SEP 08 1983

Woodland Medical Group
ATTN: Harold Daitch, M.D.
22341 West Eight Mile Road
Detroit, Michigan 48219

License No. 21-13255-01

Gentlemen:

This refers to the special safety inspection conducted by Mr. R. J. Caniano of this office on August 30 and 31, 1983, of activities authorized by NRC Byproduct Material License No. 21-13255-01 and to the discussion of our findings with you and Miss Elizabeth Taylor at the conclusion of the inspection.

The inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. The inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with personnel.

In addition to the above areas, the inspector examined actions described in your letter dated October 13, 1980, regarding apparent items of noncompliance found during our September 11, 1980 inspection. We have no further questions regarding these matters.

The inspection also included efforts to determine whether or not allegations received by the NRC from an individual wishing to remain anonymous could be substantiated. Of the eight allegations reported, one item of noncompliance with NRC requirements was identified, and is shown in the enclosed appendix.

The enclosed copy of our inspection report describes the areas that the inspector examined to determine whether or not the allegations could be substantiated.

During this inspection, certain of your activities appeared to be in noncompliance with NRC requirements, as specified in the enclosed Appendix. A written response is required.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter and the enclosures will be placed in the NRC's Public Document Room. If this report contains any information that you (or your contractors) believe to be exempt from disclosure under 10 CFR 9.5(a)(4), it is necessary that you (a) notify this office by telephone within ten (10) days from the

A/45

date of this letter of your intention to file a request for withholding; and (b) submit within twenty-five (25) days from the date of this letter a written application to this office to withhold such information. If your receipt of this letter has been delayed such that less than seven (7) days are available for your review, please notify this office promptly so that a new due date may be established. Consistent with Section 2.790(b)(1), any such application must be accompanied by an affidavit executed by the owner of the information which identifies the document or part sought to be withheld, and which contains a full statement of the reasons which are the bases for the claim that the information should be withheld from public disclosure. This section further requires the statement to address with specificity the considerations listed in 10 CFR 2.790(b)(4). The information sought to be withheld shall be incorporated as far as possible into a separate part of the affidavit. If we do not hear from you in this regard within the specified periods noted above, a copy of this letter and the enclosures will be placed in the Public Document Room.

The responses directed by this letter (and the accompanying Notice) are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

S.R. Zavk

for D. J. Sreniawski, Chief
Materials Radiation Protection
Section 2

Enclosures:
1. Appendix, Notice of Violation
2. Inspection Report No. 30-02149/83-01(DRMSP)

cc w/encls:
Michigan Department of
Public Health
Division of Radiological Health
3500 North Logan
Lansing, Michigan 48909
DMB/Document Control Desk (RIDS)

RIII
SRZ
for Caniano/db
09/19/83

RIII
SRZ
for Sreniawski
9-28-83

Module No. 78710B

MEDICAL INSPECTION REPORT

Inspection Report No. 83-01

Licensee (Name and address)

Woodland Medical Group
22431 W. Eight Mile + 41935 Twelve Mile Road
Detroit Michigan 48219.

Licensee Contact: Elizabeth Taylor R.T. Telephone No. 313-533-4700

License No. 21-13255-01 Docket No. 030-02149

Last Amendment No. 24 Date of Amendment: 11/10/82

Category: C Priority: 3

Date of Inspection: August 30 and 31, 1983

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

Summary of Findings and Action:

( ) No Noncompliance, Clear 591 issued ( ) Action on Previous N/C

( ) Noncompliance, 591 issued ( ) Regional Action

(X) Noncompliance, Appendix A ( ) Hq Action

Inspector: Roy J Caruana (Signature) 9/12/83 (Date Signed)

Approved: S. R. Jasuk for DJS (Signature) 9/28/83 (Date Signed)

Rev. 12/6/80

1. INSPECTION HISTORY

a. Item(s) of noncompliance or deviations noted during last inspection conducted on: 9/6/80 (X) Yes ( ) No

b.

