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National Veterinary Stockpile Oversight

Audit Report 33701-0001-21

September 2020

OFFICE OF INSPECTOR GENERAL

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OIG reviewed whether APHIS adequately administered the NVS to ensure it is prepared to respond to animal diseases affecting human health and the economy.

OBJECTIVE

Our objective was to evaluate APHIS' oversight of the NVS to ensure that it is prepared to respond appropriately to animal diseases affecting human health and the economy.

REVIEWED

OIG reviewed Departmental criteria, guidance, and procedures; interviewed agency officials; and reviewed documents related to the NVS from calendar years 2014 to 2019. We conducted fieldwork in Riverdale, Maryland, and visited warehouses that store NVS supplies and equipment. We performed fieldwork from August 2018 to July 2020. We conducted most of our work and identified our findings prior to the Coronavirus Disease 2019 outbreak.

RECOMMENDS

VS needs to determine the causes of inventory discrepancies, implement solutions to address them, and perform a complete physical inventory; regularly inspect equipment stored at contractor sites; and track the status of exercise participants' corrective actions to address recommendations.

WHAT OIG FOUND

Homeland Security Presidential Directive-9 established the National Veterinary Stockpile (NVS) to contain sufficient quantities of animal vaccine, antiviral, or therapeutic products to appropriately respond to the most damaging animal diseases affecting human health and the economy that will be capable of deployment within 24 hours of an outbreak. The Office of Inspector General (OIG) reviewed the Animal and Plant Health Inspection Service's (APHIS) oversight of the NVS and concluded that APHIS' Veterinary Services (VS) unit did not adequately oversee NVS supply and equipment inventory levels. Additionally, VS officials identified concerns with a contractor's maintenance of VS equipment and instituted a corrective action plan to resolve the problem. However, VS officials had not taken appropriate followup actions to ensure the contractor improved its performance and adequately maintained equipment. Also, VS did not determine whether States and vaccine manufacturers had implemented recommendations from NVS exercises designed to validate preparedness.

These issues, if not mitigated, could impact the response to an animal disease outbreak due to supply shortages or inoperable equipment. In addition, VS officials were unaware if participants in exercises designed to validate emergency preparedness had improved their ability to respond to an animal disease outbreak. We accepted management decision on all eight recommendations in the report.

United States Department of Agriculture
Office of Inspector General
Washington, D.C. 20250

DATE: September 23, 2020

AUDIT NUMBER: 33701-0001-21

TO: Kevin Shea
Administrator
Animal and Plant Health Inspection Service

ATTN: Rodney White
Director, Field Operations
Animal and Plant Health Inspection Service

FROM: Gil H. Harden
Assistant Inspector General for Audit

SUBJECT: National Veterinary Stockpile Oversight

This report presents the results of the subject audit. Your written response to the official draft is included in its entirety at the end of the report. We have incorporated excerpts from your response, and the Office of Inspector General's (OIG) position, into the relevant sections of the report. Based on your written response, we are accepting management decision for all eight audit recommendations in the report.

In accordance with Departmental Regulation 1720-1, final action is to be taken within 1 year of each management decision to prevent being listed in the Department's annual Agency Financial Report. Please follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer.

We appreciate the courtesies and cooperation extended to us by members of your staff during our audit fieldwork and subsequent discussions. This report contains publicly available information and will be posted in its entirety to our website (http://www.usda.gov/oig) in the near future.

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Background and Objective

Background

The prevention, detection, control, and eradication of animal diseases and pests are essential to protect the health and welfare of both animals and the people of the United States.[1] Homeland Security Presidential Directive (HSPD)-9, enacted in 2004, "establishe[d] a national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies."[2] HSPD-9 required the Secretary of Agriculture to develop "a National Veterinary Stockpile (NVS) containing sufficient quantities of animal vaccine, antiviral, or therapeutic products to appropriately respond to the most damaging animal diseases affecting human health and the economy that will be capable of deployment within 24 hours of an outbreak."[3] The Animal and Plant Health Inspection Service's (APHIS)[4] Veterinary Services (VS) unit manages the NVS. VS works to protect and improve the health, quality, and marketability of the Nation's animals, animal products, and veterinary biologics by preventing, controlling, and/or eliminating animal diseases, and monitoring and promoting animal health and productivity.[5]

The NVS contains supplies, equipment, and antiviral medications that States, Tribes, and territories need to respond to damaging animal disease outbreaks. Specifically, the NVS includes personal protective equipment (such as coverall suits, gloves, boot covers, goggles, and respirators) to guard against infection and other on-site hazards. In addition, the NVS has decontamination supplies, such as brushes, sprayers, and disinfectant, to deactivate pathogens and antiviral medications that could be dispensed to responders for preventative purposes.[6] Animal handling equipment (such as mobile corrals, squeeze chutes, and gates) is available to restrain and manage livestock and poultry. Depopulation equipment (such as carbon dioxide carts, whole house carbon dioxide systems, and foam depopulation units) is available to use on poultry while captive bolt kits can be used on livestock.[7]

VS uses the NVS to respond to animal disease outbreaks. Responses can require diverse resources ranging from cooling trucks to protective equipment. For example, VS used NVS

[1] 7 United States Code § 8301.
[2] HSPD-9, *Defense of United States Agriculture and Food* (Jan. 30, 2004).
[3] *Ibid*., Section 18(a).
[4] According to APHIS' website, the agency's mission is to protect the health and value of American agriculture and natural resources. United States Department of Agriculture (USDA)-APHIS, *About APHIS*, https://www.aphis.usda.gov/aphis/banner/aboutaphis (last visited on Apr. 28, 2020).
[5] USDA-APHIS, *APHIS Organization*, https://www.aphis.usda.gov/aphis/banner/aboutaphis/SA_APHIS_Organization (last visited on Feb. 3, 2020).
[6] For example, the NVS could use the supply of antiviral medications in response to a highly pathogenic avian influenza outbreak. Highly pathogenic avian influenza is a highly infectious and fatal viral disease that affects a wide range of bird species. Strains of the disease can affect other mammal species and have caused human fatalities.
[7] According to VS, "mass depopulation" is a method by which large numbers of animals must be destroyed quickly and efficiently with as much consideration given to the welfare of the animals as practicable. Foreign Animal Disease Preparedness and Response Plan, National Animal Health Emergency Management System Guidelines, *Mass Depopulation and Euthanasia* (Aug. 2015).

resources to respond to a New World screwworm[8] outbreak detected in 2016. Specifically, VS used cooling trucks from the NVS to store deer carcasses affected by New World screwworm until they could be incinerated. VS also used NVS resources to respond to a virulent Newcastle disease outbreak[9] in 2018 and 2019.[10] During this outbreak, VS provided depopulation equipment and personal protective equipment.

