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U.S. POSTAL SERVICE

Issues Associated with Anthrax Testing at the Wallingford Facility

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May 19, 2003

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Highlights

Highlights of GAO-03-787T, a testimony before the Subcommittee on National Security, Emerging Threats, and international Relations, House Committee on Government Reform

Why GAO Did This Study

The anthrax attacks of 2001 resulted in 23 cases of the disease, 5 deaths, and the contamination of numerous U.S. Postal Service facilities, including the Southern Connecticut Processing and Distribution Center in Wallingford, Connecticut (the Wallingford facility). But none of the workers at the Wallingford facility contracted the disease from the anthrax contamination. As a result, GAO was asked to examine the adequacy of methods used to determine whether the Wallingford facility and other postal facilities were contaminated. In this testimony, GAO presents its preliminary findings concerning the test results for the Wallingford facility: (1) the collection of samples to detect anthrax, (2) the meaning of the test results, and (3) the communication of the test results to workers.

What GAO Recommends

In addition to its April 2003 recommendations, for those facilities that were deemed to be free of anthrax spores based solely on a single negative result, GAO recommends that the Postmaster General work with CDC, EPA, OSHA, and other relevant agencies, and union representatives to (1) reassess the risk level associated with contamination, (2) reconsider the advisability of retesting, and (3) communicate any relevant health-related information to postal workers and the public.

www.gao.gov/cgi-bin/getrpt?GAO-03-787T.

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.

What GAO Found

At the Wallingford facility, it took four attempts before anthrax contamination was eventually identified. The first two attempts by U.S. Postal Service contractors collected samples at various places in the facility, using dry swabs, the least effective method for sample collection. The Postal Service nationwide sampling plan required that contractors use dry swabs to collect anthrax samples at more than 280 facilities, including Wallingford. But the Centers for Disease Control and Prevention (CDC), in commenting on the plan, had recommended that the Postal Service use other sampling methods. Nevertheless, the Postal Service did not revise its sampling plan, and, with a few exceptions, has not retested the other facilities that had negative test results. In the third attempt, CDC and the Agency for Toxic Substance and Disease Registry also found no contamination using wet swabs, but in the fourth attempt—using wet wipes and HEPA vacuums to collect the samples—they found contamination in samples from mail-sorting machines.

Anthrax test results, whether qualitative (positive or negative) or quantitative, cannot be interpreted as a health risk, based on current scientific knowledge. Positive test results establish the presence of contamination, but only in the samples collected. Quantitative test results, although more definitive, only indicate the extent of contamination in the samples collected, not the amount present in the whole facility. Negative results, as the initial tests at the Wallingford facility demonstrated, do not necessarily mean that a facility is free from contamination. As EPA recently reported, knowledge of the "lethal dose" (the number of spores required to kill 50 percent of people exposed to airborne anthrax) is necessary for a credible health risk assessment. Although previous estimates of a lethal dose—8,000 to 10,000 spores—are being reconsidered, there is still no agreement on the lethal dose. However, some experts now agree that only a few spores could be harmful to a susceptible individual. As CDC also concluded, even with numbers of spores as high as those found in one sample from one mail-sorting machine at Wallingford—about 3 million spores—CDC did not know how to extrapolate the quantitative test results to an individual's risk for inhalation anthrax.

In an April 2003 report, GAO found that the Postal Service's communication of test results to workers at the Wallingford facility generally appears consistent with its guidelines. But the decision not to release the first positive quantitative test results, after a worker's union requested them, was not consistent with OSHA's requirement to disclose requested results. The Postal Service said it did not release the December 2001 quantitative results because it could not validate them, as required by its guidelines, which, however, do not define validation or use it appropriately. The Postal Service communicated the results to workers as "trace" and "a concentration of spores"—terms that did not provide workers with useful information needed to make health-related decisions. It has agreed to revise the guidelines as GAO recommended. Further communications appear warranted based on GAO's ongoing work.

May 19, 2003

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to present our findings on anthrax testing conducted by the U.S. Postal Service (USPS) and the Centers for Disease Control and Prevention (CDC) at the Southern Connecticut Processing and Distribution Center in Wallingford, Connecticut (the Wallingford facility). As you know, in September and October 2001, four letters containing anthrax spores were mailed to news media personnel and congressional officials. As a result, the letters contaminated numerous postal facilities and exposed several postal workers to anthrax.[1] Some of the workers became sick, and two died of inhalation anthrax. Three others also died from inhalation anthrax, including an elderly woman in Connecticut—a postal customer. After contamination was found in the Wallingford facility, a union official raised concerns regarding how postal managers communicated test results to workers. We have issued a report in this regard.[2]

Even though our analysis of the Wallingford incident is only one part of our larger study, it gives unique insight into the lessons that need to be learned from the response of the federal government, state health departments, and USPS to the anthrax attacks in the fall of 2001. All of these entities served either as direct responders or as advisors, or both; and all were creating or adapting guidelines as the crisis progressed. The situation was further complicated by an ongoing criminal investigation, coupled with a public health emergency.

The Wallingford facility was unique in that it did not directly handle the anthrax letters. Rather, it was cross-contaminated by them, with the largest number of

[1] Technically, the term "anthrax" refers to the disease caused by *Bacillus anthracis* and not the bacterium or its spores. In this testimony, we use the term "anthrax" for ease of reading and to reflect terminology commonly used in the media and by the general public.

spores being found in a sample collected from a single machine. There was, however, evidence that the spores had become airborne (re-aerosolized) since small numbers of spores were found in elevated areas—more than 20 feet—above the previously contaminated machines. In addition, while other facilities had workers and customers who suffered from either cutaneous or inhalation anthrax, the death of a postal customer served by the Wallingford facility underlines the insidious nature of anthrax and the difficulty in determining a lethal dose, since the elderly Connecticut woman died from anthrax when no evidence of anthrax could be found in either her home or places she frequented. To compound this, a single spore was found on a letter received by another postal customer in the community, and yet no other illnesses or deaths were reported. Further, the Wallingford facility was outside the predictive analysis (a mapping of the facilities predicted most likely to be contaminated) that USPS performed to determine the impact of the contaminated letters processed through facilities in Washington, D.C., and Trenton, New Jersey, on the rest of the postal distribution network. The unpredictability of both the lethality of anthrax and the route that contaminated mail might take, makes it extremely difficult to establish the health risks associated with a release of a biological agent inside a facility, such as anthrax, that serves the public. This difficulty underscores the need for a standardized and aggressive response, as well as forward planning, to protect facility workers and the public should an anthrax attack occur again.

