SEP 24 1980

Woodland Medical Group
ATTN: Barry Samules, M.D.
22341 West Eight Mile Road
Detroit, MI 48219

License No. 21-13255-01

Gentlemen:

This refers to the routine inspection conducted by Ms. E. Matson of this office on September 11, 1980, of activities at Woodland Medical Group authorized by Byproduct Material License No. 21-13255-01 and to the discussion of our findings with Dr. Daitch on September 17, 1980.

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.

During this inspection, certain of your activities appeared to be in noncompliance with NRC requirements, as described in the enclosed Appendix A.

This notice is sent to you pursuant to the provisions of Section 2.201 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations. Section 2.201 requires you to submit to this office within twenty days of your receipt of this notice a written statement or explanation in reply, including for each item of noncompliance: (1) corrective action taken and the results achieved; (2) corrective action to be taken to avoid further noncompliance; and (3) the date when full compliance will be achieved. Be sure to address each of these items in your response.

A/28

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

Sincerely,

A. B. Davis, Chief
Fuel Facility and
Materials Safety Branch

Enclosure: Appendix A,
Notice of Violation

cc: Central Files
Reproduction Unit NRC 20b
PDR
NSIC

OFFICE ▶	RIII	RIII	RIII			
SURNAME ▶	Marson/cw	Pagliaro	Davis			
DATE ▶	9/22/80					

Appendix A

NOTICE OF VIOLATION

Woodland Medical Group License No. 21-13255-01

Based on the inspection conducted on September 11, 1980, it appears that certain of your activities were in noncompliance with NRC requirements, as noted below. Items 1 through 5 are infractions.

1. 10 CFR 20.201(b) requires you to make such surveys (evaluations) as may be necessary for you to comply with all sections of Part 20.

   Contrary to this requirement, as of September 11, 1980, you failed to make such evaluations as were necessary to assure compliance with 10 CFR 20.303, a regulation that limits the disposal of licensed material by release to a sanitary sewerage system. Specifically, you failed to evaluate the releases of Iodine-125 to the sewerage system.

2. 10 CFR 35.14(e) requires that sealed calibration or reference sources possessed pursuant to 10 CFR 35.14(d) be tested for leakage and/or contamination at intervals not to exceed six months.

   Contrary to this requirement, as of the day of the inspection, you have failed to leak test your 204 microcurie sealed Cesium-137 reference source received on May 1979, from May 1979, to February 1980. This is a period in excess of six months.

3. Condition No. 16 of your license requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

   The referenced application dated April 25, 1979, states in Item 10 the procedures described in Regulatory Guide 10.8 dated January 1979, Section 2 of Appendix D will be used for calibration of the dose calibrator. Section 2 of Appendix D requires in part, a linearity test be done quarterly.

   Contrary to the above, a linearity test has not been performed since April 8, 1980.

4. Condition No. 16 of your license requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

The referenced application dated April 25, 1979, states in Item 17, the procedures in Regulatory Guide 10.8 dated January 1979, Appendix I will be followed for area survey procedures. Appendix I requires in part, survey with a G-M survey meter be done weekly in all laboratory areas and monthly in the RIA laboratory.

Contrary to the above, G-M surveys have not been made weekly of the nuclear medicine camera room and monthly in the RIA laboratory.

5. 10 CFR 20.201(b) requires that you make such surveys as may be necessary to comply with all sections of Part 20.

Contrary to this requirement, you failed to make such surveys as were necessary to assure compliance with 10 CFR 20.301, a regulation that describes authorized means of disposing of license material contained in waste. Specifically, you failed to adequately survey for Iodine-125 in waste disposals from the RIA laboratory.

MEDICAL (Revised 8/78)

INSPECTION REPORT NO. 8001

Attached
[ ] Appendix A
[ ] Appendix B
[ ] Appendix C
[ ] Appendix D
[ ] Memo

Licensee Name and Address:
Woodland Medical Group
22341 West Eight Mile Road
Detroit, MI 48219

Licensee contact: Dr. Samuels Telephone no. 313-538-4700

License no. 21-13255-01 Last amendment and date: 22 5/30/79

Category: E, and Priority: IV, as of last amendment.

Inspection date(s): 9/11/80 Type of inspection: unannounced, routine

SUMMARY OF FINDINGS AND ACTION

[ ] No noncompliance, clear 591 issued
[ ] Noncompliance, Appendix A
[ ] Action on previous noncompliance, Appendix B
[ ] Noncompliance, 591 issued
[ ] Regional action [ ] HQ action
[ ] Supplemental info, Appendix C

RECOMMENDATIONS

See basis in Appendix C or attached memo.

