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ASPR Established Adequate Controls for Maintaining Physical Security and Inventory Records at Stockpile Site C

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Why OIG Did This Audit

• Between 1999 and 2018, the Strategic National Stockpile (Stockpile) was managed by the Centers for Disease Control and Prevention (CDC). During that time, we identified several systemic issues, such as the Stockpile's inventory system inaccurately tracking the movement and location of items.

• In 2018, HHS transferred responsibility for the Stockpile from CDC to the Administration for Strategic Preparedness and Response (ASPR). Changes in operational responsibility can create new risks that require implementation of mitigating controls.

• This audit is the third in a series that examines whether ASPR established adequate controls for maintaining (1) physical security over selected Stockpile sites and (2) its records of inventory.

What OIG Found

ASPR established adequate controls for maintaining physical security and inventory records at Stockpile Site C. For example, ASPR actively monitored the site's camera systems and restricted access to the site to maintain physical security. In addition, we identified no discrepancies during our inventory review and were able to accurately locate and identify each sample item.

What OIG Recommends

This report contains no recommendations.



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INTRODUCTION

WHY WE DID THIS AUDIT

The Department of Health and Human Services (HHS) is the Federal Government's principal agency for protecting the health of all Americans by responding to public health emergencies such as pandemics. The Strategic National Stockpile (Stockpile) is part of HHS's Federal medical response infrastructure.

Between 1999 to 2018, Stockpile was managed by the Centers for Disease Control and Prevention (CDC). During that time, we conducted several audits of Stockpile sites and confirmed that Stockpile inventory was adequately protected against theft, tampering, destruction, or other loss. However, we identified systemic issues, such as Stockpile's inventory system not always accurately tracking the movement and location of items.¹

In 2018, HHS transferred responsibility for Stockpile from CDC to the Administration for Strategic Preparedness and Response (ASPR). A change in operational responsibility for a program or activity can create new risks that require implementation of mitigating controls.

This audit is the third in a series that examines ASPR's controls for maintaining physical security and inventory at Stockpile sites.²

OBJECTIVE

Our objective was to determine whether ASPR established adequate controls for maintaining (1) physical security over Stockpile's Site C and (2) its records of inventory.

BACKGROUND

Strategic National Stockpile

Stockpile is a repository of vaccines, antibiotics, antidotes, antitoxins, medical devices, supplies, and medications meant to supplement and resupply State and local public health agencies in the event of a national emergency in the United States or its Territories. Stockpile uses multiple storage sites, allowing inventory to be flexibly deployed in response to emergencies such as anthrax attacks, chemical attacks, hazardous weather, or outbreaks of disease.

¹ <u>Public Summary Report: Readiness of CDC's Strategic National Stockpile Could Be at Risk in Case of a Public Health</u> <u>Emergency (A-04-16-03554)</u>, June 26, 2017.

² The first report in the series, <u>ASPR Established Adequate Controls for Maintaining Physical Security Over Stockpile</u> <u>Site A, but Some Inventory Discrepancies Were Identified (A-04-24-02044)</u>, was issued Sept. 30, 2024. The second report, <u>ASPR Established Adequate Controls for Maintaining Physical Security and Inventory Records at Stockpile</u> <u>Site B (A-04-24-02046)</u>, was issued Oct. 28, 2024.

Administration for Strategic Preparedness and Response

ASPR's mission is to assist the country in preparing for, responding to, and recovering from public health emergencies and disasters. ASPR also oversees advanced research, development, procurement, and stockpiling of medical countermeasures (e.g., vaccines, medicines, diagnostics, and other necessary medical supplies).

Stockpile Inventory

The Stockpile contains large quantities of medicine and medical supplies to protect the American public in the event of a public health emergency severe enough to cause local supplies to run out. These products are sometimes packaged in ways to aid efficient deployment. For example:

Federal Medical Stations

Federal Medical Stations (FMS) are caches of beds, supplies, and medicines that can be used to quickly convert a pre-identified building into a temporary medical shelter during a national emergency. Each FMS can sustain 50 to 250 stable primary or chronic care patients with medical and nursing services.

