



NRC NEWS

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OFFICE OF PUBLIC AFFAIRS, REGION III

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NRC STAFF PROPOSES \$2,750 FINE AGAINST INDIANA PHARMACY

The Nuclear Regulatory Commission staff has proposed a \$2,750 fine against Spectrum Pharmacy Inc., Mishawaka, Indiana, for shipping radioactive pharmaceuticals which exceeded federal transportation limits on radioactive contamination levels, failing to follow emergency procedures, and failing to adequately assess the levels of contamination in the pharmacy.

On August 31, 1999, a vial burst while being heated on a countertop in the nuclear pharmacy's dispensing room, spreading low levels of radioactive contamination throughout the facility. The vial, containing 950 millicuries of technetium-99, was being prepared for use in cardiac diagnostic studies.

After the rupture, pharmacy employees failed to follow emergency procedures when they did not evacuate the area of the spill and restrict access to the spill area. Because the employees did not effectively evaluate contamination levels, some packages were sent to hospitals and clinics with contamination on the surface of the packages.

The contamination in the facility included the equipment used for surveying packages before they were shipped to hospitals and clinics. The contaminated equipment prevented accurate measurements of the package contamination. The pharmacy shipped 14 packages containing radiopharmaceuticals with external surface removable contamination levels that exceeded federal limits.

The contamination was confined to the facility, the surface of the packages, and a small area outside a vent.

Technetium-99m has a half-life of six hours and, as a result, the contamination levels declined significantly through the day of the rupture and the shipment of the contaminated packages. The half-life of a radioactive material is the length of time required to lose half of its radioactivity through decay. Because of the low levels of contamination involved, there was no significant health and safety hazard to pharmacy employees, staff members at hospitals receiving the shipments, or the general public.

The NRC responded to the event on August 31 and performed several inspections of the facility and investigated the incident in the following months.

In notifying the company of the proposed fine, NRC Regional Administrator Jim Dyer noted the company's corrective actions which included changing the manner in which radiopharmaceuticals

are heated and revising the emergency procedures.

However, Dyer said that the NRC had decided to propose the fine "because of your particularly poor performance during the vial rupture and subsequent evaluation of facility, staff and package contamination. This resulted in widespread contamination of your facility and the shipment of packages with removable surface contamination in excess of regulatory limits. In particular, without NRC input during the event, the ventilation system would have remained operational, continuing to spread contamination throughout the facility."

The company has until October 23 to pay the fine or to protest it. If the fine is protested and subsequently imposed by the NRC staff, the company may request a hearing.

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