As you know, determining whether or not a facility is contaminated with anthrax is critical. This is dependent upon the effectiveness of the methods used to detect anthrax. As a result, at your request, we are conducting a study to examine the adequacy of the methods used by involved contractors and federal agencies in determining whether postal facilities were contaminated. We will report the final results of this study at a later date.

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[2] U.S. General Accounting Office, *U.S. Postal Service: Better Guidance Is Needed to Improve Communication Should Anthrax Contamination Occur in the Future*, GAO-03-316 (Washington, D.C.: April 7, 2003).

In our testimony today, at your request, our remarks will focus on our preliminary findings regarding the test results for the Wallingford facility. Specifically, we will address the issues that arose concerning the following three areas: (1) the collection of environmental samples to detect anthrax contamination, (2) the meaning of the test[3] results from the samples (both qualitative and quantitative) with respect to the health risk of the workers, and (3) the communication of the test results. Our work thus far has involved interviews with officials from USPS, CDC, and experts in this area, reviews of relevant documents and literature, and review of the documents we were provided by USPS and CDC associated with the sampling done at the Wallingford facility during November 2001 through April 2002. We did not independently assess or verify any of the laboratory test results, sampling plans, or sampling methods to determine their adequacy or accuracy. Our work has been performed in accordance with generally accepted government auditing standards.

SUMMARY

Three issues emerged with regard to the collection of environmental samples at the Wallingford facility: (1) the methods used for sampling[4], (2) the locations from which samples were collected, and (3) how many samples were collected. USPS, in response to the anthrax attack of 2001, developed a plan to test over 280 facilities nationwide, including the Wallingford facility. This plan was precautionary and assumed that those facilities were probably not contaminated with anthrax. Further, this plan specified what sample collection methods to use, where to sample, and the number of samples to be collected, among other things. At the Wallingford facility, however, it took four attempts before contamination was eventually identified. USPS used its own contractors to collect a limited

[3] The terms "test" or "testing" refer to the laboratory analysis of the samples collected.
[4] Technically, the term "sampling" refers to a strategy to extract organisms that might be present in the environment. In this testimony, however, sampling refers to the number of samples collected, as well as other associated events, on a given day.

number of samples at various places in the facility.[5] In addition, USPS collected the samples using the dry swab method, which is the least effective method for collection of samples from surfaces. On November 9, CDC officials recommended that USPS use moistened swabs; however, USPS did not incorporate this recommendation into its sampling plan.[6] According to USPS officials, in the beginning, they mirrored the methods used by CDC in other postal facilities. USPS did not find contamination. However, after the death of the elderly Connecticut woman on November 21, 2001, CDC and the Agency for Toxic Substance and Disease Registry (ATSDR) eventually used targeted sampling, focusing on the mail-sorting machines, and different sampling methods—wet wipes and high efficiency particulate air (HEPA) vacuum. CDC and ATSDR, using a CDC-contracted laboratory, collected more than three times the number of samples previously collected by USPS and found contamination in some of the samples. Experts we consulted at the U.S. Army Medical Research Institute for Infectious Disease told us that before October 2001, they had found that dry swabs were ineffective at collecting spores and that spores could not be recovered efficiently from dry swabs. Finally, even though the contamination found at the Wallingford facility was unexpected, according to a USPS official, the nationwide plan was not revised because it was 60-days removed from the event, well past the perceived incubation period as far as health risk was concerned. This approach did not take into account the possibility that if spores are present in a facility, re-aerosolization can occur at any time if the site of contamination is disturbed. The USPS official also said that, with a few exceptions, he believed, of those facilities that had tested negative during the nationwide sampling, none had been retested. Thus, the negative findings from the first three sampling attempts at the Wallingford facility raise questions about the reliability of a single negative sampling result, especially one based upon the use of a method considered the least effective, as was the case in Wallingford.

[5] CDC officials told us that the number of samples collected on a given day was, in part, governed by the capacity of the state laboratories to process the samples.

Neither qualitative (positive or negative) nor quantitative test results from a qualified laboratory can be used to establish a health risk. Concerning qualitative results, positive results only show whether contamination is present in the samples collected. However, negative results do not necessarily mean that a facility is free from contamination. Quantitative test results only show the extent of contamination in the specific samples found to be positive—not how much anthrax is present in the facility. For example, in the Wallingford facility, the level of contamination found in a dust sample collected from a mail-sorting machine was about 3-million spores (5.5 million per gram of dust). However, with regard to the health risk to an individual, although this number was significantly higher than what was considered historically to be a lethal dose for an individual—8,000 to 10,000 spores—CDC did not know how to extrapolate the amount in a sample to a person's risk for inhalation anthrax.[7] EPA recently reported that in order to perform credible risk assessments, it is essential to identify the minimum number of spores needed to cause inhalation and cutaneous anthrax. Nevertheless, there is now a consensus among the experts that a few spores could be harmful to a susceptible individual, as may have been the case in the death of the Connecticut woman.

