NRC Form 591
(12-81)
10 CFR 2.201

U[illegible]UCLEAR REGULATORY COMMISSION

SAFETY INSPECTION

DMB COPY

1. LICENSEE	2. REGIONAL OFFICE
Woodland Medical Group 22341 W. Eight Mile Rd Detroit, Michigan 48219	U.S. NUCLEAR REGULATORY COMMISSION REGION III 799 ROOSEVELT ROAD GLEN ELLYN, IL 60137

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE OF INSPECTION
030-02149	21-13255-01	July 10, 1986

Licensee:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission's (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews, with personnel, and observations by the inspector. The findings as a result of this inspection are as follows:

☐ 1. Within the scope of this inspection, no violations were observed.

☒ 2. The inspector also verified the steps you have taken to correct the violations identified during the last inspection. We have no further questions on those actions at this time.

☒ 3. During this inspection certain of your activities, as checked below, were in violation of NRC requirements. **THIS IS A NOTICE OF VIOLATION** which is required to be posted in accordance with 10 CFR 19.11.

☐ A. _____ was not properly posted to indicate the presence of a _____. 10 CFR 20.203(b), (c), (d), (e) or 34.42.

☐ B. Containers located in _____ were not properly labeled to indicate the presence of radioactive material. 10 CFR 20.203(f)(1), or (f)(2).

☐ C. _____ of sealed sources were not performed at the proper frequencies. 10 CFR _____ License Condition Number _____.

☐ D. Records of _____ were not properly maintained. 10 CFR _____ or License Condition Number _____.

☐ E. Documents were not properly posted or otherwise made available. 10 CFR 19.11.

☐ F. Reports or notifications of _____ were not made in accordance with 10 CFR _____ or License Condition Number _____.

☒ H. Dose calibrator linearity tests have not been performed at the proper frequencies. License condition No. 14

☐ I. _____

☐ J. _____

☐ K. _____

I hereby state that within 30 days the actions described by me to the inspector will be taken to correct the violations identified in the items checked above. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201. No further response will be submitted unless required by the NRC.

A153

Signature – Licensee	Date	Signature – NRC Inspector	Date
Gratuich Y. Taylor RT.	7/10/86	Jaye Simmons	7/10/86

TE07 n/a

NUCLEAR MEDICAL INSPECTION FIELD NOTES

Inspection Report No. 86001 License No. 21-13255-01
Docket No. 030-02149

Licensee (name and address)
Woodland Medical Group
Detroit, MI 48219

Licensee Contact Elizabeth Taylor Telephone No. (313) 538-4700

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

✓ Priority G-III

Program Codes:
( ) 02110 - Broad (X) 02120 - Group
( ) 02121 - Non Group (X) 02200 - Private Practice
( ) Eye Applicator ( ) 02201 - Private Practice
( ) 02210 - VAN ( ) 02500 - Pharmacy ( ) Other

Date of Inspection 7/10/86

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

Next Inspection Date 7/89

(X) Normal ( ) Reduced ( ) Extended

Summary of Findings and Action:
( ) No Noncompliance, Clear 591 issued (X) Action on Previous N/C
(X) Noncompliance, 591 issued ( ) Regional Action
( ) Headquarters Action

b. Persons contacted.
* Elizabeth Taylor - Chief Tech
Kathy Thiebaut - NMT

* Those present at exit interview.

Inspector Joyce Simmons 7/10/86
(Signature) (Date Signed)

Approved [signature] 7/14/86
(Signature) (Date Signed)

1. ORGANIZATION

a. Organizational structure meets license requirements. (X) Yes ( ) No [L/C]
Remarks. no changes

b. Use by authorized individuals. (X) Yes ( ) No [L/C]
Remarks.

c. Radiation Safety Committee meets at required intervals. ( ) Yes ( ) No n/A
Membership in accordance with 35.11(b) L/C ( ) Yes ( ) No
Remarks.

d. Record of Committee meetings. ( ) Yes ( ) No [L/C] n/A
Remarks.

