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Homeland Security, Committee on  
Appropriations, House of Representatives

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# ANTHRAX DETECTION

## DHS Cannot Ensure That Sampling Activities Will Be Validated

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Applied Research and Methods



G A O

Accountability \* Integrity \* Reliability

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Highlights of [GAO-07-687T](#), a testimony before the Subcommittee on Homeland Security, Committee on Appropriations, House of Representatives

## Why GAO Did This Study

In September and October 2001, contaminated letters laced with *Bacillus anthracis* were sent through the mail to two U.S. senators and members of the media. Postal facilities in New Jersey, Washington, D.C., and elsewhere became heavily contaminated. The anthrax incidents highlighted major gaps in civilian preparedness to detect anthrax contamination in buildings. GAO was asked 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 is not making any new recommendations.

[www.gao.gov/cgi-bin/getrpt?GAO-07-687T](http://www.gao.gov/cgi-bin/getrpt?GAO-07-687T).

To view the full product, including the scope and methodology, click on the link above. For more information, contact Keith Rhodes at (202) 512-6412 or [rhodesk@gao.gov](mailto:rhodesk@gao.gov).

# ANTHRAX DETECTION

## DHS Cannot Ensure That Sampling Activities Will Be Validated

### What GAO Found

Federal agencies conducted several sampling activities, including developing a sampling strategy and collecting, transporting, extracting, and analyzing 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, which would have allowed agencies to determine, with some defined level of confidence, when all results are negative, whether a building is contaminated.

The results of the agencies' testing in 286 postal facilities were largely negative—no anthrax was detected. However, agencies did not use validated sample collection and analytical methods. Thus, there can be little confidence in negative results. With a validated process, agencies and the public could be reasonably confident that any test results generated by that process would be reliable.

The Department of Homeland Security (DHS) is the principal agency responsible for coordinating the federal response. Thus, in its 2005 report, GAO recommended that the Secretary of Homeland Security develop a coordinated approach to improve the overall process for detecting anthrax and increase confidence in negative test results generated by that process. DHS stated that while it has overall responsibility for coordinating the federal response during future biological attacks, other agencies have the lead responsibility for validation. Therefore, uncertainty over which agency would take the lead role—that is, who is in charge—in improving the overall process for detecting anthrax, including validation of the methods, continued after GAO issued its report.

On the basis of these uncertainties, GAO recommended in its May 9, 2006, testimony that DHS's approach to validating the overall process start with a strategic plan that would include a road map outlining how individual agencies' efforts would lead to the validation of the individual activities as well as the overall process, noting that such a plan would assist DHS in monitoring progress and measuring agency performance toward improving the detection of anthrax and other prioritized threat agents.

While DHS generally agreed with these recommendations, it stated that it cannot ensure validation studies would be done, since "there are legal limitations in DHS authority to direct the activities of other agencies." Also, since validation would require a sustained effort over a long period, DHS noted that it could not mandate commitment of other agencies' funds, over which it has no control.

Until responsibility is accepted for ensuring that sampling activities will be validated, the fate of the validation process will remain uncertain. Without validation, if another anthrax attack were to occur tomorrow, federal civilian agencies would not be able to conclude with any given level of statistical confidence, in cases of negative results, that a building is free of contamination.

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Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss our findings on anthrax detection testing. The threat of bioterrorism has been recognized for a considerable time. Long before the anthrax attacks of 2001, several hoax letters indicating the presence of anthrax had been mailed to federal and state agencies, as well as to private sector organizations. These events raised the possibility that facilities could become contaminated and would therefore have to be evaluated for environmental contamination. However, federal agencies were not fully prepared to deal with environmental contamination—that is, anthrax released through the mail—including the potential for multiple dispersals in indoor environments.

In September and October 2001, contaminated letters laced with *Bacillus anthracis* were sent through the mail to two U.S. senators, Thomas Daschle and Patrick Leahy, and members of the media.<sup>1</sup> The postal facilities in New Jersey and Washington, D.C., that processed the senators' letters became heavily contaminated. Other mail routed through these facilities, as well as additional facilities in the postal network, also became contaminated. In addition, numerous federal facilities in the Washington, D.C., area were later found to be contaminated. The letters led to the first cases of anthrax disease related to bioterrorism in the United States. In all, 22 individuals contracted anthrax disease in four states—Connecticut, Florida, New Jersey, and New York—as well as in Washington, D.C. Five of these 22 individuals died.