Three major communication issues arose at the Wallingford facility: (1) the timing of the release of the quantitative results; (2) reasons for USPS withholding the quantitative results from the workers, such as a lack of confirmation and validation of the test results; and (3) the terminology used to describe the extent of contamination to the workers. First, USPS did not communicate to the workers the quantitative test results of the November 28, 2001, test until 9 months after it received them, and it did not comply with the Occupational Safety and Health Administration (OSHA) regulations, which require the release of test results to workers after they are requested. But USPS generally communicated to

[6] USPS Draft Standard Sampling Plan dated November 9, 2001. USPS's Draft Interim Guidelines replaced this plan in late November 2001.

[7] It is important to note that the range of spores (8,000 to 10,000) for the human lethal dose was extrapolated from animal studies. This range of spores refers to a dose that will kill 50 percent of

the workers the qualitative test results (positive and negative) soon after they became available. Second, USPS officials told us that USPS did not release the quantitative test results because it could not validate the confirmed results, as required by its draft guidelines. However, these guidelines did not define either confirmation or validation. The use of the terms "confirmation" and "validation" in this context has caused confusion both about (1) the status of the methodologies used to detect anthrax and (2) the communication of test results to workers. The experts we consulted told us that, in their view, the terms confirmation and validation were not used appropriately in USPS guidelines, and CDC concurs with this view. The guidelines do not specify the process and methods for confirming test results. Validation is not done after a test or a procedure has already been performed, as would have been the case with the quantitative test result. Thus, according to the experts we consulted, validation, when used in this sense, should not have prevented USPS from communicating the quantitative test results. According to USPS officials, the term validation, as used in USPS guidance, was intended to be used more for quality assurance purposes. Finally, the terminology used by USPS after discussion with the chief epidemiologist of the Connecticut Health Department was not helpful to workers in assessing their risk. USPS communicated the quantitative results to workers as "trace" amounts and "a concentration of spores." These terms did not provide workers with useful information, when it was needed most, which was when they were making decisions regarding their health risk. Further, the lack of communication of the test results may have contributed to workers' inability to make informed decisions, such as whether to continue taking their medication or work at another facility. As OSHA noted, "Failure to effectively communicate issues, which can have an effect on a worker's health and safety, can lead to fear and mistrust."

Finally, USPS and the other federal agencies involved in the communication issues we raised responded positively to the recommendations we made in our

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individuals exposed to airborne anthrax. However, the lethal dose for a person could be a few spores, as

April 2003 report aimed at enhancing communication of test results. However, our preliminary work on testing approaches revealed three other issues that we believe need to be addressed. These are, for those facilities that were deemed to be free of anthrax spores based solely on a single negative sampling result, (1) the risk level for postal workers at those facilities and the general public served by those facilities, (2) the advisability of retesting those facilities—employing the most effective sampling methods and procedures, and (3) communication to postal workers and the general public of relevant information that may be helpful regarding their health. We are making recommendations to USPS to address these issues.

BACKGROUND

On or about October 9, 2001, at least two letters containing anthrax spores entered the U.S. mail—one was addressed to Senator Thomas Daschle, the other to Senator Patrick Leahy. Before being sent to the Brentwood facility in Washington, D.C.—the facility that processed mail to the two senators—the letters were processed on high-speed mail-sorting machines at a postal facility in Hamilton, New Jersey. The Hamilton facility—also known as the Trenton postal facility—processed mail that was to be transported to the Wallingford facility for further processing.[8] A study conducted in Canada in 2001 has shown that a contaminated envelope, when opened, may cause a substantial primary aerosol event, that is, particles become airborne. Also envelopes with the open corners not specifically sealed could also pose a threat to individuals in the mail handling system.[9]

The letters to the senators contaminated the Brentwood and Hamilton postal facilities and, according to USPS, resulted in the cross-contamination of some

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may have been the case with the Connecticut woman.

[8]Two other contaminated letters were sent to a television news anchor and the editor of *The New York Post* in New York City on or around September 18, 2001. Although the letters were processed through the Hamilton (Trenton facility), it is not known whether these letters contaminated the Wallingford facility.

mail as it moved between these and other facilities in the postal system.[10] Cross-contaminated mail is believed to have been processed through the Wallingford facility on or around October 11, 2001. The possibility of cross-contamination and associated potential exposure to anthrax spores, contained in cross-contaminated mail that was processed at the Wallingford facility, went unrecognized until after the death of the Connecticut woman from inhalation anthrax on November 21, 2001. Airborne transmission of anthrax spores at the Wallingford facility and other facilities is believed to have been facilitated by the use of high-speed sorters, as well as compressed air, for routine cleaning of the mail-sorting machines.[11] As a result, USPS terminated the use of compressed air at all postal facilities on October 23, 2001.

Environmental testing and remediation for anthrax contamination in a facility consists of several steps: sample collection, laboratory identification, decontamination, and retesting. To collect samples, a sampling plan should be developed, which specifies, among other things, number of samples, specific methods to collect the samples, areas in which to sample, and instructions for submitting the samples to a qualified laboratory for analysis. A variety of sample collection methods were used in the Wallingford facility, including dry swabs, wet wipes, and HEPA vacuums. Swabs—either wet or dry—have small surface areas (similar to Q-tips®). They are typically used to sample small, nonporous surface areas (less than 100 sq. cm) that do not have a large accumulation of dust. Wet wipes--sterile gauze pads, approximately 3 inches square--are typically used for sampling larger (more than 100 sq. cm), nonporous surface areas. HEPA vacuum is a suction device with a nozzle—including a cone-shaped filtering trap or sock attached—to collect dust samples from a surface or the air. After samples have been collected, they are to be transported to a qualified laboratory for analyses.

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[9] B. Kournikakis, and others, *Risk Assessment of Anthrax Threat Letters*. Suffield: DRES Technical Report TR 2001-048, September 2001.

[10] USPS officials suspect that the source of the contamination that caused the elderly woman to contract anthrax was the October 9th set of letters processed at the Hamilton facility in New Jersey.