The NVS also includes foreign animal disease vaccines.[11] Vaccines can be capable of deployment within 24 hours, depending on type and location.[12] Although HSPD-9 stipulates that vaccines be included in the NVS, VS officials explained that vaccination is not always the best way to address an animal disease outbreak. For instance, VS officials noted that there could be international trade implications if the United States were to use a vaccine to respond to an animal disease.[13] In addition, vaccinated animals are subject to a withdrawal time, and vaccinated animals cannot enter the food chain before the withdrawal time has elapsed.[14] Vaccination might not be appropriate unless there are effective diagnostic tests that can distinguish between naturally infected and vaccinated animals. An ineffective diagnostic test could result in a disease continuing to spread. Another complication is that immunity to a disease after vaccination can take several days to occur,[15] and immunity to one type of a disease may not protect an animal against other types or subtypes.[16]

VS utilizes a variety of resources to assist with deciding what to stockpile for the NVS. The NVS Steering Committee works to ensure that decisions regarding the composition, inventory, storage, deployment, use, and staffing of the NVS are based on current threat assessments, science, predictive modeling, and expert advice.[17] The VS Scientific Working Group on Countermeasures[18] is responsible for maintaining a list of high-consequence diseases or pests

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[8] New World screwworms are fly larvae that can infest livestock and other warm-blooded animals, most often through an open wound. If not treated, infestations can be fatal.
[9] Virulent Newcastle disease is a fatal viral disease that can affect all species of birds. The disease spreads quickly and can infect and cause death, even in vaccinated poultry.
[10] Note, however, that a State Department of Food and Agriculture first detected virulent Newcastle disease in May 2018.
[11] Vaccines exist for some, but not all, animal diseases.
[12] VS has never deployed vaccine in response to an animal disease outbreak in the United States.
[13] For example, the United States generally prohibits the importation of live birds or hatching eggs from birds that have been vaccinated for certain subtypes of avian influenza.
[14] Withdrawal times are intended to ensure meat, milk, or other products from vaccinated animals are free from vaccine organism contamination.
[15] For instance, a VS Fact Sheet states immunity occurs 14 days after vaccination with one type of classical swine fever vaccine. APHIS-VS, *Questions and Answers: The National Veterinary Stockpile and Classical Swine Fever Virus Vaccine* (May 2015). Classical swine fever is a highly contagious viral disease of swine that can be fatal.
[16] For example, there are 7 known types and more than 60 subtypes of the foot-and-mouth disease virus. Foot-and-mouth is a severe and highly contagious viral disease that affects cows, pigs, sheep, and other animals with divided, or split, hooves. Most affected adult animals will not die from the disease, but it leaves them weakened, resulting in reduced meat/milk production.
[17] The Director of the NVS chairs the committee, and committee members include the APHIS Center for Veterinary Biologics, Epidemiology, and Animal Health; the Department of Health and Human Services; the Department of Homeland Security; the Agricultural Research Service; and the Federal Bureau of Investigation.
[18] Working group members include representatives from VS units, such as the Center for Epidemiology and Animal Health and the National Veterinary Services Laboratories.

that is important to VS when making stockpiling determinations.[19] In addition, VS utilized modeling performed by the Center for Epidemiology and Animal Health to assist with determining how much antiviral medication and personal protective equipment to stockpile for the NVS.[20] The model showed what different size outbreaks would require in terms of antiviral medication and personal protective equipment based on prior animal disease responses.

VS stores supplies and equipment for the NVS at various locations across the country. VS operates a main warehouse that stores a significant quantity of the NVS' resources. VS also has supplies, such as push packs,[21] stored at contractor warehouses in different locations in the continental United States. In addition, VS stores animal handling and depopulation equipment at contractor sites dispersed across the United States. According to VS officials, storing equipment and supplies at different locations allows them to deploy NVS resources to incident sites within 24 hours.

VS has contracts with commercial partners to assist with the response to an animal disease outbreak. Services include emergency air and ground transportation as well as depopulation, decontamination, and disposal activities. Contractors are able to provide responders within 24 hours, and they can access additional subcontracted personnel, if needed, for a larger response. VS trains contractor personnel to maintain, deploy, and operate NVS depopulation equipment used in response to animal disease outbreaks.

In addition to training contractor personnel, VS conducts exercises to enhance the preparedness of States to respond to animal disease outbreaks.[22] According to VS, the exercises enable stakeholders to test and validate plans and capabilities and identify gaps and areas of improvement before an actual event occurs. The exercises also allow States to validate their NVS State plans and emergency logistics support for a foreign animal disease outbreak. A State plan describes how the primary State agency, APHIS, and other organizations prepare, provide, and recover resources related to an animal disease outbreak.

Prior Audit

In a 2019 report, the Government Accountability Office (GAO) reviewed USDA's efforts to prepare for a foot-and-mouth disease outbreak.[23] The report included two recommendations to APHIS, which did not pertain to the NVS because the NVS is not responsible for managing or storing vaccine for foot-and-mouth disease. The United States, Canada, and Mexico established

[19] The list divided diseases and pests into tiers according to risk level. For example, foot-and-mouth disease is classified as a Tier 1 disease, while New World screwworm is considered to be a Tier 2 pest. The list was last issued in 2013, and the group was working to update it during our fieldwork.
[20] The Center for Epidemiology and Animal Health is a division of VS that helps APHIS strengthen animal health infrastructures both nationally and internationally through surveillance, monitoring, risk analysis, spatial epidemiology, and modeling.
[21] Push packs are configured containers of personal protection equipment for responders. Different types of push packs are available depending on the level of protection needed. They include items like coveralls, boot covers, gloves, tape, and goggles.
[22] For example, VS conducted 12 exercises with States between March 2016 and August 2019.
[23] GAO-19-103, *Foot-and-Mouth Disease USDA's Efforts to Prepare for a Potential Outbreak Could Be Strengthened* (Mar. 2019).

the North American Foot-and-Mouth Disease Vaccine Bank in 1982, which contains a variety of foot-and-mouth disease vaccine concentrates.

Objective

Our objective was to evaluate APHIS' oversight of the NVS to ensure that it is prepared to respond appropriately to animal diseases affecting human health and the economy.

Section 1: NVS Oversight Improvements

Finding 1: VS Needs To Improve Oversight of Supply and Equipment Inventory

VS did not adequately oversee the NVS supply and equipment inventory levels. This is the case because VS had not: identified and corrected the causes of inventory discrepancies, sufficiently trained staff on the inventory management system, conducted a complete physical inventory of NVS supplies and equipment since January 2017, nor updated documented procedures to reflect the current inventory management system.[24] Unreliable inventory records could result in shortages of supplies and equipment, which would hinder or delay the response to an animal disease outbreak.

VS procedures state that agency officials are to perform an annual physical inventory of NVS materials in February of each calendar year.[25] In order to complete the inventory, warehouse staff are to generate reports from the inventory management system, physically count the number of items on-hand, and compare the counts to the quantities listed in the system report. For differences between on-hand and system inventory totals that exceed 10 units, staff are to validate the on-hand quantity by a second count, or more if necessary, and enter the correct quantity into the system. In addition, VS procedures specify that agency officials need to determine the cause of discrepancies for inventory adjustments over $500 in value, or if the item needing the adjustment is determined to be sensitive in nature.[26] This physical inventory process is consistent with GAO's *Standards for Internal Control in the Federal Government*,[27] which stipulate that management periodically count and compare assets to control records.[28] GAO's standards also state that management should divide or segregate key duties and responsibilities among different people to reduce the risk of error, misuse, or fraud. These standards include separating the responsibilities for authorizing, processing, recording, and reviewing transactions.[29]

VS operates a main warehouse that stores critical NVS resources, including personal protective equipment, animal handling equipment, and decontamination supplies. In order to fulfill NVS' mission, VS needs to maintain a reliable inventory of the items at the warehouse to ensure there are sufficient supplies and equipment to respond to a damaging animal disease outbreak. We identified improvements that VS needs to make in order to adequately oversee the NVS supply and equipment inventory.

