

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 11/30/92
- C. Open violations from previous inspections: () N/A

<u>Requirement Violation</u>	<u>Corrective Action Taken (Y/N)</u>	<u>Status</u> <u>Open/Closed</u>
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10 CFR 35.51(a), on 10/13/92, the licensee used a survey instrument CLOSED that had not been calibrated from 11/8/1990 through 03/26/1992.

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

2. ORGANIZATION AND SCOPE OF PROGRAM

- A. Organizational Structure
 - Ms. Kate Uptol, CEO
 - *+ Dr. Harold Daitch, RSO
 - *+ June Burns, CNMT
 - Liz Taylor, CNMT

+ 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 so, list location(s) inspected () N/A

The Novi facility under this license was not inspected at this time. ✕

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

This licensee performs approximately 100 nuclear diagnostic studies using Tc-99m, I-131 (diagnostic and therapy, but no carcinoma above 30 mCi of NaI-131) and Xe-133 nuclides at the Detroit facility. An approximately 80 studies at the Novi facility according to the technician. This licensee does not possess Mo-99/Tc-99m generator, all doses ordered as unit doses from Syncor. According to the licensee, two technicians are currently employed for both sites and they alternate at each site. As of 1995, there were approximately 22 to 30 thyroid therapies for hyperthyroidism at the Detroit facility.

- B. Licensee does limited distribution of pharmaceuticals under Part 35 license¹ () Y (X) N

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

1. Indicate type of operation:

- a. Registered/licensed with FDA as drug manufacturer
- b. Registered/licensed with State Agency as 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:

- a. Sealed sources Y N
- b. Alpha and beta emitters Y N
- c. Generators Y N
- d. 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 Subjects² [35.6] Y N
If no, licensee has 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:

This licensee does not conduct research on human subjects according to the RSO and the technician. The clinic is specialized in the out-patient diagnostic studies and NaI-131 therapy < 30 mCi only.

- D. Radiation Safety Committee N/A
- 1. Membership as specified [35.22(a)(1)] Y N
 - 2. Meetings held quarterly [35.22(a)(2)] Y N
 - 3. Record maintained [35.22(a)(4)] Y N
 - 4. Quorums established [35.22(a)(3)] Y N
 - 5. Has sufficient authority [35.23] Y N
 - 6. Approve/disapprove credentials of individuals prior to allowing work as an authorized user or authorized nuclear pharmacist [35.22(b)(2)(ii)] Y N

E. Radiation Safety Officer

²

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

- 1. Appointed [35.21(a), 900] (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] () Y (X) N () N/A
- 2. Records of changes maintained [35.31(b)] () Y (X) N/A
- 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

G. Use by authorized individuals [L/C] (X) Y () N

NOTE: Compliance is established by meeting at least one criteria under each category.

- 1. Authorized Nuclear Pharmacist [35.13(b)] () Y () N (X) N/A

DOES NOT APPLY TO FACILITIES THAT ARE REGISTERED/LICENSED BY FDA/STATE AGENCY AS A DRUG MANUFACTURER & DISTRIBUTION IS REGULATED UNDER PART 32

- a. Certified by organization in 35.980
- b. Identified on NRC or Agreement State license
- c. Identified on permit issued by broad scope licensee
- d. Listed on facility license

- 2. Authorized User [35.13(b)] (X) Y () N

- a. Certified by organization in 35.910, 920, 930, 940, 950, or 960
- b. Identified on NRC or Agreement State license
- c. Identified on permit issued by broad scope licensee
- d. Listed on facility license

- 3. Radiation Safety Officer [35.13(c)]

- a. Listed on facility license (X) Y () N

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

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

I. Amendments since last inspection [35.13] () Y (X) N

J. Notifications since last inspection [35.14] () N/A

- 1. Licensee provided appropriate documentation to NRC for authorized nuclear pharmacists or user no later than 30 days after individual starts work [35.14(a)] () Y () N (X) N/A

- 2. Licensee notified NRC within 30 d after authorized user, nuclear pharmacist, or RSO stops work or changes name or licensee's

mailing address changes [35.14(b)]

() Y () N (X) N/A

Remarks:

3. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

- A. Instructions to workers [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:
Training program is prepared by the MPC consultant during annual or quarterly informal inservice training. Since technologists have been employed more than 16 to 20 yrs, the training involves required readings given by the consultant. The technologist training records are kept at the licensee's Detroit facility.