[11] Centers for Disease Control and Prevention, "Evaluation of *Bacillus anthracis* Contamination Inside the Brentwood Mail Processing and Distribution Center—District of Columbia; *Mortality and Morbidity Weekly Report* (2001), vol. 50, pp. 1129-1133.

A range of laboratory tests exists for detecting anthrax in a person's body and in the environment. However, analysis by the culture method is considered to be the gold standard for identifying anthrax. Qualified laboratories report anthrax test results either qualitatively (for example, as "positive" or "negative") or quantitatively (for example, as a specific number of colony-forming units (CFU)), [12] that is, living cells per gram or square inch of material sampled or in milligrams per micro liter.

USPS' SAMPLING APPROACH DID NOT IDENTIFY ANTHRAX AT THE WALLINGFORD FACILITY

USPS's initial sampling approach at the Wallingford facility was ineffective in that it did not detect contamination at the Wallingford facility as soon as was practically possible. If additional testing had not been done to determine the source of contamination for the death of the Connecticut woman from inhalation anthrax, it is possible that the contamination would have gone undetected. USPS guidelines specified the least effective method for sample collection. Assuming that there was probably no anthrax contamination, USPS, as part of its nationwide testing of over 280 facilities, initially used a precautionary approach to determine whether those facilities, including the Wallingford facility, were contaminated.[13] This approach included a method—dry swabs--considered to be the least effective for sample collection, based on comparative studies and the opinions of experts we consulted. This approach did not find contamination (negative results) in the Wallingford facility. On the other hand, CDC used an approach at the Wallingford facility that included a combination of more effective methods—wet wipes and HEPA vacuum—with which contamination was found. Further, USPS officials told us that based on their mail-tracking system, they identified some postal

[12]The term "colony-forming units" refers to the number of living cells in a sample and is typically reported per gram of material sampled for HEPA vacuum samples and per square inch for samples collected using wipes.

[13]Facilities in Florida, New Jersey, New York, and Washington, D.C., had already been tested and found contaminated.

facilities that they considered likely to have been contaminated by anthrax letters processed through those facilities.[14] However, Wallingford was not one of these. The negative test results for the sampling at the Wallingford facility must, therefore, cast doubt about the true extent of contamination in other facilities that tested "negative."

As part of its approach, USPS used its draft Standard Sampling Plan, which specified a minimum number of samples to be collected from various areas, using the dry swab method.[15] USPS used four contractors to sample the Wallingford facility. These contractors were previously contracted to conduct routine environmental sampling for such substances as air and water, rather than dealing with unusual and dangerous bacteria such as anthrax. Before the Wallingford facility was tested, USPS and CDC had learned that some of the mail-sorting machines in the facilities that processed the letters containing the anthrax powder—for example, the Brentwood and Trenton facilities—were found to be heavily contaminated. This suggests that mail-sorting machines would be a likely starting point for sample collection.

On November 11, 2001, using a contractor, USPS collected 53 samples from various sites throughout the facility using dry swabs. The test results were negative. Although USPS, as part of its nationwide sampling, had only intended to test the facility once, it retested the facility on November 21, the day that the elderly Connecticut woman died, to determine the possible source of contamination. On November 21, USPS attempted to identify the path the contaminated letter would have taken. USPS collected 64 samples from surfaces where mail was processed and from air-circulating units, using dry swabs. Again the test results were negative. The November 25, 2001, testing by CDC and the

[14] According to USPS, to determine the condition of sites of possible contamination and to evaluate specific downstream sites throughout the country, USPS obtained test equipment, systems, and contract services. When testing was completed in late November 2001, 284 facilities were tested, with 23 positive and 261 negative results.

[15] USPS contractors used the USPS Draft Standard Sampling Plan, dated November 2 and 9, 2001. The draft USPS interim guidelines, dated November 16, 2001, replaced this plan, and a subsequent version of the guidelines was issued December 4, 2001.

ATSDR, while using a different method—wet swab—also collected 60 samples, of which 8 were from mail-sorting machines. Again, the results were negative. Of the 177 samples collected during the November 11, 21, and 25 samplings, 15 samples were collected from the facility's 13 mail-sorting machines. The Connecticut Public Health Laboratory analyzed all of these samples. In addition, according to CDC officials, the numbers of samples collected on the above dates were, in part, influenced by the capacity of the Connecticut Public Health Laboratory. (See table 1 for sampling details.)

Table 1: Summary of Sampling for Anthrax Contamination between November 2001 and April 2002 and the Associated Test Results for the Wallingford Facility

Sampling date	Method used	No. of samples (Samples collected from mail-sorting machines)	Test results		Agency collecting samples [a]
			Qualitative (No. positive)	Quantitative	
Five tests performed during initial period of contamination					
11/11/01	Dry swabs	53 (1)	Negative	N/A	USPS
11/21/01	Dry swabs	64 (6)	Negative	N/A	USPS
11/25/01	Wet swabs	60 (8)	Negative	N/A	CDC
11/28/91	Wet wipes and HEPA vacuums	212 (130)	Positive (6)	3 million CFU/0.55 gram[b] 370 CFU/gram	CDC
12/2/01	Wet wipes	200 (200)	Positive (35)	N/A	CDC
Test (precautionary) performed in high-bay areas[c]					
4/21/02	HEPA vacuums	101 (N/A)	Positive (3)	1 colony from 7.50 gram sample material 10/11 colonies from 7.69 gram sample material 13/18 colonies from 5.67 gm sample material	USPS

Source: GAO (summary), USPS, and CDC (data).

[a] The USPS used a contractor; CDC was assisted by the Agency for Toxic Substances and Disease Registry.

[b] The sample collected contained 0.55 gram of material (dust) from the heavily contaminated machine. The laboratory adjusted its analyses to reflect a full gram of sample material and reported the presence of 5.5 million CFUs per gram, which the chief epidemiologist subsequently determined, through extrapolation, to be 2.9 million CFUs—or about 3 million spores— in the sample. In this testimony, we refer to the 2.9 CFU for the 0.55 grams of sample material actually collected.

