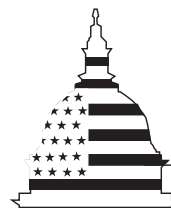


October 1999

COMBATING TERRORISM

Chemical and Biological Medical Supplies Are Poorly Managed



G A O

Accountability * Integrity * Reliability

**Health, Education, and
Human Services Division**

B-282839

October 29, 1999

The Honorable Arlen Specter, Chairman
Committee on Veterans' Affairs
United States Senate

The Honorable John Rockefeller
Ranking Minority Member
Committee on Veterans' Affairs
United States Senate

The Honorable Christopher Shays, Chairman
Subcommittee on National Security, Veterans' Affairs,
and International Affairs
Committee on Government Reform
House of Representatives

The Honorable Ike Skelton
Ranking Minority Member
Armed Services Committee
House of Representatives

The threat of chemical or biological terrorist attacks against U.S. citizens is a high-priority, national concern. The March 1995 terrorist attack in the Tokyo subway system using the nerve agent sarin, and other more recent national and international terrorist incidents have raised concerns about whether the United States can effectively respond to incidents involving chemical or biological agents. Reflecting these concerns, the federal government has established several stockpiles of antidotes and other medical supplies and plans to develop a larger national stockpile—referred to as the National Pharmaceutical Stockpile Program—to be used in the event of domestic chemical and biological attacks.

This report responds to your concerns about the adequacy of the stockpiles. Our objectives were to (1) review the accuracy and currency of the inventory tracking systems for federal medical stockpiles that would be used to treat the civilian population following a chemical or biological terrorist attack and (2) examine the internal controls in place to manage the stockpiles. We conducted a 100 percent inventory of the existing domestic federal stockpiles managed by the Department of Veterans Affairs (VA) for the Department of Health and Human Services' (HHS) Office

of Emergency Preparedness (OEP). We also conducted a 100 percent inventory of the medical supplies kept by the Marine Corps Chemical Biological Incident Response Force (CBIRF), whose mission includes responding to domestic terrorist events. We also reviewed the inventories taken and procedures followed by the vendor storing the Centers for Disease Control and Prevention's (CDC) smallpox vaccine, although we did not count the stockpile. Consistent with our review objectives, we did not assess the effectiveness and appropriateness of medical preparedness. In addition, the threat of chemical and biological terrorism is the subject of another study we recently published.¹ We conducted our review from May 1999 through September 1999 in accordance with generally accepted government auditing standards. Details of our scope and methodology are in appendix I.

Results in Brief

The U.S. ability to effectively respond to chemical or biological terrorist incidents is compromised by poor management controls and the lack of required items. Our physical inventory of OEP's stockpiles, which VA manages, compared with OEP's required list showed a discrepancy of more than 12 percent. Although most discrepancies were overages, we also found shortages. For example, we found 3,400 excess gloves at one location and 400 extra diazepam vials (a controlled substance) at another. We also found that the inventory was short of 1,000 required diazepam injectors at one location and at another location had 500 fewer vials of diazepam than required. In addition, when we compared our inventory with VA's inventory records, we found expired items. At one location, the entire amount of amyl nitrate listed in VA's records (2,000 vials) had expired 8 months before our visit, and at another location we found more than 400 vials of pralidoxime whose expiration date was recorded incorrectly. In comparing CBIRF's medical supplies with the records in its inventory tracking system, for approximately 26 percent of the inventory items we found either discrepancies between the inventory records and the amount in stock or errors in the recording of lot numbers and expiration dates.

The principal cause of problems we identified is that the responsible federal agencies did not implement basic internal controls that would reasonably assure that all medical supplies and pharmaceuticals are current, accounted for, and available for use. Consistent with the Federal Managers' Financial Integrity Act of 1982 (FMFIA), agencies should have

¹Combating Terrorism: Need for Comprehensive Threat and Risk Assessments of Chemical and Biological Attacks (GAO/NSIAD-99-163, Sept. 7, 1999).

efficient and effective internal controls over their operations and programs. Neither OEP nor CBIRF explained its lack of compliance, and we identified problems in all major aspects of internal controls—control environment, risk assessment, control activities, information and communications, and monitoring. For example, their systems lacked basic information required for good recordkeeping, such as documentation of back orders, replacements, and shipment and receipt of all pharmaceutical and medical supplies. They also did not conduct periodic inventories, maintain program policies and procedures, or provide adequate security of the stockpiles. As a result, these systems cannot be relied upon to consistently and accurately account for the items required to be in the stockpiles.

Even more will be at stake in the future as CDC establishes the National Pharmaceutical Stockpile Program. Although CDC is still in the early phases of developing this program, its current plan does not include comprehensive internal controls to prevent the types of problems we found at the other agencies. To reasonably assure the proper management of this new stockpile, as well as to correct deficiencies in the others, we are recommending actions to improve the internal control programs for the federal chemical and biological medical stockpiles.

