

(A) a detailed justification for the testing;
 (B) a detailed explanation of the purposes of the testing;

(C) a description of each chemical or biological agent tested; and

(D) the Secretary's certification that informed consent to the testing was obtained from each human subject in advance of the testing on that subject.

(10) A description of the coordination and integration of the program of the Defense Advanced Research Projects Agency (DARPA) on basic and applied research and advanced technology development on chemical and biological warfare defense technologies and systems under section 1522(c)(2) of this title with the overall program of the Department of Defense on chemical and biological warfare defense, including—

(A) an assessment of the degree to which the DARPA program is coordinated and integrated with, and supports the objectives and requirements of, the overall program of the Department of Defense; and

(B) the means by which the Department determines the level of such coordination and support.

(Pub. L. 103-160, div. A, title XVII, §1703, Nov. 30, 1993, 107 Stat. 1854; Pub. L. 105-85, div. A, title X, §1078(f), Nov. 18, 1997, 111 Stat. 1915; Pub. L. 109-364, div. A, title X, §1041, Oct. 17, 2006, 120 Stat. 2390.)

CODIFICATION

Section was enacted as part of the National Defense Authorization Act for Fiscal Year 1994, and not as part of Pub. L. 91-121, title IV, §409, Nov. 19, 1969, 83 Stat. 209, which comprises this chapter.

AMENDMENTS

2006—Subsec. (b)(10). Pub. L. 109-364 added par. (10).
 1997—Subsec. (b)(9). Pub. L. 105-85 added par. (9).

TERMINATION OF REPORTING REQUIREMENTS

For termination, effective Dec. 31, 2021, of provisions of this section requiring submittal of annual report to Congress, see section 1061 of Pub. L. 114-328, set out as a note under section 111 of Title 10, Armed Forces.

§ 1524. Agreements to provide support to vaccination programs of Department of Health and Human Services

(a) Agreements authorized

The Secretary of Defense may enter into agreements with the Secretary of Health and Human Services to provide support for vaccination programs of the Secretary of Health and Human Services in the United States through use of the excess peacetime biological weapons defense capability of the Department of Defense.

(b) Report

Not later than February 1, 1994, the Secretary of Defense shall submit to the congressional defense committees a report on the feasibility of providing Department of Defense support for vaccination programs under subsection (a) and shall identify resource requirements that are not within the Department's capability.

(Pub. L. 103-160, div. A, title XVII, §1705, Nov. 30, 1993, 107 Stat. 1856.)

CODIFICATION

Section was enacted as part of the National Defense Authorization Act for Fiscal Year 1994, and not as part of Pub. L. 91-121, title IV, §409, Nov. 19, 1969, 83 Stat. 209, which comprises this chapter.

“CONGRESSIONAL DEFENSE COMMITTEES” DEFINED

Congressional defense committees means the Committees on Armed Services and the Committees on Appropriations of the Senate and House of Representatives, see section 3 of Pub. L. 103-160, 107 Stat. 1562. See note under section 101 of Title 10, Armed Forces.

§ 1525. Assistance for facilities subject to inspection under Chemical Weapons Convention

(a) Assistance authorized

Upon the request of the owner or operator of a facility that is subject to a routine inspection or a challenge inspection under the Chemical Weapons Convention, the Secretary of Defense may provide technical assistance to that owner or operator related to compliance of that facility with the Convention. Any such assistance shall be provided through the On-Site Inspection Agency of the Department of Defense.

(b) Reimbursement requirement

The Secretary may provide assistance under subsection (a) only to the extent that the Secretary determines that the Department of Defense will be reimbursed for costs incurred in providing the assistance. The United States National Authority may provide such reimbursement from amounts available to it. Any such reimbursement shall be credited to amounts available for the On-Site Inspection Agency.

(c) Definitions

In this section:

(1) The terms “Chemical Weapons Convention” and “Convention” mean the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction, ratified by the United States on April 25, 1997, and entered into force on April 29, 1997.

(2) The term “facility that is subject to a routine inspection” means a declared facility, as defined in paragraph 15 of part X of the Annex on Implementation and Verification of the Convention.

(3) The term “challenge inspection” means an inspection conducted under Article IX of the Convention.

(4) The term “United States National Authority” means the United States National Authority established or designated pursuant to Article VII, paragraph 4, of the Convention.

(Pub. L. 105-85, div. A, title XIII, §1303, Nov. 18, 1997, 111 Stat. 1951.)

CODIFICATION

Section was enacted as part of the National Defense Authorization Act for Fiscal Year 1998, and not as part of Pub. L. 91-121, title IV, §409, Nov. 19, 1969, 83 Stat. 209, which comprises this chapter.

§ 1526. Effective use of resources for non-proliferation programs

(a) Prohibition

Except as provided in subsection (b), no assistance may be provided by the United States Gov-

ernment to any person who is involved in the research, development, design, testing, or evaluation of chemical or biological weapons for offensive purposes.

(b) Exception

The prohibition contained in subsection (a) shall not apply to any activity conducted pursuant to title V of the National Security Act of 1947 [50 U.S.C. 3091 et seq.].

(Pub. L. 106-113, div. B, §1000(a)(7) [div. B, title XI, §1132], Nov. 29, 1999, 113 Stat. 1536, 1501A-493).

REFERENCES IN TEXT

The National Security Act of 1947, referred to in subsection (b), is act July 26, 1947, ch. 343, 61 Stat. 495, which was formerly classified principally to chapter 15 (§401 et seq.) of this title, prior to editorial reclassification in chapter 44 (§3001 et seq.) of this title. Title V of the Act is now classified generally to subchapter III (§3091 et seq.) of chapter 44 of this title. For complete classification of this Act to the Code, see Tables.

CODIFICATION

Section was enacted as part of the Arms Control and Nonproliferation Act of 1999, and also as part of the Arms Control, Nonproliferation, and Security Assistance Act of 1999, and the Admiral James W. Nance and Meg Donovan Foreign Relations Authorization Act, Fiscal Years, 2000 and 2001, and not as part of Pub. L. 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.