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[24] A physical inventory consists of comparing actual counts of inventory on-hand to the totals in the inventory management system.
[25] USDA APHIS, *APHIS VS Warehouse Standard Operating Procedures (SOP) Manual* (Aug. 2017).
[26] USDA APHIS, *APHIS VS Warehouse SOP Manual* (Aug. 2017). The manual does not define what constitutes a "sensitive item."
[27] USDA Departmental Regulation 1110-002, *Management's Responsibility for Internal Control* (June 2013), states that agency heads are responsible for establishing and maintaining a system of internal controls in accordance with GAO's standards within their agencies.
[28] GAO-14-704G, *Standards for Internal Control in the Federal Government*, par. 10.03 (Sep. 2014).
[29] *Ibid*.

Inventory Data

A VS official stated that the most significant challenge with the NVS was that the current inventory management system did not keep accurate records.[30] For example, another VS official explained that the system will sometimes show that an item is on backorder, even if the item is still in stock. Another functionality issue noted by the VS official was that the system cannot change between units of measure for the same item.[31] As a result, VS used separate spreadsheets to track supply and equipment quantities, even though the system is the official record of inventory. The VS official noted that warehouse staff will perform a physical count of an item in the warehouse rather than rely on the total in the system or the separate inventory spreadsheets.

We performed a preliminary analysis to assess if the inventory management system data were consistent and could be used for additional testing. We analyzed two different versions of reports from the system that were supposed to contain the same data representing 2017 annual physical inventory count adjustments.[32] We compared the two reports and noted differences between the inventory adjustments.[33] For example, one report contained 318 inventory adjustments, while the other report contained 766 inventory adjustments. Since the two reports had a significantly different number of adjustments, we asked the VS official who provided them which report was accurate. The official clarified that the report with the 766 inventory adjustments reflected the actual 2017 annual physical inventory results.

We also analyzed the worksheets that staff completed during the on-hand count in the warehouse for the 2017 physical inventory. The worksheets showed that staff identified significant inventory discrepancies between the on-hand count in the warehouse and totals in the inventory management system. For example, the staff identified over 260 fewer units of disinfectant and over 1,400 fewer respirators on-hand than in the system. Alternatively, staff counted over 1,500 boxes of gloves, while the system had a zero balance. We also identified differences when we compared the 2017 physical inventory worksheets to the system-generated report VS identified as representing the 2017 physical inventory results. For instance, the worksheets showed a system balance of 799 units for an item, while the system-generated report had a zero balance for the same item.

Based on our preliminary analyses and VS officials' concerns about the system, we concluded that we could not rely on information from the inventory management system for further testing. In addition, VS had not taken action to identify and correct the causes for inventory count discrepancies and had not performed a complete physical inventory of NVS supplies and equipment to confirm the accuracy of the data in the inventory management system since 2017.[34]

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[30] According to a VS official, VS began using this system for NVS inventory in 2015.
[31] The official provided an example of purchasing an item by the case, but deploying the item by the box. The official stated that 1 case might contain 10 boxes.
[32] VS provided one version in May 2019, and another version in August 2019 in response to our request about actions related to an independent report on the inventory management system. We reviewed 2017 data because that was the most recently completed physical inventory VS performed.
[33] An inventory adjustment represented a difference between old and new on-hand inventory counts for the same item.
[34] We discuss these topics in more detail later in this finding.

Accordingly, VS has not identified and corrected all discrepancies between the actual on-hand inventory and the counts recorded in the system since 2017. As a result, there was no complete listing of recently validated inventory totals we could have used for additional analysis and testing.

Inventory Management Improvements Needed

VS officials had not determined the causes of discrepancies identified during a physical inventory or taken actions to correct them. When we asked a VS official about the requirement in VS procedures to determine the root cause for inventory adjustments, the official responsible for warehouse oversight stated that VS did not perform this research due to a lack of available staff.[35] We acknowledge that VS had limited staff at its warehouse. However, until VS is able to research and address the root cause of discrepancies, the issues that create inventory inaccuracies will persist and continue to create inaccurate inventory data. In addition, GAO's standards state that management is to timely remediate identified internal control[36] deficiencies.[37] To overcome staffing limitations, VS could utilize non-warehouse staff to assist with determining the causes for inventory discrepancies. In order to improve the reliability of the NVS inventory records, we recommend that VS determine the causes of inventory discrepancies. Then, VS should address the causes of inventory discrepancies, which includes resolving system functionality issues that result in incorrect inventory records.

In addition, VS had not provided further training to staff who experienced issues with using the inventory management system. According to an APHIS official, VS staff received training on the system when it was first implemented. However, staff continued to have issues with the system. The APHIS official responsible for assisting staff when they encountered problems with the system stated that it was not very intuitive and was cumbersome to operate, due to the number of keystrokes needed to enter information. The official acknowledged that staff had to use workarounds in order to address these issues. We asked if supplemental training for the staff would be beneficial. The official stated that staff would benefit from more training that included processes that do not work in the system, information on lessons learned, and best practices. However, VS had not provided additional training because, according to a VS official, it was not practical to train on a system that had functionality issues. In our view, VS should train staff on the processes necessary to operate the system, even if there are functionality issues. Sharing lessons learned and workarounds could help staff use the system more efficiently and effectively for managing inventory. In addition, VS could use system training to help address, and possibly avoid, the causes of inventory discrepancies.

In order to improve oversight of supplies and equipment, we recommend that VS identify and address the causes of inventory discrepancies and provide additional system training to staff. These actions will improve VS' ability to maintain a reliable inventory to avoid potential shortages during an animal disease outbreak response. VS generally agreed with our recommendations.

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[35] USDA APHIS, *APHIS VS Warehouse SOP Manual* (Aug. 2017).
[36] According to GAO's *Standards for Internal Control in the Federal Government*, internal control comprises the plans, methods, policies, and procedures used to fulfill an entity's mission, strategic plan, goals, and objectives.
[37] GAO-14-704G, *Standards for Internal Control in the Federal Government*, par. 17.01 (Sep. 2014).

Physical Inventory

VS had not validated its supply and equipment inventory totals in its inventory management system by conducting a complete physical inventory since 2017. VS procedures state that officials are to perform an annual physical inventory of NVS materials in February of each calendar year.[38] Accordingly, we requested the annual physical inventory results for 2017 through 2019.[39] In response to this request, a VS official provided documentation for a complete physical inventory conducted in 2017, but did not provide evidence of a complete physical inventory conducted in 2018 or 2019. We confirmed with VS officials that the last complete physical inventory of NVS items was in January 2017.