Background

The United States has established national policy for combating chemical and biological terrorism and managing the consequences of terrorist attacks. The Federal Emergency Management Agency (FEMA) is the lead agency for managing the consequences of terrorist attacks, with the authority to assign missions to any federal agency in the event of a disaster or emergency declared by the president.² FEMA coordinates the federal response through a contingency plan, known as the Federal Response Plan, that details the roles and responsibilities of federal agencies during natural or manmade emergencies. The plan also categorizes types of federal assistance into specific emergency support functions (for example, information and planning, health and medical services, urban search and rescue).

As we reported earlier, “If the consequences of a terrorist threat become imminent or actually occur, state and local authorities would initiate consequence management actions, while FEMA would monitor the situation in consultation with the President and the governor. If state and local capabilities are overwhelmed, the President could then direct FEMA, with

²Under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (P.L. 93-288), as amended.

the support of appropriate federal agencies, to assist.”³ FEMA, through the Federal Response Plan, has designated HHS as the lead agency to coordinate medical assistance in the event of a federally declared natural or manmade disaster, including chemical or biological terrorist incidents. Within HHS, OEP is responsible for implementing and coordinating this medical assistance, and in 1997 it established four National Medical Response Teams, each with a medical stockpile containing antidotes, antibiotics, and medical supplies for responding to chemical terrorist attacks. OEP also maintains one smaller stockpile that contains only antidotes for chemical incidents; this stockpile can be loaned to local governments or predeployed for special events, such as the Olympics. OEP’s stockpiles are positioned throughout the United States, and all but one are located at federally owned facilities. While OEP is responsible for these stockpiles, through an interagency agreement, it has delegated day-to-day management to VA.

CBIRF, created in 1996 by the Commandant of the Marine Corps, maintains a working stock of medical supplies to respond to chemical and biological incidents.⁴ CBIRF is the only Department of Defense (DOD) unit whose mission includes responding to and treating civilian victims of chemical or biological terrorist attacks. Its staff includes a medical unit of 27 Navy personnel who manage the working stock of pharmaceuticals and medical supplies. CBIRF also uses local government stockpiles where available to treat civilians.

In 1998, the Congress appropriated \$51 million for CDC to acquire a pharmaceutical and vaccine stockpile to counter potential biological, disease, and chemical threats to civilian populations.⁵ Currently, CDC is developing its plans to accumulate these medical supplies, and it has also recently transferred \$1.4 million of the \$51 million to OEP to augment its supply of antidotes for chemical attacks. For the past 26 years, CDC has also maintained the nation’s stockpile of smallpox vaccine through a contract with the manufacturer. This vaccine can be used against a terrorist release of smallpox.

³Combating Terrorism: Federal Agencies’ Efforts to Implement National Policy and Strategy (GAO/NSIAD-97-254, Sept. 26, 1997). In 1997, under section 1417 of title XIX of the Defense Against Weapons of Mass Destruction Act of 1996, FEMA developed and implemented a Rapid Response Information System (RRIS), which can be accessed on the Internet. The RRIS contains data on federal assets, such as decontamination units, and training programs available to assist terrorist response operations of state and local governments. It does not contain information on the contents of the existing federal stockpiles for responding to chemical or biological terrorist incidents.

⁴CBIRF officials refer to the medical supplies they maintain as a working stock. To simplify our presentation, we refer to CBIRF’s medical supplies as a stockpile.

⁵The Omnibus Consolidated and Emergency Supplemental Appropriations Act (P.L. 105-277).

In addition to federal efforts, state and local agencies have the responsibility for providing “first response” medical assistance to the civilian population in natural and manmade disasters, including chemical or biological terrorist attacks. If state and local capacities are overwhelmed by a disaster, federal assets such as the chemical and biological medical supplies that CDC, CBIRF, and OEP stockpile could be deployed to augment local responses.

FMFIA requires GAO to issue standards for internal control in government. The standards provide the overall framework for internal control, and the Office of Management and Budget (OMB) Circular A-123, Management Accountability and Control, revised June 21, 1995, provides the specific requirements for assessing and reporting on controls.

Inventory Tracking Systems Are Neither Current Nor Accurate

Our complete inventory of the OEP and CBIRF stockpiles showed that neither inventory control system accurately tracks federal medical supplies. Our comparison of OEP’s list of required items with our physical inventory revealed discrepancies for about 23,000 items, or more than 12 percent, across the five sites.⁶ Although most discrepancies were overages, others involved items that were stocked in a smaller quantity than required or were not in stock at all. For instance, some of the overages at individual sites included about 600 extra amyl nitrate inhalants; a total of 3,400 small, medium, and large pairs of gloves; about 1,000 potassium iodide tablets; and 1,000 diazepam injectors. Shortages included about 300 pralidoxime vials, 100 diazepam vials, and at two locations almost 300 potassium iodide tablets at each site. In addition, OEP’s list required 1,000 diazepam injectors in the stockpile; however, at one location, we found none, and none were recorded in VA’s inventory record. At another location, we found 500 fewer vials of diazepam than required.