Push Packages

Push Packages are pre-packaged, transport-ready containers of pharmaceuticals, including antibiotics, and medical supplies that are positioned throughout the nation in secure warehouses. These packages are designed to arrive at designated locations within 12 hours of a Federal decision to deploy Stockpile assets.

СНЕМРАСК

CHEMPACKs are "pre-positioned caches" of nerve agent antidotes placed in secure locations in local jurisdictions around the country that allow for a rapid response to a chemical incident.

Stockpile Site Management

ASPR uses a contractor to provide onsite day-to-day operational expertise in asset storage, management, monitoring, logistics, reporting, and emergency staging for the delivery of supplies during a national emergency. An integral part of Stockpile operations is coordinating response activities with the contractor to seamlessly execute movement of product, minimize damage, and update inventory records during national emergencies. ASPR conducts a comprehensive physical inventory of Stockpile sites to verify on-hand balances and assess the overall value of the inventory. This process includes checking the accuracy of storage locations, evaluating material conditions, and confirming shelf-life data. To ensure both inventory accuracy and financial integrity, ASPR performs an annual 100-percent physical inventory count at each site.

Site C Creation

The COVID-19 pandemic created extraordinary challenges for the delivery of health care and human services to the American people. During the COVID-19 pandemic, personal protective equipment (PPE) demand exceeded the amount available within the Stockpile. Congress appropriated money to ASPR under multiple supplemental appropriation packages enacted in 2020. For the Stockpile, the Coronavirus Aid, Relief, and Economic Security (CARES) Act provided funding to the SNS to acquire PPE, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests.³

Stockpile also used CARES Act funds to acquire three additional warehouses, including Site C, to store PPE. ASPR planned to use the COVID-19 funds for long-term sustainment of this PPE. However, in June 2023 and again in March 2024, ASPR stated that Congress rescinded COVID-19 funds. Because Stockpile does not have the funding to sustain PPE, Site C is scheduled to contain PPE through 2027 when the funds end.

HOW WE CONDUCTED THIS AUDIT

To conduct this audit, we assessed Stockpile's physical security controls and inventory controls at Site C based on the site's facility security level (FSL) during the week of June 3, 2024.⁴

Federal regulations require federal agencies to meet physical security standards at nonmilitary facilities in accordance with the Interagency Security Committee's (ISC) standards, policies, and recommendations.⁵ We used the ISC standards, *The Risk Management Process: An Interagency Security Committee Standard* (2021 Edition), to conduct our physical security review.⁶ This ISC Standard defines the criteria and processes facility security professionals should use in

⁵ 41 CFR § 102-81.25.

³ Pub. L. No. 116-136, 134 Stat. 561 (2020).

⁴ Physical security countermeasures are predicated on an FSL designation. Once the FSL is determined, departments and agencies will use the risk management process, resulting in either the application of the baseline Level of Protection (LOP) applicable to the facility's FSL or the application of a customized LOP to address facility-specific conditions.

⁶ The ISC was formed by Executive Order (EO) 12977 following the bombing of the Alfred P. Murrah Federal Building in Oklahoma City, Oklahoma. EO 14111, Interagency Security Committee signed on Nov. 27, 2023, supersedes EO 12977. EO 14111 reinforces the importance of the security of federal facilities and defines duties and responsibilities to establish the ISC's authority for federal facility security. Today, the ISC is chaired by the Cybersecurity and Infrastructure Security Agency (CISA) within the Department of Homeland Security and consists of a permanent body of 66 departments and agencies to address continuing government-wide physical security needs for federal facilities. Consistent with EO 14111, ISC publications, standards, and recommendations apply to all nonmilitary Executive Branch departments and agencies within the borders of the United States and its territories.

determining an FSL. This standard provides an integrated, single source of physical security countermeasures and guidance on countermeasure customization for all nonmilitary Federal facilities occupied by Federal employees. We assessed these controls by observing both external and internal countermeasures for Site C, such as lighting, cameras, security protocols, and access points.

