

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

- * Mr. Mike Koenig RSO
- SSG Menging 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
2 D.1801	Security of CIV + H ²	Y	C
2 D.2201(a)(1)	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.
3. Briefly describe scope of activities, including types and quantities of use involving byproduct material, frequency of use, staff size, etc. () N/A

Type A medical Broadscope

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

RS Office 19 FTE positions with 6 vacancies

B. Licensee does limited distribution of pharmaceuticals¹ 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 Subjects²? [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 Biassay.

3. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

- HC 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 working who handles RAM in R+B lab was unaware of the requirement to wear protective clothing when handling RAM, this individual perform supervision of individuals supply aware & will receive required user training in April*

? Biassay not performed for nuclear pharmacists

- D. Supervised individuals³ 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

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 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

However only RPO does drain disposal

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 *Instrument 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

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

- NS
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 applicable⁴ [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 99 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
 If yes, *Not currently, but used in the past*
 1. Licensee receives unit doses and relies on assay data supplied by manufacturer or properly licensed organization [35.53(b)] () Y () N NS

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 I.D. 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 maintained 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} reception for decoupling I¹³¹ 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:

11. 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

NI

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 RPD 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

Wants 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

- 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 is ~~not~~ 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

Np - Nuclear Pharmacist does not have bioassays performed after Reports each preparation > 30 mCi

- E. Reports
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]

None since 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 I¹³¹
- 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 14c - 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 decan p4 therapy room 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 bioassay on nuclear pharmacists after therapeutic dose preparation
19.12 - Failure to advise nuclear pharmacist to have bioassay performed

25. PERFORMANCE EVALUATION FACTORS

Licensee (name & location) Dept. of the Army

Inspector T.H. Darden

Inspection Date 2-11 to 14-97

- 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 *Conducted by HPO*
 A. Frequency: *Annual by Principal/Authorized user* Conducted by: _____
 B. Individuals interviewed understand safety practices Y () N

Remarks:

See Section 3

Observed one researcher handling RAmCl-32 not fitted 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 10µCi.
- 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:

Survey in CPMA, however, trigger levels established for CPMA and conversion to DPM available and known. Researcher knows CPMA trigger levels.

7. Receipt and Transfer *(2)*
- 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 media) both inside and outside. All six sides 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 | <input checked="" type="checkbox"/> | Y | <input type="checkbox"/> | N | | |
| B. | Proper storage (area, containers, labeling, etc.) | <input checked="" type="checkbox"/> | Y | <input type="checkbox"/> | N | | |
| C. | Liquid/solid waste disposal | <input checked="" type="checkbox"/> | Y | <input type="checkbox"/> | N | | |
| D. | Incineration | <input checked="" type="checkbox"/> | N/A | <input type="checkbox"/> | Y | <input type="checkbox"/> | N |
| E. | Compaction | <input type="checkbox"/> | N/A | <input checked="" type="checkbox"/> | Y | <input type="checkbox"/> | N |
| F. | Sewer discharge | <input type="checkbox"/> | N/A | <input type="checkbox"/> | Y | <input checked="" type="checkbox"/> | N |
| G. | Records maintained | <input checked="" type="checkbox"/> | Y | <input type="checkbox"/> | 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 book

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

Remarks:

12. Posting and Labeling
- | | | | | | |
|----|--|-------------------------------------|---|--------------------------|---|
| A. | NRC-3 "Notice to Workers" | <input checked="" type="checkbox"/> | Y | <input type="checkbox"/> | 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 | <input checked="" type="checkbox"/> | Y | <input type="checkbox"/> | N |
| C. | Other posting and labeling requirements met | <input checked="" type="checkbox"/> | Y | <input type="checkbox"/> | N |

Remarks:

13. Violations Observed

END