Our comparison of OEP’s stockpiles with VA’s computerized inventory records revealed a discrepancy of more than 11 percent. For the most part, discrepancies occurred in three categories—overages, shortages, and items for which lot numbers and expiration dates were recorded incorrectly. At one location, we found about 600 more amyl nitrate inhalants than recorded; we found 1,600 extra pairs of gloves at another location and 250 extra doxycycline tablets at another. Some shortages

⁶When we compared our physical inventory with OEP’s required list, we identified overages and shortages. We were also able to identify other incorrectly recorded items when we compared our physical inventory with VA’s inventory records. See appendix I for an explanation of how we calculated the discrepancy rates.

included 100 vials of diazepam, 100 Mark I injectors (a chemical antidote), and 250 doxycycline tablets. Items recorded incorrectly included 2,000 amyl nitrate inhalants, which had expired 8 months before our visit, and about 440 pralidoxime vials, 250 doxycycline tablets, and 100 ciprofloxacin tablets, whose expiration dates and lot numbers were recorded incorrectly.

The Marine Corps CBIRF stockpile had similar problems. Specifically, we determined that about 2,300 items of the 38,000-item inventory list were not in stock. These items included about 1,500 doses of an antidote. In addition, CBIRF's computerized inventory system did not identify and track 5,700 items that we found in the inventory, such as oral and nasal airways that would be deployed in response to a chemical or biological terrorist attack. However, the computerized inventory system recorded and tracked other CBIRF medical materials that would not be used in a chemical or biological incident, such as training equipment and pharmaceuticals for the general use of the unit. Additional details of the results of our inventories are in appendix II.

Lack of Controls Is the Principal Cause of Poor Inventory Management

The root cause of the inventory problems we identified was a fundamental lack of internal controls, although the agencies did not explain their lack of compliance with our internal control standards. Internal controls, as outlined by our standards for internal control, provide reasonable assurance that program objectives for effective and efficient operations, reliable financial reporting, and compliance with applicable laws and regulations are met.⁷ OEP, VA, and CBIRF did not implement the following five internal control standards for managing their stockpile programs: (1) effective control environment, (2) risk assessments, (3) control activities, (4) information and communications, and (5) monitoring.

Control Environment

OEP, VA, and CBIRF did not provide sufficient leadership and supervision to their own personnel to reasonably assure an adequate control environment for the stockpiles. While OEP has overall responsibility for managing the stockpiles, it has chosen to delegate day-to-day responsibility for stockpile management to VA through an interagency agreement. In delegating its responsibilities for the stockpiles, OEP did not provide clear guidance to VA on the requirements and standards that VA should follow to effectively manage and maintain OEP's stockpiles.

⁷See our exposure draft entitled *Internal Control: Standards for Internal Control in the Federal Government* (GAO/AIMD-99-21.3.1, May 1999).

Moreover, VA did not provide formal guidance or clearly define activities, key duties, and responsibilities for personnel charged with managing OEP's stockpiles. Similarly, the Marine Corps did not provide adequate guidance to CBIRF concerning the composition of its medical supply inventory or how to manage it.

Risk Assessment

OEP, VA, and CBIRF did not determine the hazards and risks that their stockpiles faced, assess the likelihood of each risk's occurrence, and establish plans to detect or mitigate them. For example, neither OEP nor VA assessed the possibility of the theft of stockpile items and, therefore, did not have a plan in case a theft occurred. When VA personnel counted items at one of OEP's stockpile locations, in anticipation of our visit, they found that 48 amyl nitrate inhalants were missing and presumed stolen. VA replaced the missing items, waited 30 days before reporting the missing amyl nitrate to OEP, and then raised concerns about its limited control over the secured storage and the security of the stockpile. OEP had neither addressed nor improved the storage situation at this site by September 1999. The location of the missing drugs at this site remains a mystery and is unresolved between OEP and VA.

Control Activities

OEP, VA, and CBIRF did not establish procedures to carry out control activities and manage the medical stockpiles. For example, key duties need to be segregated among different people to reduce the risk of error and fraud. However, the same individual who ordered supplies for OEP's stockpiles also replaced and disposed of items and recorded all changes in the computerized tracking system. At CBIRF, staff entering data into the computer tracking system also participated in physical inventory counts. In addition, CBIRF staff stated that some items are consumed and some are lost during exercises and are replaced from the warehouse stock, but records of such consumption and loss are not included in the computer tracking system. Both agencies' systems also lacked basic information required for adequate recordkeeping. For example, they did not document back orders, replacements, or the shipment and receipt of all pharmaceutical and medical supplies.

We found that all three agencies had not implemented adequate security measures for their medical stockpiles. For example, at three of OEP's five stockpile locations, we found that VA had comingled OEP's refrigerated supplies in unsecured refrigerators, in violation of a general maintenance and storage policy established by VA. Comingling supplies puts the

stockpile items at risk because more people have access to the items, making them more susceptible to waste, loss, unauthorized use, and misappropriation. At one site, a supply of amyl nitrate—which is a pharmaceutical with a street value—was stored in a large refrigerator in the VA Inpatient Pharmacy, comingled with other VA medical center pharmaceuticals. At another site, we found that amyl nitrate and an antidote were stored in an unsecured staff refrigerator along with employees' lunches. And at a third site, OEP's refrigerated supplies were stored with other non-OEP supplies in an unlocked refrigerator outside the secure area. VA officials explained that sometimes the secured areas where OEP's stockpiles are kept do not include electrical outlets needed to store refrigerated items.

