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

APPENDIX B
NUCLEAR MEDICINE INSPECTION FIELD NOTES
Region III

Inspection Report No. 92001 License No. 21-13255-01

Licensee (name and address) Docket No. 030-02149

Woodland Medical Group
22341 West Eight mile Road
Detroit, MI 48219

Licensee Contact **Dr. Harold Daitch, M.D.** Telephone No.**(313) 592-3560**

Last Amendment No. **26** Date of Amendment **6/26/90**

Priority : **G- 4**

Program Codes:

( ) 02110 - Broad Scope	( ) 02120 - Limited
( ) 02121 - Custom	(X) 02200 - Private Practice - Limited
( ) 02209 - In Vivo	( ) 02201 - Private Practice - Custom
( ) 02210 - Eye Applicator	( ) 02220 - Nuclear Medical Van
( ) 02400 - Veterinary	( ) 02410 - In Vitro
( ) 02500 - Pharmacy	( ) Other -

Date of Last Inspection **8/25/89**

Date of This Inspection **10/13/92**

Type of Inspection:

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

Next Inspection Date. 10/94 (X) Normal ( ) Reduced ( ) Extended

Summary of Findings and Action:

( ) No violations, Clear 591 or letter issued
(X) Violations, 591 or letter issued
( ) Action on Previous Violations

Inspector: _____ Date 10/20/92
(Signature)

Approved: _____ Date 10/26/92 A167
(Signature)

1. ORGANIZATION

a. Organizational structure meets license requirements [L/C] (X) Y ( ) N

Remarks.

Dr. Daitch reports to the management through the Chief of Staff. The Nuclear Medicine Manager and CNMT, Liz Taylor, reports to the clinic administration through Robert Bennett, the Vice President of Operations.

b. Use by authorized individuals [35.22(b)(2)] (X) Y ( ) N

Remarks.

c. Radiation Safety Committee (X) N/A

(1)	Membership as specified in [35.22(a)(1)]	( ) Y ( ) N
(2)	Meetings held quarterly [35.22(a)(2)]	( ) Y ( ) N
(3)	Quorums established per [35.22(a)(3)]	( ) Y ( ) N
(4)	Has sufficient authority per [35.23]	( ) Y ( ) N
(5)	Committee reviews conducted per [35.22(b)]	( ) Y ( ) N
(6)	Record of Committee meetings [35.22(a)(4)]	( ) Y ( ) N

Remarks.

d. Radiation Safety Officer

(1)	Appointed [35.21(a)]	(X) Y ( ) N
(2)	Fulfills duties per [35.21(b)]	(X) Y ( ) N
(3)	Has sufficient authority per [35.23]	(X) Y ( ) N

Remarks.

Dr. Daitch reviews the required records on a quarterly basis and is present on site regularly.

e. Visiting Authorized User (X) N/A

(1) Has written permission [35.27(a)(1)] ( ) Y ( ) N
(2) Copy of visitor's license on file [35.27(a)(2)] ( ) Y ( ) N
(3) Performs only those procedures authorized on visitor's license [35.27(a)(3)] ( ) Y ( ) N
(4) Uses material under licensee's license for sixty days per year or less [35.27(b)] ( ) Y ( ) N
(5) Records maintained 3 years after last visit [35.27(c)] ( ) Y ( ) N

Remarks.

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

(1) Licensee uses mobile nuclear medicine services [35.29] ( ) Y ( ) N
(2) Licensee operates mobile nuclear medicine services [35.29, 35.80] ( ) Y ( ) N

Remarks.

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

a. Last inspection conducted on **8/25/89**

b. Violations or deviations were identified (X) Y ( ) N

c. Response letter or 591 dated **10/2/89**

d. Violations from Previous Inspection

Requirement	Violation	Corrective Action Taken (Y/N)	Status
L/C 14	**Failure to calibrate survey instrument annually**	**N**	**Open**
L/C 14	**Failure to test linearity quarterly**	**Y**	**Closed**

e. Any previous violations not corrected (X) Y ( ) N

Explain.

The licensee did not calibrate the Bicron 2000 portable survey instrument between 11/8/90 and 3/26/92. This is a repeat violation and described in section 6 d.

3. SCOPE OF PROGRAM

a. License has multiple authorized locations of use (X) Y ( ) N
b. If so, list location(s) inspected ( ) N/A

The Eight Mile and Novi facilities.

c. List those individuals contacted during inspection

Robert Bennett, Vice President of Operations, Elizabeth Taylor, CNMT, June Berns, NMT, * Harold Daitch, M.D., RSO, * Dr. Seymour Mirkes, M.D., Authorized User.