The anthrax incidents in September and October 2001 highlighted major gaps in civilian preparedness to detect and respond. In today's testimony, I will discuss our findings concerning anthrax sampling activities, recommendations we made, and a major issue we identified—the Department of Homeland Security (DHS) cannot ensure and guarantee that sampling activities will be validated.

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<sup>1</sup>*Bacillus anthracis* is the microorganism that causes the disease known as anthrax.

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In developing this testimony, we relied on our prior work.<sup>2</sup> We conducted our review in accordance with generally accepted government auditing standards.

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## Results in Brief

Federal agencies responsible for responding to the 2001 anthrax incidents adopted a targeted sampling strategy that they based on their best judgment at the time. They primarily collected samples from specific areas, such as mail-processing areas, using their judgment about where anthrax would most likely be found. Such judgments can be effective in some situations—for example, in determining whether a facility is contaminated when information on the source of potential contamination is definitive. However, in the case of a negative finding, when the source of potential contamination is not definitive, the basic question—Is this building contaminated?—will remain unanswered. Therefore, in the case of a negative result, a different strategy, probability sampling, is needed. Probability sampling would have allowed agencies to determine whether the building was contaminated with some defined level of confidence.

The federal agencies—CDC, EPA, and USPS—involved in sampling the postal facilities in 2001 to detect anthrax undertook several activities. These included development of a sampling strategy followed by collection of samples using a variety of methods, transporting and extracting, and analysis of the samples. Neither these activities nor the overall process was validated for anthrax testing. Consequently, the agencies were challenged by the limited information available for reliably choosing one method over another and the lack of information on the detection limit to use when evaluating negative results.

The results of the CDC, EPA, and USPS testing in 286 postal facilities were largely negative.<sup>3</sup> Of the 286 facilities, 23 tested positive. For 2 of these 23 facilities, test results were negative at first but positive on a subsequent

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<sup>2</sup>GAO, *Anthrax Detection: Agencies Need to Validate Sampling Activities in Order to Increase Confidence in Negative Results*, [GAO-05-251](#) (Washington D.C.: Mar 27, 2005); *Anthrax Detection: Agencies Need to Validate Sampling Activities in Order to Increase Confidence in Negative Results*, [GAO-05-493T](#) (Washington D.C.: Apr. 5, 2005); and *Anthrax: Federal Agencies Have Taken Some Steps to Validate Sampling Methods and to Develop a Next-Generation Anthrax Vaccine*, [GAO-06-756T](#) (Washington D.C.: May 9, 2006).

<sup>3</sup>While the Federal Bureau of Investigation (FBI) also collected samples, we did not include the results of its testing due to its ongoing criminal investigation.

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testing. However, in 1 of these facilities—the Wallingford, Connecticut, facility—it was not until the fourth testing that positive results were obtained.

The federal agencies' activities to detect anthrax contamination were not validated. Without validation, the sampling activities could have been based on false assumptions.

For example, the lack of validated sample collection methods means that it is not known how many spores a particular method will collect from a surface and, thus, which method is appropriate for a given situation. Using an ineffective method or procedure could result in a finding of no contamination when in fact there is contamination—a false negative.

Validating the overall process, as well as the individual activities, is important because operational and health-related decisions are made on the basis of testing results generated by that process. In addition, validation would offer assurance that the results of using a particular method, which is part of that process, are robust enough to be reproduced, regardless of which agency, contractor, or laboratory is involved. Thus, agencies and the public could be reasonably confident that any test results generated by a process that includes that method would be reliable and, in particular, that any negative results would mean that a sample was free from contamination (within the method's limits of detection).

Given the lack of validated methods for detecting anthrax contamination in facilities, we recommended that the Secretary of Homeland Security develop a coordinated approach to (1) improve the overall process for detecting anthrax and (2) increase confidence in negative test results generated by that process. This approach would include working with agencies to ensure that appropriate validation studies of the overall process of sampling activities, including the methods, are conducted. Specifically, we recommended that the Secretary

1. take a lead role in promoting and coordinating the activities of the various agencies that have the technical expertise related to environmental testing;
2. ensure that a definition of validation is developed and agreed on;
3. guarantee that the overall process of sampling activities, including methods, is validated so that performance characteristics, including