[ ] Change Category to: _____ [ ] Change Priority to: _____
[ ] Next inspection date: 9/83

PERSONS CONTACTED

★ Harold Baitch, M.D.	authorized user
Elizabeth Taylor	nuclear medicine technologist
Susan Sacco	nuclear medicine technologist
June Berns	RIA technician

★ exit interview 9/17/80

Inspector: Evelyn R Matson 9/17/80
Date signed

Approved: [signature] 9/22/80
Date signed

AREAS INSPECTED AND FINDINGS

INSPECTION ITEMS		FINDING

Acceptable (A) Noncompliance NC
Unresolved (U)

1. Organization

Structure of organization as described in requirements? Lic Cond 16 — A

NOTES & REMARKS:
Dr. Samuels, user, RSO
Dr. Daitch - user
Dr. Small - user

2. Licensee internal audits Lic Cond 16 — A

Scope and frequency of audits as required?
Conducted by appropriate persons? Records maintained? Reviewed by management?
Deficiencies identified & corrected?

NOTES & REMARKS:
Medical Physics Consultants, Bill Hack visits quarterly: audits program

3. Training and qualification of personnel Lic Cond 16 — A

Training & retraining conducted as required?
Written & oral exams conducted? Examination results reviewed by management?
Instructions to workers per 19.12? 19.12

NOTES & REMARKS:
workers instructed as required

4. Radiation protection procedures Lic Cond 16 — A

Procedures available and implemented? Identify radiopharmaceutical and dose(s)? Cover handling of patients receiving therapeutic doses? Cover handling of cadavers?
Emergency procedures for spills, etc? Personnel understand procedures?

NOTES & REMARKS: Procedures are available and implemented adequately. Emergency procedures are understood.

INSPECTION ITEM	CRITERIA	FINDING

5. Use of materials — Lic Cond 16 — 2 N/C

Procurement and use as required?

Special tests (moly breakthrough, leak tests, etc) required?

Dose calibration checks performed?

Posting & labeling as required? — 20.203

NOTES & REMARKS:

moly breakthrough conducted as required, record + result appear ok.
N/C no leak test of 204 uCi Cs-137 source from 5/79 to 2/80 see append. A
dose calibrator calibrated as required except linearity see append. A

6. Storage of materials — A

Material secured in both restricted and unrestricted areas? Adequately? — 20.207

NOTES & REMARKS:

all material properly secured.

7. Facilities — Lic Cond 16 — A

As described in lic cond or application?

Any changes made? Adequacy?

NOTES & REMARKS:

facilities appear adequate.

8. Instruments — Lic Cond 16. — A

Survey meters & instruments adequate for program?

Instruments & meters operable? Calibrated? Calibration adequate?

NOTES & REMARKS:

Picker G-M last calibrated 3/12/80

Eberline E-520 serial # 1629. new instrument calibrated

INSPECTION ITEMS	CRITERIA	FINDING
9. Receipt and transfer of material		A
Written procedures for pickup, receiving, opening packages?	20.205	
Survey of packages when received?	20.205(c)(1)	
Records of survey of packages?	20.401(b)	
Transfer of materials proper? Transfer records maintained?	20.41, 30.51	
Authorized containers used? Shipping papers & package labels proper for packages on hand?	71.5	

NOTES & REMARKS: All packages delivered to nuc med lab logged in, surveyed at surface, 3 feet and when empty. Records ok. no transfers

10. Personnel protection - external		N/C
Personnel monitoring controls adequate? Exposures minimized?	20.101, 20.202	
Exposure records (NRC-4 or 5) maintained? Available for employee review?	20.102(b), 20.401(a)	
Surveys conducted? Adequate?	20.201	
Records of monitoring surveys?	20.401	
Levels in unrestricted areas within limits?	20.1, 20.105	

NOTES & REMARKS: Landauer monthly, period reviewed 3/5/77 → 7/5/80
highest whole body for one year — 250 mRem
highest yearly finger 2.180 Rem
N/C Surveys conducted as required except weekly G-M of camera area and monthly G-M of RIA lab not done. see Appendix A

11. Personnel protection - internal		A
Airborne concentrations in restricted areas?	20.103	
Exposures to minors?	20.104	
Posting of airborne radioactivity areas?	20.203(d)	
Survey, monitoring adequate for airborne radioactivity, surface contamination? Records maintained?	20.201 20.401	

Bioassay
NOTES & REMARKS:
Xenon used in ventilated room with Pulmonex system. Appears adequate.