Requirement	Type of N/C	Corrective Action Taken	Status
		(X) Yes ( ) No	Open (Closed)
1. Failed to evaluate I-125 Release to Sewer.			
2. Failed to leak test 204 uci Cs-137 source			
3. Failed to perform quarterly inventory.			
4. Failed to perform weekly surveys.			
5. Failed to survey waste containing I-125.			

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

2. ORGANIZATION

a. Administrative structure meets License requirements: (X) Yes ( ) No (L/C - MPA)

* Harold Daitch M.D. R.S.O.

* Miss Elizabeth Taylor R.T. chief technologist

* Attended Management close-out meeting

b. Use by authorized individuals: (X) Yes ( ) No (L/C - MAC)

Licensed material is used by or under the supervision of Harold Daitch M.D.

c. Isotope Committee meets at required intervals: ( ) Yes ( ) No (L/C - MPA)

N.A.

d. Record of Committee meetings: ( ) Yes ( ) No
(L/C - MPA)

3. SUMMARY OF PROGRAM

This licensee performs approximately 200 diagnostic studies at two facilities (22431 Eight Mile and 4935 Twelve Mile) Rockwood employs 4 full time technologists. Licensed material is procured from Pharmatopes (unit doses) Mallinkrodt (I-131) NEN (Tc[99m]) since 2/1/82

4. INTERNAL AUDITS OR INSPECTIONS

a. Required by License Condition: ( ) Yes (X) No

b. Audits or Inspections conducted: (X) Yes ( ) No
(L/C - MPA)

Medical Physics Consultants performs a semiannual audit of program.

c. Records maintained: (X) Yes ( ) No
(L/C - MPA)

5. TRAINING, RETRAINING AND INSTRUCTION TO WORKERS

a. Training program required by License Condition: (X) Yes ( ) No

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

c. Retraining program required by License Condition: ( ) Yes (X) No

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

e. Instruction to workers in accord with 10 CFR 19.12: ☒ Yes ( ) No
(19.12 - HAI)

6. RADIOLOGICAL PROTECTION PROCEDURES

a. Procedures referenced in License Condition: ☒ Yes ( ) No

b. Use in accordance with referenced procedure: ☒ Yes ( ) No
(L/C - MPA)

Licensee uses gloves and syringe shields.

c. Individual's understanding of procedures adequate: ☒ Yes ( ) No

7. MATERIALS, FACILITIES AND INSTRUMENTS

a. Facilities as described in License Application: ☒ Yes ( ) No
(L/C - MPA)

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

Licensed Cps I-131, Xenon-133, Am-241,
I-125 for in vitro.

c. Tests required by License Condition or Regulations

(1) Molybdenum-99 breakthrough: ☒ Yes ( ) No

(2) Performed as required: ( ) Yes ( ) No
(L/C - MCA)

N/A. Licensee gets unit doses
from Pharmatopes.

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

(4) Leak tests performed as required: (X) Yes ( ) No
(L/C - MTB; (35.14(b)(5)(i) - BFY; (35.14(e)(1)(i) - BFY)

LEAK TESTS ON Cs 137 DOSE CAL. SOURCES ARE PERFORMED EVERY 6 MONTHS.

(5) Other tests required:

d. Inventory of sealed sources

(1) Inventory of Group VI sources: ( ) Yes ( ) No
(35.14(b)(5)(v) - BFY)

N/A.

(2) Inventory of calibration sources: (X) Yes ( ) No
(35.14(f)(2) - BFY)

e. Storage 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 unauthorized removal from an unrestricted area: (X) Yes ( ) No
(20.207 - ACA or ACA)

f. Instrumentation

(1) Operable survey instruments as described or equivalent to those described in License Application: ☒ Yes ( ) No (L/C - MPA)

Eberline E 520.

Eberline G120.

(2) Capability of radiation survey instruments adequate for program

☒ Yes ( ) No

(3) Calibration of survey instruments required: ☒ Yes ( ) No

(4) Performed as required: ☒ Yes ( ) No (L/C - MPA)

CALIBRATED ANNUALLY.