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 by authorized user in accordance with [35.25] (X) Y () N

1. Supervised individuals³ are instructed in preparation of material, principles and procedures for radiation safety and QMP as appropriate [35.25(a)(1), (b)(1)] (X) Y () N

2. Licensee periodically reviews supervised individual's use of material and records kept to reflect use [35.25(a)(3)] (X) Y () N

3. Authorized nuclear pharmacist/user periodically reviews work and records of work of supervised individuals as it pertains to preparing byproduct material [35.25(b)(3)] () Y () N (X) N/A

Remarks:

E. Therapy training (X) N/A

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 () Y () N () N/A
d. Handling/shielding of sources () Y () N () N/A

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

- 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. Training for operating and emergency procedures for HDR Remote Afterloaders [L/C] Y N N/A

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

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 volatiles/gases in storage [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

Remarks:

The evacuation time and the emergency procedures are posted at the entry door to the camera room. The evacuation time was calculated by the MPC consultant based on Xe-133 spill clearance time and it was verified by the inspector.

5. EQUIPMENT

- A. Dose calibrator - Photon emitting radionuclides N/A
 - 1. Possessed and used [35.50(a)] Y N
 - 2. Constancy [35.50(b)(1)]

- a. Performed daily (x) Y () N
- b. Dedicated check source used (x) Y () N

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 (x) Y () N
- b. Includes range between 10 uCi and the highest dosage administered (x) Y () N

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

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

Not Inspected

6. Dosage readings mathematically corrected for geometry or linearity errors greater than $\pm 10\%$ [35.50(d)] () Y () N (X) N/A

7. Repaired or replaced when constancy or accuracy errors exceeded $\pm 10\%$ [35.50(d)] () Y () N (x) N/A

8. Approved procedures followed [35.21, 25, L/C] (X) Y () N

9. Records maintained and include identity of individual performing test [35.50(e)(2),(3),(4)] (X) Y () N

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

1. List type of equipment used for assay

2. Licensee has procedures for use of instrumentation [35.51(b)] () Y () N

3. Accuracy, linearity and geometric dependence tests performed prior to initial use, periodically, and following repair⁴ [35.52(b)(1), L/C] () Y () N () N/A

4. Instruments 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 if calibration errors in excess of limits are identified [L/C] () Y () N () N/A

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

Remarks:

⁴ Linearity and geometric dependence tests are not applicable if liquid scintillation is used. Linearity is not applicable if Sodium Iodide is used.

- C. Licensee uses generators () Y (X) 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] (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

Remarks:

Licensee orders pharmaceutical in unit doses from a Syncor pharmacy lab located in Detroit.

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) N/A
1. Licensee receives unit doses and relies on assay data supplied by manufacturer or properly licensed organization [35.53(b)] () Y () N
 2. Licensee measures by direct measurement or combination of measurement and calculation each dosage of alpha or beta emitting radionuclide prior to medical use [35.53(b), L/C] () Y () N
- C. Unsealed material used under 35.100(b), 200(b), or 300(b) are:
1. Obtained from manufacturer or properly licensed organization AND/OR (X) Y () N
 2. Prepared by authorized nuclear pharmacist/user or individual under the supervision of an authorized nuclear pharmacist/user [35.920] (X) Y () N
- D. Isotope, chemical form, quantity and use as authorized [31.11, 35.100, 200, 300, 400, 500, L/C] (X) Y () N
- E. Use of radiopharmaceuticals [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
- F. 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 and includes required information [35.406(a)] (X) Y () N
5. Records maintained & signed by RSO [35.59, 406] (X) Y () N

Remarks:

Leak tests and inventories are performed semi annually by the consultant Health Physicist (MPC), records appear to be adequate.

7. RADIATION SURVEYS

A. Survey instruments used to show compliance with Part 35

1. Appropriate operable survey instruments possessed [35.120, 220, 320, 420] or available [35.520] (X) Y () N () N/A
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

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 routinely prepared, administered or stored [35.70(e)] (X) Y () N
4. Quarterly in brachytherapy source storage area () Y (X) N/k

C. Trigger levels [35.70]

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

Remarks:

8. RADIOPHARMACEUTICAL THERAPY (X) 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)] () Y () N () N/A

Remarks:

9. BRACHYTHERAPY (X) N/A

- A. Safety precautions implemented to include patient facilities, 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] () Y () N () 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)] () Y () N () N/A
- E. Records maintained [35.404(b), 406(d), 415(a)(4)] () Y () N