INSPECTION ITEM	CRITERIA	FINDING
12. Effluent controls, waste disposal		2 N/C
Release of effluents controlled?	20.106, 20.303	
Waste disposals controlled?	20.301, 20.303, 20.304, 20.305	
Procedures, records maintained?	20.401, Lic Cond ____	
Surveys made? Adequate?	20.401	

NOTES & REMARKS: All mucmed waste is held for decay, monitored and recorded and thrown away when at background levels. N/C RIA solid waste is not surveyed before disposal. It is unlikely any material has actually been thrown away because of the uCi quantities used

- OVER -

13. Notifications and reports		A
To individuals.	19.13	
Overexposures, excessive levels & concentrations, incidents.	20.403, 20.405	
Personnel exposures and monitoring, termination reports.	20.407; 20.408	
Theft or loss of licensed material. none	20.402	

NOTES & REMARKS:

personnel summary submitted

14. Posting of notices		A
Part 20, license & documents, procedures, notice of violations posted?	19.11(a)	
NRC-3 posted?	19.11(c)	

NOTES & REMARKS:

all documents posted as required

15. Other license conditions	Lic	A

all other license conditions reviewed and appear adequate.

INSPECTION ITEMS	CRITERIA	FINDING

16. Confirmatory measurements — A

Xetex current calibration

hot-lab .2 mR/hr

waste storage .6 mR/hr

new generator on surface, near top 23.41 mR/hr

gonad and trunk level .7 mR/hr

leg level 1.7 mR/hr

All levels are within Part 20 limits

17. Independent inspection effort — A

Toured facility observed posting, security, waste storage, equipment etc.

All appear adequate

18. Incidents and events — A

Any incidents of misadministrations, contamination, etc, not otherwise covered by reports?

INSPECTION ITEMS	FINDING

19. Summary of Licensed Program

Kind of program; number of people; rate of use or quantities on hand; places and frequency of use; type, quantity and use as authorized; and in accord with procedure 78710B. A

Small diagnostic nuclear medicine clinic employing 2 technicians doing approx 10 to 15 patients per day. Occasional hyperthyroid using I-131 capsules of 10 - 15 mCi each patient dose.

300 mCi Mo99/Tc99m generator from NEN weekly RIA laboratory doing routine work T-3, T-4, digoxin, TSH FTI, ferritin, uses approx 200 uCi I-125 per month Xenon used occasionally.

type, quantity and use of material as authorized. users as authorized.

20. Source of Information for Items Inspected A

In accordance with items checked in Appendix D.

APPENDIX A - DOCUMENTATION OF NONCOMPLIANCE

NOTE: Bases for noncompliances to be documented here, not under Notes & Remarks for each individual item

Reference	Basis for noncompliance
Report Item 5 10 CFR 35.14c Lic Cond ____ Type A/C ____	10 CFR 35.14c requires certain sealed source be leak tested every 6 months. Contrary to this, a leak test was not performed on a 204 uCi Cs-137 source from 5/79 to 2/80 a period exceeding 6 months.
Report Item 5 10 CFR ____ Lic Cond 16 Type A/C ____	Referenced April 25, 1979, application states dose calibrator will be check for leniarity quarterly. Contrary to the above no leniarity test was done from 9/80 to 9/80. A period exceeding 3 months.
Report Item 10 10 CFR ____ Lic Cond 16 Type A/C ____	Referenced application dated April 25, 1979 states weekly surveys (G-M & wipe) will be done of all lab area & monthy of low use areas. Contrary to this, G-M surveys have not been performed of camera rooms weekly and no monthly surveys of RIA lab.
Report Item 12 10 CFR 20.201 Lic Cond ____ Type A/C ____	20.201 as related to 20.301 requires evaluation of disposals. Contrary to the above, RIA waste has not been surveyed to determine if any material is being disposed of in normal trash.
Report Item 12 10 CFR 20.201 Lic Cond ____ Type A/C ____	20.201 "evaluations" as related to 20.303 "sewerage disposal" requires that an evaluation be made of sewerage disposal to show compliance with release limits. Contrary to the above, no evaluation has been made to determine the concentration of I-125 in sewerage