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limitations, are clearly understood and results can be correctly interpreted;

4. see that appropriate investments are made in empirical studies to develop probability-based sampling strategies that take into account the complexities of indoor environments;
5. ensure that appropriate, prioritized investments are made for all biothreat agents; and
6. make sure that agency policies, procedures, and guidelines reflect the results of such efforts.<sup>4</sup>

When we issued our report, CDC, DHS, and USPS agreed with our conclusion—that methods for detecting anthrax contamination in facilities were not validated—and with the thrust of our recommendations—calling for a coordinated, systematic effort to validate the methods to be used for such testing. But they (1) disagreed with or expressed concern about our conclusions or the recommendation dealing with targeted versus probability sampling, (2) emphasized that validated testing methods for anthrax were not available in 2001 and that federal and state organizations did the best they could under the circumstances, and (3) identified factors or issues that need to be considered in validating testing methods.

In addition, uncertainty over which agency would take the lead role—that is, who is in charge—in improving the overall process for detecting anthrax, and how studies were to be funded, continued after we issued our report. DHS stated that while it has overall responsibility for coordinating the federal response during future biological attacks, EPA had the “primary responsibility for establishing the strategies, guidelines, and plans for the recovery from a biological attack,” while the Department of Health and Human Services (HHS) had the lead role for any related public health response and guidelines. DHS also stated that it coordinated regularly with EPA’s National Homeland Research Center to exchange information on research needs and to discuss priorities and gaps for a wide range of security-related research areas. DHS stated that it would coordinate with EPA to ensure that appropriate investments were made to explore improved sampling. However, it is unclear to us how DHS would ensure that appropriate prioritized investments are made for all biothreat agents and how such priorities and gaps would be addressed.

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<sup>4</sup>[GAO-05-251](#), pp. 82–83.

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On the basis of these uncertainties, we recommended in our May 9, 2006, testimony that DHS's approach to validating the overall process start with a strategic plan that includes a road map outlining how individual agencies' efforts would lead to the validation of the individual activities as well as the overall process, noting that such a plan would assist DHS in monitoring progress and measuring agency performance toward improving the detection of anthrax and other prioritized threat agents.<sup>5</sup>

On May 19, 2006, DHS officials stated that DHS cannot ensure and guarantee that validation studies would be done, since this is a shared responsibility among different agencies. DHS stated that "there are legal limitations in DHS authority to direct the activities of other agencies." Also, since validation would require a sustained effort over a long period, these officials noted that they could not mandate commitment of other agencies' funds, because of legal and budgetary limitations.

DHS officials told us in July 2006 that they recognize that DHS is the principal agency responsible for coordinating the federal response and they would work with a good faith effort toward developing a strategy for validation studies and a road map by the end of calendar year 2006, outlining how individual agencies' efforts would lead to the validation of the overall sampling process. On March 27, 2007, DHS told us that it had developed a working draft of the strategic plan and the road map by December 2006 but it could not share these with us because they were not final.<sup>6</sup>

Until responsibility is accepted for ensuring that sampling activities will be validated, the fate of the validation process will remain uncertain. Without validation, if another anthrax attack were to occur tomorrow, federal civilian agencies would not be able to conclude with any given level of statistical confidence, in cases of negative results, that a building is free of contamination.

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## Background

In October 2001, an American Media Incorporated employee died from inhalation anthrax disease. In the same month, contaminated letters laced

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<sup>5</sup>GAO-06-756T

<sup>6</sup>Also on March 27, 2007, DHS officials gave us a short status report on the Anthrax Sampling Working Group. However, we could not evaluate the significance of the activities it summarized without the strategic plan.

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with *Bacillus anthracis*, or anthrax spores, were sent through the mail to Senators Thomas Daschle and Patrick Leahy. The response to the incident in the American Media Incorporated building in Florida in September 2001 led to the identification of mail as the potential source of contamination; eventually, it led to the sampling of the postal facilities. The agencies began sampling on October 12, 2001, in Florida and stopped on April 21, 2002, when the Wallingford, Connecticut, facility was sampled for the last time. The letters led to the first cases of anthrax disease related to bioterrorism in the United States. In all, 22 individuals contracted anthrax disease in Connecticut, Florida, New Jersey, and New York, as well as in Washington, D.C., and 5 died.

