

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 6

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

Date of Inspection 8/25/89

Type of Inspection: Announced Unannounced Normal
 Initial Special Reinspection

Next Inspection Date 8/1992

Normal Reduced Extended

Summary of Findings and Action:

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

Persons contacted:

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

Those present at exit interview:

Inspector [Signature]
(Signature)

A/58
8/28/89
(Date Signed)

Approved [Signature]
(Signature)

9/5/89
(Date Signed)

DW

1. ORGANIZATION

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

b. Use by authorized individuals. 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 Yes () No.

Response letter dated 591-1 VIOLATION

b.

Requirement	Type of Violation	Corrective Action Taken		Status	
		() Yes	() No	Open	Closed

<u>DOSE CALIBRATION</u>	<u>LINEARITY TESTS NOT PERFORMED AT</u>				
<u>PROPER FREQUENCY.</u>					

(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 120 PROCEDURES
PER MONTH, 75% ARE TC^{59m} RELATED. THREE TECH'S
ARE EMPLOYED AND ROTATE BETWEEN DETROIT & NOVI CLINICS.
ONE XRAY VENTILATION IS DONE PER MONTH & 6-7 I-131 THERAPIES
FOR HYPERTHYROID AVERAGING 10 mCi. CAPSULES ARE DONE. SQUIBB
FURNISHES I-131 CAPS, SYNOR PROVIDES UNIT DOSES.

4. INTERNAL AUDITS OR INSPECTIONS

- a. Required by license condition. () Yes No
b. Audits or inspections conducted Yes () No (L/C)
c. Records maintained. 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 No
b. Training program implemented. () Yes No (L/C)
Remarks:
c. Retraining program required by license condition. Yes () No
d. Retraining program implemented. Yes () No (L/C)
Remarks:

- e. Instruction to workers in accordance with 10 CFR 19.12 Yes
() No (19.12)

Remarks:

6. RADIOLOGICAL PROTECTION PROCEDURES

- a. Procedure referenced in license condition. Yes () No
b. Used in accordance with referenced procedure. Yes () No
Remarks:

LAB COATS, GLOVES, & SYRINGE SHIELDS.

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

- d. Examples of key procedures:

- (1) ordering and accepting packages RAM Adequate () Inadequate
(2) general rules for safe use of RAM Adequate () Inadequate
(3) emergency procedures Adequate () Inadequate
(4) survey procedures Adequate () Inadequate
(5) handling of volatile RAM (e.g., Xe-133, I-131)
 Adequate () Inadequate
(6) precautions for use of RAM (sealed and unsealed) for therapy
 Adequate () Inadequate CAPSULE - I-131

7. MATERIALS, FACILITIES AND INSTRUMENTS

- a. Facilities as described in license application. Yes () No (L/C)
Remarks:

FACILITIES AS PER LICENSE CONDITION

- b. Isotope, chemical form, quantity and use as authorized. Yes () No (L/C)
Remarks:

GROUP I-IV & ^{133}Xe & Am^{241} ANATOMICAL MARKER.

- c. Tests required by license condition or regulations. ...

- (1) molybdenum-99 breakthrough. () Yes () No (35.204(a))
(2) performed as required. () Yes () No
(L/C and/or 35.204(b)) N/A
(3) records maintained. () Yes () No (35.204(c))
Remarks:

SYNCOAL

(4) Leak tests Yes () No

(5) Leak tests performed as required. 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. 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. Yes () No

(2) Radioactive material secured to prevent unauthorized removal from an unrestricted area. Yes () No (20.207)

Remarks:

f. Instrumentation.

(1) Operable survey instruments are as described or equivalent to those described in license application. Yes () No (L/C or 35.120, 35.220, 35.330, or 35.420)

Remarks:

Bicrow 2000 -

ESERLINE 500 -

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

Remarks:

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

—(4) Performed as required. () Yes No (L/C or 35.51)

Remarks:

*VIOLATION
(OVER)*

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. Yes () No

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

VIOLATION
(over)

8. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

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

Where stored?

SPINOR HAS KEY TO STORAGE AREA, DEPOSITS DOSES,
Security? RELOCKS DOOR.

a. Survey of incoming packages. Yes () No (20.205(b)(1)) - L/C
Remarks:

3 FEET SURFACE, & WIPES OF FINAL SOURCE.

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

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

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

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

F-6. 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 I 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 No Complete: () Yes () No
 (2) NRC-5: Yes () No Complete: 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. Yes () No (35.20)
 Remarks:

h. Radiation survey of unrestricted areas. 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. 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.). Yes () No (L/C or 35.70, 35.59(h), 35.315(a)(4))
 Remarks: DAILY SURVEYS
WEEKLY WIPES

k. Record of survey maintained. 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. Yes () No
Remarks:

ONE X EXPOSURE PER MONTH.

b. Monitoring for airborne radioactivity conducted. 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. 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. Yes () No

b. Release in accordance with regulatory limits. 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). 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). Yes () No (35.33a,b,c or d and 35.44)
Remarks:

13. POSTING OF NOTICES

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

14. CONFIRMATORY MEASUREMENTS/INDEPENDENT MEASUREMENTS

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

b. Survey instrument XCTB7 NRC Serial No. 0013169

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

HOT LAB:

STORAGE - 3.5 m/hr.

IMAG WIRE - 0.1 m/hr

PREP. AREA - 0.1 m/hr

15. POSTING AND LABELING

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

16. LICENSE CONDITIONS

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

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

17. BULLETINS AND INFORMATION NOTICES

a. Bulletins and Information Notices issued during current year.

b. Bulletins and Information Notices received by licensee. () 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)

	<u>Yes</u>	<u>Violation</u>
a. License makes shipments of RAM? If "Yes", complete the following items.	<input checked="" type="checkbox"/>	()
b. Such shipments consisted of: () radwaste () sources/products <input checked="" type="checkbox"/> other <u>RETURN TO SYNCO</u>		
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 - ROSE CALIBRATION LINEARITY CHECK NOT PERFORMED AT REQUIRED FREQUENCY - REPORT VIOLATION.
- 2 - SURVEY INSTRUMENT (CERBERUS-500) NOT CALIBRATED ANNUALLY.

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