NUCLEAR MEDICAL INSPECTION FIELD NOTES

Inspection Report No. 89-001 License No. 21-13255-01

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

WOODLAND MEDICAL GROUP
22341 WEST EIGHT MILE RD.
DETROIT, MI. 48219

Licensee Contact KATHY THIEBOUT - NMT Telephone No. (313) 538-4700

Last Amendment No. 25 Date of Amendment 4/23/85

Priority 3 Category G

Program Codes:
( ) 02110 - Broad
( ) 02120 - Group Hospital
( ) 02121 - Non-Group Hos.
(X) 02200 - Private Practice - Group
( ) 02201 - Private Practice - Limited
( ) 02220 - N.M. Van
( ) 02209 - InVivo Testing
( ) 02500 - Pharmacy
( ) 02210 - Eye Application
( ) Other

Date of Inspection 8/28/89

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

Next Inspection Date 8/1992

(X) Normal ( ) Reduced ( ) Extended

Summary of Findings and Action:

( ) No Violation, Clear 591 issued
(X) Violation(s), ~~591~~ LTR issued
(X) Action on Previous Violation
( ) Regional Action
( ) Headquarters Action

Persons contacted:

* KATHY THIEBOUT - NMT.
* SEYMOUR MIRKES, M.D. - AUTH USER.
ELIZABETH TAYLOR - CHIEF TECH. (BY PHONE).

Those present at exit interview: *

IA/58

Inspector _____ (Signature) 8/28/89 (Date Signed)

Approved _____ (Signature) 9/5/89 (Date Signed)

DW

1. ORGANIZATION

a. Organizational structure meets license requirements. (X) Yes ( ) No (L/C)
Remarks:

b. Use by authroized individuals. (X) Yes ( ) No (L/C)
Remarks:

c. Radiation Safety Committee meets at required intervals. ( ) Yes ( ) No (35.22 (a)(2))

Membership in accordance with 35.22 (a)(1) L/C ( ) Yes ( ) No

N/A

d. Record of Committee meetings. ( ) Yes ( ) No (L/C or 35.22 (a)(4))
Remarks:

2. INSPECTION HISTORY

a. Item(s) of violations or deviations noted during last inspection conducted on 7/10/86 (X) Yes ( ) No.

Response letter dated 5/9/86 / VIOLATION

b.

Requirement	Type of Violation	Corrective Action Taken ( ) Yes ( ) No	Status Open Clos
DOSE CALIBRATOR LINEARITY TESTS NOT PERFORMED AT PROPER FREQUENCY.			

(continue b. paragraph 20, if needed)

c. If any item(s) of violations or deviations noted during last inspection were not corrected, explain.

REPEAT VIOLATION – SEE SECTION F-6

3. SCOPE OF PROGRAM

THIS SMALL NUC. MED CLINIC PERFORMS 100 PROCEDURES PER MONTH, 75% ARE Tc^{99m} RELATED. THREE TECH'S ARE EMPLOYED AND ROTATE BETWEEN DETROIT & NOVI CLINICS. ONE XENON VENTILATION IS DONE PER MONTH & 6-7 I-131 THERAPIES FOR HYPERTHYROID AVERAGING 10 m C. ~~CAPSULES~~ ARE DONE. SQUIBB FURNISHES I-131 CAPS, SYNOR PROVIDES UNIT DOSES.

4. INTERNAL AUDITS OR INSEPCTIONS

a. Required by license condition. ( ) Yes (X) No

b. Audits or inspections conducted (X) Yes ( ) No (L/C)

c. Records maintained. (X) Yes ( ) No (L/C)
Remarks:
SEMI-ANNUALLY — M.P.C.

