

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report Nos. 030-08971/84-01
030-16024/84-01

Docket Nos. 030-08971
030-16024

License Nos. 29-15360-01
29-15360-03MD Priority 1 Category B

Licensee: Medi-Physics, Incorporated
900 Durham Avenue
South Plainfield, New Jersey 07080

Facility Name: Medi-Physics, Incorporated

Inspection At: South Plainfield, New Jersey

Inspection Conducted: September 14, 1984

Inspectors: J. Nicolosi
J. Nicolosi, Radiation Specialist

Approved by: J. Kinneman
J. Kinneman, Chief
Nuclear Materials Section A
Nuclear Materials and Safeguards Branch

10/3/84
date

10/12/84
date

Inspection Summary:

Routine Unannounced Safety Inspection Conducted September 14, 1984 (Combined Report No. 030-08971/84-01; 030-16024/84-01)

Areas Inspected: Scope of operations, organization, licensee internal audits, training and instruction to employees, materials, facilities and instruments, receipt and transfer of materials, personnel protection-external, personnel protection-internal, effluent control, waste disposal, receipt of material, quality assurance, and posting of notices.

Results: No violations were identified.

DETAILS

1. Persons Contacted

- *T. Springer, Facility Manager
- *L. McLean, Radiation Safety Officer
- L. Goddard, National Distribution Manager

*denotes those present at exit interview

2. Scope of Operations

On October 21, 1983, the licensee ceased operations for processing technetium-99m from molybdenum-99. They have no future plans to resume this operation. As of the inspection, the licensee is involved in the following licensed activities:

- 1) Redistribution of molybdenum-99/technetium-99m generators manufactured at the Tuxedo, New York facility.
- 2) Storage and redistribution of xenon-133 (gas form) manufactured at the Tuxedo, New York facility.
- 3) Instrument calibration with millicurie and microcurie quantities of licensed material authorized for possession and use under License No. 29-15360-01.

The bulk of the licensee's current activities involve the accelerator production of radioisotopes. This operation is licensed by the State of New Jersey.

No violations were identified.

3. Organization

The Radiation Safety Officer reports directly to the facility manager. The facility manager reports to the executive vice president of Medi-Physics, Incorporated in Richmond, California. Licensee organization has not changed substantially since the last inspection.

No violations were identified.

4. Licensee Internal Audits

The facility is audited annually on a formal basis by the parent corporation for overall occupational health and safety. The Radiation Safety Officers from licensee facilities in New York and Illinois also perform annual radiation safety audits. The inspector reviewed results from the 1983 audit done by the Radiation Safety Officers.

No violations were identified.

5. Training and Instruction to Employees

Licensee's records of employee training and radiation safety were reviewed. The inspector noted that attendance records are maintained.

No violations were identified.

6. Materials, Facilities and Instruments

The nature of operations at the facility are in accord with those authorized by the licensee. Restricted areas are posted where appropriate.

Records of the calibration of survey instruments were reviewed and found to be in order.

No violations were identified.

7. Receipt and Transfer of Materials

The quantities of radioactive materials on hand were determined by examination of records and compared with the licensee's possession limits, and found to be well within the authorized limits. The licensee has established effective controls to assure that possession limits are not exceeded.

The licensee has established a system whereby the customer's license number is entered into a computer along with the expiration date. Any order by a customer who is not authorized to receive the material will immediately be identified by the computer and not processed. Records of receipt and transfer of material were reviewed and found to be in order.

No violations were identified.

8. Personnel Protection-External

The inspector reviewed the licensee's records of external exposure. Exposures to personnel from use and handling licensed material is within regulatory limits. The highest annual dose to accelerator workers is 3.5 rem whole body for 1984. These personnel do not handle licensed material.

No violations were identified.

9. Personnel Protection-Internal

Since the licensee has ceased operations with licensed material except for sealed source use and molybdenum-99/technetium-99m generator and xenon-133 distribution, the licensee's bioassay programs are no longer required.

Room air sampling data were reviewed. Room air concentrations of iodine-123 were found to be within the maximum permissible air concentration for restricted areas. Xenon-133 is stored in sealed form only and is not processed in any way.

No violations were identified.

10. Effluent Control, Waste Disposal

Monitoring data for releases of radioactive material to the atmosphere were reviewed. The total releases for the year preceding the inspection were approximately 50 percent of the maximum permissible air concentration for unrestricted areas.

Procedures and records of preparation of radioactive waste for shipment for burial were reviewed and found to be acceptable. The licensee shipped four 55-gallon drums of waste since the last inspection.

No violations were identified.

11. Receipt of Material

Procedures for pickup, receipt and monitoring of packages in which radioactive material was received were reviewed and found to be adequate.

No violations were identified.

12. Quality Assurance

The licensee participates in a comparison program with the National Bureau of Standards (NBS) to assure that their product meets quality assurance standards. This program consists of analyzing radioactive samples sent by NBS and comparing the results with the known activity.

No violations were identified.

13. Posting of Notices

All notices required to be posted by 10 CFR 19.11 were posted.

No violations were identified.

14. Exit Interview

The inspector met with the individuals denoted in paragraph I at the conclusion of the inspection to summarize the scope and findings of the inspection.