO / Annually by Principal Authorized user
   A. Frequency: Annual by Principal Conducted by: _____
   B. Individuals interviewed understand safety practices (✓) Y ( ) N

Remarks:

See Section 3

Observed one researcher handling RSMCL-32) outfitted in lab coat and gloves.

6. Surveys
   A. Types of surveys performed (daily, weekly, monthly, etc.)
   Surveys performed after each use of material in quantities greater than 10 μCi.
   B. Instrumentation properly calibrated and used (✓) Y ( ) N
   C. Efficiency of counting system determined (✓) Y ( ) N
   D. Hood airflow adequate and checked as required ( ) N/A (✓) Y ( ) N
   E. Records maintained: trigger levels established, area diagram, instrument used, individual performing survey, results in proper units, decontamination performed as necessary, etc.) (✓) Y ( ) N
   F. Inspector surveyed (✓) Y ( ) N
   Results satisfactory ( ) N/A (✓) Y ( ) N

Remarks:

Surveys in CPM, however, trigger levels established in CPM and conversion to DPM available and known. Researchers knew CPM trigger levels.

7. Receipt and Transfer
   A. Incoming packages properly surveyed ( ) Y ( ) N
   B. Interlaboratory transfers performed as specified in the license ( ) N/A (✓) Y ( ) N
   C. Records maintained (✓) Y ( ) N

Remarks:

Packages received in Health Physics and surveyed (wipes and meter) both inside and outside. All six sites generally surveyed.

8. Personnel Dosimetry
   A. Appropriate dosimetry assigned and worn ( ) N/A (✓) Y ( ) N
   B. Results available to lab personnel (✓) Y ( ) N

   C. Bioassays performed (✓) N/A ( ) Y ( ) N

Remarks:

9. Handling Waste

A.	Procedures followed		(✓) Y ( ) N
B.	Proper storage (area, containers, labeling, etc.)		(✓) Y ( ) N
C.	Liquid/solid waste disposal		(✓) Y ( ) N
D.	Incineration	(✓) N/A	( ) Y ( ) N
E.	Compaction	( ) N/A	(✓) Y ( ) N
F.	Sewer discharge	( ) N/A	( ) Y (✓) N
G.	Records maintained		(✓) Y ( ) N

Remarks:

10. Inventory conducted ( ) N/A (✓) Y ( ) N
Records Maintained (✓) Y ( ) N

Remarks:

Inventory records observed on the refrigerator where material stored and in a separate log books.

11. Storage and use of RAM

A.	Adequate method to prevent unauthorized access	(✓) Y ( ) N
B.	Condition of areas acceptable	(✓) Y ( ) N
C.	Personnel wear disposable gloves and protective clothing while handling material	(✓) Y ( ) N
D.	Hands monitored after procedures or before leaving	(✓) Y ( ) N
E.	No eating, drinking, or smoking in use/storage areas	(✓) Y ( ) N
F.	No food, drink, or personal items stored in use/storage areas	(✓) Y ( ) N
G.	Use of shielding/distance while using/storing material	(✓) Y ( ) N
H.	RAM is under surveillance and control when not in storage in an unrestricted area	(✓) Y ( ) N

Remarks:

12. Posting and Labeling

A.	NRC-3 "Notice to Workers"	( ) Y (✓) N
B.	Parts 19, 20, 21, Section 206 of Energy Reorganization Act, procedures for Part 21, and license documents or a notice indicating where documents can be examined	(✓) Y ( ) N
C.	Other posting and labeling requirements met	(✓) Y ( ) N

Remarks:

13. Violations Observed

END

APPENDIX A

MEDICAL BROAD-SCOPE INSPECTION RECORD

Region I

Inspection record No. 99-01 License No. 08-01738-02

Licensee (Name and Address): Docket No. 030-01317

Army
Walter Reed Army Medical Ctr.
Washington DC 20307-5001

Licensee Contact: William Johnson Telephone No. _____

Priority: 1 Program Code: 2110

Date of Last Inspection: 2/11-13/98
Date of This Inspection: ~~3/16/99~~ 3/16 – 18/99

Type of Inspection: ( ) Announced (✓) Unannounced
(✓) Routine ( ) Special
( ) Initial

Next Inspection Date 11/2000 ( ) Normal ( ) Reduced (✓) Extended

Justification for change in normal inspection frequency: (2) clear inspections

Summary of Findings and Actions:

(✓) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
( ) Non-cited violations
( ) Violation(s), Form 591 issued
( ) Violation(s), regional letter issued
( ) Followup on previous violations

Inspector(s) Thomas K. Thompson Date 3/29/99
(Sign Name)
Thomas K. Thompson
(Print Name)

Approved M. Shanbaky Date 3/30/99
(Sign Name)
M. SHANBAKY
(Print Name)

2/80

PART I-LICENSE, INSPEC. .N, INCIDENT/EVENT, AND ENFOR(IENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:
[License amendments issued since last inspection; program changes (including major changes in facilities, activities, procedures, or personnel) noted in the license]

AMENDMENT #	DATE	SUBJECT
71	6/9/98	Add new RSC Chairman Colonel Nancy Phillips

2. INSPECTION AND ENFORCEMENT HISTORY:
(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders)

2/11-13/98 clear

3. INCIDENT/EVENT HISTORY:
(List any incidents, recordable events, or misadministrations reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

X P-32 contam. 1/26/99
Licensee has/has been following several incidence of personnel entering I-131 pt rooms who were not authorized. Custodial & nutritionist. The licensee identified the individuals & provided them,

3. FACILITIES:
[Facilities as described; uses; control of access; engineering controls,(e.g., ventilation, hoods, filters, etc); irradiators and survey instrument calibrators; maintenance by authorized persons]

Visited Forest Glenn facility and Armer Labs.
Labs in Bldg 500 no longer use byproduct material
All materials were removed except 35 in liq scint. counters
They await decommissioning survey clearance. Then these use areas will be removed.

* Gillette - being decommissioned no use
13 Tuft Cent — limited # of labs using P-32 & S-35 - active
Bldg 40 - WRAIR.
41 - HP Offices
54 - Pathology AFIP

4. EQUIPMENT AND INSTRUMENTATION:
(Dose calibrator; instrumentation for assaying alpha- and beta- radionuclides; generators; syringes and vials; survey instruments; 10 CFR Part 21 procedures; and special equipment and instrumentation) All survey instruments checked on Lab Tests were calibrated as required -

See back page

Linearity
3/1/99
~~1 test 97~~ 10/26/98 1/13/98
8/26/98
6/2/98

Capintec 35R round Constancy
30 UC not used 6/25/98 one use except for Tungs Constancy chk - commercial
6/26 Same used settings chk
6/29 Same on Moly Chromel reading
7/9 Same obtained was 9284.61 o/c Manually entered 136.90 mCi Should have been 1.36 mCi

Accuracy
2/22/99
6/98

Xe-133
Xenamatic 3000
has charcoal Trap + alarm, Alarmed chk/1 month

5. MATERIAL RECEIPT, USE, CONTROL, AND TRANSFER:
(Materials and uses authorized; use of radiopharmaceuticals; security and control of licensed materials; and procedures for receipt and transfer of licensed material)

(2) Nuc Med Pharmacy 2-3 Co Centers received per wk from Du Pont
Individual Investigators order materials
, however, all materials are received & checked against inventory by RSO personnel