(5) Dose calibrator checks required: ☒ Yes ( ) No

(6) Performed as required: ☒ Yes ( ) No (L/C - MPA)

PERFORMS - 1) DAILY CONSTANCY
2) QUART. LINEARITY
3) ANNUAL ACCURACY.

8. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL

a. Survey of incoming packages: ☒ Yes ( ) No (20.205(b)(1) - APA) or (L/C - MPA)

PERFORMS A 3 FOOT, AND SURFACE SURVEY

b. Record of survey: ☒ Yes ( ) No (20.401(b) - AEB)

c. Procedure for opening packages: (X) Yes ( ) No
(20.205(d) - APA)

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

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

Records maintained of material transferred back to Pharmacopes.

9. PERSONNEL RADIATION PROTECTION - EXTERNAL

a. Film or TLD badge supplier: Landauer Frequency: Monthly.

b. Reports reviewed by: R.S.O. Frequency: monthly

c. NRC inspector reviewed personnel monitoring records for
period 6/5/80 to 7/4/83

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) - AEA)

e. Maximum quarterly whole body exposure: 350 mRem

f. Maximum quarterly extremity exposure: 1130 mRem

g. Licensee has implemented the ALARA program: (X) Yes ( ) No

h. Radiation survey of unrestricted area: (X) Yes ( ) No
(20.201(b) to show compliance with 20.105(b) - ASI)

i. Record of survey maintained: (X) Yes ( ) No
(20.401(b) - AEB)

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

Use ARGPS surveyed daily

k. Record of survey maintained: (X) Yes ( ) No
(L/C - MSB)

10. PERSONNEL RADIATION PROTECTION - INTERNAL

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

b. Monitoring for airborne radioactivity conducted: (X) Yes ( ) No
(20.201(b) to show compliance with all sections of 20.103 - ASB)

Licensee at both locations checks Xenon trap weekly to check for leakage.

c. Records of monitoring maintained: (X) Yes ( ) No
(20.401(b) - AEB)

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) - ABJ or ABJ)

c. Solid waste disposal method: COTTONBALLS, RESIDUAL <c-99T held for decay, monitored & disposed normal trash

d. Liquid waste disposal method: Returned to Pharmatopes.

e. Disposal of solid and liquid waste in accordance with regulatory requirements: (X) Yes ( ) No

f. Records of disposal: (X) Yes ( ) No
(30.51 - BAC)

g. Survey of waste prior to disposal: (X) Yes ( ) No
(20.201(b) to show compliance with 20.301 - ASH)

h. Records of surveys maintained: (X) Yes ( ) No
(20.401(b) - AEB)

12. NOTIFICATIONS AND REPORTS

a. Licensee in compliance with 10 CFR 19.13 (Reports to individuals)
(19.13 - HAK)

(X) Yes ( ) No

b. Licensee in compliance with 10 CFR 20.405 (Over exposures)
(20.405(a) - ARM)

(X) Yes ( ) No

None occurred

c. Licensee in compliance with 10 CFR 20.403 (Incidents)
(20.403 - AR? or AR?)

(X) Yes ( ) No

None occurred

d. Licensee in compliance with 10 CFR 20.402 (Theft or loss)
(20.402(a) - ARA)
(20.402(b) - ARB)

(X) Yes ( ) No

None occurred

e. Licensee in compliance with 10 CFR 35.42 or 10 CFR 35.43 (Misadm.)
(35.42 - BFY) or (35.43 - BFY)

(X) Yes ( ) No

None occurred.

13. POSTING OF NOTICES

Notices to workers posted: (X) Yes ( ) No
(19.11(a) or (b) - HAE) (19.11(c) - HAF)

14. CONFIRMATORY MEASUREMENTS

a. Independent measurements made by inspector: (X) Yes ( ) No

b. Survey Instrument: Eberline E120 NRC Ser. No. 005261

Last date of calibration: 1/22/83

c. Describe type and results of measurements and compare with licensee's measurements: hot lab, all trash cans, general inside area all location ~~[illegible]~~ dpm/100 cm² This is equivalent to licensees results.