Information and Communications

OEP, VA, and the Marine Corps did not require periodic reporting on program status to agency management. Communication about stockpile matters between OEP and VA was infrequent and irregular. For example, both OEP and VA officials told us that they had originally planned to have quarterly teleconferences or meetings about stockpile-related issues but could demonstrate that only one meeting had taken place. Although VA has managed OEP's stockpiles since April 1997, OEP never requested that VA produce (and VA has not provided) any regular, formal, written progress or status reports on the stockpiles.

We found that the exchange of information on stockpile inventory status and managerial activities between CBIRF, the Marine Corps, and the Navy was also lacking. Marine Corps officials did not communicate clear expectations about the type, extent, and frequency of reports they expected CBIRF to produce on the status of its stockpile or about the type and frequency of oversight the Marine Corps would exert. Neither the Navy Medical Command nor the Marine Corps had ever requested that CBIRF regularly produce written progress reports, inventory status, or fiscal reports on its stockpile.

Monitoring

Neither OEP nor VA required or conducted periodic inventories of the stockpiles to determine whether stockpiled items were current, accounted for, and available for use. Although CBIRF periodically counted items in the stockpile, it does not have an approved inventory list. As a result, it cannot determine whether the stockpile contains all supplies needed to respond to a chemical or biological terrorist attack. In contrast, we determined that

the vendor storing the nation's smallpox vaccine for CDC follows standards for internal control.

CDC Is Managing a New Stockpile Program

CDC received \$51 million in fiscal year 1999 to establish the nation's National Pharmaceutical Stockpile Program. It has requested \$52 million for fiscal year 2000 to continue establishing this stockpile. Under the program, CDC will stockpile medical supplies to be used in a biological or chemical attack. Like OEP, CDC has selected VA to procure, oversee, and store the national stockpile. As the program is currently envisioned, CDC plans to require VA to begin stockpiling items 14 days after the interagency agreement is signed. However, CDC's draft National Pharmaceutical Stockpile Program plan lacks information on how CDC will review and assess the stockpile and contractor, what security measures it has to safeguard the stockpile, and which CDC personnel will manage the stockpile, stockpile operations, and command, control, and communication functions.

Conclusion

Sound management of the chemical and biological stockpiles is critical to the protection of public health in the event of a terrorist attack. However, OEP, VA, and the Marine Corps did not explain why they have not followed the basic standards of internal control we have set forth. The poor management controls and lack of required items in their stockpiles lead us to conclude that they cannot provide reasonable assurance that the required medical supplies will be available if needed.

As the federal agency primarily responsible for emergency preparedness, OEP did not provide leadership to reasonably assure that the necessary medical supplies will be current, accounted for, and available for use. In the absence of explicit requirements or oversight from OEP, VA has developed a stockpile management program without adequate internal control. CBIRF's inventory management and tracking system also did not meet basic federal standards for internal control. The inventory systems that are supposed to track and account for the stockpiles of medical supplies to be used in a chemical or biological attack are inaccurate and unreliable.

While the current stockpiles are not well managed and lack required items, even more will be at stake in the future as CDC expands its new stockpile. Developing and implementing internal controls needs to be a fundamental

aspect of managing this stockpile to avoid repeating problems we found at OEP and CBIRF.

Recommendations

To address the internal control weaknesses identified in this report, we recommend that the Department of Health and Human Services' Office of Emergency Preparedness, the HHS Centers for Disease Control and Prevention, the Marine Corps Chemical and Biological Incident Response Force, and the Department of Veterans Affairs establish sufficient systems of internal control over their chemical and biological stockpile management. The agencies need to reasonably assure that personnel carry out the following specific control activities:

- conduct risk assessments and organize program activities to identify and mitigate risks;
- arrange for periodic, independent inventories;
- implement a tracking system that retains complete documentation for all supplies that have been ordered, received, and destroyed; and
- rotate supplies properly.

Agency Comments

We sent a draft of this report to VA, HHS, and DOD for their review and comment.

While VA indicated that this is an important issue, it wanted additional time to review the results of our inventory and to respond to us later.

HHS generally agreed with our findings and recommendations and reported that it is redefining and adjusting its management oversight of OEP's stockpiles by drafting a new memorandum of agreement between VA and OEP. In addition, it said that CDC has relied on our work to develop such a memorandum with VA for the National Pharmaceutical Stockpile Program. HHS's comments are reproduced in appendix III.