The federal agencies involved in the response in the postal facilities have different responsibilities. CDC and state and local health departments primarily provided public health advice and assistance to USPS. CDC has primary responsibility for national surveillance of specific diseases, including anthrax; it also conducts epidemiologic investigations to determine, among other things, the source of the disease, and it participates in environmental sample collection and analysis activities. The FBI is responsible for criminal investigations involving interstate commerce and the mail and crimes committed on federal property. EPA is the nation's lead agency for responding to a release of hazardous substances into the environment and subsequent decontamination.

On October 8, 2001, the President created the Office of Homeland Security to develop and coordinate a comprehensive national strategy for dealing with domestic terrorist threats or attacks. The office, which had limited involvement in the 2001 response, was superseded by the Homeland Security Act of 2002, which transferred many of its functions to DHS, which became operational in 2003. DHS was created by combining many previously separate agencies and is assigned a lead role in coordinating the efforts of federal agencies that respond to acts of terrorism in the United States.

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## Major Findings

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### Sampling Strategy

The federal agencies primarily used a targeted strategy—they collected samples from specific areas considered more likely to be contaminated, based on judgments. Such judgments can be effective in some situations—for example, in determining whether a facility is contaminated when information on the source of potential contamination is definitive.

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However, in the case of a negative finding, when the source of potential contamination is not definitive, the basic question—Is this building contaminated?—will remain unanswered.

CDC and USPS officials said that they used a targeted strategy for several reasons, including limitations on how many samples could be collected and analyzed. They also said that in 2001, they lacked the data from empirical research to develop an initial sampling strategy that incorporated probability sampling. We disagree with this interpretation. Probability sampling is statistically based and does not depend solely on empirical criteria regarding the details of possible contamination.

The situation in 2001 was unique, and the agencies were not fully prepared to deal with environmental contamination. In the future, if the agencies decide to use a targeted rather than a probability sampling strategy, they must recognize that they could lose a number of days if their targeted sampling produces negative test results. In this case, additional samples would have to be collected and analyzed, resulting in the loss of critical time for public health interventions. This was so at the Wallingford postal facility in the fall of 2001, when about 3 weeks elapsed between the time the first sampling took place and the results of the fourth testing, which revealed positive results. Furthermore, about 5 months elapsed between the time of the first sampling event and the time anthrax was found in the Wallingford facility's high-bay area.

Therefore, strategies that include probability sampling need to be developed in order to provide statistical confidence in negative results. Further, even if information on all the performance characteristics of methods is not yet available, a probability sampling strategy could be developed from assumptions about the efficiency of some of the methods. And even if precise data are not available, a conservative, approximate number could be used for developing a sampling strategy. This would give agencies and the public greater confidence in negative test results than was associated with the sampling strategy used in 2001.

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## Sampling Methods

CDC, EPA, and USPS, the federal agencies involved in sampling the postal facilities in 2001 to detect anthrax, undertook several activities. These included development of a sampling strategy followed by collecting samples, using a variety of methods, and transporting, extracting, and analyzing the samples. Neither these activities nor the overall process was validated for anthrax testing. Consequently, the agencies were challenged by limited information for reliably choosing one method over another and

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by lack of information on the detection limit to use when evaluating negative results.

Federal agencies used different methods for collecting samples. While USPS generally used dry swabs to collect samples (the least effective method), CDC and EPA used multiple methods—dry swabs, premoistened swabs, wet wipes, and a high-efficiency particulate air (HEPA) vacuum—in various combinations or alone.

However, none of the agencies' collection methods were evaluated for anthrax detection in environmental samples. In the absence of empirical research, agencies had no information available for reliably choosing one method over another and no information on the limits of detection to use when evaluating negative results.

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## Results of Testing

The majority of the samples collected from the postal facilities tested negative. In all, federal agencies collected about 10,000 samples during initial testing. It is interesting that of the 9,807 samples that the agencies collected, more than 98 percent, or 9,648, were negative; a little more than 1 percent, or 159, were positive. In all, 286 facilities were tested for anthrax contamination. Of these, Brentwood, Trenton, and Morgan were primary facilities; that is, these 3 facilities processed the original letters containing the anthrax.

The results of the CDC, EPA, and USPS testing in 286 postal facilities were largely negative. Of 286 facilities, 23 tested positive. For 2 of these 23 facilities, test results were negative at first but positive on a subsequent testing. However, in 1 of these facilities—the Wallingford, Connecticut, facility—it was not until the fourth testing that positive results were obtained.

