

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT

REGION III

Report No. 70-1379/79-01

Docket No. 7001379

License No. SNM-1347

Priority I

Category B

Licensee: Parkwell Laboratories,
Incorporated
429 North High Street
Croton, OH 43103

Facility Name: Parkwell Laboratories

Inspection Conducted: March 1, 1979

Inspectors: J. A. Finn

A. G. Januska
A. G. Januska

3/16/79

3/16/79

Approved By:

J. A. Pagliaro
J. A. Pagliaro, Chief
Materials Radiological
Protection Section 2

3/19/79

Inspection Summary

Inspection on March 1, 1979 (Report No. 70-1379/79-01)

Areas Inspected: Organization; personnel radiation protection, external; personnel radiation protection, internal; surveys; materials transfer and inventory; waste disposal; facilities and equipment; independent measurements. The inspection involved 14 inspector-hours onsite by two inspectors.

Results: Of the 10 areas inspected, no apparent items of noncompliance were identified in nine areas; one item of noncompliance was identified in one area (infraction - possession of licensed material without a license, Section 12).

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DETAILS

1. Persons Contacted

*Mr. C. E. Wells, President, Parkwell Laboratories, Inc.
Mr. V. Apple, Site Manager, Nuclear Engineering Company,
Richland, Washington (telephone)

*Denotes those present at the exit interview.

2. General

Under License No. SNM-1347, expiration date April 30, 1978, the licensee purchased plutonium 238 from ORNL and fabricated sealed sources for use in heart pacemakers. Each source contains approximately 0.24 grams of plutonium 238.

Under License No. 34-13517-01, terminated on March 24, 1976, the licensee possessed and used americium 241, cesium 137, strontium 90 and cerium 144 for the fabrication and distribution of sealed sources.

3. Recent Licensing Actions, License No. SNM-1347 (See Exhibit A)

By letter dated March 21, 1978, the licensee requested renewal of the license. The timely application was acknowledged by NMSS by letter dated April 10, 1978.

A letter from NMSS dated April 28, 1978, requested the licensee to submit a complete up-to-date application.

A letter from NMSS dated August 29, 1978, informed the licensee that no response had been received to the April 28, 1978 letter, and stated that if no reply was received within 30 days, it might be necessary to deny the renewal application and terminate the license.

A letter from NMSS to the licensee, dated December 4, 1978, stated that no response had been received to previous requests. The letter stated further that the license renewal request was denied, that radioactive material was to be transferred to an authorized recipient within 30 days and the licensee was to notify NMSS of such disposition within five days.

A letter from NMSS dated January 18, 1979, requested IE to investigate to determine if the licensee had any material in his possession.

IE:III contacted the licensee by telephone on February 21, 1979, and visited the facility on March 1, 1979, to conduct the investigation and to make independent measurements.

4. Organization

There have been no changes in organization since the last inspection. Mr. C. E. Wells is the President of the Company and is also the Radiation Safety Officer. He is the only individual involved in the program.

5. Personnel Radiation Protection - External

Film badge service is provided on a bi-weekly basis by R. S. Landauer. Both whole body and wrist badges are used. The film badge processor's reports were reviewed for the first three quarters of 1978, through October 1, 1978. The total exposure for the period was 20 millirem (whole body) and 20 millirem (wrist).

The licensee makes weekly direct reading radiation measurements (beta-gamma) throughout the facilities. These surveys showed radiation levels ranging from 0.05 to 0.5 mr/hr.

6. Personnel Radiation Protection - Internal

The licensee conducts weekly contamination surveys (wipe) at 32 locations in the restricted area. Wipes are analyzed for alpha and beta-gamma activity. When the action level of $5 \times 10^{-5} \mu\text{Ci}/100 \text{ cm}^2$ (110 dpm/100 cm^2) is exceeded, the area is decontaminated. Records of surveys for the period January 1, 1978 through August 14, 1978, were reviewed. No activity above a background of $2 \times 10^{-7} \mu\text{Ci}/100 \text{ cm}^2$ (0.44 dpm/100 cm^2) was recorded.

Urine samples are taken monthly and analyzed by Controls for Environmental Pollution. A review of records for CY 1977 and for January, February and March of 1978 showed gross alpha concentrations of 0 -3 dpm/liter for each sample.

The licensee maintains a permanent air sampling program. A total of eight sampling heads are provided at fixed locations throughout the facility. Six heads are located in the building at approximately breathing zone height. Two are located in the air exhaust system (one in the exhaust manifold and the other in the stack). All eight samples are evaluated each day. The sampling rate for all heads is adjusted for an air flow of 10³ ml of air in an eight hour sampling period. A 24 hour delay is allowed for decay of naturally occurring alpha activity before evaluating the samples.

The only isotope in recent use by the licensee was plutonium 238 as oxide for the fabrication of sealed sources. The MPC values for insoluble plutonium₂₃₈ are 3×10^{-11} $\mu\text{Ci/ml}$ (restricted area) and 1×10^{-12} $\mu\text{Ci/ml}$ (unrestricted area). Limits for americium 241, previously used in the facilities, are less restrictive.

A review of air samples for 1978 showed all concentrations were at background levels (10^{-14} $\mu\text{Ci/ml}$).

7. Surveys

To date of the inspection the licensee had not been requested to make a final survey of his facility and no comprehensive survey had been made.

