March 2016

HIGH-CONTAINMENT LABORATORIES

Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety

GAO Highlights

Highlights of GAO-16-305, a report to congressional requesters

Why GAO Did This Study

Safety lapses at federal high-containment laboratories in 2014 and 2015 raised concerns about federal departments' oversight of these laboratories. These laboratories work with hazardous biological agents to develop measures to protect public and animal health and the food supply against these agents. GAO was asked to review oversight at federal high-containment laboratories.

This report examines (1) the extent to which federal agencies have comprehensive and up-to-date policies for managing biological agents in these laboratories, (2) how they oversee laboratories, and (3) the extent to which HHS and DOD have implemented recommendations from laboratory safety reviews. GAO assessed policies and oversight activities at 8 departments and their 15 component agencies that own and operate high-containment laboratories against federal internal control standards and program management leading practices, reviewed plans for implementing laboratory safety recommendations, and interviewed federal officials.

What GAO Recommends

GAO is making 33 recommendations, including that departments develop and update policies to include missing elements, ensure that oversight activity results are reported to senior officials, and develop plans with time frames for implementing safety recommendations. Six departments generally agreed with all recommendations; two departments stated that no further action was needed for some of them. As discussed in the report, GAO maintains that these actions are needed.

View GAO-16-305. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov or John Neumann at (202) 512-3841 or neumannj@gao.gov.

What GAO Found

Most of the 8 departments and 15 agencies that GAO reviewed had policies that were not comprehensive, and some departments and agencies had policies that were not up to date. Specifically, policies at 5 departments and 9 agencies were not comprehensive because they did not contain all six elements that GAO identified as key for managing biological agents in high-containment laboratories. These elements are incident reporting, roles and responsibilities, training, inventory control, inspections, and requiring adherence to or referencing leading laboratory safety guidance. Three of the 8 departments and 5 of the 15 agencies did not have policies. In addition, as of December 2015, 2 departments and 5 agencies did not have up-to-date policies. Comprehensive policies that contain all six key elements and that are reviewed and updated regularly would help departments reduce the risk of mismanaging hazardous biological agents and ensure that their policies convey consistent requirements for oversight, reflect current guidance, and address emerging threats.

The departments and agencies GAO reviewed were primarily using inspections to oversee their high-containment laboratories, but some of them were not routinely reporting inspection results, laboratory incidents, and other oversight activities, such as trend analyses, to senior officials. Specifically, 3 of the 8 departments and 13 of the 14 agencies that were operating high-containment laboratories at the time of GAO's review conducted routine laboratory inspections. Of those departments and agencies that routinely inspected laboratories, 1 department and 5 agencies did not conduct trend analyses of inspection results; senior officials at 5 departments and 8 agencies did not routinely receive inspection results; and senior officials at 4 departments did not routinely receive incident reports. These departments and agencies typically did not report this information because there was no requirement for them to do so. Routinely analyzing inspection results and incident reports and sending this information to senior officials—consistent with federal internal control standards for monitoring—would help them identify laboratory safety trends, determine whether safety lapses reflect systemic issues, and make necessary improvements.

The Department of Health and Human Services (HHS) and Department of Defense (DOD) had a number of serious laboratory safety lapses in 2014 and 2015 and were making progress in implementing recommendations from the reviews of these lapses. As of November 2015, HHS agencies—the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA)—reported implementing 91 and 6 recommendations, respectively, and were taking steps to implement others, and the National Institutes of Health (NIH) reported implementing all of its recommendations. DOD reported implementing one recommendation from its review and was taking steps to implement others. HHS and DOD have developed plans to track implementation of these recommendations, but CDC's, DOD's, and Army's plans lacked some implementation time frames. Plans that include time frames are consistent with federal internal control standards and leading practices for program management and would give HHS and DOD better assurance that they can implement these recommendations in a timely manner and assess their progress in doing so.