
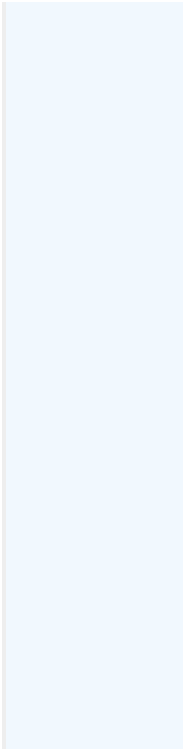


General Information			
<b>PTA / PIA Name:</b>	FDA - CECATS - QTR3 - 2025 - FDA4949385	<b>PTA / PIA ID:</b>	3509076
<b>Component Name:</b>	FDA - CDRH Export Certificate and Application Tracking System	<b>ATO Boundary Name:</b>	OC FDA Unified Registration and Listing System
<b>Overall Status:</b>	Complete 	<b># of Days - Open:</b>	3
<b>Submitter:</b>		<b>Submit Date:</b>	7/18/2025
<b>Next Assessment Date:</b>	07/20/2028	<b>Expiration Date:</b>	7/20/2028
<b>Office:</b>		<b>OpDiv:</b>	FDA
<b>Security Categorization:</b>	High		
<b>Make PIA available to Public?:</b>	Yes	<b>PIA Required:</b>	Yes
<b>General 01:</b>	Identify the Enterprise Performance Lifecycle Phase of the system.		Operations and Maintenance
<b>General 02:</b>	Is this a FISMA-Reportable system?		No
<b>General 03:</b>	Does the system have or is it covered by a Security Authorization to Operate (ATO)?		Yes
<b>General 04:</b>	ATO Date or Planned ATO Date.		7/28/2022
<b>General 05:</b>	Is the system or electronic information collection, agency or contractor operated?		Agency
<b>History Log:</b>	<a href="#">View History Log</a>		

Privacy Threshold Analysis			
<b>Privacy Threshold Analysis</b>			
<b>PTA 01:</b>	Point of Contact (POC) Name		POC Name: Anna Zhang
<b>PTA 01A:</b>	POC Title and Organization		POC Title: FURLS Manager (all modules) POC Organization: FDA
<b>PTA 01B:</b>	POC Email Address		Anna.Zhang@fda.hhs.gov
<b>PTA 01C:</b>	POC Phone Number		240-447-5198
<b>PTA 02:</b>	Indicate the following reason(s) for this PTA. Choose from the following options.		PIA Validation (PIA Refresh)

<b>PTA 02A:</b>	Describe in further detail any changes to the system that have occurred since the last PIA.	There have been no changes since the last approved PTA/PIA.
<b>PTA 03:</b>	Is the data contained in the system owned by the agency or contractor?	Agency
<b>PTA 04:</b>	Please give a brief overview of the purpose of the system by describing what the functions of the system are and how the system carries out those functions in support of HHS.	<p>The subject of this assessment is the Center for Devices and Radiological Health (CDRH) Export Certification Application and Tracking System (CECATS), one of several modules that operate within the larger system boundary of the Office of the Commissioner (OC) Food and Drug Administration (FDA) Unified Registration Listing System (OC FURLS) (assessed separately).</p> <p>The Bioterrorism Act of 2002 required the Food and Drug Administration (FDA) to develop two systems designed to safeguard the nation's food supply: one to support the registration of facilities that manufacture, process, pack, or hold food products intended for consumption in the United States (Food Facility Registration or FFR) and one to receive prior notice before food is imported or offered for import into the United States (Prior Notice System Interface or PNSI).</p> <p>FDA implemented key provisions of the Act with the creation of the FDA Industry System (FIS, assessed separately) and the OC FDA Unified Registration Listing System (OC FURLS), a portfolio of registration, listing, export certification, reporting, and user authentication applications. These systems were created, in part, to streamline and modernize how FDA manages registration and listing information for the industries it regulates.</p> <p>The OC FURLS CECATS module allows CDRH's Office of Compliance (OC) to receive, review, and issue export certificates to US exporters of regulated medical device products. This FURLS module encompasses several export certificate types, Export Permit Letters, Simple Notifications, and Certificates to Foreign Governments.</p> <p>The CECATS module provides a means for tracking certificate requests, automating the certificate process, and for FDA personnel to monitor domestic product status. It will assist FDA personnel in identifying facilities that are not in compliance with FDA laws and regulations for firm's manufacturing/distributing medical devices in the U.S. and in a foreign country. The CECATS module within OC FURLS has been in production since 2011-2012 and has since received yearly funding from CDRH for continuous improvements, enhancements, and automations of the system.</p> <p>The Food and Drug Administration (FDA) created the FDA Industry Systems (FIS) to facilitate the making of submissions to the FDA, including registrations, listings, and other notifications. FIS is the portal which goes through Online Account Administration (OAA) and into FURLS.</p>



Users access CECATS through OC FURLS. OC FURLS is used by internal and external users. Internal users of the system are FDA Employees and Direct Contractors. External users are members of the public (e.g., local/foreign industry owners, operators, and agents). Access to OC FURLS is managed by the Online Account Administration (OAA) application (the FURLS user account database and user authentication module that is the subject of its own assessment). OAA uses the business rules and infrastructure implemented by FDA's Single Sign-On (SSO) process in creating and administering FDA Personnel user accounts for internal users.

