

study involving a potential new patient population for an ICD with an approved functional indication.

## II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized will represent the agency's current thinking on functional indications for ICDs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

## III. Electronic Access

To receive "Functional Indications for Implantable Cardioverter Defibrillators" by fax, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1304 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

## IV. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collections of information addressed in the draft guidance document have been approved by OMB in accordance with the PRA under the regulations

governing IDEs (21 CFR part 812, OMB control number 0910-0078) and PMAs (21 CFR part 814, OMB control number 0910-0231). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910-0485.

## V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document on or before January 4, 2006. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 29, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

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## DEPARTMENT OF HOMELAND SECURITY

[DHS-2005-0066]

### Office of Inspector General; Privacy Act of 1974; Systems of Records

**AGENCY:** Office of Investigations, Office of Inspector General, Department of Homeland Security.

**ACTION:** Notice of revised Privacy Act systems of records.

**SUMMARY:** In accordance with the Privacy Act of 1974, the Department of Homeland Security Office of Inspector General is giving notice of a revised and updated system of records titled, "Investigations Data Management System (IDMS)."

**DATES:** Comments must be received on or before November 7, 2005.

**ADDRESSES:** You may submit comments, identified by Docket Number DHS-2005-0066, by *one* of the following methods:

EPA Federal Partner EDOCKET Web site: <http://www.epa.gov/feddoCKET>. Follow instructions for submitting comments on the Web site. DHS has joined the Environmental Protection Agency (EPA) online public docket and comment system on its Partner Electronic Docket System (Partner EDOCKET).

*Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

*Fax:* (202) 254-4285 (This is not a toll-free number).

*Mail:* Richard N. Reback, DHS, Office of Inspector General/STOP 2600, 245 Murray Drive, SW., Building 410, Washington, DC 20528.

*Hand Delivery/Courier:* Richard N. Reback, DHS, Office of Inspector General/STOP 2600, 245 Murray Drive, SW., Building 410, Washington, DC 20528.

*Instructions:* All submissions received must include the agency name and docket number for this notice. All comments received will be posted without change to <http://www.epa.gov/feddoCKET>, including any personal information provided.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.epa.gov/feddoCKET>. You may also access the Federal eRulemaking Portal at <http://www.regulations.gov>.

#### FOR FURTHER INFORMATION CONTACT:

Richard N. Reback, Department of Homeland Security, Office of Inspector General/STOP 2600, 245 Murray Drive, SW., Building 410, Washington, DC 20528 by telephone (202) 254-4100 or facsimile (202) 254-4285; Nuala O'Connor Kelly, Chief Privacy Officer, Department of Homeland Security, 601 S. 12th Street, Arlington, VA 22202-4202 by telephone (571) 227-3813 or facsimile (571) 227-4171.

#### SUPPLEMENTARY INFORMATION:

The Privacy Act embodies fair information principles in a statutory framework governing the means by which the United States Government collects, maintains, uses and disseminates personally identifiable information. The Privacy Act applies to information that is maintained in a "system of records." A "system of records" is a group of any records under the control of an agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. The Privacy Act requires each agency to publish in the **Federal Register** a description denoting the type and character of each system of records that the agency maintains, and the routine uses that are contained in each system in order to make agency record keeping practices transparent, to notify individuals regarding the uses to which personally identifiable information is put, and to assist the individual in finding such files within the agency.

The Department of Homeland Security (DHS), Office of Inspector

General (OIG) is updating and republishing a Privacy Act system of records within OIG Headquarters for its investigative files. Pursuant to the savings clause in the Homeland Security Act of 2002, Public Law 107-296, sec. 1512, 116 Stat. 2310 (Nov. 25, 2002) (6 U.S.C. 552), DHS components and offices could continue to rely on completed administrative actions after creation of the Department until those actions were amended, modified, superseded, terminated, set aside, or revoked. Two system notices previously supported the collection of investigation information by the DHS OIG, FEMA/IG-1 (General Investigative Files) and Treasury/DO .190 (Investigation Data Management System). The DHS OIG is now updating and republishing under its own nomenclature a system notice the Investigations Data Management System to cover the same records previously covered by these legacy system notices.

The DHS Inspector General is responsible for conducting and supervising audits, investigations, and inspections relating to the programs and operations of the Department. The OIG examines, evaluates and, where necessary, critiques these operations and activities, recommending ways for the Department to carry out its responsibilities in the most effective, efficient, and economical manner possible.