N- eye applicators - stored Forest Glenn
CC - old Irradiator - stored at Forest Glenn
O.4A.A - Beachy Sources
R - no longer possessed
U - Source not used - stored in Bldg 41

87119, Appendix A A.A. - Instr. cal. A/B - no longer has, disposed. Issue Date: XX/XX/XX

X - only 1.54E-3 mCi not 1 Ci
BB - Contam stds. - Bldg 41

6. THERAPIES:
(Safety precautions; postings; contamination control; stay times; surveys; release criteria of patients and rooms)

~ 22 yr I-131 inpts.
dedicated rooms used
Interviewed custodi workers about ting. Worker was aware he should not go in therapy room but didn't specifically recall ting. session -
1 Sr-89 10/14/98 Brachy Room 6562

QM

chked 9 written directives, all ok
8 I-131
1 Sr-89

Brachy

* Cs-37 9/3/98

3/19/98 Ir-192 ? Need written Directive - ~~Note~~ - not caught on audit * other record has equiv. info.
Cook

Cs-137 2/19/98

Jones Cs-137 ? ~~didn't look at this - file could not be located.~~ ok written Directive ok

Cs-137 pt on 3/4/98
Info on in+out log.

1) # Sources removed
2) Pts. Name
3) date sources removed
4) date sources returned
5) # sources returned

missing load date

Reviewed I-131 pt. survey records & bioassay data. All ok.

7. QUALITY MANAGEMENT PROGRAM (GMP) AND MISADMINISTRATIONS:
(QMP - written directives, implementation, reviews, and records; misadministrations - identification, notifications, reports, and records)

100% QM review is done by Nuclear Pharmacist. 100% review is also done of Brachy administrations

8. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL:
(Radiation and contamination surveys; air sampling; leak tests; inventories; handling of radioactive materials; protective clothing; dosimetry; records; and public doses)

Checked daily Surveys in Nuc Med. area — ok
Checked I-131 & Brachy pt. area Surveys — ok
Checked survey records in individual labs during facility tour. In all cases survey records were complete.

9. TRAINING AND INSTRUCTIONS TO WORKERS:
(Interviews and observations of routine work; staff knowledge of all routine activities; 10 CFR Part 20 requirements; therapy training and postulated emergency situations; supervision by authorized users; retraining and periodic training programs; training of ancillary personnel such as housekeeping, security, and maintenance; adequacy of training and instruction)

98'

1 - new author. reviewed 9/4/98

10. RADIATION PROTECTION:
[Radiation protection program with ALARA provisions (worker and general public external and internal exposure control; effluent control); external and internal dosimetry program; exposure evaluations; dose records and reports; and patient release]

Release for I-131 pts.
Conditional Release
< 33 mCi
Unconditional
< 7 mCi

11. RADIOACTIVE WASTE MANAGEMENT:
(Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment incinerators, hoods, vents, and compactors; and records)

All rad waste picked up & taken to Forest Glenn for compaction & stg for decay or Shipped as rad waste to Barnwell. RSO does this. Waste compactor has ventillation & air sampling is taken of effluent each use.

12. DECOMMISSIONING:
(Records of radiological conditions; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements)

Licensee is in process of decommission
* Several bldgs. & many operations to the new facility at Forest Glenn

Bldg. 40 - plans being formed to decommission & move operations to Bldg 503 at Forest Glenn. May not occur for ~~~~ 1-2 yrs!
Bldg 500 & 506, & 508 are in process of being decommi

13. TRANSPORTATION:
(Quantities and types of licensed material shipped; packaging design requirements; HAZMAT communication procedures; unit dose return; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports)

Last shipment 3/1/99 #(rad waste)
Returned shipment records randomly selected ~~for~~ in '98'. All ok.

14. NOTIFICATIONS AND REPORTS:
(Theft; loss; incidents; overexposures; change in RSO, authorized user, or nuclear pharmacist; and radiation exposure reports to individuals)

(2) incidence of contam. (1) 1/99 P-32
(2) 2/11 S-35

15. POSTING AND LABELING:
(Notices; license documents; regulations; bulletins and generic information; posting of radiation areas; and labeling of containers of licensed material)

Appropriate posting and labeling noted in Laboratories & waste stg areas.

16. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:
(Areas surveyed; comparison of data with licensee's results and regulations; and instrument type and calibration date)

Surveyed waste stg area Forest Glen (2nd fl.
Nuc. medicine Lab
Brachy source stg rm.

17. VIOLATIONS, NON-CITED VIOLATIONS (NCVs): AND OTHER SAFETY ISSUES:
(State requirement and how and when licensee violated the requirement. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

Do not review everything I visited most labs but not Taft Court

1) Daily constancy failing to note >10% error. not cited because device is not used.
2) (1) lab ~50-60 uCi R-32 unsecured but licensee is taking action. Material was locked in refrig but lock & chain could be bypassed.
3) Reviewed R-32 incident in Jan 99
4) Brachy therapy ~~records~~ source use records should be filled out in their entirety

Facilities visited Bldg 40 41 Forest Glenn
Did not visit Taft Court 54

T

18. PERSONNEL CONTACTED:
[Identify licensee personnel contacted during the inspection (including those individuals contacted by telephone).] Col - Johnson - RSO
Anna Rodriguez - PI for Nuc Medicine
Capt. John Thomas - Pharmacist
Col Arthur Martin - Chief
David Burton - Chief, Rad. Materials Control Br
Wilfred Sewchand - ~~Develop~~ Clinical Physicist

Use the following identification symbols:
Individual(s) present at entrance meeting
* Individual(s) present at exit meeting

19. PERFORMANCE EVALUATION FACTORS (PEFs):

A.	Lack of senior management involvement with the radiation safety program and/or RSO oversight		( ) Y (~~X~~) N
B.	RSO too busy with other assignments		( ) Y (~~X~~) N
C.	Insufficient staffing		( ) Y (~~X~~) N
D.	RSC fails to meet or functions inadequately	( ) N/A	( ) Y (~~X~~) N
E.	Inadequate consulting services or inadequate audits conducted	( ) N/A	( ) Y (~~X~~) N

Remarks (consider the above assessment and/or other pertinent PEFs with regard to the licensee's oversight of the radiation safety program):

21. Special Conditions or Issues:
(Special license conditions; year-2000 effects of computer software)

None

'PENDIX A - ATTACHMENT A
DECOMMISSIONING TIMELINESS INSPECTION ATTACHMENT

Licensee: Walter Reed Med. Ctr.

Date of Inspection: 3/16-18/99

1. COMPLIANCE WITH DECOMMISSIONING TIMELINESS RULE
(NOTE: Repeat the answers given in Section 12 of the main body of the inspection record. The issues in subsequent sections are dependent on the answers to these questions.)

