

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**ASPR ESTABLISHED ADEQUATE
CONTROLS FOR MAINTAINING PHYSICAL
SECURITY OVER STOCKPILE SITE A, BUT
SOME INVENTORY DISCREPANCIES WERE
IDENTIFIED**

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for Audit Services**

**September 2024
A-04-24-02044**

Office of Inspector General

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

REPORT HIGHLIGHTS



September 2024 | A-04-24-02044

ASPR Established Adequate Controls for Maintaining Physical Security Over Stockpile Site A, but Some Inventory Discrepancies Were Identified

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 part of 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 has established adequate controls for maintaining physical security over Stockpile Site A and for maintaining its records of inventory. For example, ASPR upgraded the physical security at Site A by updating camera systems and adding guards, and the Stockpile's inventory records were generally accurate. However, we noted two discrepancies related to the location and description of inventory items. These discrepancies occurred because ASPR had not conducted an inventory review since Site A was expanded and reconfigured. These discrepancies we identified were corrected before the completion of our audit.

What OIG Recommends

We recommend that ASPR correct the one Push Package sample item in its Stockpile's inventory system and complete its annual warehouse inventory check by the established target date of September 2024.

ASPR concurred with our recommendation and detailed steps it has taken and plans to take in response to our recommendation.

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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 and 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 part of a series that examines ASPR's controls for maintaining physical security and inventory at Stockpile sites.

OBJECTIVE

Our objective was to determine whether ASPR established adequate controls for maintaining (1) physical security over Stockpile's Site A 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.

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,

¹ [Public Summary Report: Readiness of CDC's Strategic National Stockpile Could Be at Risk in Case of a Public Health Emergency | Office of Inspector General | Government Oversight | U.S. Department of Health and Human Services](#), June 2017.

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.

CHEMPACK

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 performs a physical inventory of Stockpile sites to verify and validate on-hand balances and value of the inventory, assess readiness, validate storage location accuracy, and validate material condition and shelf-life data. ASPR conducts a 100 percent physical inventory count of each Stockpile site annually to assure both inventory accuracy and financial validation of reported inventory.

HOW WE CONDUCTED THIS AUDIT

To conduct this audit, we assessed the Stockpile’s physical security controls and inventory controls at Site A based on the site’s facility security level (FSL) during the week of March 4, 2024.²

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.³ We used the ISC standards, *The Risk Management Process: An Interagency Security Committee Standard* (2021 Edition), to conduct our physical security review.⁴ This ISC Standard defines the criteria and processes that facility security professionals should use in 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 A, such as lighting, cameras, guard posts, security protocols, and access points.

We assessed inventory controls by selecting and reviewing a non-statistical sample of 80 items of Stockpile inventory stored at Site A. 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 serial number, lot number, and product count—was correct. See table below for sample selection.

² Physical security countermeasures are predicated on an FSL designation. Once the FSL is determined, departments and agencies will use a risk management process to determine the baseline Level of Protection (LOP) applicable to the facility’s FSL or a customized LOP to address facility-specific conditions.

³ 41 CFR § 102-81.25

⁴ 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.

Table: Sample Selection

Sample	Inventory Type
40	Medical Devices and Other Inventory
20	Vaccines and Controlled Substances
10	Push Packages
5	CHEMPACKs
5	Federal Medical Stations
80	Total Non-Statistical Sample Selection

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 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.

Appendix A contains details of our audit scope and methodology.

FINDINGS

ASPR has established adequate controls for maintaining physical security over Stockpile Site A and for maintaining its records of inventory. For example, ASPR upgraded the physical security at Site A by updating camera systems and adding guards and the Stockpile’s inventory records were generally accurate. However, we noted the following inventory discrepancies:

- One Push Package sample item was listed as being kept in a location at Site A that no longer existed.

- One quarantined sample item did not match the product listed in the Stockpile’s inventory system.⁵

These inventory discrepancies occurred because ASPR had not conducted an inventory review since Site A was expanded and reconfigured during the summer of 2023. Instead, ASPR relied on the site contractor to verify the inventory while Site A was in transition.

ASPR Has Established Adequate Controls for Maintaining Physical Security, but Some Inventory Discrepancies Were Identified

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 upgraded its security controls at Site A to maintain adequate physical security. Specifically, ASPR implemented upgrades to its technology controls and capabilities at Site A in the summer 2023, including the following:

- additional guard posts throughout the warehouse, including a guard post dedicated to protecting controlled substances;
- a new main entrance gate and a modernized guard shack that includes updated visual security equipment;
- upgraded exterior LED lighting;
- updated camera systems that provide additional views and motion-sensing capabilities throughout the warehouse; and
- badge access limitations to key areas of the facility.

Inventory Controls Were Generally Accurate, but Some Improvements Could Be Made

The Green Book states that an organization should design control activities to achieve objectives and respond to risks.⁶ Specifically, the organization should establish physical controls to secure and safeguard vulnerable assets. Examples include security for and limited

⁵ A quarantined item is one that is temporarily unavailable while awaiting the results of either Shelf Life Extension Program testing or a quality control investigation. For example, when an item reaches its expiration date, it becomes quarantined until the expiration date is extended or the item is sent for disposal.