*Indicates presence at exit meeting

d. Briefly describe scope, including types of use involving byproduct material, frequency of use, staff size, etc.

This licensee conducts diagnostic nuclear medicine studies using Tc-99m, I-131, Xe-133. They conduct 110 studies per month at the Eight Mile facility and 60 per month at the Novi facility using unit doses. Two technologists are employed full time. They rotate between the two facilities and on one day per week are both at the Eight Mile facility. They do use Xe-133 at the eight mile facility and are set up to use it at the Novi facility but do not schedule patients for lung scans at Novi. They check the xenon traps on a monthly basis when used. They conduct 5 to 10 lung scans with xenon per year. There is only hyperthyroid therapy work conducted with less than 30 mCi of I-131 and this involves 20 patients per year at the Eight Mile and 10 per year at the Novi facility.

e. Radiation safety program changes pursuant to [35.31] ( ) Y ( ) N (X) N/A
f. Records of changes maintained [35.31(b)] ( ) Y ( ) N (X) N/A

Remarks.

4. INTERNAL AUDITS AND INSPECTIONS

a. Audits or inspections are conducted (X) Y ( ) N ( ) N/A

(1) Audits conducted by **MPC**

(2) Frequency **Semiannually using alternate quarterly visits to each facility.**

b. Audits are required by license condition ( ) Y (X) N
c. Records maintained (X) Y ( ) N

Remarks.

5. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

a. Instructions to workers per [10 CFR 19.12] (X) Y ( ) N

Remarks.

b. Training program required [L/C] (X) Y ( ) N ( ) N/A

(1) Training program implemented (X) Y ( ) N
(2) Retraining program required (X) Y ( ) N
(3) Retraining program implemented (X) Y ( ) N
(4) Records maintained (X) Y ( ) N

Remarks.

There is little turn over in personnel. Both technologists have been with the licensee for 13 and 17 years. Annual in-service for the Nuclear Medicine personnel is in place and appears to be adequate. The inspector encouraged a more thorough accounting of the in-service for each technologist. Ancillary personnel are on an annual in-service schedule. New personnel are trained at the start of employment and annually.

c. Supervision of individuals by authorized user in accordance with [35.25] (X) Y ( ) N

Remarks.

6. FACILITIES AND EQUIPMENT

a. Facilities as described in license application (X) Y ( ) N

Remarks.

No changes since last amendment.

b. Areas for storage and use of RAM

(1) Adequate method used to prevent an unauthorized individual from entering restricted area (X) Y ( ) N

(2) RAM is secured to prevent unauthorized removal from an unrestricted area [20.207] (X) Y ( ) N

Remarks.

c. Dose calibrator

(1) Licensee possesses and uses dose calibrator(s) per [35.50(a)] (X) Y ( ) N ( ) N/A

(2) Constancy checked per [35.50(b)(1)] (X) Y ( ) N

(3) Linearity tested per [35.50(b)(3)] (X) Y ( ) N

(4) Accuracy tested per [35.50(b)(2)] (X) Y ( ) N

(5) Geometry dependence tested per [35.50(b)(4)] (X) Y ( ) N

(6) Readings mathematically corrected if linearity error is greater than 10% [35.50(d)] (X) Y ( ) N

(7) Records maintained [35.50(e)] (X) Y ( ) N

(8) RSO signs linearity, accuracy and geometry dependence tests [35.50(e)] (X) Y ( ) N

Remarks.

CRC-10 and 4

d. Survey instruments

(1) Appropriate operable survey instruments possessed per [35.120,220,320,420] or available per [35.520] (X) Y ( ) N ( ) N/A
(2) Calibration performed as required in [35.51] ( ) Y (X) N
(3) Records maintained [35.51(d)] (X) Y ( ) N
(4) Proper operation checked with check source per [35.51(c)] (X) Y ( ) N

Remarks.