A. License to conduct a *principal activity* has expired or been revoked. ( ) Y (~~✓~~) N

B. Licensee has made a decision to permanently cease *principal activities*, at the entire site, or any separate buildings, or any outdoor areas, including inactive burial grounds. (~~✓~~) Y ( ) N

C. A 24-month duration has passed in which no *principal activities* have been conducted under the license at the site, or at any separate buildings, or any outdoor areas, including inactive burial grounds. ( ) Y (~~✓~~) N

D. If "Yes" to either A or B or C above:

(1) Identify Site/Bldg/Area: Letter to NRC dated 12/12/97

(2) Date of occurrence of A, B, or C: " "

2. NOTIFICATION REQUIREMENTS

A. Licensee has provided written notification to U.S. Nuclear Regulatory Commission (NRC) within 60 days of the occurrence of 1.A., 1.B., or 1.C., above. (~~✓~~) Y ( ) N

If "Yes," date of notification: Letter dated 12/12/97

B. If the licensee is requesting to delay initiation of the decommissioning process, the licensee has provided written notification to NRC within 30 days of occurrence of 1.A., 1.B., or 1.C.,above ( ) N/A ( ) Y (~~✓~~) N

If "Yes," date of notification: _____

Basis for Findings:

3. DECOMMISSIONING PLAN/SCHEDULE REQUIREMENTS

A. Licensee is required to submit a decommissioning plan per 10 CFR 30.36(g), 40.42(g), 70.38(g), or 10 CFR Part 72? ( ) Y (✓) N

If "No" to 3.A., answer the following items B. - F.:

B. The decommissioning work scope is covered by current license conditions. (✓) Y ( ) N

C. Decommissioning has been initiated within 60 days of notification to NRC, or NRC has granted a delay. ( ) Y ( ) N

D. If licensee has initiated decommissioning, give date the decommissioning was initiated:

Done historical / review
Done characterization sa

Initiation date: Summer 98'

E. If decommissioning has been completed, it was completed within 24 months of notification of NRC. (✓) N/A ( ) Y ( ) N

F. If decommissioning is still scheduled to be completed, it is on schedule to be completed within 24 months of notification of NRC. ( ) N/A ( ) Y (✓) N

Basis for Findings: ~~may~~ will need delay Lth. a. may not happen within 2 yrs. from this inspection.

If "Yes" to 3.A., answer the following items G. - J.:

G. The decommissioning plan has been submitted to NRC within 12 months of notification ( )Y( )N

If "Yes," date of submittal: See 12/12/97 Letter

If NRC approved, date of NRC approval: 1/14/98

H. Has the licensee submitted an alternative schedule request? ( )Y (~~✓~~)~~N~~

If "Yes," date of submittal: _____

I. If decommissioning has been completed, it was completed within 24 months after approval of the decommissioning plan

~~asked Licensee to send request for delay.~~ Letter 12/ (✓)N/A ( )Y( )N Indicates decom not full

J. If decommissioning is still scheduled to be completed, it is on schedule to be completed within 24 months after approval of the decommissioning plan.

NRC should send letter granting Delay. ( )N/A (✓)Y( )N

Basis for Findings:

The new bldg. at Forest Glen will not be completed until later in 1999. The ~~final~~ decommis. of other bldgs will not be complete until 1-2 yrs. after

Violations identified, if any:

APPENDIX B

MEDICAL BROAD-SCOPE INSPECTION REFERENCES*

1. ORGANIZATION AND SCOPE OF PROGRAM

10 CFR 35.6 Provisions for research involving human subjects.
10 CFR 35.29 Administrative requirements - mobile nuclear medicine service.
10 CFR 35.80 Technical requirements - mobile nuclear medicine service.
License application and applicable license conditions.

2. MANAGEMENT OVERSIGHT

A. Radiation Safety Committee

10 CFR 33.13 Requirements for issuance of a Type A specific license of broad scope
10 CFR 35.22 Radiation safety committee.
10 CFR 35.23 Statements of authority and responsibilities.
10 CFR 35.31 Radiation safety program changes.
Applicable license conditions.

B. Radiation Safety Officer

10 CFR 35.21 Radiation safety officer.
10 CFR 35.23 Statements of authority and responsibilities.
10 CFR 35.900 Radiation safety officer.

C. Audits, Reviews, or Inspections

10 CFR 35.22 Radiation safety committee.
10 CFR 20.1101 Radiation protection programs.
10 CFR 20.2102 Records of radiation protection programs.
Applicable license conditions.

D. ALARA

10 CFR 35.20 Radiation protection programs.

E. Authorized Users

10 CFR 35.11 License required.
10 CFR 35.13 License amendments.
10 CFR 35.25 Supervision.
Applicable license conditions.

* These references correspond to the sections of IP 87119, Part II of Appendix A, the "Medical Broad-Scope Inspection Record ."

3. FACILITIES

A. Access Control

10 CFR 20.1601 Control of access to high-radiation areas.
10 CFR 20.1602 Control of access to very high-radiation areas.
Applicable license conditions.

B. Engineering Controls

10 CFR 20.1701 Use of process or other engineering controls.
10 CFR 20.1702 Use of other controls
10 CFR 35.90 Storage of volatile gases.
10 CFR 35.205 Control of aerosols and gases.
Applicable license conditions.

4. EQUIPMENT AND INSTRUMENTATION

A. Dose Calibrators - Photon-emitting radionuclides

10 CFR 35.50 Possession, use, calibration, and check of dose calibrators.
Applicable license conditions.

B. Instrumentation- Alpha- or beta-emitting radionuclides

10 CFR 35.52 Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides.
Applicable license conditions.

C. Generators

10 CFR 35.204 Permissible molybdenum-99 concentrations.

D. Syringes and Vials

10 CFR 35.60 Syringe shields and labels.
10 CFR 35.61 Vial shields and labels.

E. Survey Instruments

1. Possession

10 CFR 35.120 Posession of survey instrument.
10 CFR 35.220 Possesion of survey instruments.
10 CFR 35.320 Possession of survey instruments.
10 CFR 35.520 Availability of survey instrument.
Applicable license conditions.

2. Calibration

10 CFR 35.51 Calibration and check of survey instruments.

F. Safety Component Defects

10 CFR 21.21 Notification of failure to comply or existence of a defect and its evaluation.

5. MATERIAL USE, C TROL, AND TRANSFER

A. Authorized Uses

10 CFR 31.11	General license for use of byproduct material for certain in-vitro clinical or laboratory testing.
10 CFR 35.53	Measurement of dosages of unsealed byproduct material for medical use.
10 CFR 35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies.
10 CFR 35.200	Use of unsealed byproduct material for imaging and localization studies.
10 CFR 35.204	Permissible molybdenum-99 concentrations.
10 CFR 35.300	Use of unsealed byproduct material for therapeutic administration.
10 CFR 35.400	Use of sources for brachytherapy.
10 CFR 35.500	Use of sealed sources for diagnosis.

B. Security and Control

10 CFR 20.1003	Definitions (restricted area and unrestricted area).
10 CFR 20.1801	Security of stored material.
10 CFR 20.1802	Control of material not in storage.

C. Receipt and Transfer of Licensed Material

10 CFR 20.1906	Procedures for receiving and opening packages.
10 CFR 20.1501	General.
10 CFR 20.2103	Records of surveys.
10 CFR 30.41	Transfer of byproduct material.
10 CFR 30.51	Records.

6. THERAPIES

10 CFR 35.75	Release of patients or human research subjects containing radiopharmaceuticals or permanent implants.
10 CFR 35.315	Safety precautions.

Applicable license conditions.

7. QUALITY MANAGEMENT PROGRAM AND MISADMINISTRATIONS

10 CFR 35.2	Definitions (misadministration and recordable events).
10 CFR 35.32	Quality management program.
10 CFR 35.33	Notifications, reports, and records of misadministrations.

8. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL

A. Area Surveys

10 CFR 2.01301	Dose limits for individual members of the public.
10 CFR 20.1302	Compliance with dose limits for individual members of the public.
10 CFR 20.1501	General.
10 CFR 20.2103	Records of surveys.
10 CFR 20.2107	Records of dose to individual members of the public.
10 CFR 35.70	Surveys for contamination and ambient radiation exposure rate.

Applicable license conditions.

B. Leak Tests and Inventories

10 CFR 35.59 Requirements for possession of sealed sources and brachytherapy sources.

Applicable license conditions.

9. TRAINING AND INSTRUCTIONS TO WORKERS

A. General

10 CFR 19.12 Instruction to workers.

Knowledge of 10 CFR Part 20 radiation protection procedures and requirements.

B. Specific

10 CFR 35.900	Radiation Safety Officer.
10 CFR 35.901	Training for experienced Radiation Safety Officer.
10 CFR 35.910	Training for uptake, dilution, and excretion studies.
10 CFR 35.920	Training for imaging and localization studies.
10 CFR 35.930	Training for therapeutic use of unsealed byproduct material.
10 CFR 35.932	Training for treatment of hyperthyroidism.
10 CFR 35.934	Training for treatment of thyroid carcinoma.
10 CFR 35.950	Training for use of sealed sources for diagnosis.
10 CFR 35.970	Training for experienced authorized users.
10 CFR 35.971	Physician training in a three month program.
10 CFR 35.972	Recentness of training.
10 CFR 35.980	Training for an authorized nuclear pharmacist.
10 CFR 35.981	Training for experienced nuclear pharmacists.

C. Therapy Training

10 CFR 35.310	Safety instruction.
10 CFR 35.59	Requirements for possession of sealed sources and brachytherapy sources.

D. Supervision

10 CFR 35.25 Supervision.

10. RADIATION PROTECTION

A. General

IP 83822 Radiation Protection.

B. Radiation Protection Program

1. Exposure evaluation

10 CFR 20.1501 General.

2. Programs

10 CFR 20.1101	Radiation protection programs.
10 CFR 35.20	ALARA program.

C. Dosimetry

1. Dose Limits

10 CFR 20.1201	Occupational dose limits for adults.
10 CFR 20.1202	Compliance with requirements for summation of external and internal doses.
10 CFR 20.1207	Occupational dose limits for minors.
10 CFR 20.1208	Doses to an embryo/fetus.

2. External

10 CFR 20.1203	Determination of external dose from airborne radioactive material.
10 CFR 20.1501	Dosimetry processing.
10 CFR 20.1502	Conditions requiring individual monitoring of external and internal occupational dose.

Applicable license conditions.

3. Internal

10 CFR 20.1204	Determination of internal exposure.
10 CFR 20.1502	Conditions requiring individual monitoring of external and internal occupational dose.
10 CFR 20, Subpart H	Respiratory protection and controls to restrict internal exposure in restricted areas.
10 CFR 35.205	Control of aerosols and gases.
10 CFR 35.315	Safety precautions - radiopharmaceutical therapy.

D. Records

10 CFR 20.2102	Records of radiation protection programs.
10 CFR 20.2103	Records of surveys.
10 CFR 20.2104	Determination of prior occupational dose.
10 CFR 20.2106	Records of individual monitoring results.

E. Patient Release

10 CFR 35.75	Release of patients or human research subjects containing radiopharmaceuticals or permanent implants.

11. RADIOACTIVE WASTE MANAGEMENT

A. Disposal

10 CFR 35.92	Decay in storage.
10 CFR 20.1904	Labeling containers.
10 CFR 20.2001	General waste disposal requirements.
10 CFR 20.2005	Disposal of specific waste
10 CFR 20.2103	Records of surveys.
10 CFR 20.2108	Records of waste disposal.

B. Effluents

1. General

2. Release into sanitary sewer

10 CFR 20.2003 Disposal by release into sanitary sewerage.
Applicable license conditions.

3. Release to septic tanks

10 CFR 20.1003 Definitions (sanitary sewerage).
10 CFR Part 20, App. B, Table 2 Limits.

4. Incineration of waste

10 CFR 20.2004 Treatment or disposal by incineration.

5. Control of air effluents and ashes

10 CFR 20.1201 Occupational dose limits for adults.
10 CFR 20.1301 Dose limits for individual members of the public.
10 CFR 20.1501 General.
10 CFR 20.1701 Use of process and other engineering controls.
Applicable license conditions

C. Waste Management

1. General

10 CFR 20.2001 General requirements.
IP 84850 Radioactive Waste Management - Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61

2. Waste compacted

Applicable license conditions.

3. Waste storage areas

10 CFR 20.1801 Security of stored material.
10 CFR 20.1902 Posting requirements.
10 CFR 20.1904 Labeling containers.
Applicable license conditions.

4. Packaging, Control, and Tracking

10 CFR Part 20, Appendix F Requirements for low-level waste transfer for disposal at land disposal facilities and manifests.
10 CFR 20.2006 Transfer for disposal and manifests.
10 CFR 61.55 Waste classification.
10 CFR 61.56 Waste characterization.

5. Transfer

2. Release into sanitary sewer

10 CFR 20.2003 Disposal by release into sanitary sewerage.
Applicable license conditions.

3. Release to septic tanks

10 CFR 20.1003 Definitions (sanitary sewerage).
10 CFR Part 20, App. B, Table 2 Limits.

4. Incineration of waste

10 CFR 20.2004 Treatment or disposal by incineration.

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C. Waste Management

1. General

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10 CFR 20.2006 Transfer for disposal and manifests.
10 CFR 61.55 Waste classification.
10 CFR 61.56 Waste characterization.

5. Transfer

10 CFR Part 20, Appendix F	Requirements for low-level waste transfer for disposal at land disposal facilities and manifests.
10 CFR 20.2001	General requirements.
10 CFR 20.2006	Transfer for disposal and manifests.
10 CFR 30.41	Transfer of byproduct material

6. Records

10 CFR 20.2103	Records of surveys.
10 CFR 20.2108	Records of waste disposal.

12. DECOMMISSIONING

10 CFR 30.35	Financial assurance and record-keeping for decommissioning.
10 CFR 30.36	Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.
IMC 2602	Decommissioning Inspection Program for Fuel Cycle Facilities and Materials Licensees.
IP 87104	Decommissioning Inspection Procedure for Materials Licensees
IMC 2605	Decommissioning Procedures for Fuel Cycle and Materials Licensees.
NUREG/BR-0241	NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees.

13. TRANSPORTATION

A. General

NRC Charts	Hazard Communication for Class 7 (Radioactive) Materials.
10 CFR 71.5	Transportation of licensed material.
TI 2515/133	Implementation of Revised 49 CFR Parts 100-179 and 10 CFR Part 71.

B. Shippers - Requirements for Shipments and Packaging

1. General Requirements

49 CFR Part 173, Subpart I	Class 7, radioactive material.
49 CFR 173.24	General requirements for packagings and packages.
49 CFR 173.448	General transportation requirements.
49 CFR 173.435	Table of A_1 and A_2 values for radionuclides.

2. Transport Quantities

10 CFR 71.4 Definitions of quantities.

a. All quantities

10 CFR 71.4	Definitions of quantities.
49 CFR 173.410	General design requirements.
49 CFR 173.441	Radiation level limitations.
49 CFR 173.443	Contamination control.
49 CFR 173.475	Quality control requirements prior to each shipment of Class 7 (radioactive) materials.