[c] "High-bay" areas refer to elevated areas in the facility such as pipes, ducts, joists, beams, and overhead conveyors. Precautionary testing was performed to ensure no anthrax was present during annual cleaning.

Note: N/A = Quantitative data either not applicable (no anthrax present) or not provided.

On November 28, CDC and ATSDR performed what they termed "targeted" testing, based upon new information concerning which mail-sorting machines were likely to have processed the woman's mail. CDC and ATSDR collected 212 samples using a combination of methods: wet wipes and HEPA vacuums, rather than the wet swabs CDC had previously used. This time, CDC and ATSDR collected 130 samples from the mail-sorting machines as opposed to the 15 samples collected during the three prior sampling efforts. A CDC-contracted laboratory analyzed the samples and found 6 that were positive for anthrax, 2 of which had been collected by HEPA vacuum and four by wet wipes. For the November 28 samples, the laboratory also provided two quantitative results, one of which, according to the Connecticut chief epidemiologist, was about 3 million CFUs of anthrax (that is, 5.5 million CFUs per gram of dust) in a sample collected from a heavily contaminated mail-sorting machine.

Finally, on December 2, while the contaminated machines were isolated and the process of decontamination was beginning, CDC and ATSDR used wet wipes alone to collect 200 follow-up samples from the machines to determine the extent of contamination on the machines and found 35 additional positive samples. On April 21, 2002, a USPS contractor, in consultation with CDC, OSHA, EPA, and the Connecticut Department of Public Health—using HEPA vacuums—tested elevated, or high bay, areas above the previously contaminated machines. The sampling was performed because of a USPS requirement for testing prior to the routine cleaning of elevated areas in facilities that had previously tested positive for anthrax. The effort was undertaken to protect workers from the possibility of exposure to spores that may have blown into these areas as a result of USPS's prior use of compressed air to clean its facilities. The results revealed from 1 to 18 CFUs in 3 of 101 samples collected from the elevated areas.[16] This finding indicates that spores had been airborne at some period in the facility.

[16] Specifically, the test results indicated (1) 1 CFU from 7.50 grams of material sampled, (2) 10 CFU and 11 CFU from 7.69 grams of material sampled, and (3) 13 CFU and 18 CFU from 5.67 grams of material sampled.

Based on the testing done at the Wallingford facility by USPS and by CDC and ATSDR, neither dry nor wet swabs alone identified anthrax contamination in the samples collected. Wet wipes and HEPA vacuums did identify anthrax in some samples. Experts we consulted at the U.S. Army Medical Research Institute for Infectious Disease told us that before October 2001, they had found that dry swabs were ineffective at collecting spores. CDC, on November 9, 2001, in commenting on USPS draft guidelines, recommended that USPS use sterile swab samples for environmental sampling and that these swabs be moistened with sterile water. In addition, CDC informed USPS that CDC's own draft procedures, that is, "Procedures for Collecting Environmental Sampling for Culturing Bacillus *anthracis*," continued to address bulk and vacuum samples. CDC draft guidelines did not, however, address the use of wet wipes. CDC also stated that, "some of the state labs may be less familiar with the methods needed to perform analyses for vacuum and bulk samples." Finally, CDC stated that it understood that USPS' sole use of the swab method was related to an accommodation reached with the Association of Public Health Laboratories to more effectively use state health department laboratories to assist with sample analysis. USPS also acknowledged in a subsequent draft of its guidelines that, "the Association of Public Health Laboratories does not recognize air, bulk, or HEPA vacuum for purposes for Bacillus *anthracis* identification."

USPS officials we interviewed said that in the beginning, USPS mirrored the methods used by CDC in the Brentwood and Trenton facilities. The officials noted that, at one point, "one method was recommended, and later, another method was recommended." USPS officials also told us that in the absence of any other guidance, they were attempting to use pre-existing guidance and extrapolate it to a bio-terrorist attack. In December 2001, a study carried out by CDC, ATSDR, and USPS clearly showed that sampling methods differed significantly in their ability

to detect spores, even in a heavily contaminated facility.[17] According to the study, dry swabs failed to detect spores more than 86 percent of the time, wet swabs more than 46 percent, HEPA more than 20 percent, and wipes more than 13 percent. Based on the study, CDC concluded that dry swabs should not be used to sample for anthrax. Finally, a report by the EPA, dated February 2003, on environmental sampling for anthrax spores at USPS Morgan Postal and Processing facility stated that wipe samples should be used for sampling large surface areas, and wet techniques are more effective than dry techniques. The report stated that epidemiological approaches for different scenarios of environmental sampling should be developed.[18] These issues raise questions about the reliability of a single "negative" sampling result, especially based on the least effective method—dry swabs—as was the case initially in Wallingford.[19]

TEST RESULTS CANNOT BE USED TO DETERMINE HEALTH RISK FOR WORKERS

Neither qualitative (negative or positive) nor quantitative tests results can be used to definitively establish the risk to an individual's health. Interpreting positive test results from a sample as a health risk would require a real understanding of the physical behavior of airborne anthrax spores as well as factors that may influence their behavior. Thus, while both qualitative and quantitative test results from a qualified laboratory can show that a facility is contaminated, they do not show the actual extent of contamination in the facility or the health risk for workers. In particular, qualitative test results show if a facility is contaminated or not. Further, while quantitative test results show the number of CFUs in a sample, such results can be difficult to interpret and, possibly misleading, depending upon the relative distribution of surface dust versus spores and the effectiveness of the

[17] See CDC, "Surface Sampling Methods for *Bacillus anthracis* Spore Contamination," *Emerging Infectious Diseases Journal*, Vol. 8, No. 10 (October 2002).
[18] U.S. Environmental Protection Agency: Summary Report: Peer Review Workshop on Environmental Sampling for Anthrax Spores at Morgan Postal Processing and Distribution Center, May 30, 2002, New York City, New York. (EPA 500-R-03-001, Washington, D.C., February 2003).
[19] USPS officials told us that they are in the process of revising their interim guidelines, however, we have not yet reviewed these revised guidelines.

sampling methods. Nevertheless, because of factors affecting how well a sample method picks up anthrax and limitations affecting the amount of anthrax that can be extracted from that sample, experts agree that there would be more anthrax in the facility than can be picked up by a sample. However, according to officials from the U.S. Army Medical Research Institute for Infectious Disease, what is most important is not the number of spores in a sample but whether or not any spores exist. On the other hand, EPA recently reported that in order to perform credible risk assessments, it is essential to identify the minimum number of spores needed to cause inhalation and cutaneous anthrax.