The Investigations Data Management System (IDMS) allows the OIG to receive and process allegations of violations of criminal, civil, or administrative laws and regulations relating to DHS employees, contractors and other individuals and entities associated with the DHS. IDMS also allows the OIG to manage information provided during the course of such investigations and, in the process, to facilitate its management of investigations. Through the IDMS, the OIG can create a record showing the disposition of allegations; track actions taken by DHS management regarding misconduct; track legal actions taken after referrals to the United States Department of Justice for prosecution; provide a system for creating reporting statistical information; and track OIG investigators' firearms qualification records and government property records.

This system notice makes several changes to the existing record systems on which DHS had been relying. It changes the address of the system location, revises the routine uses to conform them more closely to the needs and requirements of DHS, and more fully describes the categories of

individuals and of records that are maintained in IDMS.

In accordance with 5 U.S.C. 552a(r), a report of this revised system of records has been provided to the Office of Management and Budget (OMB) and to the Congress.

#### **DHS-OIG-002**

##### **SYSTEM NAME:**

Department of Homeland Security (DHS) Office of Inspector General (OIG) Investigations Data Management System (IDMS).

##### **SECURITY CLASSIFICATION:**

Classified, sensitive.

##### **SYSTEM LOCATION:**

This system of records is located in the OIG Office of Investigations in Washington, DC and in OIG field offices nationwide.

##### **CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals filing complaints of criminal, civil, or administrative violations, including, but not limited to, fraud, waste, or mismanagement; individuals alleged to have been involved in such violations; individuals identified as having been adversely affected by matters investigated by the OIG; individuals who have been identified as possibly relevant to, or who are contacted as part of an OIG investigation, including: (A) Current and former employees of DHS; United States Department of the Treasury, United States Department of Justice, and Federal Emergency Management Administration legacy employees; and persons whose association with current and former employees relate to alleged violations which affect the integrity or facilities of the DHS; and, (B) witnesses, complainants, confidential or non-confidential informants, suspects, defendants, or parties who have been identified by the DHS OIG, other DHS units, other agencies, or members of the general public in connection with authorized OIG functions; and DHS OIG Office of Investigations employees who are required to qualify with firearms and receive government property.

##### **CATEGORIES OF RECORDS IN THE SYSTEM:**

Records include: (A) letters, memoranda, and other documents citing complaints of alleged criminal or administrative misconduct; (B) investigative files, which include: (1) Reports of investigation resulting from allegations of misconduct or violations of law with related exhibits, statements, affidavits, records or other pertinent documents (including those obtained

from other sources, such as Federal, State, local, or foreign investigative or law enforcement agencies and other government agencies) obtained during investigations; (2) transcripts and documentation concerning requests and approval for consensual (telephone and non-telephone) monitoring; (3) reports from or to other law enforcement bodies; (4) prior criminal or non-criminal records of individuals as they relate to investigations; (5) subpoenas issued pursuant to OIG investigations and legal opinions, advice, and other legal documents provided by agency counsel; (6) reports of actions taken by management personnel regarding misconduct allegations and reports of legal actions, including actions resulting from violations of statutes referred to the United States Department of Justice for prosecution; (7) records involving the disposition of investigations and resulting agency actions (e.g., criminal prosecutions, civil proceedings, administrative action); and (8) other documentation and materials created during the course of or arising out of OIG investigations; and (C) property records and Firearms and Training qualification records for all OIG Office of Investigations employees;

Records contain the name and/or other personal identifying information for OIG Office of Investigations employees; names and other personal identifying information for individuals who are investigated or involved as complainants, witnesses, informants, or otherwise in OIG investigations; and details relating to investigations and complaints, such as the date of the complaint; case number(s); name of the complainant; matters alleged; referral documents; research materials; and other documentation.

##### **AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

5 U.S.C.A. App. 3; 5 U.S.C. 301; 6 U.S.C. 101, 113(b), 555.

##### **PURPOSE(S):**

The records and information collected and maintained in this system are used to receive and process allegations of violations of criminal, civil, and administrative laws and regulations relating to DHS programs, operations, and employees, as well as contractors and other individuals and entities associated with the DHS; monitor case assignments, disposition, status, and results; manage investigations and information provided during the course of such investigations; track actions taken by management regarding misconduct and other allegations; track legal actions taken following referrals to the United States Department of Justice

for prosecution or litigation; provide information relating to any adverse action or other proceeding that may occur as a result of the findings of an investigation; retrieve investigation results performed on individuals covered in this system; provide a system for creating and reporting statistical information; and to provide a system to track OIG investigator's firearms qualification records and property records.