Testing results differed between the primary facilities and Wallingford. In the 3 primary facilities, results were positive each time a facility was tested, with the important exception of the two quick tests in Brentwood. In Wallingford, considered less likely to be contaminated, results were positive only on the fourth sampling. These results underscore the importance of retesting and cast doubt on the efficiency of the judgmental sampling strategy.

Of the 263 facilities that tested negative, only 9 were sampled more than once. A facility in West Trenton tested negative, even though an employee had contracted cutaneous anthrax. The facility in West Trenton was tested

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twice by the FBI and once by CDC, during which a total of 57 samples were collected, with negative results.

Final, or confirmed, results will be negative if contamination is not present in a facility. However, a result can be erroneously negative for several other reasons, such as (1) the sampling method was not efficient enough, (2) samples were not collected from places where contamination was present, (3) not enough samples were collected, (4) not enough spores were recovered from the sample material, or (5) analysis of the sample extract was not sensitive enough to detect anthrax spores that were present.

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## Conclusions

The agencies that sampled postal facilities in 2001—USPS, CDC, and EPA—did not use validated sample collection and analysis methods to perform their tests. According to these agencies, validated methods were not available at that time. They conducted several interdependent activities, including sample strategy development, followed by sample collection, transportation, and analysis of the samples to detect anthrax. Neither these activities nor the overall process had been validated for anthrax testing.

Validation is a formal, empirical process in which an authority determines and certifies the performance characteristics of a given method. Therefore, investments are also needed to validate these methods, as well as the overall anthrax detection process. Validating the overall process, as well as the individual activities, is important because operational and health-related decisions are made on the basis of testing results that the process generates.

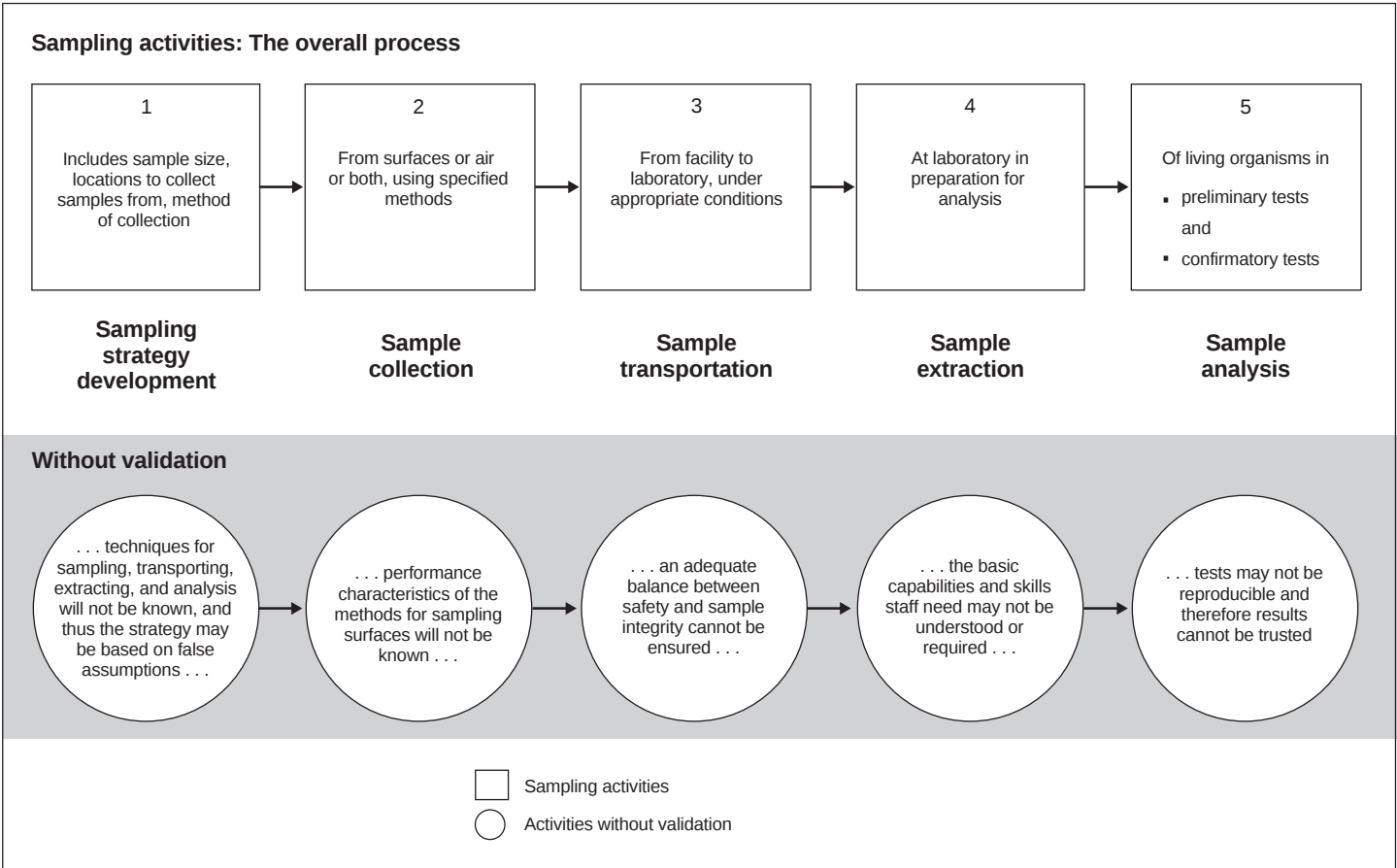
CDC and USPS officials said that they used targeted sampling; that is, they collected samples from specific areas considered—based on agencies' technical judgments—more likely to be contaminated. Such judgments can be effective in some situations, for example, in determining the source of contamination in a disease outbreak investigation, provided results are positive. However, if the results are negative, the basic question—Is this building contaminated?—cannot be answered with statistical confidence.

