LABORATORY ERROR, IRRADIATION EFFECTIVENESS PROBLEMS WITH ANTHRAX SAMPLE SHIPMENTS

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Failure of an irradiation procedure to inactivate *Bacillus anthracis* spores led to the shipment of viable spores to 70 labs in 20 U.S. sites and 5 foreign countries. The spores were prepared at the U.S. Army’s Life Sciences Testing Facility (LTSF), Dugway Proving Ground, Utah and shipped on April 29, 2015 by commercial courier as part of a Department of Defense (DoD) effort to develop new diagnostic tests to identify the agents of bioterrorism. All samples associated with the failed inactivation were recalled by DoD.

After one of the commercial laboratories involved in the study grew small amounts of *B. anthracis* from one of the samples, the Centers for Disease Control and Prevention (CDC) confirmed that the irradiation process did not completely inactivate the spores and that low levels of viable organism were present in the samples. CDC reported that the risk to laboratory workers who handled these samples was low, but not zero. Workers that manipulated samples outside of appropriate containment equipment and utilized procedures that may have created an aerosol which could cause inhalation anthrax were offered prophylaxis. Thirty-one personnel including 8 U.S. citizens and 23 DoD employees received post-exposure prophylaxis. No suspected or confirmed cases of anthrax have been reported in the potentially exposed lab workers.

Facilities that received sample shipments were instructed to destroy the samples by autoclaving, transferring them to a select agent-registered laboratory for destruction or retaining the samples if the facility is registered as a select agent laboratory for *B. anthracis*. The Federal Select Agent Program is working with affected sites and state and local authorities to account for all samples.

Laboratories that received *B. anthracis* samples from LTSF after June 1, 2014 were instructed to clean and decontaminate their facility. Recommendations for decontamination varied based on the lot number of samples received. The Environmental Protection Agency (EPA) suggested use of products currently registered for use against *B. anthracis*, but several agents including ethylene oxide, paraformaldehyde, hydrogen peroxide, peracetic acid, and sodium hypochlorite are not registered for use against *B. anthracis*. Use of unregistered products for anthrax decontamination requires a Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) crisis exemption. EPA staff will work with state and local authorities to develop and approve decontamination plans.

Facilities receiving the samples were located in California, Utah, Texas, Tennessee, Virginia, Massachusetts, Wisconsin, Maryland, New Jersey, New York, Delaware, Washington, Illinois, Florida, Arizona, Ohio, North Carolina, Rhode Island, Pennsylvania, Washington D.C., Japan, United Kingdom, Korea, Australia, and Canada.