

91-121, title IV, §409, Nov. 19, 1969, 83 Stat. 209, which comprises this chapter.

§ 1527. Improved biosafety for handling of select agents and toxins

(a) Quality control and quality assurance program

The Secretary of Defense, acting through the executive agent for the biological select agent and toxin biosafety program of the Department of Defense, shall carry out a program to implement certain quality control and quality assurance measures at each covered facility.

(b) Quality control and quality assurance measures

Subject to subsection (c), the quality control and quality assurance measures implemented at each covered facility under subsection (a) shall include the following:

- (1) Designation of an external manager to oversee quality assurance and quality control.
- (2) Environmental sampling and inspection.
- (3) Production procedures that prohibit operations where live biological select agents and toxins are used in the same laboratory where viability testing is conducted.
- (4) Production procedures that prohibit work on multiple organisms or multiple strains of one organism within the same biosafety cabinet.
- (5) A video surveillance program that uses video monitoring as a tool to improve laboratory practices in accordance with regulatory requirements.
- (6) Formal, recurring data reviews of production in an effort to identify data trends and nonconformance issues before such issues affect end products.
- (7) Validated protocols for production processes to ensure that process deviations are adequately vetted prior to implementation.
- (8) Maintenance and calibration procedures and schedules for all tools, equipment, and irradiators.

(c) Waiver

In carrying out the program under subsection (a), the Secretary may waive any of the quality control and quality assurance measures required under subsection (b) in the interest of national defense.

(d) Study and report required

(1) Study

The Secretary of Defense shall carry out a study to evaluate—

- (A) the feasibility of consolidating covered facilities within a unified command to minimize risk;
- (B) opportunities to partner with industry for the production of biological select agents and toxins and related services in lieu of maintaining such capabilities within the Department of the Army; and
- (C) whether operations under the biological select agent and toxin production program should be transferred to another government or commercial laboratory that may be better suited to execute production for non-Department of Defense customers.

(2) Report

Not later than February 1, 2017, the Secretary shall submit to the congressional defense committees a report on the results of the study under paragraph (1).

(e) Comptroller General review

Not later than September 1, 2017, the Comptroller General of the United States shall submit to the congressional defense committees a report that includes the following:

- (1) A review of—
 - (A) the actions taken by the Department of Defense to address the findings and recommendations of the report of the Department of the Army titled “Individual and Institutional Accountability for the Shipment of Viable Bacillus Anthracis from Dugway Proving Grounds”, dated December 15, 2015, including any actions taken to address the culture of complacency in the biological select agent and toxin production program identified in such report; and
 - (B) the progress of the Secretary in carrying out the program under subsection (a).
- (2) An analysis of the study and report under subsection (d).

(f) Definitions

In this section:

- (1) The term “biological select agent and toxin” means any agent or toxin identified under—
 - (A) section 331.3 of title 7, Code of Federal Regulations;
 - (B) section 121.3 or section 121.4 of title 9, Code of Federal Regulations; or
 - (C) section 73.3 or section 73.4 of title 42, Code of Federal Regulations.
- (2) The term “covered facility” means any facility of the Department of Defense that produces biological select agents and toxins.

(Pub. L. 114-328, div. A, title II, §218, Dec. 23, 2016, 130 Stat. 2052.)

Editorial Notes

CODIFICATION

Section was enacted as part of the National Defense Authorization Act for Fiscal Year 2017, and not as part of Pub. L. 91-121, title IV, §409, Nov. 19, 1969, 83 Stat. 209, which comprises this chapter.

Statutory Notes and Related Subsidiaries

“CONGRESSIONAL DEFENSE COMMITTEES” DEFINED

Congressional defense committees means the Committees on Armed Services and Appropriations of the Senate and the House of Representatives, see section 3 of Pub. L. 114-328, 130 Stat. 2025. See note under section 101 of Title 10, Armed Forces.

§ 1528. Congressional notification of biological select agent and toxin theft, loss, or release involving the Department of Defense

(a) Notification requirement

Not later than 15 days after notice of any theft, loss, or release of a biological select agent or toxin involving the Department of Defense is provided to the Centers for Disease Control and