

and additional information on the rulemaking process, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Denise Beavers, Office of Regulations and Policy (HFS-24), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1721.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of December 9, 2004 (69 FR 71562), FDA issued a final rule to implement section 306 of the Bioterrorism Act. The regulation requires the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. Such records are to allow for the identification of the immediate previous sources and the immediate subsequent recipients of food. Persons subject to the regulation are required to be in compliance by December 9, 2005, June 9, 2006, or December 11, 2006, depending on the size of the business. On September 12, 2005, FDA issued the first edition of a guidance entitled "Questions and Answers Regarding Establishment and Maintenance of Records." This guidance entitled "Questions and Answers Regarding Establishment and Maintenance of Records (Edition 2)" responds to questions about the final rule on records. It is intended to help the industry better understand and comply with the regulation in 21 CFR part 1, subpart J. FDA is issuing this guidance as a Level 1 guidance. The guidance represents the agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. Consistent with FDA's good guidance practices regulation § 10.115(g)(2) (21 CFR 10.115), the agency will accept comments, but it is implementing the guidance document immediately, in accordance with § 10.115(g)(2), because the agency has determined that prior public

participation is not feasible or appropriate. As noted, the final rule requires that covered persons begin to establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food by December 9, 2005, June 9, 2006, or December 11, 2006, depending on the size of the business. Clarifying the provisions of the final rule will facilitate prompt compliance with these requirements and complete the rule's implementation.

FDA continues to receive large numbers of questions regarding the records final rule, and is responding to these questions under § 10.115 as promptly as possible, using a question-and-answer format. The agency believes that it is reasonable to maintain all responses to questions concerning establishment and maintenance of records in a single document that is periodically updated as the agency receives and responds to additional questions. The following four indicators will be employed to help users of this guidance identify revisions: (1) The guidance will be identified as a revision of a previously issued document, (2) the revision date of the guidance will appear on its cover, (3) the edition number of the guidance will be included in its title, and (4) questions and answers that have been added to the original guidance will be identified as such in the body of the guidance.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments and the guidance may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**III. Electronic Access**

Persons with access to the Internet may obtain the guidance at <http://www.cfsan.fda.gov/guidance.html>.

Dated: November 15, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-23062 Filed 11-21-05; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF DEFENSE**

**Office of the Secretary**

**32 CFR Part 310**

**Department of Defense Privacy Program**

**AGENCY:** Department of Defense.

**ACTION:** Final rule.

**SUMMARY:** The Department of Defense updates policies and responsibilities for the Defense Privacy Program which implements the Privacy Act of 1974 by showing organizational changes and realignments and by revising referenced statutory and regulatory authority.

**DATES:** *Effective Date:* November 7, 2005.

**FOR FURTHER INFORMATION CONTACT:** Mr. Vahan Moushegian, Jr., at (703) 607-2943.

**SUPPLEMENTARY INFORMATION:** The proposed rule was published September 7, 2005 at 70 FR 53135. No comments were received. The Office of the Secretary is therefore adopting the rule as published.

**Executive Order 12866, "Regulatory Planning and Review"**

It has been determined that Privacy Act rules for the Department of Defense are not significant rules. The rules do not (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy; a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

**Public Law 96-354, "Regulatory Flexibility Act" (5 U.S.C. Chapter 6)**

It has been determined that Privacy Act rules for the Department of Defense do not have significant economic impact on a substantial number of small entities because they are concerned only with the administration of Privacy Act systems of records within the Department of Defense.

**Public Law 96-511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35)**

It has been determined that Privacy Act rules for the Department of Defense impose no information requirements beyond the Department of Defense and that the information collected within the Department of Defense is necessary and consistent with 5 U.S.C. 552a, known as the Privacy Act of 1974.

**Section 202, Public Law 104-4, "Unfunded Mandates Reform Act"**

It has been determined that Privacy Act rulemaking for the Department of Defense does not involve a Federal mandate that may result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100 million or more and that such rulemaking will not significantly or uniquely affect small governments.

**Executive Order 13132, "Federalism"**

It has been determined that Privacy Act rules for the Department of Defense do not have federalism implications. The rules do not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

**List of Subjects in 32 CFR Part 310**

Privacy.

■ Accordingly, 32 CFR part 310, Subpart A—DoD Policy, is amended as follows:

**PART 310—DOD PRIVACY PROGRAM**

■ 1. The authority citation for 32 CFR part 310 continues to read as follows:

**Authority:** Pub. L. 93-579, 88 Stat 1896 (5 U.S.C. 552a).

■ 2. Section 310.1 is revised to read as follows:

**§ 310.1 Reissuance.**

This part is reissued to consolidate into a single document (32 CFR part 310) Department of Defense (DoD) policies and procedures for implementing the Privacy Act of 1974, as amended (5 U.S.C. 552a) by authorizing the development, publication and maintenance of the DoD Privacy Program set forth by DoD Directive 5400.11<sup>1</sup> and 5400.11-R, both entitled: "DoD Privacy Program."