⁶ Green Book, Principle 10

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 80 sample items we reviewed, we identified the following discrepancies:

- One Push Package sample item was listed in a location that did not exist at Site A. Stockpile personnel told us that prior to retrofitting the warehouse, pallets were double stacked, meaning they were placed on the front and back of shelves. The inventory records reflected those shelving locations. After retrofitting, pallets were no longer double-stacked. However, our sample item was listed in the inventory records as being in a double-stacked location. Stockpile personnel stated that this would have been identified during the next comprehensive warehouse inventory check that was scheduled for September 2024.
- One quarantined sample item should have contained 108 cases of medium gloves. However, we found the location contained a pallet of 60 cases of small gloves. According to Stockpile personnel, the 108 cases of medium gloves were mistakenly placed in the wrong location when they were received in the warehouse. During our review, Stockpile personnel moved both the medium gloves and the small gloves to their proper locations and corrected the issue during our onsite review.

These inventory discrepancies occurred because ASPR had recently expanded and reconfigured Site A but had not conducted an inventory since the expansion. Instead, ASPR relied on the site contractor to verify the inventory while Site A was in transition. Also, ASPR relied on its regularly scheduled annual 100 percent physical inventory count of Stockpile assets, which had not yet occurred, to identify discrepancies. This annual 100 percent physical inventory count is scheduled to be conducted in September of 2024.

RECOMMENDATIONS

We recommend that ASPR correct the one Push Package sample item in its Stockpile's inventory system and complete its annual warehouse inventory check by the established target date of September 2024.

ADMINISTRATION FOR STRATEGIC PREPAREDNESS AND RESPONSE COMMENTS AND OIG RESPONSE

In response to our draft report, ASPR concurred with our recommendation. ASPR stated that it corrected the location of the Push Package sample item in the Stockpile's inventory system the same week as our site visit. In addition, ASPR stated that SNS will perform the annual warehouse inventory check of Site A during the second week of September 2024.

We appreciate the documentation that ASPR provided to support the correction of the Push Package sample item after our site visit had ended but before the issuance of this report.

ASPR provided technical comments which we addressed, as appropriate, in the report. ASPR's written comments, excluding the technical comments, are included as Appendix B.

APPENDIX A: SCOPE AND METHODOLOGY

SCOPE

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

Our onsite review of Site A was during the period March 4, 2024, through March 8, 2024.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable regulations, policies, and guidance pertaining to physical security and asset management;
- reviewed applicable contracts and memorandums of understanding;⁷
- conducted an onsite review of Site A, 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 80 items of Stockpile inventory at Site A by:
 - sorting the Stockpile's list of assets for Site A by inventory type and warehouse location;
 - randomly selecting lines of inventory from each inventory type for review; and
 - physically reviewing the selected sample items within Site A;
- discussed any discrepancies with management while onsite; and
- discussed our findings and recommendations with ASPR personnel.

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.

⁷ A memorandum of understanding is a document that describes the broad outlines of an agreement between two or more parties.

APPENDIX B: ADMINISTRATION FOR STRATEGIC PREPAREDNESS AND RESPONSE COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Administration for Strategic
Preparedness and Response

Administrator and Assistant Secretary
for Preparedness and Response
Washington, D.C. 20201

TO: Amy J. Frontz
Deputy Inspector General for Audit Services

FROM: Dawn O'Connell
Administrator and Assistant Secretary for Preparedness and Response

SUBJECT: Office of the Inspector General Draft Report: *ASPR Has Established Adequate Controls for Maintaining Physical Security Over Stockpile Site A, But Some Inventory Discrepancies Were Identified (A-04-24-02044)*

DATE: September 5, 2024

The Administration for Strategic Preparedness & Response (ASPR) acknowledges the findings and recommendations included in the report issued by the HHS Office of the Inspector General (OIG) examining whether ASPR established adequate controls for maintaining the physical security over the Strategic National Stockpile (SNS) sites and records of stockpile inventory, specifically for Site A. ASPR appreciates OIG acknowledging ASPR's efforts to enhance the physical security measures of Site A since it was last audited 10 years ago.

During the inventory sampling of Site A, OIG found that one Push Package sample was listed in the Stockpile's inventory system as stored in an erroneous location. As a result, OIG included a recommendation in the issued report that ASPR correct the one Push Package sample item in its Stockpile's inventory system and complete its annual warehouse inventory check by the established target date of September 2024. **ASPR concurs with this recommendation, and considers the recommendation partially implemented.**

- SNS corrected the location of the Push Package sample in the Stockpile's inventory system the same week of the site visit, evidence of which has been shared with OIG. Based on this immediate correction, there is no further action for ASPR to take in implementing the recommendation to correct the sample location in the Stockpile's inventory system.
- Going forward, SNS will perform the annual warehouse inventory check of Site A during the second week of September 2024, and will share with OIG evidence that the inventory check occurred once completed.

A handwritten signature in cursive script that reads "Dawn O'Connell".

Dawn O'Connell
Administrator and Assistant Secretary for Preparedness and Response

Attachments

- Appendix 1 – Technical Comments