Appendix

NOTICE OF VIOLATION

Woodland Medical Group License No. 21-13255-01

As a result of the inspection conducted on August 30 and 31, 1983, and in accordance with the NRC Enforcement Policy, 47 FR 9987 (March 9, 1982), the following violation was identified:

10 CFR 71.5(a) requires that no licensee shall transport any licensed material outside the confines of his plant or other place of use unless the licensee complies with the applicable regulations of the Department of Transportation in 49 CFR Parts 170-189.

49 CFR 173.393(h) states that no significant removable radioactive contamination shall be on the external surface of packages.

49 CFR 173.397(a)(1) states that in assessing the surface contamination of a package, a sufficient number of measurements must be taken so as to yield a representative assessment of the contamination situation.

Contrary to the above, no measurements were taken on the external surfaces of packages containing licensed material to assure that there was no removable radioactive contamination present. Specifically from February 1, 1982 through August, 1983, you routinely failed to perform wipe tests on packages being returned to Pharmatopes on a daily basis that contained up to 17.8 millicuries of technetium-99M products.

This is a Severity Level IV violation (Supplement V).

Pursuant to the provisions of 10 CFR 2.201, you are required to submit to this office within thirty days of the date 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. Consideration may be given to extending your response time for good cause shown.

9-28-83
Dated

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

A/46

U. S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 30-02149/83-01(DRMSP)

Docket No. 30-02149 License No. 21-13255-01
Category G Priority 3

Licensee: Woodland Medical Group

Special Inspection At: Woodland Medical Group
22341 West Eight Mile Road
Detroit, Michigan 48219
and
Woodland Medical Group
41935 Twelve Mile Road
Novi, Michigan 48050

Inspection Conducted: August 30-31, 1983

Inspector: S.R. Fasuk for R. J. Caniano
Radiation Specialist — Date: 9-28-83

Reviewed by: S.R. Fasuk for D. J. Sreniawski, Chief
Materials Radiation Protection Section 2 — Date: 9-28-83

W. L. Axelson, Chief
Material and Safeguards Branch — Date: 9-26-83

Inspection Summary

Special Inspection on August 30-31, 1983 (Report No. 30-02149/83-01(DRMSP))
Areas Inspected: This was a special unannounced inspection to review the facts surrounding several allegations received by the NRC in a letter dated July 16, 1983, from an individual wishing to remain anonymous. In addition, the inspection included a routine inspection of the radiological health program.
Results: Of the eight allegations made, one appears to be substantiated, and is an apparent item of noncompliance.

DETAILS

1. Persons Contacted

*Harold Daitch, M.D., Radiation Safety Officer
*Elizabeth Taylor, Chief Technologist
Linda Sias, Technologist
Robert Eluskie, Courier for Woodland Medical Group

*Denotes those present at the exit interview on August 31, 1983.

2. Purpose of Inspection

On July 22, 1983, Region III received a letter dated July 16, 1983, from an individual wishing to remain anonymous requesting an inspection be performed of the licensee's facilities. The letter listed eight areas where the individual believed the licensee was in violation of its license.

This special inspection was in response to allegations concerning the following areas:

a. Department of Transportation (DOT) regulations are not being observed on outgoing packages containing unused doses, used syringes, etc., being returned to Pharmatopes. Pharmatopes was the nuclear pharmacy used by the licensee.

b. DOT regulations are not being observed when sending materials from the Detroit facility to the Novi facility. No DOT labeling or surveys are performed on the shipments.

c. Wipe tests are not being performed on incoming packages received from commercial suppliers or Pharmatopes.

d. Improper waste disposal techniques for IV tubing containing thallium-201. The readings at the trash can are always above background.

e. Many doses of 28 to 30 millicuries are administered to patients and are recorded as such. The Head Technologist has stated that a 50 percent dose variance from the stated dose of 20 millicuries is acceptable for patient administration.

f. Misadministrations of radiopharmaceuticals via improper routes of administration. The alleger observed several incidents of doses being administered subcutaneously and the radiologist stating that the study will be repeated at a later date due to technical difficulties.

g. Improper quality control is being performed on the large field of view (LFOV) camera at the Detroit site. Very few bar phanthoms were being performed at that site.

h. Violations concerning oral consumption are many in this department. Smoking, eating, and the use of the nuclear medicine refrigerator for storing of food is occurring in the department. An electric coffee pot may be found at the Detroit site.

All of the alleged violations occur at the Detroit site. Alleged violations b, c, d, and f also occur at the Novi site.

2. Special Inspection Findings

a. The allegation concerning DOT regulations (item a) not being observed for doses being returned to Pharmatopes was substantiated. The licensee routinely sent syringes containing residual amounts of technetium-99M products back to Pharmatopes for disposal without verifying that no removable radioactive contamination was present on the packages. The shipments were made several times each week. Two specific dates when licensed material was returned to Pharmatopes for disposal are as follows:

On August 11 and 24, 1983, two Specification 7A, Type A packages containing 15.8 millicuries and 17.3 millicuries, respectively, of technetium-99M were sent back to Pharmatopes for disposal without being wipe tested to check for removable contamination.

Failure to ensure that no removable contamination was present on packages containing licensed material constitutes noncompliance with 10 CFR 71.5(a) which requires that no license shall transport any licensed material outside the confines of his plant or other place of use unless the licensee complies with the applicable regulations of the Department of Transportation in 49 CFR Parts 170-189.