When we asked why VS officials did not perform complete inventories in 2018 and 2019, an official cited limited staff resources. Specifically, the official stated that VS did not perform an annual physical inventory in 2018 or 2019 due to the virulent Newcastle disease outbreak response and the lack of necessary staff due to retirement.[40] VS provided documentation of a June 2019 cyclical inventory that, according to VS officials, included only 10 percent of the warehouse rows that hold NVS supplies and equipment. Since VS has not performed a complete physical inventory of supplies and equipment to validate the data in the inventory management system and adjust the data to reflect actual quantities on hand since 2017, officials have not ensured that the information in the system is reliable. An annual physical inventory is also important because it allows VS officials to better plan restocking purchases by identifying existing supply shortages and surpluses.

Therefore, we recommend that VS perform a complete physical inventory of NVS supplies and equipment and update the inventory management system with the on-hand counts. When we discussed our concerns with VS, an official agreed about the need to perform a physical inventory. Another VS official noted that staffing constraints limited VS' ability to perform previous physical inventories. As such, we recommend that VS utilize staff who are independent of recording inventory transactions and performing warehouse operations to conduct a physical inventory. Utilizing non-warehouse staff to perform the annual physical inventory would allow VS to mitigate staff limitations and would be consistent with GAO's standards because VS would be separating the duties of processing and reviewing inventory data.[41]

Warehouse Procedures

VS did not update its *APHIS VS Warehouse SOP Manual* to inform staff how to use the current inventory management system. We determined that the manual was not updated after VS could not provide us with discrepancy reports related to the physical inventories mentioned in the procedures. A VS official stated that the current inventory system cannot generate these reports,

[38] USDA APHIS, *APHIS VS Warehouse SOP Manual* (Aug. 2017).
[39] Specifically, we requested discrepancy reports that VS was to generate as the result of an annual physical inventory for these years.
[40] We note that virulent Newcastle disease was detected in May 2018, and that a lead material handler at the warehouse retired at the end of 2018.
[41] GAO-14-704G, *Standards for Internal Control in the Federal Government*, par. 10.03 (Sep. 2014).

so VS compared the inventory totals before and after inventory adjustments. The official stated that VS has not updated the procedures to reflect the current inventory management system. According to the procedures, a VS official is to review and update it annually, or as needed. VS officials stated that they did not update the procedures to reflect the new system because they did not fully understand the processes for operating it. Furthermore, they continued to experience functionality and accuracy issues.

VS needs to update the *APHIS VS Warehouse SOP Manual* to reflect processes necessary to operate with the current inventory management system. An update to the manual will ensure that the procedures reflect the actual steps that need to be taken at the warehouse. In addition, having up-to-date procedures will help ensure that activities are performed correctly if there is staff turnover, or when new or additional staff may be added, such as to perform physical inventories. In addition, documenting inventory procedures is consistent with GAO's standards, which state that management is to develop and maintain documentation of its internal control system.[42]

Overall, VS needs to increase its oversight of NVS supply and equipment inventory. Specifically, VS should identify and correct the causes of inventory discrepancies, provide additional training to staff on the inventory management system, utilize independent staff to perform a complete physical inventory of NVS supplies and equipment, and update the *APHIS VS Warehouse SOP Manual*. These actions should help improve VS' ability to manage the NVS supply and equipment inventory to ensure that it is adequate to respond to an animal disease outbreak.

We discussed our findings and recommendations with VS officials. Overall, VS agreed to implement all of our recommendations. In response to our draft report, VS informed us that it completed a physical inventory of NVS supplies and equipment in calendar year 2020.[43] In addition, VS provided a summary of inventory management system training that was given to its staff in January 2020.

Recommendation 1

Determine the causes of inventory discrepancies between actual counts of NVS supplies and equipment in the VS warehouse and the counts in the inventory management system. Then implement solutions to correct the causes of discrepancies, which includes resolving system functionality issues that result in incorrect inventory records.

Agency Response

In its September 3, 2020, response, APHIS stated that it agrees with and has implemented this recommendation. VS conducted a full physical inventory on February 18-21, 2020. After this inventory count, VS determined that the inventory discrepancies occurred because of functional errors with the inventory management system, cyclic inventories, and because of staff procedural errors. VS has identified and addressed staff procedural errors and has implemented weekly

[42] GAO-14-704G, *Standards for Internal Control in the Federal Government*, par. 3.09 (Sep. 2014).
[43] We did not review the results of the 2020 inventory during our fieldwork.

refresher training for all warehouse employees. This weekly schedule, which started on August 14, 2020, and will last for 12 weeks, includes the topics of inventory management, quality control, unit of measure, and inventory transfers. Additionally, beginning August 2020, VS implemented monthly cyclic counts. VS will utilize APHIS' Information Technology Division to assist in developing a workable solution to functional errors in the inventory management system. APHIS stated it will implement this recommendation by August 31, 2021.

OIG Position

We accept management decision for this recommendation.

Recommendation 2

Provide training to staff on processes necessary to operate the inventory management system.

Agency Response

In its September 3, 2020, response, APHIS stated that it agrees with and has implemented this recommendation. VS implemented weekly training for all warehouse employees that includes the topics of inventory management, quality control, unit of measure, and inventory transfers. This training began on August 14, 2020, and will last for 12 weeks.

OIG Position

We accept management decision for this recommendation.

Recommendation 3

Perform a complete physical inventory of NVS supplies and equipment, then update the inventory management system with the on-hand counts. VS should utilize staff who are independent of warehouse operations to perform this inventory.

Agency Response

In its September 3, 2020, response, APHIS stated that it agrees with and has implemented this recommendation. VS conducted a complete physical inventory on February 18–21, 2020, and updated the inventory management system to reflect the actual on-hand counts of NVS supplies and equipment. VS has scheduled the next complete physical inventory review for the week of February 15, 2021. For the February 2020 full inventory review, VS will use staff independent of warehouse operations.

OIG Position

We accept management decision for this recommendation.

Recommendation 4

Update the *APHIS VS Warehouse SOP Manual* to reflect the processes necessary to operate the inventory management system.

Agency Response

In its September 3, 2020, response, APHIS stated that it agrees with and has implemented this recommendation. In July 2020, VS updated the warehouse SOP to reflect the processes necessary to operate the inventory management system. This update includes information on creating a storage rule; receiving and filing a purchase order item; and creating sales orders, among other topics.

OIG Position

We accept management decision for this recommendation.

Finding 2: Additional Controls Needed To Ensure Equipment and Vaccines Are Available for Use

VS works with contractors, who store and maintain NVS equipment, and with manufacturers, who produce and store NVS vaccines. However, when VS officials identified concerns with a contractor responsible for equipment maintenance, they did not take appropriate followup actions to ensure the contractor maintained equipment adequately. Also, VS requested that a contractor located in Europe store vaccine in the United States, but did not validate that the contractor had done so. These issues occurred because VS did not implement its process to visit contractor sites where equipment was stored and did not have a process to re-examine the quality and quantity of vaccine after it was relocated to the United States for storage. These issues could jeopardize VS' ability to respond appropriately to a damaging animal disease outbreak with working equipment or sufficient vaccine.