Negative test results, as shown at the Wallingford facility, do not necessarily mean that a facility is free from contamination. Test results at a contaminated facility could be negative if (1) the sampling method used was not sufficiently effective; (2) samples were not collected from places where contamination was actually present; and (3) an insufficient number of samples were collected. Concerning the sampling methods used in the Wallingford facility, for example, the samplings conducted on 3 different days, which involved collecting a limited number of samples from various places in the facility, using either dry or wet swabs, came out negative, while a subsequent sampling—which used (1) a combination of sampling methods, (2) a different sampling approach, and (3) an increased number of samples—came out positive. It is, therefore, essential to have a sound sampling plan that includes effective methods and do repeat testing if it is considered necessary.

Once contamination is confirmed, actions must be taken to protect the workers and decontaminate the facility. Interpretation of the positive test results requires a real understanding of the physical processes involved in generating airborne particles, such as anthrax; the behavior of such particles; and the factors that influence their behavior. Evaluation of the health risks involves the assessment of components that govern the particle-size profile, stability, and biological impact. The greatest risk to a worker's health in the Wallingford facility appears to have

come from the particles that became airborne as mail that had been cross-contaminated passed through the sorting machines. In the case of the Wallingford facility, postal officials suspect that contamination of the facility may have occurred a few days after October 9, when the second set of letters, those addressed to the two senators, passed through the Trenton facility. It is likely that this high-risk period would have been no more than a few hours, while spores were still airborne. Nevertheless, once spores have settled, a risk can arise if spores again become airborne, thus making it possible for workers to inhale them.

Investigations of anthrax contamination in the U.S. Senate Office building found that simulated day-to-day office activities (that is, paper handling, foot traffic, mail sorting, trash container movement, patting chairs) resulted in spores again becoming airborne. Eighty percent of these airborne particles were in the size range 0.9 to 3.5 microns and, thus, would be capable of causing inhalation anthrax.[20] It was noted that even minimal movement caused viable spores to become airborne. It is therefore very likely that compressed air, used for machine cleaning, could provide sufficient energy to cause particles to become airborne, particularly from areas where there are high local concentrations of spores, as was the case in Wallingford. Similarly, the processing of a cross-contaminated letter through a sorting machine may also provide sufficient energy to cause spores to again become airborne. Based on these findings, it is important to recognize that in a mail-processing facility that has tested positive for anthrax, there is a risk to the health of workers because spores may become airborne again after the primary event—the passage of the contaminated letters—has occurred. In addition, these spores could then create a risk of cross-contamination of mail.

USPS asked CDC whether it should conduct additional testing of postal facilities to assure workers safety. On February 25, 2002, in its response, CDC stated that additional testing was not warranted at that time. CDC noted several reasons for not retesting those facilities including, (1) qualitative or quantitative testing for

anthrax does not accurately correlate with exposure threshold or predictors of disease at these work sites; (2) since the initial contamination, there has been no report indicating increased risk for disease among the workers at these sites; and (3) there is a good reason to believe that the risk for workers has decreased since the initial attack as a result of USPS's newly adopted prevention and control measures, such as repetitive machine decontamination, medical monitoring, and revised operating and maintenance procedures.

According to the experts, the level of contamination found at the Wallingford facility was significantly higher than the level—8,000 to 10,000 spores—historically considered likely to cause disease in the individual when inhaled in a fine powder form. However, there is now a consensus among the experts that even a few spores could be harmful to a susceptible individual, as may have been the case in the death of the Connecticut woman. According to officials from the U.S. Army Medical Research Institute of Infectious Disease, what is most important is not the number of spores in a facility but whether or not any spores are found.

In an attempt to lessen the risk that spores might become airborne, USPS stopped the use of compressed air for cleaning mail-sorting machines and also revised its cleaning methods to include those less likely to cause spores to be blown about the facility, for example, wet mopping instead of dry brushing.

USPS'S FAILURE TO RELEASE QUANTITATIVE RESULTS CAUSED COMMUNICATION PROBLEMS AT THE WALLINGFORD FACILITY

USPS generally provided the Wallingford facility's test results to workers at the facility within 1 day of receiving the results, consistent with USPS guidelines requiring that workers be notified "as soon as possible." However, USPS did not inform the workers as promptly after contamination was identified in the facility

[20] C.P. Weiss and others, "Secondary Aerosolization of Viable Bacillus *anthracis* Spores in a Contaminated

in December 2001, and it also did not promptly provide information to workers on the quantitative test results after a union official requested them.

On December 2, 2001—when anthrax contamination was first identified in the facility—USPS met with workers to inform them that "trace" amounts of anthrax had been found in samples collected on November 28. Knowing that the laboratory initially identified a small number (one or two CFUs) of anthrax spores, the chief epidemiologist for Connecticut—who helped lead the investigation—told district postal managers that it would be accurate to use the term "trace" to describe the extent of contamination. On December 12, 2001—2 days after district postal managers said they received written confirmation of the presence of about 3 million spores in one of the samples collected on November 28 and, possibly, 4 days after headquarters postal managers received the results—district postal managers told us that they informed workers of the following: While trace amounts of anthrax existed on three mail-sorting machines, a "concentration" of spores had been identified in a sample collected from a fourth machine. But it was not until 9 months after USPS had received the quantitative results of the November 28, 2001, testing that it provided the information to the workers.