5. TRAINING, RETRAINING, AND INSTRUCTION TO WORKERS

a. Training program required by license condition. ( ) Yes (X) No

b. Training program implemented. ( ) Yes (X) No (L/C)
Remarks:

c. Retraining program required by license condition. (X) Yes ( ) No

d. Retraining program implemented. (X) Yes ( ) No (L/C)
Remarks:

e. Instruction to workers in accordance with 10 CFR 19.12 (X) Yes
( ) No (19.12)
Remarks:

6. RADIOLOGICAL PROTECTION PROCEDURES

a. Procedure referenced in license condition. (X) Yes ( ) No

b. Used in accordance with referenced procedure. (X) Yes ( ) No
Remarks:
LAB COATS, GLOVES, & SYRINGE SHIELDS.

c. Individuals understanding of procedures adequate. (X) Yes ( ) No
Remarks:

d. Examples of key procedures:

(1) ordering and accepting packages RAM (X) Adequate ( ) Inadequate

(2) general rules for safe use of RAM (X) Adequate ( ) Inadequate

(3) emergency procedures (X) Adequate ( ) Inadequate

(4) survey procedures (X) Adequate ( ) Inadequate

(5) handling of volatile RAM (e.g., Xe-133, I-131)
(X) Adequate ( ) Inadequate

(6) precautions for use of RAM (sealed and unsealed) for therapy
(X) Adequate ( ) Inadequate CAPSULE - I-131

7. MATERIALS, FACILITIES AND INSTRUMENTS

a. Facilities as described in license application. (X) Yes ( ) No (L/C)
Remarks:
FACILITIES AS PER LICENSE CONDITION

b. Isotope, chemical form, quantity and use as authorized. (X) Yes ( ) No (L/
Remarks:
GROUP I-IV & XENON-133 & Am^{241} ANATOMICAL MARKER.

c. Tests required by license condition or regulations.

(1) molybdenum-99 breakthrough. ( ) Yes ( ) No (35.204(a))

SYNCOR (2) performed as required. ( ) Yes ( ) No N/A
(L/C and/or 35.204(b))

(3) records maintained. ( ) Yes ( ) No (35.204(c))
Remarks:

(4) leak tests (X) Yes ( ) No

(5) leak tests performed as required. (X) Yes ( ) No (L/C) (35.59 (b)(1), 35.59 (b)(2), 35.59 (c)(1))
Remarks:
Performed By M.P.C. — 3/9/89.

(6) other tests required (e.g., physical inventories; surveys to ensure that patients contain 30 millicuries of Au-198, I-131 before leaving hospital) (L/C or 35.75)

d. Inventory of sealed sources.

N/A (1) Inventory of Group VI sources. ( ) Yes ( ) No (35.59 (g))

(2) Inventory of calibration sources. (X) Yes ( ) No (35.59 (g))
By MPC — 3/9/89.

e. Areas for storage and use of radioactive materials.

(1) Method used to prevent an unauthorized individual from entering a restricted area is adequate. (X) Yes ( ) No

(2) Radioactive material secured to prevent unauthroized removal from an unrestricted area. (X) Yes ( ) No (20.207)
Remarks:

f. Instrumentation.

(1) Operable survey instruments are as described or equivalent to those decribed in license application. (X) Yes ( ) No (L/C or 35.120, 35.220, 35.330, or 35.420)
Remarks:
Bicron 2000 -
Eberline 520.

(2) Capability of radiation survey instruments is adequate for program (X) Yes ( ) No
Remarks:

(3) Calibration of survey instruments required. (X) Yes ( ) No

VIOLATION (OVER) —(4) Performed as required. ( ) Yes (X) No (L/C or 35.51)
Remarks:

F-4. License Condition 14 states that the License is based on statements and representations contained in certain referenced Applications and letters.

The referenced Application dated January 28, 1985 states that Appendix D of Regulatory Guide 10.8 Revision 1 will be followed for Calibration of Survey Instruments. Appendix D states that the Frequency for Calibration of Survey Instruments shall be at least Annually.

Contrary to the above, the Eberline-520 Survey Instrument was not Calibrated at least Annually. Specifically, the Eberline-520 Survey Instrument located at the Detroit Clinic was last Calibrated on December 7, 1987.

Note: This appears to be an example of oversight by Medical Physics Consultants and does not represent willful disregard for NRC requirements.

Further, the Inspector performed a side-by-side evaluation with a Xetex #008368 (Calib 9/18/89) and the instrument in question appeared to be functioning accurately.