GAO's *Standards for Internal Control in the Federal Government* state that management retains responsibility for the performance of processes assigned to service organizations.[44, 45] In addition, management is responsible for monitoring the effectiveness of internal control over the assigned processes performed by a service organization.[46] Management should use ongoing monitoring, separate evaluations, or a combination of the two to obtain reasonable assurance of the operating effectiveness of the service organization's internal controls over the assigned processes.[47] VS developed a procedure related to NVS contractor equipment maintenance that required agency officials to conduct a minimum of one visit to each contractor's location each year.[48] VS did not have a procedure to validate vaccine quantity and quality after it was relocated to a different manufacturer site for storage.

VS has contracts with commercial partners of the NVS to assist with aspects of a response to an animal disease outbreak. For example, VS entered into contracts with 2 partners to store NVS animal handling and depopulation equipment at 15 contractor sites.[49] As a result, VS has the capability to deploy equipment from several locations across the United States to respond to multiple, large-scale, simultaneous animal disease outbreaks. The contractors are responsible for performing quarterly maintenance on all equipment stored at their sites. In addition, VS has contracts with vaccine manufacturers to produce and store various animal disease vaccines. These contracts allow VS to acquire a limited supply of vaccine prior to a disease outbreak and to establish a reliable source of additional vaccine that VS can purchase during an outbreak if the existing inventory proves to be insufficient.

VS needs to implement additional controls to ensure equipment and vaccines are available for use in response to an animal disease outbreak. Additional controls are needed because VS had

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[44] GAO-14-704G, *Standards for Internal Control in the Federal Government*, par. OV4.01 (Sep. 2014).
[45] The standards define "service organization" as an external party that performs operational process(es) for an entity.
[46] GAO-14-704G, *Standards for Internal Control in the Federal Government*, par. 16.08 (Sep. 2014).
[47] *Ibid*.
[48] USDA APHIS, *NVS Depopulation, Disposal, and Decontamination (3D) SOP* (provided in May 2019).
[49] Equipment stored at contractor sites includes foam units, carbon dioxide units, support trailers, and animal handling equipment.

not adequately followed up on a contractor with known maintenance issues to verify that the contractor had maintained NVS equipment adequately. VS also requested that a manufacturer transfer previously purchased vaccine from Europe to the United States for easier deployment. However, VS officials did not verify that the transfer was successful because there was no policy in place to do so.

Equipment Storage and Maintenance

In 2017, VS officials determined that the contractor mainly responsible for storing NVS equipment was not performing required maintenance.[50] VS officials discovered this issue after observing damage to equipment during a visit to one site and noticing that the contractor was not requesting reimbursement for maintenance services. Examples of damaged equipment included one foam unit trailer with sun-bleached hoses, a dead battery, a clogged fuel tank, and an inoperable valve.[51] A second foam unit had no brakes, a dead battery, and a motor that would not start. A third foam unit had cracked valves due to freezing weather conditions and needed to have its carburetor cleaned before its motor would operate properly. VS and the contractor agreed upon a plan to correct the maintenance deficiencies. In the corrective action plan, the contractor identified factors that contributed to the maintenance issues such as not following written procedures when performing maintenance or inspections on units, using non-qualified or untrained personnel, and storing equipment outside without protective covers.[52] If this non-functional equipment needed to be deployed for use during an animal disease outbreak, personnel onsite would not be able to respond appropriately.

Despite identifying problems with contractor maintenance in 2017, VS had not conducted regular site visits at the contractor's locations to confirm that the equipment was properly maintained. VS' procedure related to NVS contractor equipment maintenance required that agency officials conduct a minimum of one visit to each contractor's location each year. Accordingly, we requested evidence that VS officials performed site visits at contractor locations from 2017 through 2019. In response, VS officials provided us with information about two site visits conducted in 2017—one of which identified damaged equipment. However, VS did not perform regular site visits to validate that the contractor was maintaining NVS equipment. VS also provided documents pertaining to quarterly maintenance that contractors had performed on the equipment from January 2018 through March 2019.[53] While we recognize that the quarterly maintenance reports can be an indicator that maintenance was performed, actual site visits can verify the condition of the equipment and the effectiveness of any corrective actions.

We discussed performing site visits with VS officials and they acknowledged that they did not routinely visit contractor locations to verify that contractors properly maintained NVS

[50] VS stored equipment at 15 contractor sites. This contractor was responsible for storing and maintaining equipment at 14 sites, while a different contractor held equipment at 1 site.
[51] Foam can be used for depopulating poultry.
[52] Corrective actions included having dedicated contractor officials travel to each storage site to train local employees to perform required maintenance until there are adequate experts at or near all storage sites, and having these officials submit inspection documents to VS within 5 days of the completion of maintenance.
[53] We reviewed the records, and the records supported that the contractors submitted invoices to VS for performing maintenance at all 15 contractor sites.

equipment. A VS official stated that performing an annual site visit at each contractor storage location might not be feasible due to travel funding limits. The official also stated that VS can inspect and observe equipment when it is deployed for training purposes. We agree that training sessions can provide VS officials with supplemental opportunities to observe equipment and determine if the contractor has been maintaining it. However, we note two limitations: (1) VS conducted a limited number of contractor training sessions,[54] which may not provide VS with the opportunity to inspect all equipment from all 15 contractor sites; and (2) in order to ensure equipment is operational for training sessions, the equipment should be assessed beforehand. Therefore, we recommend that VS develop and implement a schedule to inspect NVS equipment stored at contractor sites, at least on a rotational basis, to verify that assets are properly maintained.

Vaccine Storage and Transfer

In 2014, VS purchased vaccine from a manufacturer located in Europe and an official from VS' Center for Veterinary Biologics visited the manufacturer in 2015 to perform an acceptance visit. During this visit, VS officials toured the facility, discussed storage and cold-chain management,[55] and confirmed vaccine manufacture—including the bottling, testing, storage, and inventory of vaccines. In 2016, VS requested the manufacturer transfer the vaccine to its facility in the United States so that it could be deployed faster in the event of an animal disease outbreak.[56]

We requested documentation from VS showing receipt verification of the vaccine at the United States facility, and VS did not provide any evidence in response to this request. In addition, we asked the VS official who oversaw the contracts with vaccine manufacturers if the vaccine transfer was verified. The official responded that VS did not validate the number of vaccine doses that were transferred from Europe to the United States. We also confirmed with VS that there were no written procedures for overseeing the movement of vaccines between storage locations.[57] If the vaccines were damaged or lost while being transported to the United States, VS may not have been able to respond appropriately to an animal disease outbreak if the complete supply of vaccine was needed. While the vaccine that VS relocated expired during our audit, VS planned to purchase a new supply of the vaccine and transfer it to the United States once it was manufactured.