The Special Assistant to the Assistant to the Secretary of Defense for Civil Support as well as CBIRF officials acknowledged weaknesses in CBIRF's inventory management controls and described corrective actions that DOD intends to take. For example, CBIRF is in the process of defining its medical inventory, will institute a risk assessment and mitigation activities, and will conduct independent inventories. DOD officials also told us that CBIRF's primary mission is to support war fighters, although it also supports civilian agencies. For this reason, CBIRF officials asked that we delete their

agency from the report. However, we believe we appropriately included CBIRF for two reasons. First, a Marine Corp document entitled The Chemical/Biological Incident Response Force states CBIRF's mission is to respond to chemical or biological incidents worldwide and, when directed, to assist local civilian and military agencies. CBIRF officials also told us that responding to civilian incidents is a part of their mission. Second, OEP's plan reflects its intention to rely on CBIRF to assist in the treatment of civilian victims. We have made technical clarifications in response to other CBIRF comments where appropriate.

As we agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days after its date. We will then send copies to appropriate congressional committees and the federal agencies discussed in this report. We will also make copies available to others who are interested.

Please contact me at (202) 512-7101 or Ronald Guthrie, Assistant Director, at (303) 572-7332 if you have any questions. Other major contributors to this report were Martin Eble, Lesia Mandzia, Lawrence Moore, Carolina Morgan, and Thomas Yatsco.



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Abbreviations

CBIRF	Chemical Biological Incident Response Force
CDC	Centers for Disease Control and Prevention
DOD	Department of Defense
EMSHG	Emergency Management Strategic Healthcare Group
EPS	Emergency Pharmacy Services
FEMA	Federal Emergency Management Agency
FMFIA	Federal Managers' Financial Integrity Act of 1982
HHS	Department of Health and Human Services
OEP	Office of Emergency Preparedness
OMB	Office of Management and Budget
RRIS	Rapid Response Information System
SAMS	Ships Automated Management System
VA	Department of Veterans Affairs

Scope and Methodology

Our objectives were to (1) review the accuracy and currency of the inventory tracking systems for federal medical stockpiles that would be used to treat the civilian population following a chemical or biological terrorist attack and (2) examine the internal controls in place to manage the stockpiles. We obtained documents and interviewed officials at the Centers for Disease Control and Prevention (CDC) and the Office of Emergency Preparedness (OEP) at the Department of Health and Human Services (HHS), the vendor storing the smallpox vaccine for CDC, the Marine Corps Chemical Biological Incident Response Force (CBIRF) at the Department of Defense (DOD), the Department of Veterans Affairs (VA), and the Federal Emergency Management Agency (FEMA).

To assess the accuracy and currency of the inventory tracking systems that monitor OEP's medical stockpiles, we (1) obtained OEP's required list of medical supplies, (2) obtained VA's computerized inventory tracking records of OEP's stockpiles, and (3) conducted a 100 percent inventory of each of OEP's stockpiles. We then conducted three analyses. Our first analysis compared the findings of our 100 percent inventory with VA's computerized inventory records to test their accuracy. Our second analysis compared OEP's list of required items with VA's computerized inventory records. Our third analysis compared OEP's required list of items with our inventory count. A discrepancy was recorded if (1) an item specified on VA's inventory record was not found in the specified container (shortage), (2) an item not on the record was found in the container (overage), or (3) an item had incorrect recordkeeping for either the lot number or the expiration date. We calculated the discrepancy rate by dividing the number of discrepancies we found by the total number of items recorded on the inventory. Therefore, in some cases, multiple discrepancies were assessed for a single item. For instance, an item located in the wrong container was counted as both a shortage in the container it belonged in and an overage in the container it was found in.

Since CBIRF did not have an approved inventory list, we compared the results of our inventory of CBIRF's stockpile with its computerized inventory records. We also reviewed the inventories taken and procedures followed by the vendor storing the smallpox vaccine for CDC.

We reviewed the unclassified version of Presidential Decision Directive 39, the fact sheet available on Presidential Decision Directive 62, and the Stafford Act to determine U.S. policy on chemical and biological terrorism. Also, to assess the adequacy of internal controls, we applied criteria from our exposure draft entitled Internal Control: Standards for Internal

Control in the Federal Government (GAO/AIMD-99-21.3.1, May 1999). We also considered the Federal Managers' Financial Integrity Act of 1982 (FMFIA); Office of Management and Budget (OMB) Circular A-123, Management Accountability and Control, revised June 21, 1995; and Federal Financial Management System Requirements of the Joint Financial Management Improvement Program.

We did not examine stockpiles and inventories for noncivilian use used by U.S. military forces and managed by the Defense Logistics Agency. We also excluded from our scope stockpiles that are maintained by Metropolitan Medical Response System teams in several U.S. cities to prepare for chemical and biological terrorist incidents.

Stockpile Tracking System Control Deficiencies

Our exposure draft entitled Internal Control: Standards for Internal Control in the Federal Government requires that agencies

1. have an effective control environment,
2. conduct risk assessments,
3. implement control activities that are linked to the results of a mission risk assessment,
4. properly record information and communicate with management, and
5. ensure monitoring.⁸

The purpose of the standards issued pursuant to FMFIA is to provide reasonable assurance that key objectives are met, including effective and efficient operations, reliable financial and other reporting, and compliance with applicable regulations and other laws. Agencies are to view these standards as elements of an ongoing internal control process that must be constantly maintained.