■ 3. Section 310.3 is amended by revising paragraph (a) to read as follows:

**§ 310.3 Applicability and scope.**

(a) Applies to the Office of the Secretary of Defense (OSD), the Military Departments, the Chairman of the Joint Chiefs of Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense (IG, DoD), the Defense Agencies, the DoD Field Activities, and all other organizational entities in the Department of Defense (hereinafter referred to collectively as "the DoD Components"). This part is mandatory for use by all DoD Components. Heads of DoD Components may issue supplementary instructions only when necessary to provide for unique requirements within heir Components. Such instructions will not conflict with the provisions of this part.

■ 4. Section 310.4 amended by revising the definition of "Individual" to read as follows:

**§ 310.4 Definitions.**

*Individual.* A living person who is a citizen of the United States or an alien lawfully admitted for permanent residence. The parent of a minor or the legal guardian of any individual also may act on behalf of an individual. Members of the United States Armed Forces are individuals. Corporations, partnerships, sole proprietorships, professional groups, businesses, whether incorporated or unincorporated, and other commercial entities are not individuals.

■ 5. Section 310.5 is amended as follows:

- a. Removing the introductory text;
- b. Revising paragraphs (a) and (g);
- c. Adding paragraph (j) to read as follows:

**§ 310.5 Policy.**

a. The privacy of an individual is a personal and fundamental right that shall be respected and protected.

(g) Disclosure of records pertaining to personnel of the National Security Agency, the Defense Intelligence Agency, the National Reconnaissance Office, and the National Geospatial-Intelligence Agency shall be prohibited to the extent authorized by Public Law 86-36 (1959) and 10 U.S.C. 424. Disclosure of records pertaining to personnel of overseas, sensitive, or routinely deployable units shall be prohibited to the extent authorized by 10 U.S.C. 130b. Disclosure of medical

records is prohibited except as authorized by DoD 6025.18-R.<sup>2</sup>

(j) DoD Field Activities shall receive Privacy Program support from the Director, Washington Headquarters Services.

■ 6. Section 310.6 is amended by revising paragraphs (a)(4), (b), (c) introductory text, (c)(3), (d) introductory text and (d)(5); and adding paragraph (a)(5) to read as follows:

**§ 310.6 Responsibilities.**

- (a) \* \* \*
- (4) Serve as the Chair to the Defense Privacy Board and Defense Data Integrity Board (§ 310.9).
- (5) Supervise and oversee the activities of the Defense Privacy Office (§ 310.9).
- (b) The Director, Washington Headquarters Services, under the DA&M, OSD, shall provide Privacy Program support for DoD Field Activities.
- (c) The General Counsel of the Department of Defense (GC, DoD) shall:

- (3) Serve as a member of the Defense Privacy Board, the Defense Data Integrity Board, the Defense Privacy Board Legal Committee (§ 310.9).
- (d) The Secretaries of the Military Departments and the Heads of the Other DoD Components, except as noted in Sec. 310.5(j), shall:

(5) Submit reports, consistent with the requirements of DoD 5400.11-R, as mandated by 5 U.S.C. 552a and OMB Circular A-130, and as otherwise directed by the Defense Privacy Office.

■ 7. Section 310.9 is amended as follows:

- a. Revise paragraphs (a)(1), (b)(1), (c)(1);
- b. Redesignate the second paragraph (c) as a new paragraph (d);
- c. Revise newly redesignated (d)(2)(vi) and (d)(2)(x) to read as follows:

**§ 310.9 Privacy boards and office composition and responsibilities.**

(a) \* \* \*

(1) *Membership.* The Board shall consist of the DA&M, OSD, who shall serve as the Chair; the Director of the Defense Privacy Office, DA&M, who shall serve as the Executive Secretary and as a member; The representatives designated by the Secretaries of the Military Departments; and the following officials or their designees: The Deputy Under Secretary of Defense for Program

<sup>1</sup> Copies of DoD issuances may be obtained at <http://www.dtic.mil/whs/directives/>.

<sup>2</sup> See footnote 1 to § 310.1.

Integration (DUSD (PI)); the Assistant Secretary of Defense for Health Affairs; the Assistant Secretary of Defense for Networks and Information Integration (ASD(NII))/Chief Information Officer (CIO); the Director, Executive Services and Communications Directorate, Washington Headquarters Services (WHS); the GC, DoD; and the Director for Information Technology Management Directorate (ITMD), WHS. The designees also may be the principal point of contact for the DoD Component for privacy matters.