(5) Dose calibrator checks required. (X) Yes ( ) No

VIOLATION (OVER) (6) Performed as required. ( ) Yes (X) No (L/C or 35.50)

8. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

Receipt of incoming packages during "off-duty" hours by whom?

Where stored?
SYNCOR HAS KEY TO STORAGE AREA, DOSIMETRY DOSES, RECORDS DOOR.

Security?

a. Survey of incoming packages. (X) Yes ( ) No (20.205(b)(1)) - L/C)
Remarks:
3 FOOT, SURFACE, & WIPES OF FINAL SOURCE.

b. Record of survey. (X) Yes ( ) No (20.401(b))
Remarks:

c. Procedure for opening packages. (X) Yes ( ) No (L/C; 20.205(d))
Remarks:

d. BPM transferred in accordance with 10 CFR 30.41. (X) Yes ( ) No (30.41)
Remarks:

e. Records of receipt and transfer maintained. (X) Yes ( ) No (30.51)
Remarks:

F-4. License Condition 14 states that the license is based on statements and representations contained in certain referenced applications and letters.

The referenced application dated January 28, 1985, states that Appendix D Section 2 of Regulatory Guide 10.8 Revision 1 will be followed for calibration of dose calibrators. Appendix D Section 2 states that instrument linearity will be checked quarterly.

Contrary to the above, the dose calibrator was not checked for linearity quarterly. Specifically, linearity check was not performed in the fourth quarter 1988.

Note: This is a repeat violation identified in a July 10, 1986 inspection.

At the time of this inspection, the use of a lineator device was discussed with the licensee to help expedite linearity tests.

Also, this appears to be an oversight by licensee and does not represent carelessness or willful disregard.

9. PERSONNEL RADIATION PROTECTION - EXTERNAL
(Obtain information regarding whole body and extremity monitors)

a. Film or TLD badge supplier LANDAUER Frequency MONTHLY

b. Reports reviewed by RSO Frequency MONTHLY
(Are badges assigned to personnel as per licensee's correspondence with NRC?)

c. NRC inspector reviewed personnel monitoring records for period 12/1986 to 7/1989

d. NRC forms or equivalent.

(1) NRC-4: ( ) Yes (X) No Complete: ( ) Yes ( ) No

(2) NRC-5: (X) Yes ( ) No Complete: (X) Yes ( ) No
(20.401 (a))
Remarks:

	'86	87	88	7/89
e. Maximum quarterly whole-body exposure.	280	390	200	130
f. Maximum quarterly extremity exposure.	680	1060	1280	620

g. Licensee has implemented an ALARA program. (X) Yes ( ) No (35.20)
Remarks:

h. Radiation survey of unrestricted areas. (X) Yes ( ) No
(20.201(b) to show compliance with 20.105 (b), 35.415(a)(4), 35.315(a)(4)
Remarks:

i. Record of surveys maintained. (X) Yes ( ) No (20.401 (b) to show compliance with 20.105(b) 35.315(a)(4) or 35.415(a)(4))
Remarks:

j. Radiation survey of use areas (hot lab, therapy treatment area, patient's room, etc.). (X) Yes ( ) No (L/C or 35.70, 35.59(h), 35.315(a)(4))
Remarks: DAILY SURVEYS
WEEKLY WIPES

k. Record of survey maintained. (X) Yes ( ) No (L/C, 35.70(h), 35.415(a)(4))

10. PERSONNEL RADIATION PROTECTION - INTERNAL

a. Potential for exposure of individuals to airborne radioactive material exists. (X) Yes ( ) No
Remarks:

ONE X RAY PER MONTH.

b. Monitoring for airborne radioactivity conducted. (X) Yes ( ) No (20.201(b)) to show compliance with all sections of 20.103 - (L/C, or 35.205)
Remarks:

SEMI-ANNUAL ROOM AIR-FLOW CHECKED - 3/9/89

MONTHLY TRAP CHECKED.

c. Records of monitoring maintained. (X) Yes ( ) No (20.401(b) or L/C or 35.205(d))
Remarks:

d. Bioassay program implemented as described in correspondence with NRC ( ) Yes ( ) No (L/C or 35.315(a)(8)) N/A - AS PER LICENSE APPLICATION.