According to USPS, it did not release the quantitative test results to workers because it could not validate the confirmed results, as required by its guidelines, which state that results cannot be released until confirmed data are received from CDC or a state public health laboratory. However, the guidelines do not define the meaning of either "confirmation" or "validation," nor do they specify the steps that must be taken to validate test results. According to USPS managers, USPS could not ensure that the sampling had been done in accordance with procedures specified in the guidelines and, thus, could not validate the results, as required by the guidelines.[21] A USPS headquarters' manager told us that the term validation

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U.S. Senate Office," *Journal of American Medical Association*, vol. 288 (2002), pp. 2853-2858.

[21]U.S. Postal Service, *Interim Guidelines for Sampling, Analysis, Decontamination, and Disposal of Anthrax for U.S. Postal Service Facilities* (Dec. 4, 2001). These guidelines were developed as the anthrax

was intended to describe a method for ensuring that work had been done in accordance with USPS' sampling and testing procedures and for coordinating the release of validated results. A USPS official also told us that the term validation, as used in USPS guidance, was intended to be used more for quality assurance purposes. The guidelines do not specify who is to do the validation or how it is to be done, particularly when the testing is not done or sponsored by USPS. Thus, the use of the terms confirmation and validation in the context of USPS guidelines has caused confusion about (1) the status of the methods used to detect anthrax (e.g., were the methods appropriately used) and (2) whether and when test results were to be communicated to workers.

The experts we consulted told us that, in their view, the terms confirmation and validation were not used appropriately in USPS guidelines. Confirmation is a process in which a qualified laboratory, using specific tests, determines the presence of anthrax in a sample. Normally, validation is a process that is carried out before a test or procedure is used for a specific purpose to ensure that such a test or procedure is effective. Thus, according to these experts, validation is not usually done after a test or a procedure has already been performed, as would have been the case had the results been validated in the manner described by USPS officials. Thus, according to the experts we consulted, validation, when done appropriately, should not have prevented USPS from communicating the quantitative test result.

These experts also (1) told us that the sampling method (HEPA vacuums) used to collect the samples that were quantified was appropriate and (2) agreed that the lack of documentation about the extent of surface area sampled, especially given the complexity of the facility's mail-sorting machines, could have made interpretations of the results difficult.[22] They explained that the method of

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crisis unfolded, with input and guidance from several federal agencies, including CDC and OSHA, and the national unions that represent postal workers.

[22]We consulted with numerous experts in the field of microbiology, including Dr. Jack Melling, former Director and Chief Executive Officer of the British Center for Applied Microbiology Research, Porton Down; Dr. Paul Keim, Professor in Microbiology, Northern Arizona University; Col. Eric Henchal,

counting CFUs is a long-standing, definitive, and universally accepted microbiological technique for determining the amount of bacteria in a given sample, including anthrax. The results show how many spores have replicated to form colonies, which can then be seen by the naked eye. Thus, regardless of the sampling issues at Wallingford, none of the agencies involved provided any evidence indicating that the number of CFUs identified by the laboratory was incorrect.

USPS communicated the quantitative results to workers as "trace" amounts and "a concentration of spores," based on discussions with the chief epidemiologist of the Connecticut Health Department. However, according to the experts we consulted, use of the terms trace amounts or concentration of spores did not provide workers with useful information, when it was needed most, which was when they were making decisions regarding their health risk.

According to experts we consulted, the use of the term "concentration" to convey the finding of about 3 million spores in one sample may have been misleading because it did not adequately convey the potential health risk associated with the sample, along with any limitation associated with the results. The experts also said that providing information about the actual test results to workers would have given them better information for making informed medical decisions. In this case, according to the experts we consulted, an appropriate way to communicate the results to workers would have been to indicate that 2.9 million CFUs (from 0.55 grams of dust) were found in a sample from one machine, along with appropriate limitations regarding the sampling procedures used.

Following a request for test results by a union leader and an investigation by OSHA, USPS eventually released the quantitative results 9 months later. The delay was not consistent with OSHA regulations. OSHA did not cite USPS for failure to disclose the quantitative test results within 15 working days of the union leader's

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Department of the Army; and Dr. Barbara Johnson, former Safety Officer at the Dugway Proving Grounds,

January and February 2002 requests; however, in an October 7, 2002, letter to USPS, OSHA noted that a "failure to effectively communicate issues which can have an effect on a worker's health and safety, can lead to fear and mistrust."

In addition, two federal guidelines, developed in 2002 by GSA and the National Response Team, suggest that more—rather than less—information should be disclosed. For example, GSA's guidelines emphasize the need for "timely, clear, consistent, and factual" information, including any limitations associated with the information, so that people can make informed decisions. The other set of guidelines, developed by the National Response Team, warns agencies not to withhold information because it could affect the agency's credibility. However, neither USPS's guidance nor the more recent federal guidelines fully address the communication-related issues concerning anthrax that developed at the Wallingford facility. For example, none of the guidelines specifically require the full disclosure of all test results, including quantitative test results. Likewise, OSHA regulations for communicating test results to workers do not address the need for full, immediate, and proactive disclosure. Thus, we made several recommendations to minimize the likelihood that the communication-related problems at the Wallingford facility will recur elsewhere (see appendix I). USPS, EPA, and GSA generally agreed with our recommendations affecting them, but OSHA did not comment on our recommendation to it.

Our work to date on this study has revealed three other issues that we believe need to be addressed. These are, for those facilities that were deemed to free of anthrax spores based solely on a single negative sampling result, (1) reassessing the risk level for postal workers at those facilities and the general public served by those facilities, (2) reconsidering the advisability of retesting those facilities—employing the most effective sampling methods and procedures, and (3) communicating to the postal workers and the general public the results of the reassessment of health risk, the advisability of retesting, the rationale for these

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Department of the Army.

decisions, and other relevant information that may be helpful regarding the health of the postal workers and the general public.