.9 CFR 173.476	Approval of spec... form Class 7 (radioactive) materials.

b. Limited quantities

49 CFR 173.421	Excepted packages for limited quantities of Class 7 (radioactive) materials.
49 CFR 173.422	Additional requirements for excepted packages containing Class 7 (radioactive) materials.

c. Type A quantities

49 CFR 173.412	Additional design requirements for Type A packages.
49 CFR 173.415	Authorized Type A packages.
49 CFR 178.350	Specification 7A; general packaging, Type A .

d. Type B quantities

IP 86740, Section 2	Inspection of transportation activities.

e. LSA material and SCO

49 CFR 173.403	Definitions.
49 CFR 173.427	Transport requirements for low specific activity (LSA) Class 7 (radioactive) materials and surface contaminated objects (SCO).

3. HAZMAT Communication Requirements

49 CFR 172.200-205	Shipping papers.
49 CFR 172.300-338	Marking packages.
49 CFR 172.400-450	Labeling packages.
49 CFR 172.500-560	Placarding vehicles.
49 CFR 172.600-604	Emergency response information and guidance.

C. HAZMAT Training

49 CFR 172.702	Applicability and responsibility for training and testing.
49 CFR 172.704	Training requirements.

D. Transportation by Public Highway

49 CFR 171.15	Immediate notice of certain hazardous materials incidents.
49 CFR 171.16	Detailed hazardous materials incident reports.
49 CFR 177.800	Responsibility for compliance and training.
49 CFR 177.816	Driver training.
49 CFR 177.842	Loading and unloading: Class 7 (radioactive) material.

14. NOTIFICATIONS AND REPORTS

10 CFR 19.13	Notifications and reports to individuals.
10 CFR 20.2201	Reports of theft or loss of licensed material.
10 CFR 20.2202	Notification of incidents.
10 CFR 20.2203	Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.
10 CFR 30.50	Reporting requirements.
10 CFR 35.14	Notifications (RSO, authorized users, and nuclear pharmacists).

15. POSTING AND LABELING

10 CFR 19.11	Posting of notices to workers.
10 CFR 20.1902	Posting requirements.
10 CFR 20.1903	Exemptions to posting requirements.
10 CFR 20.1904	Labeling containers.
10 CFR 20.1905	Exemptions to labeling requirements.
10 CFR 21.6	Posting requirements.

16. INDEPENDENT AND CONFIRMATORY MEASUREMENTS

No references.

17. VIOLATIONS, NON-CITED VIOLATIONS AND OTHER SAFETY ISSUES

NUREG/BR-0195, Rev.1	NRC Enforcement Manual.
NUREG-1600	General Statement of Policy and Procedures for NRC Enforcement Actions.

18. PERSONNEL CONTACTED

No references.

19. PERFORMANCE EVALUATION FACTORS

IP 87101	Performance Evaluation Factors.

END

Exit Meeting

18 MAR 99

NAME / Title	ORG / DEPT
CPT Arthur Morton, C, HPO Operations	WRAMC, HPO
CPT Justin Hartings, HPO	
David Burton	C, RMC Branch WRAMC, HPO
Nancy Phillips	DCCS WRAMC
MAJ Brian Goldsmith	C. Radiation Oncology WRAMC
CPT John D. Thomas	Nuclear Pharmacy WRAMC
LTC Robert Massey	Nuclear Pharmacy WRAMC
Wilfred Seewaldt	Radiation Oncology WRAMC
COL William B Johnson	C, HPO/RPO WRAMC
Dr. Zongmei Sheng	AFIP
Thomas K. Thompson	USNRC

1998 Occupational Radiation Exposure Walter Reed Army Medical Center, Washington, DC						
			Average Radiation Dose (millirem)			
Organization/Section	N	N>0	EXTREMITY	SKIN	EYE	TEDE
Walter Reed	516	170	319	102	102	46
Cardiology	52	40	414	218	236	64
Medical Maintenance	23	6	NA	24	35	43
Endocrinology	2	0	0	0	0	0
Gastroenterology	28	2	13	7	5	14
Health Physics	15	6	128	20	21	22
Radiology Physicians	25	15	587	62	55	41
Special Procedures	14	13	39	328	356	100
Imaging Section Radiology	7	1	NA	17	19	25
X-ray Technologists	53	7	NA	77	103	55
Nuclear Medicine	31	23	519	98	97	104
Radiation Oncology	32	7	159	26	12	14
Urology	32	14	151	31	23	13
Ward 65 (Implants)	26	7	NA	22	9	9
Ward 75 (Oblations)	45	5	NA	20	14	16
Speech Pathology	8	0	NA	0	0	0
Research Workers	106	21	274	53	49	32
Veterinary Medicine	15	3	168	36	43	70

RADIATION DOSES (millirem) 1998 WRAMC for all Workers				
	SKIN	EYE	TEDE	FINGER
n	516	516	516	328
n>0	170	161	128	82
min value	4	4	1	12
max value	3222	3316	601	3876
sum (d)	17261	16476	5837	26151
avg dose	102	102	46	319

Cardiology 1998 Radiation Doses (millirem)				
	SKIN	EYE	TEDE	FINGER
n	52	52	52	54
n>0	40	36	31	5
min value	4	4	0	31
max value	928	964	316	1516
sum (d)	8701	8510	1974	2069
avg dose	218	236	64	414

Medical Maintenance 1998 Radiation Doses (millirem)				
	SKIN	EYE	TEDE	FINGER
n	23	23	23	NA
n>0	6	6	6	NA
min value	7	7	7	NA
max value	36	101	145	NA
sum (d)	144	209	257	NA
avg dose	24	35	43	NA

Endocrinology 1998 Radiation Doses (millirem)				
	SKIN	EYE	TEDE	FINGER
n	2	2	2	1
n>0	0	0	0	0
min value	0	0	0	0
max value	0	0	0	0
sum (d)	0	0	0	0
avg dose	0	0	0	0

Gastro 1998 Radiation Doses (millirem)				
	SKIN	EYE	TEDE	FINGER
n	28	28	28	28
n>0	2	1	1	2
min value	5	5	14	12
max value	8	5	14	13
sum (d)	13	5	14	25
avg dose	7	5	14	13

HEALTH PHYSICS 1998 Radiation Doses (millirem)				
	SKIN	EYE	TEDE	FINGER
n	15	15	15	12
n>0	6	6	6	1
min value	4	4	4	128
max value	92	98	101	128
sum (d)	122	128	131	128
avg dose	20	21	22	128