2. INSPECTION HISTORY

a. Item(s) of noncompliance or deviations noted during last inspection conducted on 8/30+31/83 (X) Yes ( ) No.
Response letter dated 10/18/83

b.

Requirement	Type of N/C	Corrective Action Taken (X) Yes ( ) No	Status Open / Closed
✓ failure to wipe external surface of out going Pharmatope package			

(continue b. paragraph 21, if needed)

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

3. SCOPE OF PROGRAM Clinic performs about 150 studies per month - receives ✓ Unit doses from Pso-Diagnostic Services - a total of 3 fulltime techs cover Bethesda and navi facilities - Hyperthyroids dosed with I 131 capsules only

4. INTERNAL AUDITS OR INSPECTIONS

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

b. Audits or inspections conducted. (X) Yes ( ) No [L/C]
Remarks. Wm Hack, Ph.D. - semi annually at each facility.

c. Records maintained. (Y) Yes ( ) No [L/C]
Remarks.

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.

not reviewed

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. (N) Yes
( ) No [19.12]
Remarks.

6. RADIOLOGICAL PROTECTION PROCEDURES

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

b. Used in accordance with referenced procedure. (Y) Yes ( ) No
Remarks.

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

d. Examples of key procedures:

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

7. MATERIALS, FACILITIES AND INSTRUMENTS

a. Facilities as described in license application. (Y) Yes ( ) No
[L/C]
Remarks.

b. Isotope, chemical form, quantity and use as authorized.
(✓) Yes ( ) No [L/C]
Remarks.

c. Tests required by license condition or regulations.

(1) molybdenum-99 breakthrough. ( ) Yes ( ) No
(2) performed as required. ( ) Yes ( ) No
[L/C and/or 35.14(b)(4)(iii)]
(3) records maintained. ( ) Yes ( ) No [35.14(b)(4)(iv)]
Remarks. unit doses only from local pharmacy

(3) Leak tests. (X) Yes ( ) No

(4) Leak tests performed as required. (✓) Yes ( ) No
[L/C] [35.14(b)(5)(i) or 35.14(e)(1)(i)]
Remarks.

(5) 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].

d. Inventory of sealed sources.
(1) Inventory of Group VI sources. ( ) Yes ( ) No N/A
[35.14(b)(5)(v)]

(2) Inventory of calibration sources. (✓) Yes ( ) No
[35.14(f)(2)]

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. N/A

f. Instrumentation.

(1) Operable survey instruments are as described or equivalent to those described in license application. (✓) Yes ( ) No
[L/C]
Remarks.

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

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

(4) Performed as required. (X) Yes ( ) No [L/C]
Remarks.

n/c see page 10

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

(6) Performed as required. ( ) Yes ( ) No [L/C]

8. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

Receipt of incoming packages during "off-duty" hours by whom? Where stored? Security? [L/C] Packages are left outside the front door. BPM of the day is put into a locked box by Supervisor.

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

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.

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 as received
(Are badges assigned to personnel as per licensee's correspondence with NRC?)

c. NRC inspector reviewed personnel monitoring records for period 1/84 to 5/86

d. NRC forms or equivalent.

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

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

e. Maximum ~~quarterly~~ Annual whole-body exposure. 490 mrem

f. Maximum ~~quarterly~~ Annual extremity exposure. 750 mrem

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

h. Radiation survey of unrestricted areas. (X) Yes ( ) No
[20.201(b) to show compliance with 20.105(b)]
Remarks.

i. Record of surveys maintained. (X) Yes ( ) No
[20.401(b) to show compliance with 20.105(b)]
Remarks.

j. Radiation survey of use areas (hot lab, therapy treatment area, patient's room, etc.). (X) Yes ( ) No [L/C]
Remarks.

k. Record of survey maintained. (X) Yes ( ) No [L/C]
Remarks.