Remarks:

10. RADIOACTIVE WASTE

- A. Disposal
 1. Decay-in-storage (X) 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. Improper/unauthorized disposals [20.2001] () Y () N
- 4. Records maintained [20.2103(a), 2108, L/C] () Y () N

B. Effluents

- 1. Release to sanitary sewer [20.2003] () Y () N (X) N/A
 - 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] () Y () N
 - d. Procedures to ensure representative sampling and analysis implemented [20.1501, L/C] () Y () N
- 2. Release to septic tanks [20.2003] () Y () N (X) N/A
 - a. Within unrestricted limits [App B, Table 2] () Y () N
- 3. Waste incinerated () Y () N (X) N/A
 - a. License authorizes [20.2004(a)(3)] () Y () N
 - b. Licensee directly monitors exhaust [L/C] () Y () N
 - c. Airborne releases evaluated and controlled [20.1501, 1701] () Y () N
- 4. Air effluents and ashes controlled [20.1201, 1301, 1501, 2001, L/C] {See also IP 87102, RG 8.37} (X) Y () N
 - a. Compliance with air emission requirements in Part 20
 Licensee demonstrated compliance with air emission requirements in 10 CFR 20 () Y () N

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

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

Basis for Determination: Spent Xe-133 gas is trapped by a charcoal cartridge, therefore no venting to the atmosphere. According to the approved license conditions no effluent estimation is necessary. The inspector stressed to the RSO that EPA requires USNRC' licensees to comply with the NESHAP program per 40 CFR Part 61 and this should be communicated to the MPC consultant. Records review indicated that consultant's reports since 1993 did not indicate that this facility is exempted from reporting based on RAM possession limits. Inspector ^{verified} reviewed that the licensee does not possess sufficient RAM to exceed Part 20 requirements.

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 (charcoal, HEPA, etc.) analyzed with appropriate instrumentation (X) Y () N

Remarks:

According to the technician, spent gas~~es~~^{es} of Xe-113 is trapped in a charcoal cartridge trap and each month the trapped effluent is collected in a plastic bag. The bag is analyzed with the gamma camera peaked at Xe-133 energy and by comparing background counts, the technician could determine charcoal break-through. No problem was noted on the licensee's Xe-133 effluent breakthrough.

- C. Waste storage (X) N/A
1. Protection from elements and fire [L/C] () Y () N
 2. Control of waste maintained [20.1801] () Y () N
 3. Containers properly labeled and area properly posted [20.1902, 1904] () Y () N
 4. Package integrity adequately maintained [L/C] () Y () N
- D. Records of surveys and material accountability are maintained [20.2103, 2108] () Y () N

Remarks:

Generated waste is decayed and stored in the hot lab, all contaminated syringes are currently returned to Syncor Pharmacy.

11. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

- A. Describe how packages are received and by whom: () N/A
 Packages (ammo boxes containing unit doses) are delivered directly to the hot lab every morning by the Syncor courier. The courier has access to the licensee's facility keys and has a direct access to the hot lab. The lab is always locked according to the licensee after each delivery during off hours.

- 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) performed within time specified [20.1906(c)] (X) Y () N
- F. Transfer(s) between licensees performed per [30.41] () Y (X) N/A
- 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. Package receipt/distribution activities evaluated for compliance with 20.1301 [20.1302] () Y (X) N/I

Remarks:

The technologist at the facility is cognizant on the multiplication factor to convert cpm to dpm for the well counter. No problem was noted during the inspection. The well counter was calibrated by the Health Physicist MPC consultant, no deficiency was noted.

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

A. Licensee shipments are:

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

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

- 1. Licensee assumes shipping responsibility () Y (X) N
- 2. If NO, describe arrangements made between licensee and radiopharmacy for shipping responsibilities:
Currently, unit doses are delivered and spent syringes/waste are collected by the Syncor courier during each morning or afternoon.