When the level of contamination is extremely high and dispersed in a facility, the method of sampling (for example, wipes versus swabs) is not as critical if the purpose is to find some contaminant. However, at lower levels, a way of interpreting the significance of negative results is needed, and this requirement emphasizes the importance of validation of the

methods and the need for statistically based sampling strategies. This emphasizes the need for methods that have been validated, and sampling strategies that are likely to find contamination at low levels. Probability-based sampling does allow conclusions, at specific levels of confidence, about testing results.

Using a probability-based sampling strategy, together with validated methods for detecting contamination, would provide a known level of confidence with which to interpret any negative results. This would allow agencies to be more definitive in determining necessary actions. Figure 1 shows how lack of validation could affect individual activities—including the sampling strategy—as well as the results generated by the overall process.

Figure 1: Lack of Validation Can Affect Individual Activities and the Overall Process



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

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The lack of validated methods for assessing contamination in postal facilities impeded the agencies in responding to the incidents. The significance of the lack of validated methods was exemplified in the case of the one postal facility where negative preliminary results were obtained by field-based methods of analysis, with limitations that appear not to have been well understood by some agencies. Negative results do not necessarily mean a facility is free from contamination. As we reported, results can be negative if (1) samples were not collected from places where anthrax was present, (2) the detection limit of the method was greater than the actual contamination level, (3) not enough samples were recovered from the sample material, (4) analysis of the sample extract did not detect spores, or (5) anthrax was not present in the facility.

In addition, while the 2001 events involved anthrax, many other biothreat agents exist. Differences in their characteristics mean different solutions. Accordingly, efforts to develop sampling strategies and to validate methods should address requirements specific to those threat agents as well. However, since addressing other agents would consume resources and time, all these efforts should be prioritized in a long-term strategy.

The several agencies that dealt with the anthrax attacks generally worked well together, but we have identified areas that would have benefited from one agency's taking the lead in coordinating the response. Given the mission of DHS and its responsibilities, it appears that DHS is now well positioned to take a lead role in promoting and coordinating the activities of the various agencies that have technical expertise related to environmental testing. In addition, it is important that all participating agencies recognize and support DHS in that role and that they have an effective structure for participating in identifying and addressing the appropriate issues.