Control Environment

Our Standards for Internal Control in the Federal Government states that “Management and employees should establish and maintain an environment throughout the organization that sets a positive and supportive attitude toward internal control and conscientious management.” OEP, VA, and CBIRF did not establish an adequate control environment to effectively carry out their medical stockpile management responsibilities. According to OEP officials, VA’s management of its stockpiles is based completely on the interagency agreement and on trust. OEP also did not require regular reports from VA, including inventories and financial reports (although it has been receiving financial reports since May 1999), and did not require or arrange for periodic, independent inventories of its stockpiles. OEP officials told us that they presumed that VA would perform inventory control functions as part of its stockpile maintenance responsibilities, as outlined in the interagency agreement. However, the agreement is silent about these requirements. The responsibility for managing OEP’s stockpiles is fragmented within the VA organization. Because of the lack of clear lines of command, the employees who manage OEP’s stockpiles from day to day receive little

⁸GAO/AIMD-99-21.3.1. We quote this source throughout this appendix as we discuss each of the five standards for internal control.

supervision from upper-level VA management. For example, although the interagency agreement with OEP was negotiated with and signed by VA's Emergency Management Strategic Healthcare Group (EMSHG), the group plays no role in the management of OEP's stockpiles. Another group within VA—the Emergency Pharmacy Services (EPS)—actually manages OEP's stockpiles. The director of a VA Consolidated Mail-Out Pharmacy that is independent of EMSHG heads the EPS group. The director of EPS divides his time between managing OEP's stockpiles and directing this pharmacy. He acknowledged that no clear chain of command exists. In the absence of adequate internal supervision and oversight, employees of EPS have not appropriately managed OEP's stockpiles.

Marine Corps managers also did not provide leadership for CBIRF's activities adequate to establish an environment to support internal control. Specifically, the Marine Corps did not provide written standards and expectations to CBIRF's personnel on stockpile control activities; did not request regular reports from CBIRF on the status of its medical stockpile, including inventories and financial reports; and did not arrange for periodic, independent inventories of CBIRF's stockpile.

Risk Assessment

Our Standards for Internal Control in the Federal Government states that "Internal control should provide for an assessment of the risks the agency faces from both external and internal sources." Risk management is the deliberate process of understanding risk—the likelihood that a threat will harm an asset with some severity of consequences—and then deciding on and implementing actions to create a certain level of protection or preparedness. Agencies should conduct risk assessment to (1) identify all potential internal and external risks, (2) prioritize the risks by assessing their likelihood and their effect on mission needs, and (3) take steps to mitigate those risks.

While required to do so by our standards for internal control, OEP, VA, and CBIRF have not performed mission risk assessments for their stockpiles. These agencies have not identified the risks that could threaten the availability and usefulness of their medical stockpiles, and they have not prioritized the risks according to their likelihood or their severity. As a result, the agencies have not taken steps to prevent, detect, or provide contingency plans if those threats were realized.

Control Activities

Our Standards for Internal Control in the Federal Government states that “Internal control activities help ensure that management’s directives are carried out. The control activities should be effective and efficient in accomplishing the agency’s control activities.” OEP, VA, and CBIRF did not establish clear policies and procedures that allow them to carry out control activities and appropriately manage drugs and medical supplies. We found a lack of (1) controls over computerized inventory systems, (2) periodic inventories, and (3) inventory security.

Computerized Inventory Systems Are Inadequate

The agencies’ computerized inventory systems should include controls over the hardware, operating system, and database management systems that ensure that all transactions affecting their stockpiles are recorded and that all data in these systems are complete and accurate. However, VA’s and CBIRF’s systems lack fundamental controls, which impedes their ability to comprehensively track medical supplies. This, in turn, places at risk their ability to fulfill their missions. Both agencies’ systems lack basic information, such as

- documentation of back orders, replacements, and shipment and receipt of all pharmaceuticals and medical supplies;
- the identity of all individuals who entered and made changes to the databases, the changes they made, and the dates and times they made them; and
- detailed, verifiable historical records on all replaced and discarded pharmaceuticals and medical supplies or a history of additions, deletions, and changes to the physical stock.

CBIRF’s computer system has additional problems that make it unreliable for accurately tracking the medical supplies in the stockpile. According to CBIRF’s personnel, the computer system they use to track their inventory—known as the Ships Automated Management System (SAMS)—was originally developed for use in remote locations such as on ships at sea and is not suitable for CBIRF’s mission. They noted that many of the supplies in the stockpile have not been assigned permanent Navy supply numbers in SAMS. These numbers are needed to order stockpile replacements through the Navy’s procurement system, and SAMS does not record a supply item without an assigned number. As a result, CBIRF staff had to create ad hoc (or dummy) numbers for many stockpile items so that SAMS can record them in the database.

CBIRF's computer system has also shown serious instability in recent months, including a complete computer system failure just before our visit. The system failure reportedly destroyed all CBIRF's inventory information and forced unit personnel to recreate their entire database by physically counting each item in their stockpile and reentering all inventory data back into the computer system.