D. Packages () N/A

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

- E. Shipping Papers (X) N/Insp.
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 (X) N
- B. Licensee implemented ALARA 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] () Y () N (X) N/A
 3. Supplier **LANDAUER** Frequency **Monthly**
 4. Supplier is NVLAP-approved [20.1501(c)] (X) Y () N
 5. Dosimeters exchanged at required frequency [L/C] (X) Y () N
- D. Internal Dosimetry (X) 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 [35.205] () Y () N
 4. Monitoring/controlling program implemented (includes bioassays) [35.315(a), 205(d), L/C] () Y () N
 5. Respiratory protection equipment [20.1703] () Y () N
- E. Reports
1. Reviewed by **RSO and Consultant** Frequency **Quarterly**
 2. Inspector reviewed personnel monitoring records for period
 3. Prior dose determined for individuals likely to receive doses [20.2104] () Y () N
 4. Maximum exposures TEDE **40 mrem - 1994**
40 mrem - 1995 Other Ext. 150 mrem-94
250 mrem-95
 5. Maximum CDEs Organs
 6. Maximum CEDE
 7. Licensee sums internal and external [20.1202] (X) Y () N
 8. TEDEs and TODEs within limits [20.1201] (X) Y () N
 9. NRC forms or equivalent [20.2104(d), 2106(c)]

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

10. Worker declared her pregnancy in writing during inspection period (review records) () Y () N (X) N/A
 If yes, licensee in compliance with [20.1208] () Y () N
 and records maintained [20.2106(e)] () Y () N

F. Who performed any PSEs at this facility (number of people involved and doses received) [20.1206, 2104, 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

Remarks:

14. MISADMINISTRATIONS AND RECORDABLE EVENTS (X) N/A

A. If misadministrations or recordable events (defined in 35.2) have occurred since the 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. <u>Survey instrument</u>	<u>Serial No.</u>	<u>Last calibration</u>
Ludlum-3	046891	01/02/96

B. Inspector's measurements were compared to licensee's (X) Y () N

- C. Describe the type, location, and results of measurements:
 The highest readings were located inside the hot lab at the Detroit licensee's facility, maximum reading was 0.5 mR/hr inside the lead shield where check sources are kept, all spent syringes are kept inside the Syncor's ammo box. An ambient background of 0.05 mR/hr was detected in the middle of the hot lab, a reading of 0.03 mR/hr was detected in the camera room, outside the hot lab. At the unrestricted area, adjacent to the hot lab indicated a reading of 0.03 mR/hr at 30 cm from the wall surface.

16. NOTIFICATION AND REPORTS

- A. Licensee in compliance with [19.13, 30.50] (reports to individuals, public and occupational, monitored to show compliance with Part 20) (X) Y () N () N/A
- B. Licensee in compliance with [20.2201, 30.50] (theft or loss) (X) Y () N () None
- C. Licensee in compliance with [20.2202, 30.50] (incidents) (X) Y () N () None
- D. Licensee in compliance with [20.2203, 30.50] (overexposures and high radiation levels) (X) Y () N () 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

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)] (X) Y () N
- b. Records include all information outlined in [30.35(g)] (X) Y () N

Remarks:

The licensee does not possess unsealed sources greater than 120 days T1/2 and the licensee maintains facility drawing and survey records.

19. BULLETINS AND INFORMATION NOTICES

Not Inspected

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

Remarks:

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

A. Special license conditions or issues to be reviewed:

B. Evaluation:

21. CONTINUATION OF REPORT ITEMS (X) N/A

22. VIOLATIONS, NCVs, AND OTHER ISSUES (X) N/A

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.

23. DEBRIEF WITH LICENSING STAFF (X) N/A

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

Items discussed:

24. EPA REFERRAL FORM () N/A

A. EPA referral form for air effluents sent to appropriate EPA regional office per IP 87102 (X) Y () N

If no, explain:

25. PERFORMANCE EVALUATION FACTORS

Licensee
Woodland Medical Center
22341 W. Eight Mile Rd.
Detroit, MI 48219

Inspector Tony Go / S. Mulay

Inspection Date 01/25/95

- 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):

Regional follow-up on above PEFs citations:

ATTACHMENT A
QUALITY MANAGEMENT PROGRAM (QMP)
QM FIELD NOTES

1. GENERAL

A. Facility name(s): Woodland Medical Group
 B. License number(s): 21-13255-01
 C. Docket number(s): 030-02149
 D. Last inspection date(s): 10/13/92
 E. Current inspection date(s): 1/25/96
 F. Most recent QMP and certification received by NRC [35.32(e), (f)(2)] Date: 6/17/94

2. PREPARATION

A. Be familiar with the submitted QMP and any modifications in preparation for inspection of the licensee's implemented QMP. Familiarization should focus upon awareness of the submitted program in order to compare the written program with the program as implemented.