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## Recommendations for Executive Action

Given the lack of validated methods for detecting anthrax contamination in facilities, we recommended in our 2005 report that the Secretary of Homeland Security develop a coordinated approach to (1) improve the overall process for detecting anthrax and (2) increase confidence in negative test results generated by that process. This approach would include working with agencies to ensure that appropriate validation studies of the overall process of sampling activities, including the methods, are conducted. Specifically, we recommended that the Secretary

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1. take a lead role in promoting and coordinating the activities of the various agencies that have the technical expertise related to environmental testing;
  2. ensure that a definition of validation is developed and agreed on;
  3. guarantee that the overall process of sampling activities, including methods, is validated so that performance characteristics, including limitations, are clearly understood and results can be correctly interpreted;
  4. see that appropriate investments are made in empirical studies to develop probability-based sampling strategies that take into account the complexities of indoor environments;
  5. ensure that appropriate, prioritized investments are made for all biothreat agents; and
  6. make sure that agency policies, procedures, and guidelines reflect the results of such efforts.

When we issued our report, CDC, DHS, and USPS agreed with our conclusion—that methods for detecting anthrax contamination in facilities were not validated—and with the thrust of our recommendations—calling for a coordinated, systematic effort to validate the methods to be used for such testing. But they (1) disagreed with or expressed concern about our conclusions or the recommendation dealing with targeted versus probability sampling, (2) emphasized that validated testing methods for anthrax were not available in 2001 and that federal and state organizations did the best they could under the circumstances, and (3) identified factors or issues that need to be considered in validating testing methods.

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## Who Is Responsible for Ensuring and Guaranteeing That Anthrax Detection Methods Will Be Validated?

After we issued our 2005 report, it became evident that there was uncertainty over which agency would take the lead role in improving the overall process for detecting anthrax and how studies were to be funded. For example, DHS stated that while it has overall responsibility for coordinating the federal response during future biological attacks, EPA had the “primary responsibility for establishing the strategies, guidelines, and plans for the recovery from a biological attack” and HHS had the lead role for any related public health response and guidelines. DHS also stated that it coordinated regularly with EPA’s National Homeland Research Center to exchange information on research needs and to discuss priorities and gaps for a wide range of security-related research areas.

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DHS stated that it would coordinate with EPA to ensure that appropriate investments were made to explore improved sampling. However, it is unclear to us how DHS would ensure that appropriate prioritized investments are made for all biothreat agents and how such priorities and gaps would be addressed.

On the basis of these uncertainties, we recommended in our May 9, 2006, testimony that DHS's approach to validating the overall process should start with a strategic plan that includes a road map outlining how individual agencies efforts would lead to the validation of the individual activities as well as the overall process, noting that such a plan would assist DHS in monitoring progress and measuring agency performance toward improving the detection of anthrax and other prioritized threat agents.

On May 19, 2006, DHS officials stated that while they concurred with the recommendations from our report and accepted the overall responsibility to ensure the methods will be validated, they stated that "there are legal limitations in DHS authority to direct the activities of other agencies." They said that while they take a lead role in coordinating the meetings and in bringing people from different agencies together, they cannot guarantee that the overall process of sampling will be validated because different agencies have responsibility for different aspects of validation, and DHS's control over other agencies actions and budgets is ultimately limited. They stated that DHS cannot ensure and guarantee that validation studies would be done, since this is a shared responsibility among different agencies. Also, since validation would require a sustained effort over a long period, DHS noted that it could not mandate commitment of other agencies' funds, over which it has no control.

DHS officials told us in July 2006 that they recognize that DHS is the principal agency responsible for coordinating the federal response and they would work with a good faith effort toward developing a strategy for validation studies and a road map by the end of calendar year 2006 outlining how individual agencies' efforts would lead to the validation of the overall sampling process. On March 27, 2007, DHS told us that it had developed a working draft of the strategic plan and the road map by December 2006 but it could not share these with us because they were not final.

Until responsibility is accepted for ensuring that sampling activities will be validated, the fate of the validation process will remain uncertain. Without validation, if another anthrax attack were to occur tomorrow, federal

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civilian agencies would not be able to conclude with any given level of statistical confidence, in cases of negative results, that a building is free of contamination.

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Mr. Chairman, this concludes my prepared remarks. I would be happy to respond to any questions that you or other members of the subcommittee may have at this time.

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## Contacts and Acknowledgments

For further information regarding this statement, please contact Keith Rhodes at (202) 512-6412, or [rhodesk@gao.gov](mailto:rhodesk@gao.gov), or Sushil K. Sharma, Ph.D., Dr.PH, at (202) 512-3460, or [sharmas@gao.gov](mailto:sharmas@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. William Carrigg, Barbara Chapman, Crystal Jones, Penny Pickett, and Elaine Vaurio made key contributions to this statement.

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