U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Report No. 030-32013/96-002 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
No. Billerica, Massachusetts 01862

Facility Name: DuPont Merck Pharmaceutical Company

Inspection At: No. Billerica, Massachusetts

Inspection Conducted: August 27, 1996

Inspectors: C. Thor Oberg, Health Physicist — 11/26/96 date

Approved By: John D. Kinneman, Chief
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety — 11/26/96 date

Inspection Summary: Announced, reactive inspection conducted August 27, 1996, to review an exposure, in excess of the annual limit, to an individual's film badge, and the status of the licensee's investigation of the exposure (Inspection Report No. 030-32013/96-002). The exposure results were reported to the licensee on August 15, 1996, by the film badge supplier/processor. Review continued until receipt of the licensee's reports dated September 13, 1996 and October 11, 1996.

Areas Inspected: Organization and scope of licensed activity, licensee action following notification of the high dose, licensee interviews and review of event, review of licensee dosimetry test data inspection tour, licensee conclusions and corrective actions, review of licensee's September 13, 1996, report, and review of licensee's October 11, 1996, report.

Results: No safety issues or violations were identified. The licensee initiated an immediate investigation into the event. The licensee's investigation identified no apparent high exposure to the individual assigned the badge, but concluded that tampering with the badge was a possibility; therefore, the licensee conducted further investigation. On September 13, the licensee submitted a 30 Day Report in accordance with 10 CFR 20.2203. On October 11, 1996 the licensee submitted a final report which indicated that they were unable to positively explain the exposure.

DETAILS

1. Persons Contacted

* Raymond A. Shepard,	Director, Billerica Site; Chairperson, Environmental Health and Safety Committee
* Dennis Dumas,	Associate Director, Safety and Environmental Engineering; Radiation Safety Officer
* John R. Laferriere,	Developmental Health Physicist, Safety and Environmental Affairs
* Roy A. Greaves,	Supervisor, Radiation Protection and Environmental Engineering
Joseph Dumont,	Health Physicist, Radiation Protection Office
Will Bigelow,	Lead Technician, Xenon-133 production, Bionuclides Manufacturing
Glenn A. Gerecke,	Area Supervisor, Radiation Protection; Chairperson, Radioisotope committee
Tom Golembeski,	Supervisor, Bionuclides Manufacturing

* Those in attendance at the exit interview.

2. Organization and Scope of Licensed Activities

The Safety and Environmental Engineering Department of the DuPont Merck Pharmaceutical Company (the licensee) is responsible for radiation safety services including waste management for the site. The Associate Director of Safety and Environmental Engineering and Radiation Protection Officer is Dennis Dumas who reports to Raymond Shepard, Director of the Billerica Site. Mr. Shepard reports to Ken Kasses, President of the Radiopharmaceutical Division.

The Safety and Environmental Engineering organization includes Radiation Protection, Environmental Engineering, and Developmental Health Physicists. The Radiation Protection staff provides health physics services to the various laboratories and performs confirmatory monitoring for regulatory compliance.

The licensee is authorized by License No. 20-28598-01 to possess curie quantities of licensed material for manufacturing and distributing radioactive and radio labelled materials to persons authorized by specific and general licenses or by those exempt from licensing. License No. 20-28598-01 is a Type A License of Broad Scope that authorizes activities at the licensee's facility.

Among the principle uses of byproduct materials at the licensee's Billerica Site is the manufacturing and packaging of molybdenum-99/technetium-99m (Mo-99/Tc-99m) generators, associated products, and xenon-133 (Xe-133) for use in medical facilities.

No safety issues or violations were identified.

3. Licensee Action Following Notification of the High Dose

On August 15, 1996, Landauer, Inc., notified the licensee that a returned and processed film badge, used by an individual during the week of July 29 to August 4, 1996 (7/29 - 8/4/96), received a deep dose exposure of 5,530 millirem (mrem) from high energy [>1 million electron volt (Mev)] photons. The individual works on the Xe-133 production and gas dispensing system. At the licensee's request, Landauer, Inc., examined the film and advised the licensee that: Proper loading of the film was indicated, the dose was determined from the slow emulsion film density which was consistent with high photon energy exposure, the film was properly identified with the assigned individual, the film packet showed no evidence of contamination or tampering, and evaluation of the processed film did not indicate exposure to Xe-133. Landauer recommended that the licensee conduct mock-up experimental film badge exposures to determine the specific conditions that created the observed aluminum-to-lead (Al/Pb) filter ratio identified from the film emulsion densities.