3. MODALITIES

A. Identify licensee procedures and attach appropriate inspection module(s):

Module:

- | | | | | | |
|----|--|-------------------------------------|---|-------------------------------------|---|
| 1. | NaI I-125 or I-131 > 30 μ Ci and/or Therapeutic radiopharmaceutical other than NaI | <input checked="" type="checkbox"/> | Y | <input type="checkbox"/> | N |
| 2. | High-Dose-Rate Remote Afterloading Brachytherapy | <input type="checkbox"/> | Y | <input checked="" type="checkbox"/> | N |
| 3. | All Other Brachytherapy | <input type="checkbox"/> | Y | <input checked="" type="checkbox"/> | N |
| 4. | Strontium-90 eye applicator | <input type="checkbox"/> | Y | <input checked="" type="checkbox"/> | N |
| 5. | Teletherapy | <input type="checkbox"/> | Y | <input checked="" type="checkbox"/> | N |
| 6. | Gamma Stereotactic Radiosurgery | <input type="checkbox"/> | Y | <input checked="" type="checkbox"/> | N |
| 7. | Event (misadministration or other) | <input type="checkbox"/> | Y | <input checked="" type="checkbox"/> | N |

4. SAMPLING (Inspector random sample of each modality)

Total Written Directives

Minimum Target Sample

1 to 5
 5 to 100
 > 100

All
 5%
 94
 95

	Total W.D.* Prev. Yr	Total W.D.* Curr. Yr	Target Sample	Number Reviewed
1. NaI I-125 or I-131 > 30 μ Ci	22	24	10	10
2. Therapeutic Radiopharmaceutical other than NaI				
3. HDR remote afterloading brachytherapy				
4. Other brachytherapy				
5. Sr-90 eye applicator				
6. Teletherapy				
7. Gamma Stereotactic Radiosurgery				

* Full calendar year

If two (2) or more written directives are incomplete or missing, the review must be expanded to assess whether this is an isolated occurrence or represents a substantial failure of the QMP.

3. Therapeutic Radiopharmaceutical other than NaI

~~(X)~~ N/A

OBJECTIVE 1

- A. A written directive (order for a specific patient, dated & signed by authorized user (a.u.) or physician under supervision of an a.u.) is prepared for each patient [35.32(a)(1)] () Y () N _____
- B. Written directives, as applicable, contain required information, radiopharmaceutical, dosage, and route of administration [35.2] () Y () N _____
- C. Exceptions to written directives are documented [footnote to 35.32(a)(1)] () N/A
 - 1. Written revisions () Y () N _____
 - 2. Oral revisions () Y () N _____
 - 3. Oral directives () Y () N _____

OBJECTIVE 2

- A. Licensee uses more than one method to verify the patient's identity [35.32(a)(2)]: () Y () N _____

Remarks:

OBJECTIVE 3 (Does not apply)

OBJECTIVE 4

- A. Procedures implemented to verify, prior to administration, that the specific details are in accordance with written directive [35.32(a)(4)] () Y () N _____
- B. Procedures may include: (not requirements)
 - 1. Dosage measured prior to administration () Y () N
 - 2. Radiopharmaceutical, dosage and route of administration confirmed immediately prior to administration () Y () N
- C. Record of administration maintained in auditable form [35.32(d)(2)] () Y () N _____

MODULE 1

GREATER THAN 30 MICROCURIES NaI I-125 or I-131
AND
RADIOPHARMACEUTICAL THERAPY

1. SUPERVISION

- A. Supervised individual(s) instructed in QMP applicable to the modality of use [35.25(a)(1)] Y () N

List individual(s) found to be inadequately trained:

The Technologist at the Woodland Detroit facility and the RSO were knowledgeable and adequately trained in the QMP.