\* \* \* \* \*

(b) \* \* \*

(1) *Membership.* The Board shall consist of the DA&M, OSD, who shall serve as the Chair; the Director of the Defense Privacy Office, DA&M, who shall serve as the Executive Secretary; and the following officials or their designees: The representatives designated by the Secretaries of the Military Departments; the DUSD (PI); the ASD (NII)/CIO; the GC, DoD; the Inspector General, DoD; the ITMD, WHS; and the Director, Defense Manpower Data Center. The designees also may be the principal points of contact for the DoD Component for privacy matters.

\* \* \* \* \*

(c) \* \* \*

(1) The Committee shall consist of the Director, Defense Privacy Office, DA&M, who shall serve as the Chair and the Executive Secretary; the GC, DoD, or designee; and civilian and/or military counsel from each of the DoD Components. The General Counsels (GCs) and The Judge Advocates General of the Military Departments shall determine who shall provide representation for their respective Department to the Committee. This does not preclude representation from each office. The GCs of the other DoD Components shall provide legal representation to the Committee. Other DoD civilian or military counsel may be appointed by the Executive Secretary, after coordination with the DoD Component concerned, to serve on the Committee on those occasions when specialized knowledge or expertise shall be required.

\* \* \* \* \*

(d) *The Defense Privacy Office.*

\* \* \* \* \*

(2) \* \* \*

(vi) Review proposed DoD Component privacy rulemaking, to include submission of the rule to the Office of the **Federal Register** for publication and providing OMB and the Congress reports, consistent with 5 U.S.C. 552a,

OMB Circular A-130, and DoD 5400.11-R.

\* \* \* \* \*

(x) Compile and submit the "Biennial Matching Activity Report" to the OMB as required by OMB Circular A-130 and DoD 5400.11-R, and such other reports as required.

\* \* \* \* \*

Dated: November 16, 2005.

**L.M. Bynum,**

*OSD Federal Register Liaison Officer,  
Department of Defense.*

[FR Doc. 05-23070 Filed 11-21-05; 8:45 am]

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**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 117**

**[CGD05-05-129]**

**RIN 1625-AA-09**

**Drawbridge Operation Regulations; Elizabeth River, Eastern Branch, VA**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of temporary deviation from regulations.

**SUMMARY:** The Commander, Fifth Coast Guard District, has approved a temporary deviation from the regulations governing the operation of the Berkley Bridge, at mile 0.4, across the Eastern Branch of the Elizabeth River in Norfolk, Virginia. To facilitate electrical and mechanical repairs, this deviation allows the drawbridge to remain closed-to-navigation each day, from 7 a.m. to 7 p.m., on four two-day closure periods: November 29 & 30, 2005; December 28 & 29, 2005; January 24 & 25, 2006; and February 21 & 22, 2006.

**DATES:** This deviation is effective from 7 a.m. on November 29, 2005, to 7 p.m. on February 22, 2006.

**FOR FURTHER INFORMATION CONTACT:** Gary Heyer, Bridge Management Specialist, Fifth Coast Guard District, at (757) 398-6629.

**SUPPLEMENTARY INFORMATION:** The Berkley Bridge, a lift-type drawbridge, has a vertical clearance in the closed position to vessels of 48 feet, at mean high water.

The bridge owner, the Virginia Department of Transportation, has requested a temporary deviation from the current operating regulation set out in 33 CFR 117.1007, to effect electrical and mechanical repairs of the draw span.

To facilitate the repairs, the drawbridge will be closed to navigation each day, from 7 a.m. to 7 p.m., on four two-day closure periods: November 29 & 30, 2005; December 28 & 29, 2005; January 24 & 25, 2006; and February 21 & 22, 2006. During these periods, the repairs require immobilizing the operation of the lift span in the closed-to-navigation position. At all other times, the drawbridge will operate in accordance with the current operating regulations outlined in 33 CFR 117.1007.

The Coast Guard has informed the known users of the waterway so that they can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(c), this work will be performed with all due speed in order to return the bridge to normal operation as soon as possible. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: November 10, 2005.

**Waverly W. Gregory, Jr.,**

*Chief, Bridge Administration Branch, Fifth Coast Guard District.*

[FR Doc. 05-23029 Filed 11-21-05; 8:45 am]

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**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 165**

**[COTP Jacksonville 05-153]**

**RIN 1625-AA87**

**Security Zone; Sea Buoy at the Entrance of St. Mary's River to Kings Bay, GA**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary moving security zone around foreign naval submarines in transit within the area between 12 nautical miles offshore from the baseline, also known as the shoreline, at the mouth of the St. Mary's River to the Kings Bay Naval Submarine Base, Kings Bay, GA. The security zone includes all waters within 500 yards in any direction of the submarine. The rule prohibits entry into the security zone without the permission of the Captain of the Port (COTP) Jacksonville or his designated representative. Persons or vessels that receive permission to enter the security zone must proceed at a minimum safe speed, must comply with