On August 16, 1996, the licensee called Region I regarding the badge exposure. The licensee advised the Region of the above facts and that the individual's extremity badge exposures, reported as 640 and 510 mrem (right and left respectively), were consistent with normal operations with Xe-133. Upon notification from the film badge processor, the individual had been immediately prohibited from work with or around radioactive material until further notice. Licensee representatives stated that they were continuing their investigation and review of the cause of the exposure.

No safety issues or violations were identified.

4. Licensee Interviews and Review of Event

The licensee has been reviewing the matter with the individual who was assigned and wore the badge, the area supervisor, and other workers in the area. The Commonwealth of Massachusetts was notified of the event by the licensee.

The license carefully reviewed the individual's work assignments. No unusual situation or work function was identified that could have caused the high dose to the film badge. The individual's routinely worn pocket dosimeter, recharged about monthly, read approximately 170 to 180 mrem on August 11, 1996, and he did not recall his electronic chirper alarming unusually during the period in question. On Friday, August 2, 1996, the individual placed his badge on the desk in the office area, from which the badges would be collected on Monday, August 5, for shipment to, and processing by, Landauer, Inc. The licensee determined that the only time that the individual's film badge was not within his control was while on the distribution/collection desk from July 26 to 28, 1996, prior to use, and after August 2, 1996. He was on vacation for the following week and had left his badge on the group desk at the end of his shift. The electronic chirper he had used was functioning properly when used on August 12, 1996. However, this unit is missing and was not located by September 13, 1996.

During the inspection, the Region I (RI) personnel discussed the high badge reading event, and the results of the licensee's investigation to date, with those individuals

identified in Section 1. of this report. The licensee believes that the event was the result of tampering with the individual's badge. The licensee's investigation revealed nothing that would indicate a specific individual tampered with the badge. However, persons in the temporary employment group contracted by the licensee to assist the workers during production runs have not been questioned concerning the event. A third-party investigation will most likely include discussion of the event with these individuals.

Based on the fact that the licensee believes that the high badge exposure may be the result of tampering, the licensee plans to contract with a professional security firm for a formal investigation.

No safety issues or violations were identified.

5. Review of Licensee Dosimetry Test Data

The licensee performed custom irradiations of film badges which were then processed by Landauer, Inc., in the same manner as the individual's badge. This was done in an attempt to duplicate the observed Al/Pb film filter density ratio determined for the exposed badge.

RI personnel reviewed the results of the licensee's experimental tests, mock-up irradiations of film badges with processing and evaluating by Landauer, Inc. By assessing the dose to the film through the badge holder filters, Landauer reported the density ratio for the Al/Pb filters. Seven test badges were exposed by the licensee. These were various geometric exposures to a shielded Mo-99/Tc-99m generator, to unshielded Mo-99/Tc-99m sources, and to an unshielded Cesium-137 (Cs-137) source. The badge was exposed perpendicular and at an angle to the Cs-137 source. Only the filter ratio of the exposure at an angle to the Cs-137 source was similar to that of the exposure through the filters of the event badge. This badge provided a Al/Pb filter ratio of 0.58/1 while the filter ratio from the test badge placed at an angle from the Cs-137 source was 0.55/1. The other test badge ratios ranged from 0.70/1 to 1.26/1. For personnel working with Xe-133, the film density ratio for the Al/Pb filters is about 7.7/1, considerably different from the high dose exposure received by the badge. From these exposure test badge results the licensee concluded that the exposure was to the badge and not to the individual.