Periodic Inventories Are Not Conducted

Medical supply inventories should be periodically counted and compared with records to ensure physical control over assets. However, before our audit, neither OEP nor VA had ever conducted a complete physical inventory of OEP's stockpiles. While VA possessed the required list of items that OEP wanted in the stockpile, after initially acquiring the medical supplies for the stockpile, VA never again compared OEP's required stockpile list with the actual items in each stockpile. When we compared OEP's required list with VA's inventory records from its computer tracking system, we found 17,000 discrepancies (9 percent). When we conducted our inventory of the items in the five stockpiles, we found that out of approximately 195,000 total items, there were about 22,000 discrepancies between VA's computerized inventory tracking system and the actual items maintained in the stockpiles—a discrepancy of about 11 percent. And when we compared OEP's required list with our inventory results, we found a discrepancy rate of more than 12 percent, or 23,000 discrepancies.

Discrepancies included overages, shortages, and incorrectly recorded items. Stockpile overages included both pharmaceuticals and general medical supplies, but most were general medical supplies such as gloves, bandages, and needles. For example, at one stockpile location, when we compared both VA's inventory list and our inventory results with the OEP list of required items, we found that VA purchased and maintained an excess of 2,400 pairs of gloves. The OEP list required 2,400 pairs of the nonlatex gloves; VA's inventory list showed 3,200 pairs in the stockpile; we found 4,800 pairs. At another location, we found 159 injector devices in the stockpile that were not on OEP's required list. VA's inventory system showed the amount although OEP had not required it.

Other discrepancies included shortages and incorrectly recorded items. Some of the shortages included controlled substances and antidotes. At two locations, the entire amount of diazepam, a controlled substance, was not in the stockpile. That is, it did not appear on VA's inventory list and we did not find it during our inventory, even though OEP required it. At one location, we found more than 1,000 additional potassium iodide tablets

than OEP required. Yet VA's inventory spreadsheet showed that it stored the same amount that OEP required. And at another location, when we compared our inventory results with VA's computerized inventory records, we found that the lot numbers of 438 vials of pralidoxime were recorded incorrectly.

CBIRF did not have an approved list of what should be in its inventory. Consequently, we were unable to determine whether any discrepancies existed between the actual stockpile of medical supplies and an approved list of medical supplies. Neither CBIRF personnel nor we could determine whether the correct medical supplies and quantities were on hand. Instead of physically counting the items in the stockpile and comparing the results with an approved list, CBIRF officials told us that they periodically count their medical supplies and then adjust their computer records to reflect the results of that most recent count. Nonetheless, when we compared our 100 percent inventory count with CBIRF's computer records of the stockpile, we found shortages and overages in CBIRF's stockpile. Specifically, we found that out of approximately 38,000 total items listed on CBIRF's computerized inventory record, there were about 10,000 discrepancies between CBIRF's inventory record and the actual items in the stockpiles—a discrepancy rate of about 26 percent.

Discrepancies in CBIRF's stockpile included overages, shortages, incorrect expiration dates, and incorrect lot numbers. We found about 5,700 items that were not recorded in the SAMS database but were in CBIRF's stockpile, accounting for excesses in the stockpile of approximately 15 percent. In total, we also found that about 2,300 items were not in CBIRF's stockpile—an antidote accounted for 65 percent of these items. CBIRF staff explained that 967 of the atropine injectors we identified actually constituted a data entry error—the contents of one container were entered into the database twice, using two different names for the same container. Finally, CBIRF's database comingles more than 3,000 training and unit medical supplies in the same database with the CBIRF stockpile supplies, making it difficult to place special emphasis on and track mission-critical items.⁹ CBIRF officials are unable to determine whether the necessary items are in its inventory because of inaccuracies in the computerized inventory system and the lack of an authorized list of medical supplies.

⁹Small quantities of medical supplies and pharmaceuticals that are used for the general medical care of CBIRF members.

Inventories Lack Security

In managing medical supply inventories that are vulnerable to risk of loss or unauthorized use, agencies should establish physical security procedures to reasonably assure that stockpiles remain intact and are available for use. Four of OEP's five stockpiles are located at VA facilities, and one is at a local nonfederal facility. The physical security at the various sites differs, but most stockpiles were stored in caged and locked areas. However, at one location, the windows in the building housing the stockpile had padlocked fencing material covering them, but the windows were open and the fencing material was loose, posing a risk of unauthorized access. Further, neither VA nor CBIRF had implemented sign-in sheets or logs to record entry and exit from the stockpiles that would allow management to review the security of and frequency of visits to the stockpiles.

Like OEP, the Marine Corps has not communicated clear expectations to CBIRF medical personnel about how their medical stockpile should be secured. CBIRF had no sign-in procedures or logs for recording access to its warehouse and trucks where its supplies are stored. Therefore, it cannot ensure that proper access is maintained at those locations. We found that antidotes were stored in an unsecured office inside the warehouse—an area that many CBIRF staff can gain access to. The office was kept at a cool temperature to accommodate the antidotes but was not always monitored. In contrast, CBIRF's physical security for its controlled substances was adequate. CBIRF maintains these items in a separate building, in a secured safe that had a sign-in book and was inventoried quarterly.