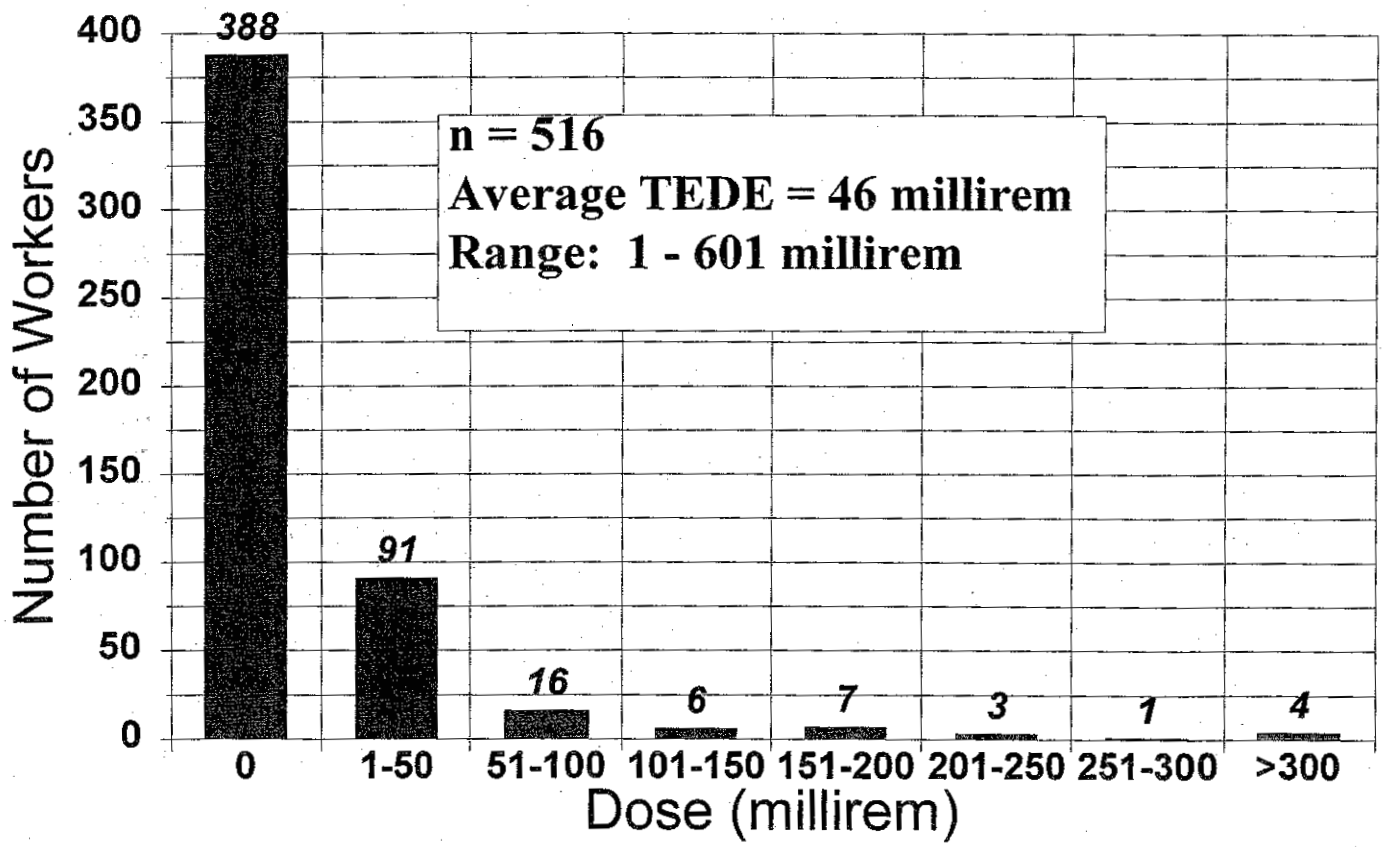
NUCLEAR MEDICINE Radiation Doses (millirem)				
	SKIN	EYE	TEDE	FINGER
n	31	31	31	29
n>0	23	23	22	20
min value	4	4	4	12
max value	332	346	346	2435
sum (d)	2260	2237	2294	10373
avg dose	98	97	104	519

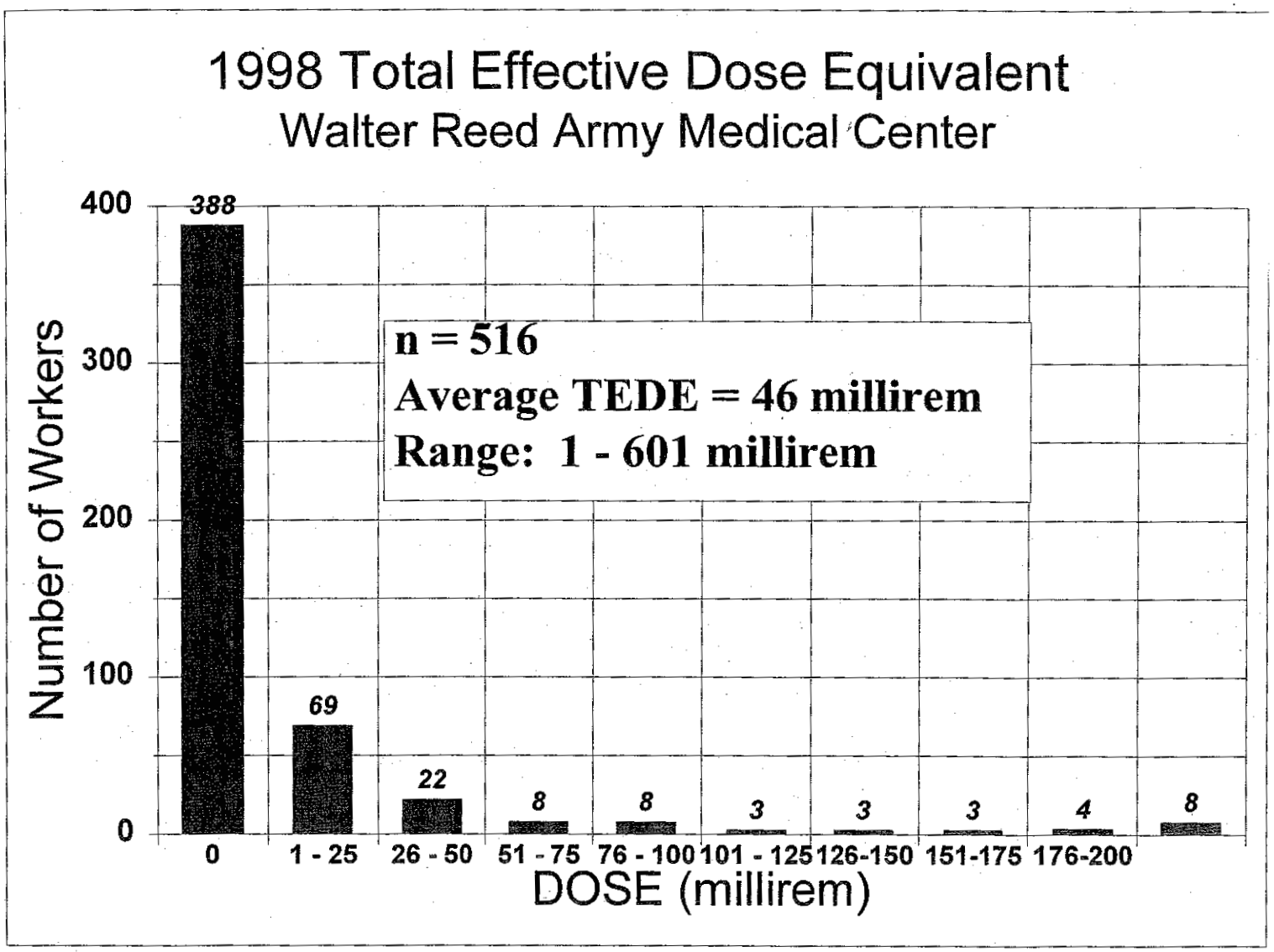
RADIATION ONCOLOGY Radiation Doses (millirem)				
	SKIN	EYE	TEDE	FINGER
n	32	32	32	12
n>0	7	7	5	7
min value	4	4	4	12
max value	79	48	43	718
sum (d)	185	86	70	1115
avg dose	26	12	14	159