49 CFR 173.393(h) states that no significant removable radioactive contamination shall be on the external surface of packages.

49 CFR 173.397(a)(1) states that in assessing the surface contamination of a package, a sufficient number of measurements must be taken so as to yield a representative assessment of the contamination situation.

One item of noncompliance was identified.

b. The allegation concerning DOT regulations not being observed for doses being transferred from the Detroit site to the Novi site was not substantiated. The inspector learned that 2.5 to 4.4 millicuries of thallium-201 are transferred to the Novi facility twice a week, and 50 to 80 microcuries of iodine-131 diagnostic capsules are transferred to Novi every other week. The Detroit facility receives the thallium-201 from the New England Nuclear Corporation and the

iodine-131 capsules from the Mallinckrodt Corporation. Once received, the Detroit facility will remove the material needed at that facility and the remainder is transferred via courier to the Novi facility in the original labeled and sealed shipping container. This transfer of material is authorized by Dr. Harold Daitch. Dr. Harold Daitch has delegated this responsibility to the couriers for the Woodland Medical Group. The inspector interviewed the courier that transports the material from the Detroit facility to the Novi facility and the individual appears to be well instructed on the safe handling of packages containing radioactive material.

According to 10 CFR 71.8, physicians are exempt from the regulations for the packaging and transportation of radioactive material to the extent that they transport licensed material for use in the practice of medicine.

No items of noncompliance were identified.

c. The allegation concerning wipe tests not being performed on incoming packages received from commercial suppliers or Pharmatopes was not substantiated. According to the license issued May 30, 1979, the licensee is not required to perform a wipe test on incoming packages. In reviewing receipt records at both facilities, the inspector determined the licensee does perform the required three foot and surface surveys on all incoming packages containing radioactive material.

No items of noncompliance were identified.

d. The allegation concerning disposal techniques for IV tubing containing thallium-201 and readings at the trash can being above background was not substantiated. According to statements made by the licensee, IV tubing once removed from the patient is held for decay in the waste area and disposed of in normal trash once the readings are below background. In reviewing disposal records the licensee's last disposal occurred on June 22, 1983. Records revealed that a survey was taken of the waste prior to disposing it in normal trash and the reading was less than background. The inspector performed an independent survey using an Eberline E-120 NRC No. 005261 survey meter, calibrated on July 22, 1983, of all trash cans at the Detroit site and Novi site. No readings were above background.

No items of noncompliance were identified.

e. The allegation concerning administration of patient doses in the upper 20 millicurie range and that doses varying by 50 percent of the stated dose is considered acceptable for patient administration was not substantiated. Patient records were reviewed from

January 4, 1983, to August 30, 1983, and various other dates and revealed a maximum dose given to a patient of 23.0 millicuries of technetium-99M MDP. In reviewing receipt records from Pharmatopes it was also noted that the licensee from January 4, 1983, to August 30, 1983, did not receive any dose in excess of 50 percent of the prescribed dose. Dr. Harold Daitch confirmed that the Woodland Medical Group would not administer a dose to any patient that varied more than 50 percent of the prescribed dose unless it was authorized by him and that it would be beneficial to the patient. The Nuclear Regulatory Commission does not regulate the amount of the administered dose. However, if the administered dose is greater than 50% of the prescribed dose, then the licensee must report the event to the NRC pursuant to 10 CFR 35.43.

No items of noncompliance were identified.

f. The allegation of wrongdoing concerning misadministration of radiopharmaceuticals via improper routes of administration was not substantiated. The inspector learned that approximately once per month due to difficulty with injecting a radiopharmaceutical dose, part or all of the injection may be given subcutaneously. The physician is made aware of the subcutaneous injection and normally will repeat the study 48 hours later. On July 6, 1983, and August 24, 1983, two patients were given subcutaneous injections of technetium-99M for a brain scan. In discussing these specific incidents with Dr. Daitch, the inspector learned that he was fully aware that the injections were administered subcutaneously due to the fact that the patients both had poor veins and the technologist had difficulty injecting the patients. Both patients were given repeat studies, free of charge 48 hours later. Subcutaneous injections of radiopharmaceuticals due to technical difficulties are not considered radiopharmaceutical misadministrations.

No items of noncompliance were identified.

g. The allegation that improper quality control on the large field of view camera at the Detroit site was not substantiated. According to the license issued May 30, 1979, the licensee is not required to perform any quality control on their diagnostic imaging equipment. The imaging devices used by the licensee at both of the facilities are entirely used for diagnostic purposes and are not used for any radiological safety purposes. The NRC has no jurisdiction over imaging devices not containing licensed material that is used only for diagnostic imaging. Licensee representatives showed the inspector flood fields performed at the Detroit site from April 24, 1982, to June 29, 1983, and from January 4, 1983, to August 30, 1983, from the Novi site. These studies were performed daily as recommended by the camera manufacturer.

No items of noncompliance were identified.

h. The allegation concerning consumption of food and the storage of food and beverages in the nuclear medicine refrigerator was not substantiated. On the dates of this inspection, the inspector did not observe any food or beverage or any individual smoking in or around either nuclear medicine departments. There was no storage of any food or beverages in the nuclear medicine refrigerator at the Detroit site, and the only coffee pot that was observed at the Detroit site was in the ultrasound department where no radioactive material is stored or used.

No items of noncompliance were identified.