Effective Communication and Information Exchange

Our Standards for Internal Control in the Federal Government states that "Information should be recorded and communicated to management and others within the entity who need it and in a form and within a time frame that enables them to carry out their management control and other responsibilities." The exchange of information on stockpile inventory status and managerial activities among management within and across agencies was lacking. OEP officials did not communicate clear expectations about the type, extent, and frequency of reports they expected VA to produce on the status of OEP's stockpile. Their expectations regarding the type and frequency of oversight they would exert were also not clear. OEP intermittently requested fiscal reports from VA, which provided expenditure and financial reports for April, November, and December 1997 and October 1998. The reports varied significantly in the amount of information they offered and did not provide a clear and consistent picture of stockpile status and the program's financial status.

Monitoring

Our Standards for Internal Control in the Federal Government states that “Internal control monitoring should assess the quality of performance over time and ensure that the findings of audits and other reviews are promptly resolved.” All organizations that depend on a stockpile of assets to meet their mission must assure themselves that these assets are current, accounted for, and available for use. However, OEP, VA, and CBIRF have not implemented adequate systems to monitor their medical stockpiles and the activities of the staff who manage them. OEP did not require and VA did not perform regular audits or other reviews of the design and implementation of the stockpile program. Because no inventories had ever been conducted, neither VA nor OEP management could identify overages and shortages in supplies, correct deficiencies, implement improvements, or demonstrate that the program stockpiles were controlled in accordance with existing laws and standards.

Comments From the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

OCT 26 1999

Washington, D.C. 20201

Ms. Cynthia A. Bascetta
Associate Director
Veterans' Affairs and Military Health
Care Issues
United States General Accounting Office
Washington, D.C. 20548

Dear Ms. Bascetta:

The Department appreciates the opportunity to comment on the General Accounting Office's (GAO) draft report, "Combating Terrorism: Chemical/Biological Medical Supplies Poorly Managed," before its publication.

The Department believes the threat of chemical or biological attacks against citizens of the United States is of significant national concern. Preparing our Nation's capability and capacity to manage the human health effects of such attacks is of the highest priority to the Department of Health and Human Services (the Department).

Created by congressional mandate in Fiscal Year 1997, the domestic preparedness program included elements for which the Department was assigned primary responsibility. Part of this responsibility was the development of Federal medical response teams, which included specialized pharmaceuticals and antidotes primarily for chemical incidents, which this report addresses. Presidential Decision Directive 62 directs the Department to work with the Department of Veterans Affairs (VA) to ensure adequate stockpiles of antidotes and other pharmaceuticals.

We have already initiated efforts to remedy the deficiencies identified in GAO's report, in particular the re-defining and adjusting of the Department's management oversight of the VA-provided support activity. Based on our discussions with GAO staff, we are drafting a new memorandum of agreement between VA and the Department's Office of Emergency Preparedness (OEP), which will eliminate shortcomings identified by GAO. This oversight requirement, reflected in the new agreement, will most likely require additional OEP resources. Also, the Centers for Disease Control and Prevention (CDC) has found GAO's insights very helpful as CDC develops the national pharmaceutical stockpile and drafts their memorandum of agreement with VA.

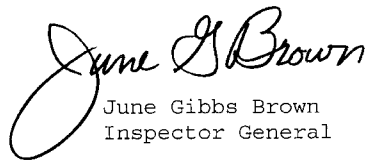
**Appendix III
Comments From the Department of Health
and Human Services**

Page 2 - Ms. Cynthia A. Bascetta

We appreciate GAO's offer to provide us with continuing technical assistance in enhancing our oversight of the stockpile program. With this assistance, we are confident that appropriate management control of our chemical and biological stockpile will be rapidly achieved.

These comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

Sincerely,



June Gibbs Brown
Inspector General

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for General Accounting Office reports. The OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

Glossary

The pharmaceuticals listed here may have alternative uses in a chemical or biological incident. We have described their primary purposes.

Amyl Nitrate

An inhalation drug that is used as an antidote for cyanide poisoning. It is also a common recreational stimulant known as a popper.

Atropine

A cardiac drug that is also used to reverse the effects of organophosphate poisoning.

Ciprofloxacin

A drug, also known as Cipro, that is used to treat infections, including anthrax.

Controlled Substance

A substance that has a high potential for abuse, as classified by the Controlled Substances Act, title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

Diazepam

A drug that is used to treat the symptoms of anxiety, convulsions, and muscle spasms. Its brand name is Valium.

Doxycycline

A drug that can be used to treat bacterial infections, including anthrax.

Mark I

An injection kit that contains an atropine auto-injector and a pralidoxime chloride auto-injector. Together, the drugs are used as an antidote for nerve gas poisoning.

Nasal Airway

A device that is inserted into an unobstructed pharynx through the nose to provide an airway.

Oral Airway

A device that is inserted into an unobstructed pharynx through the mouth to provide an airway.

Potassium Iodide

A drug that is used to help relieve breathing and lung problems.

Pralidoxime

A drug that is used as an antidote for organophosphate poisoning.

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