APPENDIX A

NUCLEAR MEDICINE INSPECTION RECORD

Region III

Inspection record No. **99-001**

License No. **21-13255-01**

Licensee (Name and Address):
Woodland Medical Group
22341 W. Eight Mile Road
Detroit, MI 48219

Docket No. **030-02149**

Licensee Contact: **Harold Daitch, M.D., RSO**

Telephone No. **313.538.4700**

Priority: **G 3** Program Code: **02120**

Date of Last Inspection: **1/25/96**
Date of This Inspection: **03/10/99**

Type of Inspection:

( ) Announced
(X) Routine
( ) Initial

(X) Unannounced
( ) Special

Next Inspection Date **3/2004** ( ) Normal ( ) Reduced (X) Extended

Justification for change in normal inspection frequency: **Per MC2800, good inspection history**

Summary of Findings and Actions:

(X) No violations cited, **clear U.S. Nuclear Regulatory Commission (NRC) Form 591** or regional letter issued
( ) Non-cited violations
( ) Violation(s), Form 591 issued
( ) Violation(s), regional letter issued
( ) Followup on previous violations

Inspector(s) _____ Date MAR 17 1999
(Sign Name)
D. A. Piskura, Health Physicist

Approved _____ Date 3/18/99
(Sign Name)
John R. Madera, Chief, Nuclear Materials Inspection Branch, No. 1

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PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:
(License amendments issued since last inspection, or program changes noted in the license)

AMENDMENT # DATE SUBJECT

No amendments have been issued since the last inspection.

2. INSPECTION AND ENFORCEMENT HISTORY:

(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders)

A Form-591 was issued in the field on the day of the last inspection with no violations identified.

3. INCIDENT/EVENT HISTORY:
(List any incidents, recordable events, or misadministrations reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

According to the licensee, there have been no events, incidents, or misadministrations since the last inspection.

PART II - INSPECTION DOCUMENTATION

* References that correspond to each inspection documentation topic are in Inspection Procedure (IP) 87115, Appendix B, "Nuclear Medicine Inspection References."

The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that all areas indicated in this part are not required to be addressed during each inspection. However, for those areas not covered during the inspection, a notation ("Not Reviewed" or "Not Applicable") should be made in each section, where applicable.

All areas covered during the inspection should be documented in sufficient detail to describe what activities and procedures were observed and/or demonstrated. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. If the licensee demonstrated any practices at your request, describe those demonstrations. The observations and demonstrations you describe in this report, along with measurements and some records review, should substantiate your inspection findings. Attach copies of all licensee documents and records needed to support violations.

1. ORGANIZATION AND SCOPE OF PROGRAM:
(Management organization; authorities and responsibilities; authorized locations of use; type, quantity, and frequency of byproduct material use; staff size; mobile nuclear medicine service; limited distribution of pharmaceuticals; and research involving human subjects)

Gwen MacKenzie, Sr. VP of Primary Care Services

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Kate Upton, Administrator, Primary Care Services, Oakland Network

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Carolyn Zolnowski, Manager, Radiology

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Harold Daitch, M.D., RSO and authorized user

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Nuclear Medicine Staff

This licensee is an out-patient clinic with authorization to perform nuclear medicine activities at two locations of use: Detroit and Novi, Michigan. This inspection was conducted at the licensee's Novi, Michigan clinic. The clinic is staffed with two full-time technologists who performs approximately 80+ diagnostic nuclear medicine procedures per month (for both sites). The licensee receives licensed material in unit dose form from Syncor Pharmacy. The majority of the studies are cardiac and bone imaging. Xenon-133 lung studies are occasionally performed by the clinic. The licensee is authorized for 35.300 materials (excluding I-131 in excess of 30 millicuries). Typically in a year, the licensee treats 10-15 cases of hyperthyroidism with 10-29 mCi of I-131 in capsule form. Waste is held for DIS (gloves and sharps) and returned to the pharmacy (syringes).

No violations of NRC requirements were identified during this inspection.

2. MANAGEMENT OVERSIGHT:
(Management support to radiation safety; Radiation Safety Committee; Radiation Safety Officer; and program audits, including as low as is reasonably achievable (ALARA) reviews)

The licensee is not required to have a Radiation Safety Committee. The licensee hired a consultant, Dawn Edwards of MPC to review and audit its radiation safety program on a quarterly basis. The last audit was conducted on 11/23/98 with no unusual findings.

No violations of NRC requirements were identified.

3. FACILITIES:
(Facilities as described; uses; control of access; and engineering controls)

The licensee is authorized to use licensed material at its clinics. The inspector determined that the licensee's Novi facilities observed during this inspection were

the same as those described in the licensee's NRC license application and supporting material. The technologist informed the inspector that the hot lab and scan room are locked during off-hours to prevent unauthorized access by individuals.

No violations of NRC requirements were identified.

4. EQUIPMENT AND INSTRUMENTATION:
(Dose calibrator; instrumentation for assaying alpha- emitting and beta-emitting radionuclides; generators; syringes and vials; survey instruments; 10 CFR Part 21 procedures; and special equipment and instrumentation.)

