

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Report No. 030-32013/96-004 Program Code 03211
Docket No. 030-32013
License No. 20-28598-01 Priority 1 Category B
Licensee: DuPont Merck Pharmaceutical Company
331 Treble Cove Road
North Billerica, Massachusetts 01862
Facility Name: DuPont Merck Pharmaceutical Company
Inspection At: 331 Treble Cove Road
North Billerica, Massachusetts 01862
Inspection Conducted: December 9, 1996

Inspector:

Betsy Ullrich
Betsy Ullrich

12/19/96
date

Approved By:

John D. Kinneman
John D. Kinneman, Chief
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

1/7/97
date

Inspection Summary: Announced, limited, safety inspection performed on December 9, 1996 of licensee actions related to a spill of liquid from a holding tank containing molybdenum-99 and technetium-99m. The spill occurred on December 1 and was reported to the NRC on December 2. (Inspection Report No. 030-32013/96-004)

Areas Inspected: Licensee organization; incident description; initial response activities; current status of the contaminated area; licensee investigative and corrective actions; licensee sampling and analysis; confirmatory and independent surveys; licensee notification to the NRC.

Results: No violations were identified.

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December 1. Outside the cordoned area, no contamination was detected in excess of the MDA. Inside the cordoned area, samples ranged from the MDA to 8.7 microcuries for one soil sample taken in the area near the doors.

Surface water samples were taken from standing water outside the cordoned area including beyond the perimeter fence. Samples were transferred into 450-milliliter Marinelli beakers and analyzed using the high-purity germanium detector connected to a multi-channel analyzer. No contamination was detected in the samples in excess of the MDA.

6. Confirmatory and Independent Surveys

The licensee performed their surveys using a Ludlum Model 3 survey meter with a Ludlum Model 44-38 energy-compensated G-M detector. The Model 44-38 detector has 30 mg/cm² stainless steel walls and a rotary beta window on the side of the detector. Licensee measurements were made at approximately 30 centimeters above the surface, with the beta window open.

During the inspection, independent measurements were performed by the NRC using a Ludlum Model 14C survey meter with a Ludlum Model 44-7 thin-end window G-M detector, combined Serial No. NRC009663. The Model 44-7 detector has a mica window of 1.7 mg/cm² and has an active area of 6.4 cm². Background radiation levels measured with this instrument were less than 0.05 mR/hr. Radiation levels measured outside the cordoned area were not distinguishable from background. Radiation levels measured inside the cordoned area ranged from background to approximately 6 mR/hr, near the doors. The ambient radiation level measured inside the tank room was about 5 mR/hr, but ranged considerably depending on the proximity to the holding tanks. The radiation levels at the viewing area of the lead shield around the tanks exceeded 20 mR/hr.

Confirmatory measurements were made during the inspection by directly comparing the readings of the licensee's instrument and the NRC's instrument. Detectors were held side-by-side at approximately 30 centimeters above the surface at several selected locations inside and outside the cordoned area. Outside the cordoned area, at background radiation levels, measurements were in good agreement. Inside the cordoned area, the NRC instrument was generally higher by about a factor of 2. When the thin-end window of the detector on the NRC instrument was shielded, the licensee measurements and the NRC measurements were in good agreement. The difference in the readings appears to be the higher sensitivity of the thin-end window detector for beta particles, compared to the side-window detector used by the licensee. Licensee measurements were in good agreement with measurements recorded in earlier surveys.

7. Licensee Notification to the NRC

The licensee notified the NRC of the December 1, 1996 spill on December 2 by telephone to the NRC Operations Center. The licensee also contacted the Region I Office by telephone after making the report to the Operations Center. They believed the spill required reporting pursuant to 10 CFR 30.50(b)(1) in that an unplanned contamination event occurred which met all of the reporting requirements: (i) they had to restrict access to the area for more than 24 hours, (ii) the spill contained greater than the limit of 5 times the lowest annual limit of intake (ALI) for molybdenum-99 (the molybdenum-99 ALI is 3 millicuries; 5 times the ALI is 15 millicuries, and the spill was of 50 millicuries), and (iii) access was restricted for reasons other than to allow radionuclides with half-lives of less than 24 hours to decay.

The licensee's reporting of the event was appropriate. Notification was made as required, and the licensee provided to the Operations Center the information required by 10 CFR 30.50(c)(1). The licensee expressed concern that this information, including the name of a licensee representative, was made available by the NRC over the internet and the individual received inquiries about the event. They were particularly concerned that, had the event included personnel radiation exposure data, the names of these individual receiving exposures should not be released.

Licensee representatives stated that they are aware of the requirement to provide a written report within 30 days of the initial report, and that they will provide the information required in 10 CFR 30.50(c)(2). A draft report is in progress.

7. Exit Meeting

The inspector met with the individuals identified in Section 1 and discussed the findings of the inspection. Licensee representatives confirmed that they will provide the required 30-day report on time.

4. Licensee Investigation and Corrective Actions

The licensee assembled an investigation team to review the cause and to recommend corrective and preventive actions. The investigation team included the Director of the Billerica Site, the Director of Manufacturing, the Supervisor of Maintenance, a Site Engineer, the Radiation Protection Officer, and the Supervisor of Radiation and Environmental Engineering as the representative of the response team. The investigation team reviewed the circumstances of the spill and verified that the Building 200 Holding Tanks 1 and 2 are the only closed tanks having an air vent system of this type. The team also recommended corrective actions.

The corrective actions implemented by December 9 as a result of the investigation team recommendations were:

- 1) The use of a log book to document when transfers of liquids to and from the holding tanks take place, including the date of the transfer, the volume transferred, and the person performing the activity.
- 2) Implementation of a procedure which requires that the Building 200 Holding Tank 2 be emptied immediately prior to any transfer of liquid to it.
- 3) Installation of a liquid level alarm on Holding Tank 2, which alarms at 75% of capacity. This alarm is interlocked with the pump so that no additional liquid can be transferred to Holding Tank 2 once the alarm level is reached.

Additional actions which are planned include: 1) installation of continuous liquid level monitors in the holding tanks, and 2) installation of sensors in the air vent conduits, which will be interlocked with the pump to prevent transfer of liquid if any liquid is detected in the air vent conduit.

5. Licensee Sampling and Analysis

The Radiation Protection Office laboratory equipment and standard analytical procedures were reviewed during the routine annual inspection of DuPont Merck during July 17 to 19, 1996, and found to be satisfactory. For this incident, the same standard procedures and equipment were used to analyze wipe samples, water samples, and bioassay samples.

The licensee analyzed soil samples by placing each sample, approximately two tablespoons of soil, in a petri dish. Each sample was counted for 5 minutes with a high-purity germanium detector (HPGe) connected to a multi-channel analyzer. The minimum detectable activity (MDA) for this analysis was 2 E-4 microcuries of technetium-99m per sample. Each sample was also analyzed using a reverse-electrode germanium detector (REGe), and the results were similar to those of the HPGe. All results of the soil samples were back-decayed to 2:00 p.m. on Sunday,