September 2010

BIOLOGICAL LABORATORIES

Design and Implementation Considerations for Safety Reporting Systems

GAO Accountability·Integrity·Reliability

Highlights

Highlights of GAO-10-850, a report to congressional requesters

Why GAO Did This Study

As the number of biological labs increases, so too do the safety risks for lab workers. Data on these risks—collected through a safety reporting system (SRS) from reports of hazards, incidents, and accidents—can support safety efforts. However, no such system exists for all biological labs, and a limited system—managed by the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS)—applies to only a subset of these labs. While a national SRS has been proposed, design and implementation are complex. In this context, GAO was asked to identify lessons from (1) the literature and (2) case studies; and to apply those lessons to (3) assess CDC and APHIS's theft, loss, or release (TLR) system for select agents, such as anthrax, and (4) suggest design and implementation considerations for a labwide SRS. To do its work, GAO analyzed SRS literature; conducted case studies of SRSs in aviation, commercial nuclear, and health care industries; and interviewed agency officials and biosafety specialists.

What GAO Recommends

GAO recommends that, in developing legislation for a national SRS for biological labs, Congress consider provisions for certain system features. GAO also recommends three improvements to the CDC and APHIS TLR system.

HHS disagreed with the first two recommendations and partially agreed with the third. USDA agreed with the three recommendations.

View GAO-10-850 or key components.
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What GAO Found

According to the literature, effective design and implementation of a safety reporting system (SRS) includes consideration of program goals and organizational culture to guide decisions in three key areas: (1) reporting and analysis, (2) reporter protection and incentives, and (3) feedback mechanisms. Program goals are best identified through stakeholder involvement and organizational culture, through assessment.

Case studies of SRSs in three industries—aviation, commercial nuclear, and health care—indicate that (1) assessment, dedicated resources, and management focus are needed to understand and improve safety culture; (2) broad reporting thresholds, experience-driven classification schemes, and local-level processing are useful SRS features in industries new to safety reporting; (3) strong legal protections and incentives encourage reporting and prevent potential confidentiality breaches; and (4) a central, industry-level unit facilitates lesson sharing and evaluation.

While the CDC and APHIS Select Agent Program (SAP) has taken steps in the three key areas to improve the usefulness of the TLR system for select agents, steps for improvement remain. Specifically, the agencies have taken steps to better define reportable events, ensure the confidentiality of reports, and dedicate resources to use TLR data for safety improvement. However, lessons from the literature and case studies suggest additional steps in the three key areas to enhance the usefulness of the system. For example, lowering reporting thresholds could provide precursor data and limited immunity could increase the incentive to report. Finally, the CDC and APHIS are in a unique position—as recognized authorities in the lab community and with access to TLR reports from across the industry—to guide SRS evaluation and ensure safety lessons are broadly disseminated.

For a national safety reporting system for all biological labs, existing information—about labs' organizational culture and the lab community's limited experience with SRSs—suggests the following features in the three key areas:

- *Reporting and analysis.* Reporting should be voluntary; available to all workers; cover hazards, incidents, and less serious accidents; accessible in various modes (Web and postal); and with formats that allow workers to report events in their own words to either an internal or external SRS system.
- *Reporter protections and incentives.* Strong confidentiality protections, data deidentification processes, and other reporting incentives are needed to foster trust in reporting.
- *Feedback mechanisms.* SRS data should be used at both the local and industry levels for safety improvement. An industry-level entity is needed to disseminate SRS data and to support evaluation.