10. PERSONNEL RADIATION PROTECTION - INTERNAL

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

b. Monitoring for airborne radioactivity conducted. ( ) Yes ( ) No
[20.201(b) to show compliance with all sections of 20.103 - L/C]
Remarks.

c. Records of monitoring maintained. ( ) Yes ( ) No [20.401(b) or L/C]
Remarks. N/A

✓ d. Bioassay program implemented as described in correspondence with NRC. ( ) Yes (X) No Capsules only

11. RADIOACTIVE EFFLUENT AND WASTE DISPOSAL

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

b. Release in accordance with regulatory limits. ( ) Yes ( ) No [20.106(a)]
Remarks.

c. State solid waste disposal method. Held for decay

✓ d. State liquid waste disposal method. Return to Supplier

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

f. Records of disposal. (X) Yes ( ) No [30.51]
Remarks.

g. Survey of waste prior to disposal. (X) Yes ( ) No [20.201(b) to show compliance with 20.301]
Remarks.

h. Records of surveys maintained. (X) Yes ( ) No [20.401(b)]
Remarks.

12. NOTIFICATIONS AND REPORTS

a. Licensee in compliance with 10 CFR 19.13 (reports to individuals). (X) Yes ( ) No [19.13]
Remarks.

b. Licensee in compliance with 10 CFR 20.405 (overexposures). (X) Yes ( ) No [20.405(a)]
Remarks.

c. Licensee in compliance with 10 CFR 20.403 (incidents). (X) Yes ( ) No [20.403]
Remarks.

d. Licensee in compliance with 10 CFR 20.402 (theft or loss). (X) Yes ( ) No [20.402(a) or 20.402(b)]
Remarks.

e. Licensee in compliance with 10 CFR 35.42 or 10 CFR 35.43 and 35.44 (misadministration). (X) Yes ( ) No [35.42, 35.43 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

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

b. Survey instrument Xetex NRC Serial No. 008989

c. Describe type and results of measurements and compare with licensee's measurements. ✓
NRC: 0.8 mr/hr
LIC: 1.0 mr/hr

15. INDEPENDENT MEASUREMENTS

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

b. Survey instrument Xetex NRC Serial No. 008989

c. Describe type and results of measurements. ✓
Rose Prep Area: 0
Waste Storage (Top open) 10 mr/hr

16. POSTING AND LABELING

Posting and labeling in accordance with 10 CFR 20.203. ( ) Yes (X) No [20.203]
Remarks.

17. LICENSE CONDITIONS

a. All license conditions reviewed during inspection. ( ) Yes ( ) No Inspection in accordance with memo dated 10/16/86

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

18. BULLETINS AND INFORMATION NOTICES N/A

a. Bulletins and Information Notices issued during current year.

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

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

19. TRANSPORTATION (10 CFR 71.5a and 49 CFR 171-178) N/A

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

b. Such shipments consisted of:
( ) radwaste
( ) sources/products
( ) other _____

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))	( )	( )

e. For shipments:

Licensee uses authorized packages? [(173.415-16)]	( )	( )
Package type used. _____		
For DOT-7A, licensee has performance test records on file? (173.415(a))]	( )	( )
For special form sources, licensee has performance tests records on file for each source design? [(173.476(a))]	( )	( )
Packages are properly labeled? [(172.403)] [(173.441)]	( )	( )
Packages are properly marked? [(172.200)]	( )	( )
Proper shipping papers are prepared for each shipment? [(172.203(d))]	( )	( )

Remarks. Unit doses and spent doses returned to supplier.

20. ITEMS OF NONCOMPLIANCE

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

✓ From page 5: L/C 14 references application dated 1/20/85 which requires linearity tests to be performed quarterly. Contrary to the requirement linearity tests were not performed in the 1st + 4th quarters of 1985. Corrective action: Ms Taylor stated as of immediately linearity tests will be performed at the required frequencies.