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Highlights

Highlights of [GAO-05-493T](#), a testimony before Chairman, Subcommittee on National Security, Emerging Threats, and International Relations, House Committee on Government Reform, House of Representatives

Why GAO Did This Study

In September and October 2001, letters laced with *Bacillus anthracis* (anthrax) spores were sent through the mail to two U.S. senators and to members of the media. These letters led to the first U.S. cases of anthrax disease related to bioterrorism. In all, 22 individuals, in four states and Washington, D.C., contracted anthrax disease; 5 died. These cases prompted the Subcommittee to ask GAO to describe and assess federal agencies' activities to detect anthrax in postal facilities, assess the results of agencies' testing, and assess whether agencies' detection activities were validated.

What GAO Recommends

GAO recommends that the Department of Homeland Security (DHS) develop a coordinated approach to working with federal agencies, so that appropriate validation studies of various activities involved in detecting anthrax are conducted. The DHS Secretary should also ensure that an agreed-on definition of validation is developed; appropriate investments are made to explore improved sampling strategies; and agencies' policies, procedures, and guidelines reflect the results of all these efforts. DHS stated that while it has the overall responsibility for coordination, EPA and HHS have the lead roles in responding to biological attacks. DHS said that it would coordinate with EPA to ensure that appropriate investments are made to explore improved sampling.

www.gao.gov/cgi-bin/getrpt?GAO-05-493T.

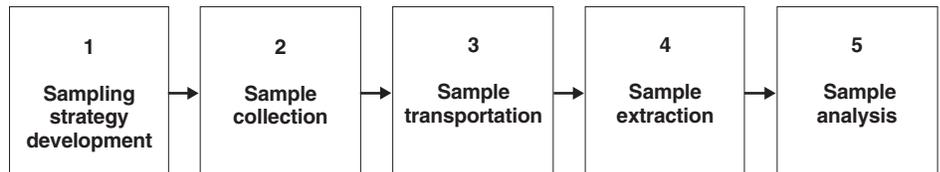
To view the full product, including the scope and methodology, click on the link above. For more information, contact Keith Rhodes, 202-512-6412, rhodesk@gao.gov.

ANTHRAX DETECTION

Agencies Need to Validate Sampling Activities in Order to Increase Confidence in Negative Results

What GAO Found

The U.S. Postal Service, Centers for Disease Control and Prevention (CDC), and Environmental Protection Agency (EPA) conducted several interdependent activities, including sample collection and analytic methods, to detect anthrax in postal facilities in 2001. They developed a sampling strategy and collected, transported, extracted, and analyzed samples. They primarily collected samples from specific areas, such as mail processing areas, using their judgment about where anthrax would most likely be found—that is, targeted sampling. The agencies did not use probability sampling in their initial sampling strategy. Probability sampling would have allowed agencies to determine, with some defined level of confidence, when all results are negative, whether a building is contaminated. This is important, considering that low levels of anthrax could cause disease and death in susceptible individuals.



Source: GAO analysis of CDC, EPA, and USPS data.

The results of the agencies' testing in 286 postal facilities were largely negative—no anthrax was detected. But negative results do not necessarily mean that a facility is free from anthrax. In addition, agencies' detection activities (for example, sample collection and analytical methods) were not validated. Validation is a formal, empirical process in which an authority determines and certifies the performance characteristics of a given method. Consequently, the lack of validation of agencies' activities, coupled with limitations associated with their targeted sampling strategy, means that negative results may not be reliable.

In preparing for future incidents, the agencies have (1) made some changes based on what has been learned about some of the limitations of their sampling strategies, (2) made some revisions to their guidelines, and (3) funded some new research. In addition, the Department of Homeland Security (DHS) has taken on the role of coordinating agencies' activities and has undertaken several new initiatives related to anthrax and other biothreat agents. However, while the actions DHS and other agencies have taken are important, they do not address the issue of validating all activities related to sampling. Finally, the agencies have not made appropriate and prioritized investments to develop and validate all activities related to anthrax and other biothreat agents.