15. POSTING AND LABELING

Posting and labeling in accordance with 10 CFR 20.203: (X) Yes ( ) No (20.203 - AL? or AL?)

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 CIRCULARS

a. Bulletins and Circulars issued during current year:

b. Bulletins and Circulars received by licensee: (X) Yes ( ) No

c. Licensee took appropriate action in response to Bulletins and Circulars: (✓) Yes ( ) No

18. TRANSPORTATION

a. Licensee ships radioactive waste to burial site or spent generators to supplier for disposal: ( ) Yes (X) No

b. Packages contain greater than exempt quantities (1 mCi) of radioactive material: ( ) Yes ( ) No

c. If greater than exempt quantities are shipped, only packages which have met DOT Spec 7A performance criteria, as described in 49 CFR 173.398(b), are used: ( ) Yes ( ) No (71.5(a) - LAB)

N.C. see PAGE 13.

d. Document showing that package meets DOT Spec 7A performance criteria is maintained, as required by 49 CFR 173.395(a)(1): ( ) Yes ( ) No (71.5(a) - LAB)

19. ITEMS OF NONCOMPLIANCE

Note: Attach a copy of Appendix A of the enforcement letter.

20. CONTINUATION OF REPORT ITEMS

N.C.: 10 CFR 71.5 REQUIRES THE LICENSEE TO FOLLOW APPLICABLE REGULATIONS IN 49CFR 170-189. 49CFR 173.393(b) STATES THAT THERE BE NO REMOVABLE CONTAMINATION PRESENT ON SURFACES OF PACKAGES, 49CFR 173.397(a)(1) STATES THAT IN ASSESSING THE SURFACE CONTAMINATION OF A PACKAGE, A NUMBER OF MEASUREMENTS MUST BE TAKEN SO AS TO YIELD THE ASSESSMENT OF THE CONTAMINATION. IT WAS LEARNED THROUGH STATEMENTS AND A REVIEW OF RECORDS, THAT THE LICENSEE DOES NOT PERFORM ANY WIPE TESTS ON PACKAGES THAT ARE RETURNED TO PHARMATOPES PRIOR FOR DISPOSAL. THE LICENSEE BEGAN USING PHARMATOPES ON FEB 2, 1982 AND WAS NOT AWARE THAT THE TEST WAS REQUIRED. SOME SPECIFIC DATES THAT LICENSED MATERIAL WAS RETURNED TO PHARMATOPES AND THE QUANTITIES SENT ARE AS FOLLOWS.

8/4/83 - 15.2 MILLICURIES Tc-99m RETURNED.
8/24/83 - 17.3 MILLICURIES Tc-99m RETURNED.
NO WIPE TESTS WERE PERFORMED ON THESE 2 PACKAGES.

LICENSEE PREPARATION FOR 10 CFR 61 COMPLIANCE

Docket No. 03002149 License No. 21-13255-01

Licensee: Woodland Medical Group

Inspection No. 83-01 Inspection date 8/13/83

1. Licensee aware of new requirements of 10 CFR 61?

   Yes ✓ No _____

   If "No, was licensee informed that requirements exist and supplied with a copy of fact sheet?

2. If licensee is aware of 10 CFR 61, has he developed, is developing, or does he plan to develop specific procedures to effect compliance with 10 CFR 61?

   Yes _____ No _____

   If "No", explain why.

   N/A

3. If the licensee has developed procedures, do they address:

   a. Waste classification methods?

      Yes _____ No _____ N/A

   b. Manifest system description and records, including methods of tracking such records?

      Yes _____ No _____ N/A

   c. Waste form requirements when applicable, including the process control program, waste characterization methods, and use of high integrity containers?

      Yes _____ No _____ N/A

Comments

NOTE: Attach any relevant documentation which may be made available by licensee.

Inspector Roy Lanham
FTS 7385721