VIOLATION

Eberline E-520 and Bicron 2000

10 CFR 35.51(a) requires the licensee to calibrate the survey instruments used annually. The licensee calibrated the Bicron 2000 portable instrument on November 8, 1990 and again on March 26, 1992, a period exceeding the annual requirement. The licensee's consultant identified the need to calibrate the instrument during the November 1991 visit but the licensee did not take action on this matter prior to the next visit by the consultant in March of 1992, which then exceeded the annual frequency. This matter was corrected by the March 26, 1992, calibration and the Eberline E-520 instrument was calibrated on schedule in October, 1992. It appears that the that the licensee is being more diligent in meeting this requirement. The licensee did not document this as a licensee identified and corrected violation. This is a repeat violation but does not appear to be ongoing in duration.

e. Syringes containing RAM properly labeled and shielded unless contraindicated per [35.60] (X) Y ( ) N

f. Vials containing RAM properly labeled and shielded per [35.61] (X) Y ( ) N

Remarks.

One administration was observed at the Eight Mile facility. Although the Novi facility was visited, no patients were served by the staff.

7. RADIOLOGICAL PROTECTION PROCEDURES

a. Radioactive materials used in accordance with current procedures [L/C] ( ) Y ( ) N

Remarks.

b. Individual's understanding of current procedures is adequate

(1) in general rules for safe use of RAM (X) Y ( ) N
(2) in emergency procedures (X) Y ( ) N

Remarks.

8. MATERIALS

a. Licensee uses unit doses (X) Y ( ) N

b. Licensee uses generators ( ) Y (X) N

c. Licensee possesses sealed sources or brachytherapy sources per [35.59] ( ) Y (X) N

d. Isotope, chemical form, quantity and use as authorized [L/C, 31.11, 35.100,200,300,400,500] (X) Y ( ) N

Remarks.

Materials received from Syncor.

e. Molybdenum-99 breakthrough (X) N/A

(1) Test performed per [35.204(b)] ( ) Y ( ) N
(2) Records maintained per [35.204(c)] ( ) Y ( ) N

Remarks.

f. Leak tests and Inventory

(1)	Leak tests performed on sealed sources ~~and brachytherapy sources~~ per [35.59(b)]	(X) Y ( ) N
(2)	Inventory of sealed sources ~~and brachytherapy~~ sources per [35.59(g)]	(X) Y ( ) N
(3)	Leak tests records in microcuries	(X) Y ( ) N
(4)	Leak test/inventory records signed by RSO	(X) Y ( ) N
(5)	Records maintained of leak tests and inventories for 5 years	(X) Y ( ) N

Remarks.

9. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

a. Describe how packages are received and by whom: ( ) N/A

Packages are delivered during the working hours directly to the hot lab by the courier. Deliveries of the unit doses made prior to work hours are delivered to a locked box in a fenced locked parking area. The box is not marked when material is in the "locker" so as to limit attention to the container. This procedure is instituted due to the neighborhood of Eight Mile Road. All doses are delivered directly to the Hot Lab at the Novi facility. All materials are opened by the technologist.

b.	Opening procedures established and followed [20.205(d)]	(X) Y ( ) N
c.	Incoming packages wiped per [20.205(b)]	(X) Y ( ) N
d.	Incoming packages surveyed per [20.205(c)]	(X) Y ( ) N
e.	Transfer(s) performed per [30.41]	(X) Y ( ) N
f.	Records of surveys and receipt/transfer maintained per [20.401(b) and 30.51]	(X) Y ( ) N

Remarks.

The licensee identified and corrected the receipt records that recorded the incoming wipes in CPM not DPM. The inspector encouraged proper documentation of licensee identified violations.

10. AREA SURVEYS ( ) N/A

a.	Ambient exposure rate surveys conducted per [35.70(a),(b),(c)]	(X) Y ( ) N
b.	Contamination surveys conducted per [35.70(e),(f)]	(X) Y ( ) N
c.	Trigger levels established [35.70(d), (g)]	(X) Y ( ) N
d.	Exposure rate survey records in Mr/hr	(X) Y ( ) N
e.	Contamination survey records in dpm/100 cm^2	(X) Y ( ) N
f.	Records maintained per [35.70(h)]	(X) Y ( ) N

Remarks.

Trigger levels are established as indicated in the application dated 3/15/90. The trigger levels were not readily posted on the survey documents and the technologist agreed to correct this immediately and discuss this with the other technologist to assure that action is taken at the trigger level. There were no measurements in excess of the trigger levels observed during the review.