APPENDIX B - LICENSEE ACTION ON PREVIOUS INSPECTION FINDINGS

Identification and summary of action taken	Status
Report no: _____ Type a/c: _____ Describe: _____ Action taken: N/A	OPEN CLOSED
Report no: _____ Type a/c: _____ Describe: _____ Action taken:	OPEN CLOSED
Report no: _____ Type a/c: _____ Describe: _____ Action taken:	OPEN CLOSED
Report no: _____ Type a/c: _____ Describe: _____ Action taken:	OPEN CLOSED
Report no: _____ Type a/c: _____ Describe: _____ Action taken:	OPEN CLOSED

APPENDIX D - SOURCE OF INFORMATION

(✓) appropriate item

1. Discussions with:

___ a. Hospital Administrator
___ b. Heads of Departments in which BPM is used.
___ c. Isotope Committee Members
___ d. Radiation Safety Officer
✓ e. Authorized Users
___ f. Physicians working under the supervision of authorized users.
✓ g. Chief Nuclear Medicine Technologist
✓ h. Medical Technologist
___ i. Student trainees in Nuclear Medicine Technology
___ j. Others; Specify _____

2. Records Review

✓ a. Radiological Protection Procedures
✓ b. Emergency Procedures
✓ c. BPM Receipt
✓ d. BPM Transfer
___ e. BPM Use
___ f. BPM Inventory
✓ g. Waste Disposal
✓ h. Instrumentation - Calibration, Results, Schedules
✓ i. Special Tests - Moly breakthrough, etc.
✓ j. Leak Tests
✓ k. Radiation Surveys
✓ l. Personal Monitoring
___ m. Effluent Evaluation
___ n. Shipping Incidents
___ o. Notification and Report
___ p. Others; Specify _____

APPENDIX C - SUPPLEMENTARY INFO

[ ] Uncorrected/repeated noncompliance
[ ] Unusual occurrence, conditions, etc
[ ] Basis for change of Category or Priority
[ ] Unresolved item
[ ] Inspector's comments

APPENDIX D - SOURCE OF INFORMATION
(continued)

3. Observations

___ a. Dose Preparation

___ b. Dose Calibrator Usage

___ c. Administration of Dose to Patient

___ d. Use of Instruments

✓ e. Laboratory Facilities and Equipment

✓ f. Others; Specify thyroid scan

4. Independent Measurements

✓ a. Direct Radiation

___ b. Smear Surveys

___ c. Dosimetric Readings, Where Appropriate

___ d. Others; Specify _____

Appendix ____ MC 9270[illegible]

Licensee: _____ License No. _____

Follow-up on Bulletins and Circulars

A. Bulletins sent for Action

1. Bulletin No(s). _____

2. Written response timely? _____

3. Written response acceptable? _____

4. Bulletin and response reviewed by appropriate licensee personnel? _____

5. Information discussed in licensee's response was accurate? _____

6. Action taken by the licensee as required by bulletin and described in licensee's response? _____

B. Circulars and Bulletins sent for Information

1. Circular and Bulletin No(s). 79-01, 79-14, 79-06, 8

2. Received by licensee management?

yes

3. A review for applicability was performed?

yes

4. For those applicable to the facility, appropriate corrective actions have been taken or are scheduled to be taken?

yes

(Use reverse side and additional pages for comments)

INSPECTION PLAN AND REPORT NUMBER _____

PLANNING SHEET

Date: _____

Licensee: _____ License no: _____

Inspection Items	Scheduled for inspection	Post-inspection status	Module no.	766 Time Info
Management meeting - Entrance and Exit Interviews *[REQUIRED]*	✓	C	30703B	
Initial Management Meeting			30800B	
Program requirements, MC 28__ *[REQUIRED]*	✓	C		
Licensee Event Followup			92700B	
Followup on Inspector-identified problems			92701B	
Followup on Noncompliance and Deviations			92702B	
IE Bulletin/Immediate Action Letter Followup			92703B	
Followup on Headquarters Requests			92704B	
Followup on Regional Requests			92705B	
Independent Inspection Effort *[REQUIRED]*	✓	C	92706B	
Inspector Dispatched to Site			93700B	
Followup on Significant Event Occurring During Inspection			93701B	

does not ship at all.

3. If the licensee has no waste packages on hand to inspect, check this line and send response form 2 if all findings are satisfactory ✓.

4. If the licensee has a package(s) available to inspect, perform the inspection and send response form 3 if packages are satisfactory ___.

5. If deficiencies in the above are noted use form 4 in your response to headquarters. Document below which licensee actions are needed to bring program up to requested level.

_____

_____

_____

_____

_____

_____