According to a VS official, this was the first time vaccine was relocated from Europe to the United States for storage purposes. The official also stated that the vaccine was produced and stored by a reputable manufacturer. When we asked why the vaccine transfer was not validated, a VS official stated that the manufacturer is responsible for properly storing the vaccine after the

[54] According to VS officials, VS tries to hold two training sessions per year, and that attendance is generally limited to the number of individuals needed to operate the equipment being used in the training. VS conducted six training sessions with contractors between September 2017 and September 2019.
[55] Vaccines must be transported and stored within a relatively narrow range of temperatures. Cold chain is a system used to ensure that vaccines stay within an appropriate temperature range from the manufacturer to the point of administration.
[56] According to VS, the manufacturer transferred over 1 million doses of vaccine to its facility in the United States.
[57] VS has procedures that cover the deployment of vaccine in response to an animal disease outbreak.

contract to purchase the vaccine is signed and VS performs an acceptance visit. However, without a process to validate the vaccine quantity and quality after relocation for storage, VS cannot ensure that its vaccine inventory is complete and available for use in response to an animal disease outbreak. The development and implementation of a process to oversee the movement of vaccine should include steps to determine if the vaccine was held at the proper temperature and whether any vaccine was lost or damaged during transit. A transfer process would conform to GAO standards for oversight mentioned above. The process would also be consistent with the Federal Acquisition Regulation.[58]

Overall, VS needs to implement additional controls to ensure equipment is properly maintained and to validate that vaccine is unaffected if it is relocated for storage purposes. This increased oversight would be consistent with the Federal Acquisition Regulation and GAO's standards.[59] The additional controls will also provide VS with increased assurance that equipment and vaccine will be available to appropriately respond to a damaging animal disease outbreak.

We discussed our findings and recommendations with VS officials. Overall, VS agreed to implement both of our recommendations. In response to our draft report, VS provided us with draft procedures to address our recommendations.

Recommendation 5

Develop and implement a schedule to inspect NVS equipment stored at contractor sites to verify that assets are properly maintained.

Agency Response

In its September 3, 2020, response, APHIS stated that it agrees with and has implemented this recommendation. In July 2020, VS developed a policy which includes a schedule for when site visits will be conducted to verify that assets are properly maintained. Between January 2020 and March 2020, VS conducted three site visits to review NVS equipment stored at contractor sites; however, due to the recent Coronavirus Disease 2019 outbreak, further site visits have been postponed until travel restrictions are lifted for non-essential travel.

OIG Position

We accept management decision for this recommendation.

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[58] The Federal Acquisition Regulation is the primary regulation for use by all executive agencies in their acquisition of supplies and services with appropriated funds. A process to transfer vaccine for storage purposes would be consistent with the Federal Acquisition Regulation because VS would be conducting quality assurance on the vaccine to determine if the supply still conformed to contract requirements after it was relocated. Federal Acquisition Regulation, Part 46, Subpart 46.401(a).

[59] Federal Acquisition Regulation, Part 46, Subpart 46.401(a) and GAO-14-704G, *Standards for Internal Control in the Federal Government*, pars. OV4.01 and 16.08 (Sep. 2014).

Recommendation 6

Develop and implement a process to validate the quantity and quality of vaccine if it is transferred from one location to another for storage purposes. This process should include steps to determine if the vaccine was held at the proper temperature and if any vaccine was lost or damaged during transit.

Agency Response

In its September 3, 2020, response, APHIS stated that it agrees with and has implemented this recommendation. VS has developed and issued a SOP on the vaccine acceptance process dated March 13, 2020. The SOP provides the detailed process for conducting vaccine acceptance inspections and the actions necessary when the contracting officer and program approved relocation of a vaccine to an alternate location, to include determination that the vaccine was held at the proper temperature or if the vaccine was lost or damaged during transit.

OIG Position

We accept management decision for this recommendation.

Finding 3: VS Needs To Better Track Corrective Actions From NVS Exercises

VS had not determined whether States and vaccine manufacturers implemented recommendations from NVS exercises.[60] This occurred because VS officials had not followed up with exercise participants to track the status of their corrective actions to address recommendations provided in after-action reports. Instead, VS relied on the exercise participants to implement recommendations without further followup. As a result, VS was unaware if exercise participants improved their preparedness to respond to an animal disease outbreak based on exercise recommendations.

According to Departmental guidance, exercises are the primary tool for assessing preparedness and identifying areas for improvement, and issues and observations from exercises are to be captured in an after-action report.[61] The guidance states that agencies and offices should plan, conduct, and evaluate their exercises using applicable guidelines and principles provided by the Department of Homeland Security's (DHS) Homeland Security Exercise and Evaluation Program (HSEEP).[62] Consistent with Departmental guidance, the training and exercise plan for the NVS states that VS applies HSEEP methods, procedures, and processes. HSEEP stipulates that corrective actions captured in the after-action report should be tracked and continually reported on until completion.[63] In addition, HSEEP states that stakeholders are able to demonstrate that exercises have yielded tangible improvements in preparedness by tracking corrective actions to completion.[64]

Between March 2016 and September 2019, VS conducted 12 exercises with States and 5 exercises with vaccine manufacturers related to the NVS. VS considers these exercises to be valuable tools to mitigate the risk of being unprepared to respond rapidly during an animal disease outbreak. According to DHS' National Response Framework, most incidents occur and are managed locally, and States play a critical role in preparation and response.[65] Therefore, conducting exercises with States is particularly important. States voluntarily participate in the exercises in order to validate plans to acquire, receive, store, stage, and distribute NVS resources needed for an animal disease response. NVS-related exercises have resulted in over 230 recommendations made to VS, States, and vaccine manufacturers.

We concluded that VS officials did not track the status of States' and vaccine manufacturers' corrective actions as the result of exercises. We discussed NVS-related exercises with the VS

[60] VS conducted both tabletop and full-scale exercises. A tabletop exercise is intended to generate discussion of various issues regarding a hypothetical, simulated emergency. These exercises are aimed at facilitating understanding and identifying strengths and areas for improvement. A full-scale exercise is typically the most complex and resource-intensive type of exercise, and it validates many facets of preparedness.
[61] USDA Departmental Manual 1800-001, *Incident Preparedness, Response, and Recovery*, Chapter 8 (Dec. 2011).
[62] *Ibid*.
[63] DHS, *HSEEP*, Chapter 6 (Apr. 2013). This stipulation is also in the latest version of HSEEP, which DHS issued in January 2020. HSEEP does not specify where corrective actions should be tracked and reported.
[64] *Ibid*.
[65] DHS, *National Response Framework*, "Guiding Principles" (Oct. 2019). This framework provides foundational emergency management doctrine for how the Nation responds to all types of incidents.

official responsible for NVS training and exercise coordination, and we asked how VS determined if States implemented recommendations. The VS official stated that each individual State is responsible for tracking the recommendations that pertain to its activities. The official noted that VS expected a State to update its NVS State plan as the result of an exercise, but VS does not have approval authority over the plan.[66] VS also provided us with a corrective action status report that VS used to track completion of the recommendations pertaining to VS activities resulting from exercises with States.[67] We reviewed the report and confirmed that it did not track recommendations made to States. Since VS was not tracking the status of State recommendations, VS was unaware if States took corresponding corrective actions that would have improved preparedness to respond to an animal disease outbreak.

