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ANTHRAX

DHS Faces Challenges in Validating Methods for Sample Collection and Analysis

Highlights of GAO-12-488, a report to congressional requesters

Why GAO Did This Study

In 2005, assessing federal agencies' activities for detecting *Bacillus anthracis* in postal facilities, GAO reported that the test results of their sampling were largely negative. GAO found that the agencies had not used validated sampling methods and approaches that would have given a defined level of confidence for negative results. Consequently, GAO recommended several actions. In this study, GAO was asked to identify the extent to which (1) DHS's actions have addressed GAO's recommendations regarding sampling, (2) the environmental sampling methods for *B. anthracis* spore detection in initial public health sampling and microbial forensic investigations have been validated, and (3) any challenges remain to completing validation. GAO analyzed agency documents and interviewed agency officials.

What GAO Recommends

To ensure validated sampling methods and approaches are available for decision makers to respond to an indoor *Bacillus anthracis* release, DHS should (1) update the strategic plan and its roadmap with an agreed scope and timelines, and (2) complete the validation project. The Secretary of HHS and the Administrator of EPA should support DHS's goal of achieving validated sampling methods and a statistically based sampling approach. DHS agreed with our recommendations; EPA and HHS disagreed with our recommendation to them, stating that such an approach was not feasible or necessary. We continue to believe a validated statistical sampling approach will provide a broader range of options for decision makers responding to future incidents.

View GAO-12-488. For more information, contact Timothy M. Persons, Chief Scientist, at (202) 512-6412 or personst@gao.gov.

What GAO Found

A workgroup—led by the U.S. Department of Homeland Security (DHS) and made up of DHS and the Centers for Disease Control and Prevention (CDC), the Environmental Protection Agency (EPA), the Federal Bureau of Investigation (FBI), and the National Institute of Standards and Technology (NIST)—has attempted to address GAO's recommendations to (1) validate environmental sampling methods for detecting *Bacillus anthracis* and (2) conduct studies to develop probability-based sampling approaches for indoor environments. This workgroup has taken some actions to validate environmental sampling methods (collection, transportation, preparation, analysis) and develop statistically based sampling approaches that will provide confidence statements when test results are negative. These activities were projected to be completed by fiscal year 2013, but delays are now expected.

While progress has been made in validating sampling methods for detecting *Bacillus anthracis* spores in indoor environments, their validation is not yet complete. Some studies have not begun. Although more is known about the methods' performance characteristics—such as their limits of detection—other aspects of the methods are unknown, such as false negative rates. CDC has validated the preparation and analysis but not the collection methods for the swab and wipe. CDC states that field validation would be too difficult and laboratory validation of collection methods is not required. However, experts GAO talked to stated that collection methods could be validated in a laboratory.

Agencies that perform environmental sampling take the lead in validating the sampling methods. The FBI does not typically use CDC's environmental sampling methods and validating its methods is outside the scope of the DHS-led workgroup. The FBI's environmental sampling methods are not validated but the agency relies on DHS's National Bioforensic Analysis Center (NBFAC) to validate its microbial forensic analytical methods. Thus, the FBI, through NBFAC, and CDC are attempting to validate analytical methods for *Bacillus anthracis* but neither is validating the collection methods. Nevertheless, improvements in sample collection procedures for the swab and wipe could be useful to the FBI in developing its sampling plans or in evaluating its sampling methods.

The workgroup must address several remaining challenges before the validation project can be completed: (1) clarifying the strategic plan's scope—some agencies believe it is overly ambitious and differ on whether it includes linking sampling results to a risk-based decision process—and determining whether the workgroup is to continue; (2) reaching consensus on the range of sampling approaches that should be available to decision makers in different phases of a response; (3) establishing realistic estimates of the time for completing prioritized validation activities; (4) addressing scientific gaps, such as assessing risk in the absence of dose-response data; and (5) ensuring the availability of funds for critical tasks. While validating the methods provides information on performance characteristics, human health risks from any particular level of exposure remain uncertain. Since the workgroup has invested about $12 million and considerable resources over about 7 years, it would be prudent for it to complete prioritized tasks. Thus, the workgroup may wish to consider carefully what work is needed and think strategically in terms of its investments and their potential benefits.