The Novi clinic possessed a Capintec CRC-7 dose calibrator. Constancy checks are preformed daily using a Cs-137 vial source. Linearity checks are performed quarterly using the sheild method; last linearity test was performed on 11/23/98. Accuracy checks are performed annually using two sources; last accuracy test was performed on 11/23/98. The inspector reviewed a random sample of dose calibrator test records for the 1997 to YTD period and did not identify any unusual test results or violations of NRC requirements.

The Novi clinic possessed Eberline E-520 survey instrument calibrated annually by the MPC consulting firm. The instrument was found to be operable and was last calibrated on 2/23/99.

No violations of NRC requirements were identified.

5. MATERIAL USE, CONTROL, AND TRANSFER:
(Materials and uses authorized; use of radiopharmaceuticals; security and control of licensed materials; and procedures for receipt and transfer of licensed material)

Packages are delivered to the hot lab only during normal working hours. The inspector reviewed the package receipt/transfer survey log for 1998 to YTD 1999 which indicated that radiation levels and removable contamination on incoming and outgoing packages were within regulatory limits. Interviews with the technologist confirmed the she was aware of package survey requirements.

The inspector reviewed a random sample of patient administration records (1998 to YTD 1999) and compared the dose administrated with the dose indicated in the licensee's diagnostic clinical procedures dosage chart. In all cases reviewed, the inspector did not identify any cases where the administered dose exceeded the approved range indicated in the dosage chart . The inspector observed the technologist assay a 20 mCi unit dose of Tc-99m MDP for a bone scan; assay results were within 10% of the pharmacy's. The inspector also observed the technologist administer this dose and noted that she used a syringe shield and wore gloves and an extremity badge.

No violations of NRC requirements were identified.

6. RADIOPHARMACEUTICAL THERAPY:
(Safety precautions; surveys; and release criteria of patients and rooms)

Not applicable for this licensee. The licensee only administers I-131 in quantities less than 30 millicuries. Therefore, the clinic may release patients in accordance with Section 35.75, based on the administered activity.

7. QUALITY MANAGEMENT PROGRAM (QMP) AND MISADMINISTRATIONS:
(QMP - written directives, implementation, reviews, and records; misadministrations - identification, notifications, reports, and records)

The licensee is following its QMP dated 7/15/94. The licensee's consultant reviews the clinic's QMP at quarterly intervals. She reviewed 100% of the cases and found no misadministrations. The inspector reviewed a random sampling of written directives (5 cases total) and found no violations of NRC requirements.

8. AREA RADIATION SURVEYS AND CONTAMINATION CONTROL:
(Radiological surveys; air sampling; leak tests; inventories; handling of radioactive materials; records; and public doses)

Based on record reviews and discussions with licensee personnel, the inspector determined that daily exposure-rate and weekly contamination surveys, had been adequately performed by the clinic. The licensee does not use volatile iodine or noble gases, therefore public dose from effluents is minimal.

The licensee possessed 1 Cs-137 and 1 Ba-133 vials and one Am-241 anatomical marker sources which require leaking testing and inventory. The last inventory and leak tests were performed on 11/23/98; leak test results were less than 185 Bq (0.005 μCi).

No violations of NRC requirements were identified.

9. TRAINING AND INSTRUCTIONS TO WORKERS:
(Interviews and observations of routine work; staff knowledge of all routine activities; 10 CFR Part 20 requirements; therapy training and postulated emergency situations; supervision by authorized users)

The licensee's consultant provides annual training to the nuclear medicine technologist and during her quarterly visits; last annual training session on 5/13/98. During the inspection, the inspector discussed with licensee representatives radiation safety training given to licensee personnel and reviewed those topics discussed. From those reviews and discussions with licensee personnel, the inspector determined that the technologist working in the nuclear medicine department was trained prior to beginning her duties with licensed materials. The inspector determined that the licensee's training program sufficiently addressed radiation safety. No concerns or problems were noted with

the licensee's training program. No violations of NRC requirements were identified.

10. RADIATION PROTECTION:
(Radiation protection program with ALARA provisions; external and internal dosimetry; exposure evaluations; dose records; and patient release)

The inspector reviewed radiation exposure dosimetry records from January 1996 to present and discussed those records with licensee representatives to determine if the licensee's personnel dosimetry program met regulatory and license requirements. The inspector also observed the use of personnel dosimetry by licensee personnel handling licensed materials. From reviews and discussions, the inspector determined that licensee personnel were issued Landauer whole body and extremity dosimetry and that the dosimetry was exchanged on a monthly basis.