**ROUTINE USES OF THESE RECORDS:**

In addition to those disclosures generally permitted under 5 U.S.C. 552a (b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

(A) To an appropriate Federal, State, territorial, tribal, local, or foreign law enforcement agency, licensing entity, or other appropriate authority charged with investigating, enforcing, prosecuting, or implementing a law (criminal, civil, administrative, or regulatory), where DHS becomes aware of an indication of a violation or potential violation of such law or where required in response to a compulsory legal process.

(B) To Federal intelligence community agencies and other Federal agencies to further the mission of those agencies relating to persons who may pose a risk to homeland security.

(C) To international governmental authorities in accordance with law and formal or informal international agreement.

(D) To a court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil or criminal discovery or proceedings, litigation, and settlement negotiations.

(E) To Federal, State, local, or foreign government entities or professional licensing authorities responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license, or where DHS OIG becomes aware of an indication of a violation or potential violation of civil or criminal law or regulation or where DHS has received a request for information that is relevant or necessary to the requesting entity's hiring or retention of an employee, or the issuance of a security clearance, license, contract, grant, or other benefit.

(F) To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or

other assignment for the Federal Government, when necessary to accomplish an agency function related to this system of records.

(G) To the United States Department of Justice or other Federal agency conducting litigation or in proceedings before any court, adjudicative or administrative body, when: (a) DHS; (b) any employee of DHS in his/her official capacity; (c) any employee of DHS in his/her individual capacity where the Department of Justice or DHS has agreed to represent the employee; or, (d) the United States or any agency thereof, is a party to the litigation or has an interest in such litigation.

(H) To third parties during the course of an investigation to the extent necessary to obtain information pertinent to the investigation.

(I) To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

(J) To the National Archives and Records Administration or other Federal Government agencies pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

(K) To appropriate persons engaged in conducting and reviewing internal and external peer reviews of the OIG to ensure adequate internal safeguards and management procedures exist or to ensure that auditing standards applicable to Government audits are applied and followed.

(L) To the President's Council on Integrity and Efficiency (PCIE) and other Federal agencies, as necessary, if the records respond to an audit, investigation or review which is conducted pursuant to an authorizing law, rule or regulation, and in particular those conducted at the request of the PCIE pursuant to Executive Order No. 12993.

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

None.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records in this system are stored on paper media and in digital or other electronic form in a secure Local Area Network (LAN) server and/or Wide Area Network (WAN) environment.

**RETRIEVABILITY:**

Paper media are retrieved alphabetically by name of subject or complainant, by case number, and/or by

special agent name and/or employee identifying number. Electronic media are retrieved by the name or identifying number for a complainant, subject, victim, or witness; by case number; by special agent name or other personal identifier; or by regional office designation.

**SAFEGUARDS:**

Information in this system is safeguarded in accordance with applicable laws, rules and policies, including the DHS Information Technology Security Program Handbook. All records are protected from unauthorized access through appropriate administrative, physical, and technical safeguards. These safeguards include restricting access to authorized personnel who have a need-to-know and using locks and password protection identification features. IDMS file areas are locked at all times, and facilities are protected from the outside by security personnel.

**RETENTION AND DISPOSAL:**

Investigative files are stored at OIG's Office of Investigations in Washington, DC, and in OIG field offices. OIG is in the process of developing a records retention schedule in conjunction with the National Archives and Records Administration (NARA).

**SYSTEM MANAGER(S) AND ADDRESSES:**

The System Manager is the Assistant Inspector General for Investigations, OIG Office of Investigations/STOP 2600, 245 Murray Drive, SW., Building 410, Washington, DC 20528.

**NOTIFICATION PROCEDURES:**

To determine whether this system contains records relating to you, write to the System Manager identified above.

**RECORD ACCESS PROCEDURES:**

Same as "Notification Procedures" above. Provide your full name and a description of information that you seek, including the time frame during which the record(s) may have been generated. Individuals requesting access must comply with the Department of Homeland Security's Privacy Act regulations on verification of identity (6 CFR 5.21(d)).