SPECIAL PROCEDURES Radiation Doses (millirem)				
	SKIN	EYE	TEDE	FINGER
n	14	14	14	14
n>0	13	12	8	3
min value	4	4	4	12
max value	3222	3316	601	91
sum (d)	4264	4268	799	118
avg dose	328	356	100	39

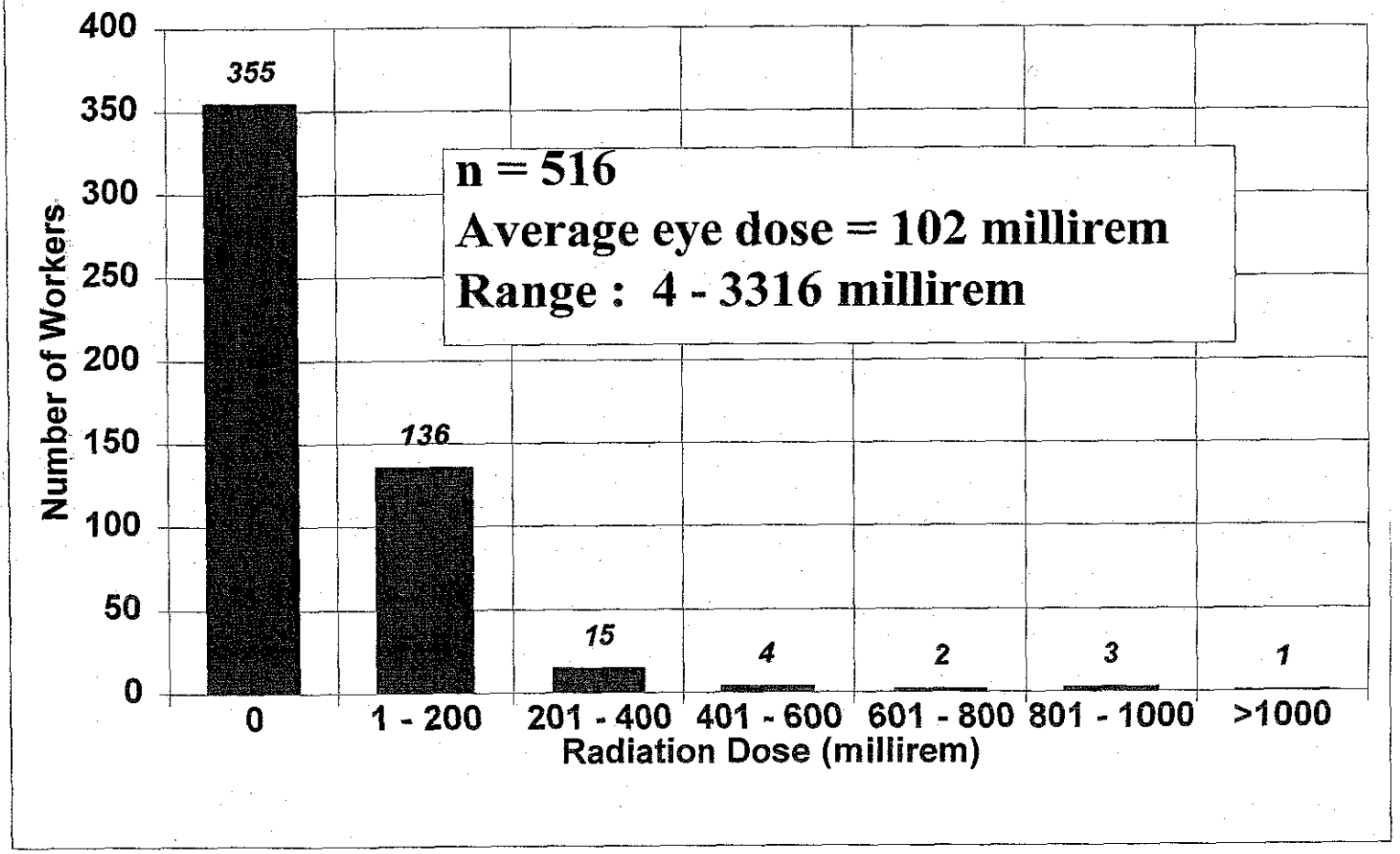
WARD 65 (Implants) Radiation Doses (millirem)				
	SKIN	EYE	TEDE	FINGER
n	26	26	26	NA
n>0	7	7	5	NA
min value	4	4	4	NA
max value	55	11	11	NA
sum (d)	154	61	44	NA
avg dose	22	9	9	NA

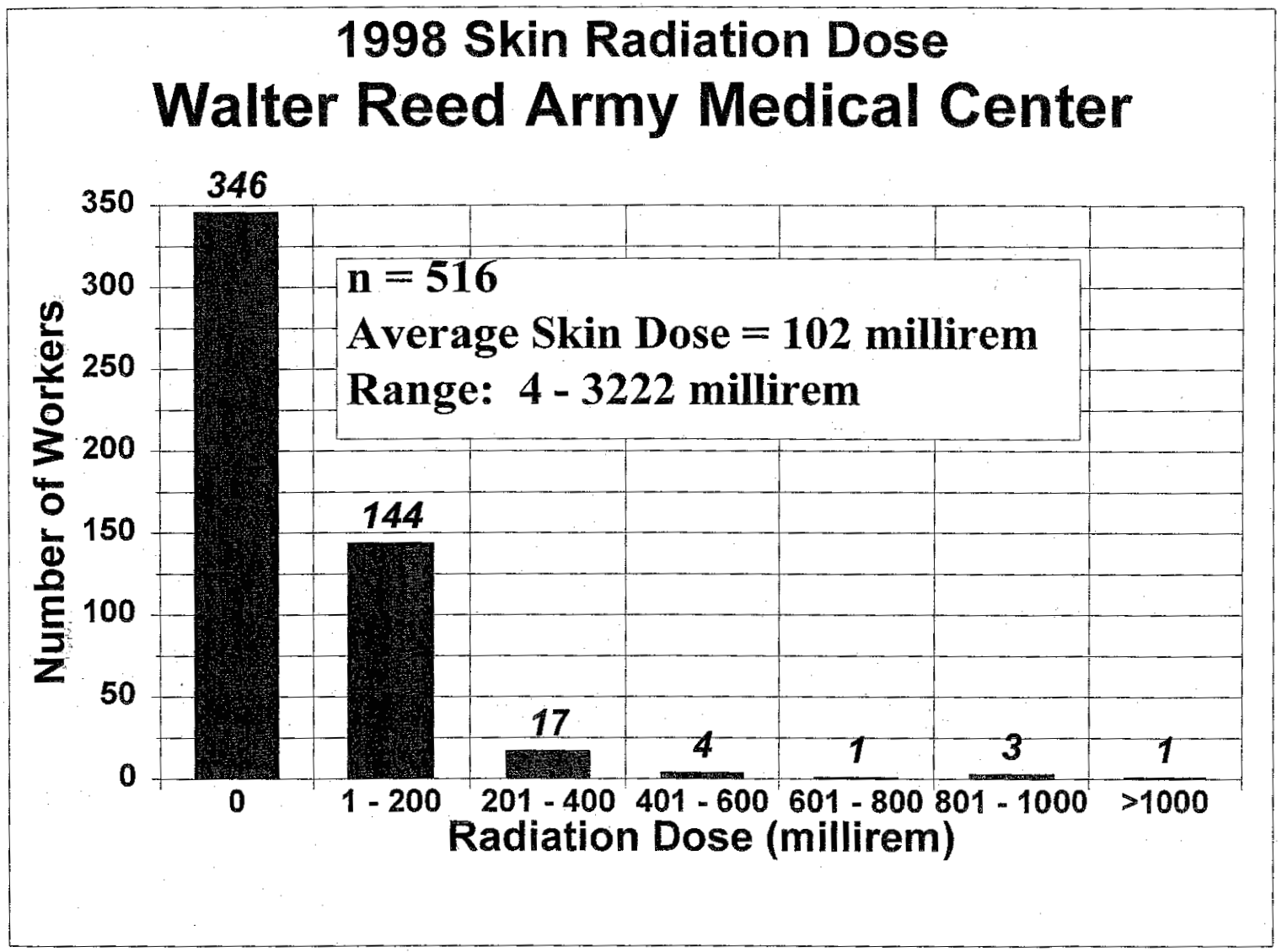
1998 Total Effective Dose Equivalent
Walter Reed Army Medical Center