8. Material Transfers and Inventory

During the period August 15, 1978 through September 8, 1978, ten shipments of sources were made to Coratomic, Indiana, Pennsylvania. Each shipment contained four completed plutonium 238 sources, each source containing approximately 0.24 grams of plutonium 238.

A waste shipment of five containers was made to Nuclear Engineering Company, Richland, Washington on September 14, 1978.

According to statements of the licensee and to inventory records, no material was on hand following these shipments, with the exception of contamination in the facility.

9. Waste Disposal

Solid waste is transferred to an authorized waste disposal agency. Airborne radioactivity from the gloveboxes is exhausted through a stack. No waste is released to the liquid effluent system.

On September 14, 1978, five containers of waste were shipped to Nuclear Engineering Company, Richland. The containers included two boxes containing three gloveboxes, associated piping, and filters. Miscellaneous waste was contained in three 55-gallon drums. The 0.0106 uCi plutonium calibration source was included in the shipment. A total of 0.17 grams of plutonium 238 was contained in the shipment.

The shipment arrived at NECo on October 6, 1978. No problems were identified during surveying and offloading the shipment.

The last previous waste shipment, made on February 6, 1976, contained plutonium 238, americium 241 and cerium 144.

10. Facilities and Equipment

The licensee's facilities consist of a 50 x 25 foot single-story building approximately one mile north of the center of Croton, Ohio (population 500). Source fabrication has been conducted in Rooms 7 and 8 (See Exhibit B). No radioactive work has been performed in the rest of the building.

Air was exhausted from gloveboxes through individual HEPA filters to a manifold located at the South end of the building. From the manifold, air passed through a final HEPA filter and was exhausted through a 50 foot stack. The exhaust air was diluted by outside air controlled by a butterfly valve. The exhaust blower is located at the base of the stack.

The following changes have been made since the January 1978 inspection:

- a. The exhaust system has been shutdown, gloveboxes have been disconnected from the exhaust manifold, and holes in the manifold have been covered with plastic.
- b. The plutonium 238 source fabrication glovebox located in Room 8 was removed, along with two other gloveboxes, and shipped as waste to NECo.
- c. All used HEPA filters were shipped to NECo as waste.
- d. A series of electrolytic cells was installed in Room 7 for use in a new nonradioactive program.
- e. An engine and associated electrical generators were installed in Room 8.

Major contaminated equipment still on hand include:

- a. A glovebox in Room 7.
- b. The effluent exhaust manifold and stack system.

The following radiation detection equipment was on hand: one Eberline Model LCS-1 Laboratory Counting System with a Model FC1/FC2 Flow Counter, two Eberline Model RM-31 survey instruments with alpha scintillation probes and one Eberline Model E500B GM survey meter for beta-gamma measurements.

11. Independent Measurements

The licensee's facility was surveyed for fixed and removable alpha activity. Horizontal surfaces were chosen as indicators of adequate decontamination, prior to a comprehensive survey to demonstrate compliance with guidelines for decontamination of facilities for unrestricted use. Emphasis was placed on the rooms (7 and 8) where incoming shipments were opened and the material utilized. After a number of areas were found to be above the applicable guidelines, and it was obvious that an adequate decontamination had not been performed, the facility was surveyed to determine the scope and magnitude of radioactivity remaining. Exhibit C shows survey locations. Exhibits D and E show the results of direct and smear surveys.

Direct surveys were made with a calibrated Eberline Gas Proportional Alpha Counter. The instrument was checked for operability and reproducible results with an alpha standard before, during and after the survey. Smears were taken with Nu Con Smears and counted on an Eberline Mini Scaler (MS-2) and an Eberline Flow Counter (FC-2) with 90% Argon and 10% Methane counting gas. Operating voltages were determined from plateaus run on February 26, 1979. Alpha and beta backgrounds, and efficiencies using a Pu-239 and Cs-137 standard, respectively, were measured immediately prior to counting. A blank smear was counted after every tenth smear was counted.

Direct survey results ranged from no activity detectable to 3×10^4 d/m/61 cm² in accessible areas and 2×10^5 d/m/61 cm² in a sealed exhaust plenum. Smear results ranged from no activity detectable to greater than 2700 d/m/100 cm² alpha and no activity detectable to 90 d/m/cm² beta in accessible areas. A direct beta survey made with a calibrated Eberline Geiger

Counter (E-530) indicated no beta activity except in two gloveboxes which read 100 and 200 c/m. An air sample collected during the survey indicated no detectable airborne alpha activity. No surveys were made on or outside of the facility due to wet surfaces.

12. Item of Noncompliance

Subsequent to expiration of the license on December 4, 1978, the licensee continued to possess plutonium 238 in the form of contaminated equipment and facilities. This constitutes noncompliance with 10 CFR 70.3, License Requirements, in that the licensee possessed licensed material without a valid license.

13. Exit Interview

At the conclusion of the inspection, inspection findings were discussed with Mr. Charles Wells, President. The inspectors pointed out that contamination levels found during the inspection showed a need for additional surveys and decontamination before the facilities could be released for unrestricted use. Mr. Wells agreed that nothing would be removed from the building until such release. Mr. Wells was informed that NRC would contact him at an early date in regard to decontamination requirements.