11. RADIOPHARMACEUTICAL THERAPY (X) N/A

a.	Licensee provides safety instruction [35.310] and implements safety precautions [35.315] or equivalents [L/C]	( ) Y ( ) N
b.	Patient room contamination surveys per [35.315]	( ) Y ( ) N
c.	Release of patients containing radiopharmaceuticals meets [35.75]	( ) Y ( ) N
d.	Thyroid burden measured on individuals involved in dose administrations [35.315(a)(8)]	( ) Y ( ) N
e.	Records maintained	( ) Y ( ) N

Remarks.

Only hyperthyroid treatments are conducted using less than 30 mCi of I-131.

12. BRACHYTHERAPY (X) N/A

a.	Licensee provides safety instruction [35.410] and implements safety precautions [35.415] or equivalent [L/C]	( ) Y ( ) N
b.	Patient surveys performed per [35.406]	( ) Y ( ) N
c.	Release of patients containing permanent implants meets [35.75]	( ) Y ( ) N
d.	Release of patients treated with temporary implants meets [35.404]	( ) Y ( ) N

e. Brachytherapy sources inventoried per [35.406] ( ) Y ( ) N
f. Brachytherapy source storage area surveyed quarterly and record signed by RSO [35.59(h)] ( ) Y ( ) N
g. Records maintained ( ) Y ( ) N

Remarks.

13. PERSONNEL RADIATION PROTECTION - EXTERNAL

a. Film or TLD supplier **Landauer** Frequency **Monthly**

b. Supplier is NVLAP - approved (X) Y ( ) N

c. Reports reviewed by **RSO** Frequency **Monthly**

d. NRC inspector reviewed personnel monitoring records for period **January, 1990** to **April, 1992**

e. NRC forms or equivalent

(1) NRC-4: ( ) Y ( ) N Complete: ( ) Y ( ) N (X) N/A
(2) NRC-5: (X) Y ( ) N Complete: (X) Y ( ) N ( ) N/A
[20.401(a)]

f. List maximum exposures (millirem):

g. Licensee has implemented an ALARA program [35.20] (X) Y ( ) N

Remarks.

YEAR	WHOLEBODY	EXTREMITY
1992	20	120
1991	150	480
1990	30	80

14. PERSONNEL RADIATION PROTECTION - INTERNAL ( ) N/A

a. Potential for exposure of individuals to airborne RAM exists ( ) Y ( ) N N/A
b. Monitoring for airborne radioactivity conducted [20.201(b) to meet 20.103, 35.90, and 35.205] ( ) Y ( ) N

c. Records maintained [20.401, 35.205(d), and L/C] ( ) Y ( ) N N/A
d. Bioassay program implemented as described in correspondence with NRC ( ) Y ( ) N N/A
e. Radioactive gases

(1) Clearance time and safety procedures are posted [35.205(d)] (X) Y ( ) N
(2) Reusable collection systems checked monthly (X) Y ( ) N
(3) Ventilation rates checked each six months for negative pressure [35.205(e)] (X) Y ( ) N

Remarks.

No aerosols used and very few studies at Novi. They conduct 5 to 10 lung ventilation studies per year at the Eight Mile facility.

15. RADIOACTIVE EFFLUENT AND WASTE DISPOSAL

a. RAM in effluents to unrestricted areas ( ) Y (X) N
b. Release in accordance with regulatory limits [20.106(a)] ( ) Y ( ) N N/A

Remarks.

c. Describe waste disposal method(s) - solid and liquid:

Hold for decay and return to the vendor.

d. If LLW is stored because access to a burial site has been denied, answer (1), (2), and (3) below:

(1) Adequate control of waste in storage is maintained (X) Y ( ) N
(2) Package is labeled and package integrity is adequately maintained (X) Y ( ) N
(3) Adequate records of surveys and material accountability are maintained (X) Y ( ) N

e. Disposal of waste in accordance with regulatory requirements [20.301 and 35.92] (X) Y ( ) N
f. Decay-in-storage waste disposed per [35.92] (X) Y ( ) N
g. Records maintained [20.401(b) and 35.92(b)] (X) Y ( ) N

Remarks.

16. NOTIFICATION AND REPORTS

a.	Licensee in compliance with [19.13] (reports to individuals)	( ) Y ( ) N (X) N/A
b.	Licensee in compliance with [20.402] (theft or loss)	( ) Y ( ) N (X) None
c.	Licensee in compliance with [20.403] (incidents)	( ) Y ( ) N (X) None
d.	Licensee in compliance with [20.405] (overexposures)	( ) Y ( ) N (X) None

Remarks.