**CONTESTING RECORD PROCEDURES:**

See "Notification procedures" and "Record access procedures" stated above.

**RECORD SOURCE CATEGORIES:**

The information in this system of records is obtained from sources including, but not limited to, the individual record subjects; DHS officials

and employees; employees of Federal, State, local, and foreign agencies; and other persons and entities.

**EXEMPTIONS CLAIMED FOR THE SYSTEM:**

Pursuant to 5 U.S.C. 552a(j)(2) this system is exempt from the following provisions of the Privacy Act: 5 U.S.C. 552a (c)(3) and (4); (d); (e)(1), (e)(2), (e)(3), (e)(4)(G), (e)(4)(H), (e)(5) and (e)(8); (f)(2) through (5); and (g). Pursuant to 5 U.S.C. 552a (k)(1), (k)(2) and (k)(5), this system is exempt from the following provisions of the Privacy Act, subject to the limitations set forth in those subsections: 5 U.S.C. 552a (c)(3), (d), (e)(1), (e)(4)(G), (e)(4)(H), and (f).

Dated: September 26, 2005.

**Nuala O'Connor Kelly,**

*Chief Privacy Officer, Department of Homeland Security.*

[FR Doc. 05-20038 Filed 10-5-05; 8:45 am]

**BILLING CODE 4410-10-P**

**DEPARTMENT OF HOMELAND SECURITY**

**Bureau of Customs and Border Protection**

**Proposed Collection; Comment Request Application for Extension of Bond for Temporary Importation**

**AGENCY:** Customs and Border Protection (CBP), Department of Homeland Security.

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning the Application for Extension of Bond for Temporary Importation. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)).

**DATES:** Written comments should be received on or before December 5, 2005, to be assured of consideration.

**ADDRESSES:** Direct all written comments to the Bureau of Customs and Border Protection, Information Services Group, Room 3.2.C, 1300 Pennsylvania Avenue, NW., Washington, DC 20229.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to the Bureau of Customs and Border Protection, Attn.: Tracey Denning, Room 3.2.C, 1300 Pennsylvania Avenue NW., Washington, DC 20229, Tel. (202) 344-1429.

**SUPPLEMENTARY INFORMATION:** CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual cost burden to respondents or record keepers from the collection of information (a total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

*Title:* Application for Extension of Bond for Temporary Importation.

*OMB Number:* 1651-0015.

*Form Number:* CBP Form 3173.

*Abstract:* Imported merchandise that is to remain in the Customs territory for one year or less without duty payment is entered as a temporary importation. The importer may apply for an extension of this period on CBP Form 3173.

*Current Actions:* There are no changes to the information collection. This submission is being submitted to extend the expiration date.

*Type of Review:* Extension (without change).

*Affected Public:* Business or other for-profit institutions.

*Estimated Number of Respondents:* 16,800.

*Estimated Time Per Respondent:* 1 minute.

*Estimated Total Annual Burden Hours:* 348.

*Estimated Total Annualized Cost on the Public:* N/A.

Dated: September 28, 2005.

**Tracey Denning,**

*Agency Clearance Officer, Information Services Branch.*

[FR Doc. 05-20112 Filed 10-5-05; 8:45 am]

**BILLING CODE 9110-06-P**

**DEPARTMENT OF HOMELAND SECURITY**

**Bureau of Customs and Border Protection**

**Proposed Collection; Comment Request; NAFTA Regulations and Certificate of Origin**

**AGENCY:** Customs and Border Protection (CBP), Department of Homeland Security

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning the NAFTA Regulations and Certificate of Origin. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)).

**DATES:** Written comments should be received on or before December 5, 2005, to be assured of consideration.

**ADDRESSES:** Direct all written comments to the Bureau of Customs and Border Protection, Tracey Denning, Information Services Group, Room 3.2.C, 1300 Pennsylvania Avenue, NW., Washington, DC 20229.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to the Bureau of Customs and Border Protection, Attn.: Tracey Denning, Room 3.2.C, 1300 Pennsylvania Avenue, NW., Washington, DC 20229, Tel. (202) 344-1429.

**SUPPLEMENTARY INFORMATION:** CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual cost burden to respondents or record keepers from the collection of information (a total capital/startup costs and operations and maintenance costs).