11. RADIOACTIVE EFFLUENT AND WASTE DISPOSAL

a. Radioactivity in effluents to unrestricted areas. (X) Yes ( ) No

b. Release in accordance with regulatory limits. (X) Yes ( ) No (20.106(a))
Remarks:

c. State solid waste disposal method.

DECAY TO BKG → TRASH

RETURN TO SYNCOR

d. State liquid waste disposal method.

SAME AS "C"

e. Disposal of solid and liquid waste in accordance with regulatory requirements (decay in storage). (X) Yes ( ) No (L/C or 35.92)
Remarks:

f. Records of disposal. ⋈ Yes ( ) No (30.51 or 35.92(b))
Remarks:

g. Survey of waste prior to disposal. ⋈ Yes ( ) No
(20.201(b) to show compliance with 20.301 35.92(a)(2))
Remarks:

h. Records of surveys maintained. ⋈ Yes ( ) No (20.401(b) or 35.92(b))
Remarks:

12. NOTIFICATIONS AND REPORTS

a. Licensee in compliance with 10 CFR 19.13 (reports to individuals).
⋈ Yes ( ) No (19.13)
Remarks:

b. Licensee in compliance with 10 CFR 20.405 (overexposures).
⋈ Yes ( ) No (20.405(a))
Remarks:

c. Licensee in compliance with 10 CFR 20.403 (incidents).
⋈ Yes ( ) No (20.403)
Remarks:

d. Licensee in compliance with 10 CFR 20.402 (theft or loss).
⋈ Yes ( ) No (20.402(a) or 20.402(b))
Remarks:

e. Licensee in compliance with 10 CFR 35.33 and 35.44 (misadministration). (X) Yes ( ) No (35.33a,b,c or d) and 35.44)
Remarks:

13. POSTING OF NOTICES

Notices to workers posted. (X) Yes ( ) No (19.11(a) or (b)) (19.11(c))
Remarks:

14. CONFIRMATORY MEASUREMENTS/INDEPENDENT MEASUREMENTS

a. Measurements made by inspector. (X) Yes ( ) No

b. Survey instrument XETEX NRC Serial No. 0013169

c. Describe type and results of measurements and compare with licensee's measurements.

HOT LAB:

STORAGE – 3.5 m/hr. IMAGING – .1 m/hr

PREP. AREA – .1 m/hr.

15. POSTING AND LABELING

Posting and labeling in accordance with 10 CFR 20.203. (X) Yes ( ) No (20.203 or 35.60 or 35.66)
Remarks:

16. LICENSE CONDITIONS

a. All license conditions reviewed during inspection. (X) Yes ( ) No

b. Activities were conducted in accordance with license conditions, except as noted elsewhere in this report (X) Yes ( ) No

17. BULLETINS AND INFORMATION NOTICES

a. Bulletins and Information Notices issued during current year.

b. Bulletins and Information Notices received by licnesee. ( ) Yes ( ) No.
Remarks:

NOT INSPECTED

c. Licensee took appropriate action in response to Bulletins and Information Notices. ( ) Yes ( ) No
Remarks:

18. TRANSPORTATION (10 CFR 71.5a and 49 CFR 171-178)

	Yes	Violation
a. License makes shipments of RAM? If "Yes", complete the following items.	(X)	( )

b. Such shipments consisted of:
( ) radwaste
( ) sources/products
(X) other RETURN TO SYNCOR

c. For radwaste, shipments are:
( ) by licensee, using common carrier
( ) through Radwaste Broker
name of Broker_____

d. Licensee is aware of 10 CFR 61: Radwaste requirements for generators?	( )	( )
Licensee has classified and characterized its radwaste? (20.311(d))	( )	( )

19. LIST OF VIOLATION(S)

1- Dose Calibration Linearity Check not Performed at Required Frequency — Report Violation.

2 - Survey Instrument (Eberline -500) not Calibrated Annually.

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