17. MISADMINISTRATIONS

a.	Misadministrations have occurred	( ) Y (X) N
	(1) Diagnostic	( ) Y (X) N
	(2) Therapeutic	( ) Y (X) N
b.	Licensee in compliance with reporting therapeutic misadministrations [35.33(a),(b)]	( ) Y ( ) N N/A
c.	Licensee in compliance with reporting diagnostic misadministrations, if required [35.33(c)]	( ) Y ( ) N
d.	Appropriate action taken to prevent recurrence	( ) Y ( ) N
e.	Records maintained [35.33(d)]	( ) Y ( ) N

Remarks.

18. POSTING AND LABELING

a. NRC-3 "Notice to Workers" posted (X) Y ( ) N
b. Parts 19, 20, and 21 and license 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 [20.203] (X) Y ( ) N

Remarks.

19. TRANSPORTATION (10 CFR 71.5(a) and 49 CFR 171-189)

a. Licensee makes shipments of RAM ( ) Y (X) N
b. If so, describe shipment content and method:

c. Licensee is aware of 10 CFR 61 requirements ( ) Y ( ) N ( ) N/A
d. Licensee classifies and characterizes waste ( ) Y ( ) N ( ) N/A
e. Shipments

(1) Authorized packages used [173.415,416] ( ) Y ( ) N ( ) N/A
(2) Package type used
(3) For DOT-7A packages, performance test record on file [173.415(a)] ( ) Y ( ) N ( ) N/A
(4) For special form sources, performance test record on file [173.476(a)] ( ) Y ( ) N ( ) N/A
(5) Packages properly labeled [172.403, 173.441] ( ) Y ( ) N ( ) N/A
(6) Packages properly marked [173.200] ( ) Y ( ) N ( ) N/A
(7) Proper shipping papers prepared and used [172.200-204] ( ) Y ( ) N ( ) N/A

Remarks.

f. Licensee makes return shipments of radiopharmacy doses (X) Y ( ) N ( ) N/A

(1) If YES, licensee assumes responsibility of all shipper requirements ( ) Y (X) N

(2) If NO, describe arrangements made between licensee and radiopharmacy as to performance of shipper responsibilities:

The licensee provides wipe test and dose rate information as directed by the pharmacy and the vendor is the shipper.

20. 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.

Not inspected

21. INDEPENDENT MEASUREMENTS

a. Survey instrument used **Xetex 305B**

b. NRC Serial No. **008359**

c. Last date of calibration **06-22-92**

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

e. Describe the type and results of measurements:

Hot lab 0.4 mR/hr
Imaging Rooms 0.0 mR/hr
Storage 0.0 mr/hr

22. BULLETINS AND INFORMATION NOTICES

a. Bulletins, Information Notices, etc., received by the licensee (X) Y ( ) N

b. Licensee took appropriate action in response to Bulletins, INs, etc. (X) Y ( ) N

Remarks.

23. CONTINUATION OF REPORT ITEMS - USE BACK OF PAGE IF NECESSARY

24. LIST OF VIOLATIONS

See Section 6 d.

25. PERFORMANCE EVALUATION FACTORS

Licensee

Woodland Medical Group
22341 West Eight mile Road
Detroit, MI 48219

Inspector

Mark Mitchell

Inspection Date

October 13, 1992

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

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

Regional follow-up on above PEFs citations:

LICENSEE RESPONSE EVALUATION
(TO BE FILED IN LICENSE FILE)

LICENSE FILE Mitchell

Licensee Woodland Medical Group License No. 21-13255-01

Inspection Date(s) October 13, 1992 Docket No. 030-02149

Date Licensee Letter Mailed NOV 05 1992 Response Due Date 12/8/92

Response Overdue _____

First Response Evaluation

Licensee Called _____

Date Received DEC 01 1992

New Due Date _____

X Adequate

_____ Inadequate (provide reasons and actions taken)

Reasons: 1) Letter implies concurrence with the violation.
2) Patch was calibrated 3/6/92
3) RPE consultant will Play ~~[illegible]~~ during visits 2x per year.
4) Compliance 3/6/92 + 11/30/92 Agreement with RPE.

Actions Taken

New Due Date _____

Inspector's Signature [signature] 12/11/92

Section Chief's Signature [signature] 12/16/92

Second Response Evaluation

Date Received _____

_____ Adequate

_____ Inadequate (provide reasons and actions taken)

Reasons:

Actions Taken

New Due Date _____

Inspector's Signature _____

Section Chief's Signature _____

PLEASE EXPEDITE