VS also did not track recommendations pertaining to vaccine manufacturers as the result of NVS-related exercises. Based on our review of the corrective action status report, we also determined that it did not include recommendations for vaccine manufacturers. Accordingly, we confirmed with a VS official that VS did not track vaccine manufacturers' corrective actions to address recommendations from NVS exercises. When we asked why VS did not track vaccine manufacturers' corrective actions, the official responded that the vaccine manufacturers should address the recommendations based on their existing contracts with VS.

Exercises are a valuable tool in identifying areas in need of improvement, and VS cannot know if the exercise participants initiated actions to increase preparedness without proper tracking and followup. VS can plan actions to help avoid or overcome issues that may arise during an actual animal disease outbreak by being aware of unresolved exercise recommendations. For example, one NVS-related exercise recommendation was for a State to identify where animal disease outbreaks have occurred and/or are likely to occur and to determine warehouse and staging area facility requirements that will be needed to support operations in these locations. Another recommendation to that State was to identify both a location where VS could ship vaccine and the responsible official who would monitor and manage its distribution.

In addition, VS may use vaccine to respond to an outbreak, so VS engaged manufacturers in exercises. VS needs to know if manufacturers took actions to address recommendations for improvement prior to deploying the vaccine. For instance, recommendations to vaccine manufacturers from NVS-related exercises included developing instructions to interpret temperature-monitoring information included with a vaccine shipment and discussing guaranteed quality assurance levels with critical material vendors.[68]

Accordingly, VS needs to develop and implement a process to track the status of participants' corrective actions to address recommendations from NVS-related exercises. This process should

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[66] An NVS State plan is approved by a State official and describes how the primary State agency, APHIS, other government agencies, non-governmental organizations, and private-sector organizations prepare, provide, and recover resources during an animal disease event. According to a VS official, States are not required to have a plan.
[67] The report included information for recommendations such as the associated exercise, completion date, completion percentage, and corrective action description.
[68] Quality assurance levels are important in order to meet regulatory requirements for certain materials used in vaccine production.

include steps for VS to request that exercise participants provide an update on their actions to address outstanding recommendations within 1 year of the exercise and to document the participants' responses. This process would be consistent with HSEEP because VS would be tracking and reporting on corrective actions until completion.[69]

In addition, VS needs to improve and document its process for tracking its own corrective actions as a result of NVS-related exercises with States and vaccine manufacturers. VS maintained a corrective action status report to track completion of its own recommendations resulting from NVS-related exercises with States. We reviewed the report and confirmed that it did not include recommendations for VS that resulted from exercises with vaccine manufacturers. Also, the status report showed recommendations from exercises with States as complete, but it did not list completion dates.[70] We discussed missing recommendation information with the responsible VS official. He acknowledged that recommendation tracking is an area where VS can improve and that the status report should record the actual completion date for the corrective action. The official stated that staff turnover likely caused the recommendation information to be missing from the report.

We also determined VS did not have a documented process on how to utilize and update the corrective action status report. When we asked a VS official if there was a document that described how VS maintained the corrective action status report, the official referred to HSEEP as VS' documented process. According to the VS official, HSEEP provided a sufficiently documented process for tracking corrective action implementation. However, HSEEP is guidance issued by DHS, and it does not include details specific as to how VS manages the corrective action status report.

Therefore, VS should document the process to utilize and update the corrective action status report. This process should include steps to: (1) track recommendations applicable to VS resulting from NVS-related exercises with both States and vaccine manufacturers, and (2) update the report annually to ensure the information is accurate and complete. By including these steps in the documented process, VS can comply with GAO's standards[71] to develop and maintain documentation of internal controls. In addition, VS can be consistent with HSEEP guidance to track and report on the status of corrective actions until completion and address the completion-date deficiencies in the corrective action status report.[72]

We discussed our findings and recommendations with VS officials. Overall, VS agreed to implement each of our recommendations. In response to our draft report, VS provided us with draft procedures to address each of our recommendations.

Recommendation 7

Develop and implement a process to track the status of exercise participants' corrective actions to address recommendations from NVS-related exercises.

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[69] DHS, *HSEEP*, Chapter 6 (Apr. 2013).
[70] We identified 14 recommendations with missing completion dates out of 71 recorded recommendations.
[71] GAO-14-704G, *Standards for Internal Control in the Federal Government*, par. 3.09 (Sep. 2014).
[72] DHS *HSEEP*, Chapter 6 (Apr. 2013).

Agency Response

In its September 3, 2020, response, APHIS stated that it agrees with and has implemented this recommendation. VS has implemented an annual process to track the status of exercise participant's corrective actions to address recommendations made from NVS exercises. The process is described in an SOP dated May 26, 2020.

OIG Position

We accept management decision for this recommendation.

Recommendation 8

Document the process to utilize and update the corrective action status report. This process should include steps to: (1) track recommendations applicable to VS resulting from NVS-related exercises with States and vaccine manufacturers, and (2) update the report annually to ensure the information is accurate and complete.

Agency Response

In its September 3, 2020, response, APHIS stated that it agrees with and has implemented this recommendation. VS developed two separate SOPs for exercises with vaccine manufacturers and with States, Tribes, and Territories to address this recommendation. Both SOPs established procedures to track the progress of these entities in their completion of the recommended corrective actions identified during an exercise. The Corrective Action Tracker report is updated monthly to ensure that the information is accurate and complete.

OIG Position

We accept management decision for this recommendation.

Scope and Methodology

We performed audit fieldwork from August 2018 through July 2020. We conducted our audit by meeting with VS officials in Riverdale, Maryland, and visiting VS' main warehouse and a contractor warehouse that stored NVS supplies and equipment. We also reviewed non-statistically selected documents from calendar years 2014 through 2019 associated with NVS operations. We conducted the majority of our work and identified our findings prior to the Coronavirus Disease 2019 outbreak.

To accomplish our objective, we performed the following procedures:

- reviewed HSPD-9, DHS guidance, Departmental criteria, GAO's *Standards for Internal Control in the Federal Government*, and VS policies and procedures to identify NVS oversight requirements;
- interviewed and submitted questions for written response to VS officials to obtain an understanding of VS' oversight of the NVS;
- identified contracts related to vaccine production and storage; equipment maintenance and storage; and animal depopulation, decontamination, and disposal services to determine how these contracts enhanced VS' ability to utilize the NVS to respond to damaging animal disease outbreaks;
- evaluated after-action reports and corrective action tracking documents from exercises related to the NVS to determine if participants took action based on exercise outcomes and recommendations;
- became familiar with high-consequence foreign animal diseases to understand the threats they pose;
- compared animal population and dispersion data from the 2017 Census of Agriculture to storage sites for NVS resources and concluded that the locations were reasonable;
- assessed reports on responses to animal disease outbreaks to identify improvements made to the NVS based on these incidents;
- analyzed notes from the NVS Steering Committee and the VS Scientific Working Group on Countermeasures meetings to identify how these organizations contribute to NVS stockpiling determinations;
- reviewed modeling tools created by APHIS' Center for Epidemiology and Animal Health to understand stockpiling determinations for antiviral medication and personal protective equipment; and
- discussed our findings and recommendations with VS officials.