2. NaI I-125 or I-131 > 30 μ Ci () N/A

OBJECTIVE 1

Number
Missed

- A. A written directive (order for a specific patient, dated & signed by authorized user (a.u.) or physician under supervision of an a.u.) is prepared for each patient [35.32(a)(1)] Y () N 0

- B. Written directives, as applicable, contain required dosage information [35.2] Y () N 0

- C. Exceptions to written directives are documented [footnote to 35.32(a)(1)] N/A

1. Written revisions () Y () N _____
2. Oral revisions () Y () N _____
3. Oral directives () Y () N _____

OBJECTIVE 2

- A. Licensee uses more than one method to verify the patient's identity [35.32(a)(2)] Y () N 0

Remarks: *By name, Birth date and Social Security Number*

OBJECTIVE 3 (Does not apply)

OBJECTIVE 4

- A. Procedures implemented to verify, prior to administration, that the specific details are in accordance with written directive [35.32(a)(4)] Y () N 0

- B. Procedures may include: (not requirements)

1. Dosage measured prior to administration Y () N
2. Dosage confirmed just prior to administration Y () N

C. Record of administration maintained in auditable form [35.32(d)(2)] Y () N 0

Remarks:

OBJECTIVE 5

A. Procedures implemented to ensure that unintended deviations are identified, evaluated, and corrective action taken [35.32(a)(5)] Y () N

1. Recordable event(s) self-identified since the last inspection [35.32(c), 35.2] Y N
Dates of events:

2. Recordable events identified by inspector [35.32(c), 35.2] Y N

3. Misadministration resulted from the unintended deviation (If yes, also complete module 7) Y N

B. Procedures implemented to evaluate & respond within 30 days to each recordable event discovered [35.32(c)] Y N

C. Procedures may include: (not requirements)

1. Assemble relevant facts including cause Y () N

2. Identify corrective action to prevent recurrence Y () N

3. Retain a record of items 1 and 2 Y () N

D. Licensee reported misadministration(s) since the last inspection (If yes, also complete module 7) [35.33(a)] Y N

E. Licensee identified misadministrations that were not subsequently reported (If yes, also complete module 7) [35.33(a)] Y N

Remarks:

OBJECTIVE 5

- A. Procedures implemented to ensure that unintended deviations are identified, evaluated, and corrective action is taken [35.32(a)(5)] () Y () N
1. Recordable event(s) self-identified since the last inspection [35.32(c), 35.2] () Y () N
Dates of events:
2. Recordable events identified by inspector [35.32(c), 35.2] () Y () N
3. Misadministration resulted from the unintended deviation (If yes, also complete module 7) () Y () N
- B. Procedures implemented to evaluate & respond within 30 days to each recordable event discovered [35.32(c)] () Y () N
- C. Procedures may include: (not requirements)
1. Assemble relevant facts including cause () Y () N
2. Identify corrective action to prevent recurrence () Y () N
3. Retain a record of items 1 and 2 () Y () N
- D. Licensee reported misadministration(s) since the last inspection (If yes, also complete module 7) [35.33(a)] () Y () N
- E. Licensee identified misadministrations that were not subsequently reported (If yes, also complete module 7) [35.33(a)] () Y () N

Remarks:

4. PERIODIC REVIEWS OF THE QMP

- A. Review conducted of the QMP at intervals no greater than 12 months [35.32(b)(1)] (X) Y () N
Date of last review: 8/25/95
- B. Review includes a representative sample of all patient administrations including all recordable events and misadministrations [35.32(b)(1)(i)(ii)(iii)] (X) Y () N

The licensee should utilize a representative sampling process which embodies a valid statistical sampling methodology. Regulatory Guide 8.33 provides an example using the acceptance sampling tables of 10 CFR 32.110 and assuming an error rate of 2%. If the tables in 10 CFR 32.110 are used, any table is acceptable.

- C. If review identified recordable events or misadministrations not previously identified, the review was expanded by the licensee to ensure the events were isolated () Y (X) N/A
- D. Licensee evaluated each review to determine the effectiveness of the QMP [35.32(b)(2)] (X) Y () N
- E. Based on evaluation of reviews, the licensee made modifications to meet Objectives [35.32(b)(2)] () Y (X) N/A
- F. Modifications sent to NRC within 30 days [35.32(e)] () Y () N (X) N/A
- G. Records of reviews including evaluation and findings maintained for at least 3 years [35.32(b)(3)] (X) Y () N

5. RESULTS OF REVIEW

Briefly describe the overall implementation of the QMP and summarize the inspection findings. If necessary, use an attachment.

a Review of the Licensee's QM Program indicated that there were no recordable events since 1993 because I-131 >30 uci doses are administered within ±10% of the dose indicated on the written directive. The QM Program is also reviewed Quarterly or Semiannually by Tom MPL consultant to determine for possible recordable events or misadministrations - RSO and Authorized users are proactive with the QM Program.

6. Time spent completing this module: 1.0 hours