Based on the above referenced reviews, discussions, and observations, the inspector determined that the licensee was maintaining personnel radiation exposures ALARA and that no NRC regulatory radiation exposure limit had been exceeded for licensee personnel. The following table summarizes the maximum annual personnel exposures in mSv (in mRem):

Year	TEDE (whole body)	SDE (extremity)
1996	1.1 (110)	5.1 (510)
1997	1.9 (190)	3.2 (320)
1998	1.3 (130)	1.2 (120)
1/1999	0.3 (30)	0.5 (50)

11. RADIOACTIVE WASTE MANAGEMENT:
(Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment incinerators, hoods, vents and compactors; and records)

The clinic does not dispose of licensed material via the sanitary sewer system. Waste generated by the clinic is allowed to decay to >10 half-lives. The waste is then surveyed in a low background area and if the radiation levels are indistinguishable from background, the waste is discarded as non-radioactive waste. Review of the licensee's DIS log for 1998-YTD 1999 found no violations of NRC requirements.

12. DECOMMISSIONING:
(Records of radiological conditions; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements)

This licensee maintains all records of surveys, leak tests and disposal/transfers for future decommissioning purposes.

No violations of NRC requirements were identified.

13. TRANSPORTATION:
(Quantities and types of licensed material shipped; packaging design requirements; hazardous materials (HAZMAT) communication procedures; unit dose return; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports)

This item was not reviewed during this inspection.

14. NOTIFICATIONS AND REPORTS:
(Theft; loss; incidents; overexposures; change in Radiation Safety Officer (RSO), authorized user, or nuclear pharmacist; and radiation exposure reports to individuals)

According to the RSO, the clinic has not experienced any medical misadministrations, recordable events, or lost/stolen radioactive material since the last inspection.

No violations of NRC requirements were identified.

15. POSTING AND LABELING:
(Notices; license documents; regulations; bulletins and generic information; posting of radiation areas; and labeling of containers of licensed material)

During the inspection, the inspector observed that those areas within the licensee's facility where radioactive materials were used had been adequately posted with appropriate radiation postings to warn individuals of the radiation hazards associated with those areas. Also, the inspector observed that sealed sources, radiopharmaceuticals, and waste containers had appropriate labels to identify the radioactive materials in them. The hot lab was also posted with emergency/decon procedures and the approved "dosage chart."

The inspector concluded that the licensee had adequately posted areas and labeled radioactive materials in accordance with NRC regulatory requirements. No violations of NRC requirements were identified.

16. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:
(Areas surveyed; comparison of data with licensee's results and regulations; and instrument type and calibration date)

NRC survey instrument used: Ludlum Model 3, Tag no. 045625, last calibrated on 9/10/98.

A side-by-side comparison of the licensee's survey instruments and the inspector's instrument was made with a 1 μCi Cs-137 check source. All instruments were within 20% agreement. The inspector performed direct radiation measurements in and around the licensee's hot lab which indicated similar results as noted in the licensee's survey records, <516 nC/kg/hr

(2mR/hour). Maximum levels were measured at the surface of the L-shield, 39 nC/kg/hr (0.15 mR/hr). Radiation levels in the unrestricted areas outside the hot lab, and the scan room were at background, <5 nC/kg/hr (<0.02 mR/hr).

No violations of NRC requirements were identified.

17. VIOLATIONS, NON-CITED VIOLATIONS (NCVs) AND OTHER SAFETY ISSUES:
(State requirement and how and when licensee violated the requirement. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

On the day of the exit meeting with the licensee staff, a NRC form-591 was issued which indicated that no violations of NRC requirements were identified.

18. PERSONNEL CONTACTED:
(Identify licensee personnel contacted during the inspection [including those individuals contacted by telephone].)

Harold Daitch, M.D., RSO and authorized user
***#Carolyn Zolnowski, Radiology Manager**
***#Elizabeth Taylor, CNMT**

Use the following identification symbols:
Individual(s) present at entrance meeting
* Individual(s) present at exit meeting

19. PERFORMANCE EVALUATION FACTORS:

A.	Lack of senior management involvement with the radiation safety program and/or RSO oversight	( ) Y (X) N
B.	RSO too busy with other assignments	( ) Y (X) N
C.	Insufficient staffing	( ) Y (X) N
D.	Radiation Safety Committee (RSC) fails to meet or functions inadequately	( ) N/A ( ) Y (X) N
E.	Inadequate consulting services or inadequate audits conducted	( ) N/A ( ) Y (X) N

Remarks (consider the above assessment and/or other pertinent performance evaluation factors (PEFs) with regard to the licensee's oversight of the radiation safety program):**NONE**

20. Special Conditions or Issues:
(*Special license conditions; year-2000 effects of computer software*)

PART III - POST- INSPECTION ACTIVITIES

1. REGIONAL FOLLOW UP ON PEFs:

No negative PEFs were identified.

2. DEBRIEF WITH REGIONAL STAFF:
(Post-inspection communication with supervisor, regional licensing staff, Agreement State Officer; and/or State Liaison Officer)

The inspector discussed the inspection findings with her supervisor.

3. YEAR-2000 ISSUES:
(Convey, to the NMSS Year-2000 Coordinator, all year-2000 licensee-identified problems and corrective actions taken.)

The licensee uses the Unit Dose Manager System and stated that this software is Y2K compatible.

END