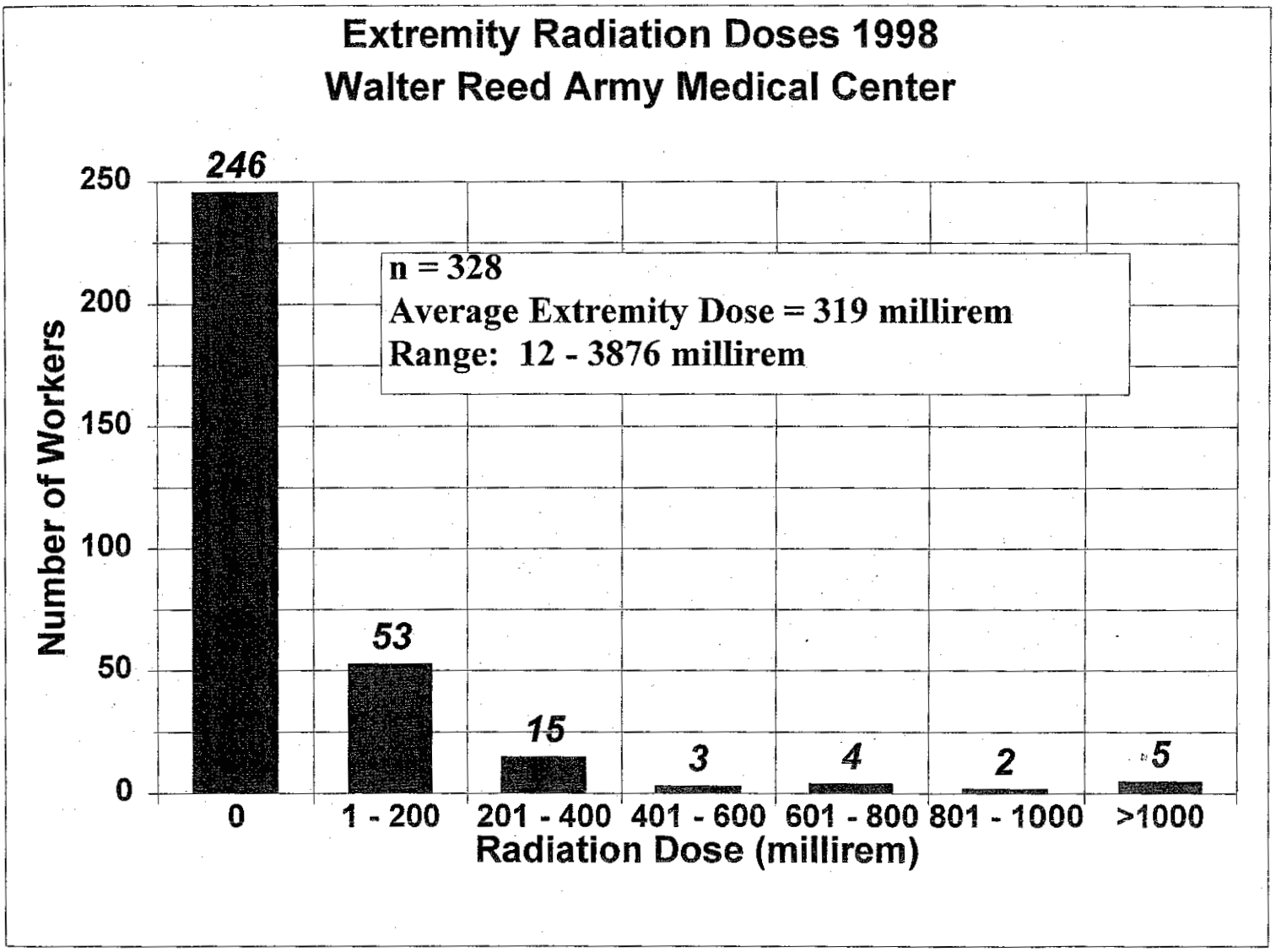



1998 Total Effective Dose Equivalent
Walter Reed Army Medical Center
Number of Workers
400
300
200
100
0
388
69
22
8
8
3
3
3
4
8
n = 516
Average TEDE = 46 millirem
Range: 1 - 601 millirem
0
1 - 25
26 - 50
51 - 75
76 - 100
101 - 125
126-150
151-175
176-200
DOSE (millirem)

Lens of Eye Radiation Dose
Walter Reed Army Medical Center




1998 Skin Radiation Dose
Walter Reed Army Medical Center
n = 516
Average Skin Dose = 102 millirem
Range: 4 - 3222 millirem
Number of Workers
350
300
250
200
150
100
50
0
346
144
17
4
1
3
1
0
1 - 200
201 - 400
401 - 600
601 - 800
801 - 1000
>1000
Radiation Dose (millirem)


Extremity Radiation Doses 1998
Walter Reed Army Medical Center
n = 328
Average Extremity Dose = 319 millirem
Range: 12 - 3876 millirem
Number of Workers
250
200
150
100
50
0
246
53
15
3
4
2
5
0
1 - 200
201 - 400
401 - 600
601 - 800
801 - 1000
>1000
Radiation Dose (millirem)

1998 Occupation Radiation Dose Data Distributions for Walter Reed Army Medical Center

--- TEDE ---	
--x axis-- Dose mR	--y axis--- frequency
0	388
1-50	91
51-100	16
101-150	6
151-200	7
201-250	3
251-300	1
>300	4

------- SKIN ----------	
--x axis-- Dose mR	--y axis--- frequency
0	346
1 - 200	144
201 - 400	17
401 - 600	4
601 - 800	1
801 - 100	3
>1000	1

-------- EYE ---------	
--x axis-- Dose mR	--y axis--- frequency
0	355
1 - 200	136
201 - 400	15
401 - 600	4
601 - 800	2
801 - 100	3
>1000	1

---- EXTREMITY	
--x axis-- Dose mR	--y axis--- frequency
0	246
1 - 200	53
201 - 400	15
401 - 600	3
601 - 800	4
801 - 100	2
>1000	5