The licensee discussed the whole body, deep dose equivalent (WB,DDE) of 280 mrem they intended to assign to the individual whose badge received the high exposure during the week of 7/29 to 8/4/96. Regional personnel believe this to be a reasonable dose based on the historical dose values and the extremity readings for the week of the event. The RI personnel were provided a copy of the individual's exposure record for 1996. In addition, the RI personnel reviewed the 1996 weekly exposure records for the licensee's Mo-99/Tc-99m and Xe-133 production area workers. The weekly WB,DDE doses ranged from 40 to 140 mrem (weekly action limit 150 mrem), and the weekly extremity shallow dose equivalent (SDE) ranged from about 150 to 1,200 mrem. Based on the information available, the individual who wore the badge was assigned a dose of 280 mrem by the licensee for the period of 7/29 - 8/4/96.

On September 13, 1996, the licensee issued their report in accordance with 10 CFR 20.2203 requirements. The report discusses the results of the film badge custom irradiations and indicated that the exposure was not from work with Xe-133, thallium-201 (Tl-201), or Mo-99/Tc-99m generators.

No safety issues or violations were identified.

6. Inspection Tour

To familiarize themselves with the areas where the individual worked, the inspectors toured the appropriate Building 200 production areas. They observed the desk, in a portable wall, open office area, on which the film badges were deposited for distribution and collection.

The operations in the Xe-133 production fill area were reviewed as well as the operations that were planned but not conducted with the shielded empty Mo-99 containers. This operation is conducted in the old Mo-99/Tc-99m generator production area at the two heavily shielded, Mo-99 loading cells. These cells are now used as empty Mo-99 container storage areas for decay-in-storage. The licensee's new Mo-99/Tc-99m generator production area is in a different location in Building 200 than the old production area. The shielded loading cells are now needed only infrequently for special production runs.

The work areas were orderly. Staff members were apparently in control of operations, wearing appropriate safety equipment and following required procedures.

RI personnel held separate personal discussions with the production area supervisor, and with the individual whose badge received the high exposure. These discussions did not reveal any significant differences from the information obtained by the licensee. The individuals were asked if they had any questions of the NRC. The individual who wore the badge wanted to know when he would be allowed to go back to work in the production area. He was advised that this was the decision of the licensee and would most likely be when and if the licensee determined that the exposure was to the badge and not the individual.

No safety issues or violations were identified.

7. Licensee Conclusions and Corrective Actions

Corrective actions taken or planned by the licensee are: A communication discussing tampering with dosimetry badges and the consequences for such actions, distributed to all employees; and a review was conducted of distribution and collection procedures for the badges. The licensee discussed the fact that 15 years of operation with out an incident with film badges indicates that changes may not be warranted. however, after a thorough review, the licensee decided to modify their procedures. New badges will

be distributed from a locked box by an area representative and the used badges will be deposited directly into another locked box for collection.

No safety issues or violations were identified.

8. Review of Licensee's September 13, 1996, Report

The licensee's report dated September 13, 1996, was reviewed by NRC Region I staff. The report confirmed licensee action taken and planned as discussed in foregoing sections of this report.

The licensee concluded that:

- The employee was not wearing the badge when it received the exposure, this was an exposure to the badge and not the individual;
- The only time that the employee was not in direct control of his dosimetry badges was when these were delivered and stored at a common desk area on July 26 to 28, and on August 2, 1996; and
- The exposure was caused by tampering, most likely by exposure to a Mo-99/Tc-99m generator.

The licensee has retained the services of a private investigating agency to conduct a third-party investigation of the event. This agency initiated their investigation during the week on September 9, 1996, and completed by early October 1996.

9. Review of Licensee's October 11, 1996, Report

The third party investigation group issued their report to the licensee on September 30, 1996. The licensee's report, dated October 11, 1996, of the third party investigation cited the following:

> The third party investigation report did not provide a positive cause for the reading on the badge. It did, however, confirm the findings of the licensee's investigation report dated September 13, 1996.
>
> The investigation resulted in a higher level of awareness by site personnel concerning the dosimetry program and how seriously the NRC and the Company view events as occurred.

6. Exit Interview

RI personnel held an exit interview with those individuals identified in Section 1. of this report to discuss the findings of the inspection. The NRC personnel noted that the licensee had, in a timely fashion, expended considerable time and effort to determine if the 5,530 mrem exposure was to the badge or the individual. Licensee representatives said that they would consider a third-party investigation and would include a final determination on such an investigation in their 30 day report.