We assessed inventory controls by selecting and reviewing a non-statistical sample of 100 PPE items of Stockpile inventory stored at Site C. Examples of PPE items we reviewed were gloves, masks, respirators, and face shields. For each item in our sample, we checked the item in the warehouse location to verify that it existed; that it was in the specified location; and that any other identifying information associated with each product—such as the expiration date, lot number, and product count—was correct.

We used the Government Accountability Office's *Standards for Internal Control in the Federal Government, September 2014,* GAO-14-704G (Green Book) as the basis of our review of internal controls. The Green Book states that internal control is not one event, but a series of actions that occur throughout an entity's operations. Internal control is recognized as an integral part of the operational processes management uses to guide its operations rather than as a separate system within an entity (Green Book Overview 1.05). Further, effective operations produce the intended results of an organization through operational processes (Green Book Overview 2.19).

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

The appendix contains details of our audit scope and methodology.

FINDINGS

ASPR established adequate controls for maintaining physical security and inventory records at Stockpile Site C. For example, ASPR actively monitored the site's camera systems and restricted access to the site to maintain physical security. In addition, we identified no discrepancies during our inventory review.

ASPR ESTABLISHED ADEQUATE CONTROLS FOR MAINTAINING PHYSICAL SECURITY AND INVENTORY RECORDS

Physical Security Controls Were Adequate

"Appendix B: Countermeasures" (2022 edition) to *The Risk Management Process: An Interagency Security Committee Standard* (2021 Edition) is used by Federal agencies to mitigate risk to Federal facilities. It details the types of countermeasures the facility should have in place based on the risk assessment conducted for that specific facility.

We determined that ASPR has adequate security controls at Site C. Specifically, ASPR's controls included the following:

- a main entrance that was manned by a security guard and included a motorized gate and a fence made out of wrought iron steel;
- a central security command post and 24/7 armed guards;
- exterior LED lighting;
- camera systems that include motion detection to actively monitor the interior and exterior of the warehouse; and
- badge access limitations to key areas of the facility.

Inventory Records Were Accurate

The Green Book states that an organization should design control activities to achieve objectives and respond to risks.⁷ Specifically, the organization should establish physical controls to secure and safeguard vulnerable assets. Examples include security for and limited access to assets and equipment that might be vulnerable to risk of loss or unauthorized use. The organization should periodically count and compare those assets to control records.

Of the 100 sample items we reviewed, we identified no discrepancies and were able to accurately locate and identify each sample item.

This report contains no recommendations.

⁷ Green Book, Principle 10.

APPENDIX: SCOPE AND METHODOLOGY

SCOPE

We reviewed Site C's security and inventory controls. We limited our assessment to Site C's physical security controls in place at the time of our onsite review and the inventory stored during that time.

Our review of Site C was during the period June 3, 2024, through June 7, 2024.

METHODOLOGY

To accomplish our objective, we took the following steps:

- reviewed applicable regulations, policies, and guidance pertaining to physical security and asset management;
- reviewed applicable contracts and memorandums of understanding;⁸
- conducted an onsite review of Site C, including:
 - physical security measures, and
 - inventory management practices;
- interviewed applicable ASPR, Stockpile, site contractor, and onsite security officials;
- selected and reviewed a non-statistical sample of 100 PPE items of Stockpile inventory at Site C; and
- discussed the results of our audit with ASPR personnel.

On December 5, 2024, we provided ASPR with our draft audit report. On December 17, 2024, ASPR provided us with technical comments, and we made the changes as appropriate.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusion based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

⁸ A memorandum of understanding is a document that describes the broad outlines of an agreement between two or more parties.

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