We interviewed officials knowledgeable about the VS inventory management system used to track NVS supplies and equipment, reviewed procedures related to NVS inventory management, and reviewed an agency process mapping and system requirements report about the system. We compared reports generated by the VS inventory management system to check for consistency and compared data from the system to source documentation to assess reliability. Based on this analysis and discussions with agency officials, we concluded that we could not rely on the information in the inventory management system for further testing (see Finding 1). However, this did not limit our audit, as we did not rely on the system's data to achieve our audit objective.

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 objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

Abbreviations

3D	Depopulation, Disposal, and Decontamination
APHIS	Animal and Plant Health Inspection Service
DHS	Department of Homeland Security
GAO	Government Accountability Office
HSEEP	Homeland Security Exercise and Evaluation Program
HSPD	Homeland Security Presidential Directive
NVS	National Veterinary Stockpile
OIG	Office of Inspector General
SOP	Standard Operating Procedures
USDA	United States Department of Agriculture
VS	Veterinary Services

AGENCY'S
RESPONSE TO AUDIT REPORT

United States Department of Agriculture

United States Department of Agriculture

Marketing and Regulatory Programs

Washington, DC 20250

TO: Gil H. Harden
Assistant Inspector General
For Audit

FROM: Kevin Shea /S/
Administrator

SUBJECT: Animal and Plant Health Inspection Service (APHIS) Response and Request for Management Decision on the Office of Inspector General Report, "National Veterinary Stockpile Oversight" (33701-01-21)

Thank you for the opportunity for APHIS to comment on this report. APHIS agrees with all of the OIG Recommendations and has implemented each of the Recommendations with corrective actions and newly developed and implemented policies and/or procedures completed during the course of the OIG audit. APHIS continues to improve its management and oversight of the National Veterinary Stockpile (NVS) to ensure that the agency stands adequately prepared to respond to animal diseases affecting human health and the economy.

Recommendation 1: Determine the causes of inventory discrepancies between actual counts of NVS supplies and equipment in the VS warehouse and the counts in the inventory management system. Then implement solutions to correct the causes of discrepancies, which includes resolving system functionality issues that result in incorrect inventory records.

APHIS Response: APHIS agrees with and has implemented this Recommendation. APHIS' Veterinary Services (VS) program conducted a full physical inventory count February 18-21, 2020. After this inventory count, VS determined that the inventory discrepancies occurred because of functional errors with the inventory management system, cyclic inventories, and because of staff procedural errors. VS has identified and addressed staff procedural errors, and has implemented weekly refresher training for all warehouse employees. This weekly schedule, which started on August 14, 2020 and will last for 12 weeks, includes the topics of inventory management, quality control, unit of measure, and inventory transfers. Additionally, beginning August 2020, VS implemented monthly cyclic counts. VS will utilize APHIS' Information Technology Division (ITD) to assist in developing a workable solution to functional errors in the inventory management system. Once training has been conducted, the new procedures will be added to the Warehouse Standard Operating Procedures. APHIS will implement this Recommendation by August 31, 2021.

Recommendation 2: Provide training to staff on processes necessary to operate the inventory management system.

APHIS Response: APHIS agrees with and has implemented this Recommendation. In addition, as referenced in our response to Recommendation #1, VS has implemented weekly training for all warehouse employees that includes the topics of inventory management, quality control, unit of measure, and inventory transfers. This training began on August 14, 2020 and will last for 12 weeks.

Recommendation 3: Perform a complete physical inventory of NVS supplies and equipment, then update the inventory management system with the on-hand counts. VS should utilize staff who are independent of warehouse operations to perform this inventory.

APHIS Response: APHIS agrees with and has implemented this Recommendation. VS conducted a complete physical inventory February 18-21, 2020 and updated the inventory management system to reflect the actual on-hand counts of NVS supplies and equipment. VS has scheduled the next complete physical inventory review for the week of February 15, 2021. For the February 2021 full inventory review, VS will use staff independent of warehouse operations.

Recommendation 4: Update the Warehouse SOP Manual to reflect the processes necessary to operate the inventory management system.

APHIS Response: APHIS agrees with and has implemented this Recommendation. In July 2020, VS updated the Warehouse Standard Operating Procedures to reflect the processes necessary to operate the inventory management system in the section titled, Section VIII, *Appendix A: Elite Updated Cheat Sheets (DMS, WMS, and TMS)*. This update includes information on creating a storage rule; receiving and filing a purchase order item; and creating sales orders, among other topics.

Recommendation 5: Develop and implement a schedule to inspect NVS equipment stored at contractor sites to verify that assets are properly maintained.

APHIS Response: APHIS agrees with and has implemented this Recommendation. In July 2020, VS developed a policy, *LC-2020-004, Guidelines for Conducting Site Visit*, dated July 20, 2020, which includes a schedule for when site visits will be conducted to verify that assets are properly maintained. Between January 2020 through March 2020, VS conducted three site visits to review NVS equipment stored at contractor sites, however, due to the recent COVID-19 outbreak, further site visits have been postponed until travel restrictions are lifted for non-essential travel.

Recommendation 6: Develop and implement a process to validate the quantity and quality of vaccine if it is transferred from one location to another for storage purposes. This process should include steps to determine if the vaccine was held at the proper temperature and if any vaccine was lost or damaged during transit.

APHIS Response: APHIS agrees with and has implemented this Recommendation. VS has developed and issued a Standard Operating Procedures on vaccine acceptance process, in a SOP titled, National Veterinary Stockpile (NVS) Vaccine Acceptance Standard Operating Procedures (SOP) for Finished Final Products, dated March 13, 2020. The SOP provides the detailed process for conducting vaccine acceptance inspections and the actions necessary when the contracting officer and program approves relocation of a vaccine to an alternate location, to include determination of the vaccine was held at the proper temperature or if the vaccine was lost or damaged during transit.

Recommendation 7: Develop and implement a process to track the status of exercise participants' corrective actions to address recommendations from NVS-related exercises.

APHIS Response: APHIS agrees with and has implemented this Recommendation. VS has implemented an annual process to track the status of exercise participant's corrective actions to address recommendations made from NVS exercises. The process is described in a SOP titled NVS CAP Tracker Guidance, dated May 26, 2020. VS staff enters the participants' corrective actions into an Excel spreadsheet (CAP Tracker) and establishes that the owners of the corrective actions update the status of their assigned actions. This will ensure that corrective actions are consistently reviewed and remain on target for implementation.

Recommendation 8: Document the process to utilize and update the corrective action status report. This process should include steps to: (1) track recommendations applicable to VS resulting from NVS-related exercises with States and vaccine manufacturers, and (2) update the report annually to ensure the information is accurate and complete.

APHIS Response: APHIS agrees with and has implemented this Recommendation. VS developed two separate SOPs to address this Recommendation; one SOP for vaccine manufacturers titled Future Exercise Planning Guidance for Vaccine Manufacturers, dated July 14, 2020,and another SOP for States, Tribes and Territories, titled Future Exercise Planning Guidance with States, Tribes and Territories, dated, July 14, 2020, respectively. Both SOPs established procedures to track the progress of all the entities listed above in their completion of the recommended corrective actions identified during exercise. The Corrective Action Tracker report is updated monthly to ensure that the information is accurate and complete.

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