CONCLUSIONS

The Wallingford incident gives unique insight into the lessons that need to be learned from the response of the federal government, state health departments, and USPS to the anthrax attacks in the fall of 2001. The unpredictability of the lethality of anthrax; the broad spectrum of the population at risk of exposure, including postal workers, postal customers and others; and the inability to determine the route that contaminated mail might take as well as the extent of cross-contamination, are all factors that make it extremely difficult to establish the health risks associated with a release of a biological agent, such as anthrax, inside a facility that serves the public. This difficulty underscores the need for a standardized and aggressive response as well as forward planning to protect both the workers and the public should this happen again.

When considering the testing approach taken, and the methods used, to detect anthrax in postal facilities in the fall of 2001, it is important to recognize that the knowledge and experience of public health officials and others in this area were continually evolving. Experts we consulted and studies we reviewed indicated that the use of dry swabs alone were the least effective method of detecting anthrax. In addition, CDC recommended that dry swabs should not be used for anthrax detection. Initial sampling of the Wallingford facility, using USPS nationwide sampling guidelines (which provided for the use of dry swabs), did not find contamination. Also, use of the same guidelines to conduct nationwide testing may not have identified anthrax contamination that could have existed in some of those facilities that tested negative using dry swabs alone.

In February 2002, CDC advised USPS, that to ensure worker safety, there was no need to retest postal facilities for a variety of reasons. Accordingly, USPS followed CDC's advice and did not retest any of those facilities. However, in our discussion with CDC officials, they agreed that there are many uncertainties associated with anthrax risk assessment. For example, we do not know the lethal dose for an individual, how to extrapolate contamination in a facility to a health risk for an individual, and whether postal facilities still contain spores, and the reliability of the methods used to rule out anthrax contamination. CDC also agreed that there could still be spores in some facilities. Consequently, there remains a risk, albeit probably low, of further infection. While CDC judges the risk to be low, we believe that it is important that this judgment of the risk be communicated to workers and the general public so that they are in a position to make informed decisions about their health and safety.

Public health response is most effective and efficient when it is proactive, when it focuses on prevention, rather than on consequent management. Thus, the Wallingford incident illustrates the challenges facing the federal government, the state health departments, the network of diagnostic laboratories and those companies that serve the general public, including USPS. The challenge can be summed up in one question, "Is it safe?" This is what everyone asked during the fall of 2001, and this is what everyone is trying to answer to this day. Unfortunately, the best answer anyone can give is, "It is probably safe." Once a building has been contaminated, one can never say there is no risk, but there can be a low risk. What all those who are trying to protect the public health must realize is that they are defining the risk level for others: in this case, the postal workers as well as the general public.

RECOMMENDATIONS

The impact of additional anthrax cases could result in illness or loss of life as well as loss of confidence in the nation's postal system. Further, even though the health risk is probably low, it is uncertain; we therefore recommend that the Postmaster General, in consultation with CDC, EPA, OSHA, as well as any other relevant agencies and postal unions, for those facilities that were deemed to free of anthrax spores based solely on a single negative sampling result, (1) reassess the risk level for postal workers at those facilities and the general public served by those facilities, (2) reconsider the advisability of retesting those facilities and employing the most effective sampling methods and procedures, and (3) communicate to the postal workers and the general public the results of the reassessment of health risk, the advisability of retesting, the rationale for these decisions, and other relevant information that may be helpful regarding the health of the postal workers and the general public.

Mr. Chairman, this concludes our statement. We will be happy to answer any questions you or members of the Subcommittee may have.

CONTACTS AND ACKNOWLEDGMENTS

Should you or your offices have any questions concerning this report, please contact me at (202) 512-6412 or Bernie Ungar at (202) 512-2834. We can also be reached by e-mail at rhodesk@gao.gov and ungarb@gao.gov. Individuals making key contributors to this testimony were Don Allison, Hazel Bailey, Latesha Love, Laurel Rabin, Cady Summers, and Kathleen Turner. Drs. Jack Melling and Sushil Sharma provided technical expertise.

Appendix I

RECOMMENDATIONS CONTAINED IN OUR APRIL 2003 REPORT ON THE WALLINGFORD FACILITY

To help prevent the recurrence of the communication problems that occurred at the Wallingford facility, we recommended that the Postmaster General; the Administrator of the General Services Administration; and the Administrator of the Environmental Protection Agency, as Chairperson of the National Response Team, work together to, where applicable, revise guidelines to

- require prompt communication of test results, including quantified results when available, to workers and others;
- specify the terminology that should be used to communicate quantitative test results to workers and others (e.g., the number of colony-forming units per gram or square inch of material sampled) and any limitations associated with the test results;
- define what is meant by the validation of test results and explain the steps that must be taken to validate sampling or testing methods that are undertaken by the agency itself or by another organization;
- specify the actions that should be taken if test results cannot be validated, including a strategy for communicating unvalidated results;
- specify the agencies that should be involved in deciding what to communicate to workers and others, as appropriate;
- require documentation of the basis for decisions made, including the (1) advice the organization receives from public health officials and others about the communication of health-related information to workers and others, as appropriate, and (2) specific content of what agencies and other organizations communicate to workers and others; and
- reflect the Occupational Safety and Health Administration's regulations for disclosing test results requested by workers or their designated

representatives.

In light of new concerns about the possibility and impact of future terrorist actions using unforeseen hazardous substances, we also recommend that the Assistant Secretary for Occupational Safety and Health consider whether the Occupational and Health Administration regulations should require—in emergency situations—full and immediate disclosure of test results to workers, regardless of whether the information is requested by a worker or his or her designated representative.

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