OC FURLS modules provide the capability for industry, both domestic and foreign, to register food, poultry, tobacco and medical facilities, request export certificates, provide product information, and apply to be added to listing programs. FDA manages these requests, communicates with industry, and approves or rejects submissions through the OC FURLS modules.

**PTA 05:**

List and/or describe all the types of information that are collected, maintained, and/or shared by the system regardless of whether that information is PII and how long that information is stored.

Users access CECATS through OC FURLS. Access to OC FURLS is managed by the Online Account Administration (OAA) application (the FURLS user account database and user authentication module that is the subject of its own assessment). OAA uses the business rules and infrastructure implemented by FDA's Single Sign-On (SSO) process in creating and administering FDA Personnel user accounts for internal users.

Internal FDA users authenticate using Single Sign On (SSO). All modules require that the external users log into the system for authentication to determine which modules within OC FURLS the user can access per the users' access request. Users may be external (to FDA) industry users (local/foreign industry owners, operators, and agents) or state agency users under contract with the FDA. Users may also be internal (to FDA) such as permanent agency employees or FDA direct contractors.

CECATS collect the same PII as OAA. OAA collects the following personally identifiable information (PII) data on external users: first and last name, state liaison email address (for state access), work phone number, fax number, email address, mailing address, Dun & Bradstreet Data Universal Numbering System number (DUNS number) and access credentials (username/password). The username is assigned by the system using the facility name and a random five-digit number, and the password is encrypted and stored within OC FURLS. OAA also collects the following non-PII data: job title, state agency (for state access), company Uniform Resource Locator (URL), security questions, and security question responses.

OC FURLS CECATS module also collects additional PII consisting of company taxpayer identification number (ID). The company taxpayer identification number is only associated with CECATS external users.

Non-PII data such as facility or product information is collected in all OC FURLS modules as required. Registrants may voluntarily submit additional non-PII data consisting of seasonal start/end dates or establishment type.

PII is stored temporarily in accordance with the National Archives and Records Administration (NARA) records retention standards.

**PTA 05A:**

Are user credentials used to access the system?

Yes

**PTA 05B:**

Please identify the type of user credentials used to access the system.

HHS User Credentials

HHS/OpDiv PIV Card

Non-HHS User Credentials

Username

Password

<b>PTA 06:</b>	Describe why each type of information is collected, maintained, and/or shared by the system. Specify what information is collected about each category of individual.	<p>The OC FURLS CECATS module allows CDRH's Office of Compliance (OC) to collect, verify, track, and issue export certificates.</p> <p>OC FURLS is a web-based system that allows foreign and domestic facilities to register with the FDA. It supports the implementation of FDA regulations that require facilities manufacturing, processing or holding any FDA regulated products to register with the FDA. Most FURLS users are industry account holders (e.g., local/foreign industry owners, operators, and agents) who utilize OC FURLS to register their food, medical device, tobacco or poultry facilities. The remaining OC FURLS users are FDA employees and direct contractors who use the system to access facility registration information. Industry account holders access the OC FURLS CECATS module via web-based authentication using username and password which is managed at the database level. FDA Employees and Direct Contractors access the OC FURLS CECATS module using a network-level SSO process using multi-factor authentication.</p> <p>OAA is used to maintain the account information used to access all OC FURLS modules to include CECATS. An alert module is used to send mass notifications to selected facilities. An Enterprise Service Bus (ESB) sends notifications to industry resulting from registration actions and controls the schedule of batch processes. An ESB is a set of rules and principles for integrating numerous applications together over a "bus-like" structure which allows systems to communicate without dependency on or knowledge of other systems on the bus. PNSI is integrated with OAA's user authentication and authorization capabilities. Once a user is authenticated via OAA, they are provided access to PNSI based on the user's role.</p> <p>OC FURLS users who access or use the system do not use any personal identifiers to retrieve records held in CECATS.</p>
<b>PTA 07:</b>	Does the system collect, maintain, use, or share PII?	Yes
<b>PTA 08:</b>	Does the system include a website or online application?	Yes
<b>PTA 08A:</b>	Provide the URL(s).	<a href="https://www.access.fda.gov/cecats/mainMenu.htm">https://www.access.fda.gov/cecats/mainMenu.htm</a>
<b>PTA 08B:</b>	Are any of the website or online applications accessible by the public (including publicly accessible log in pages)?	Yes

<b>PTA 09:</b>	Describe the purpose of the website, who has access to it, and how users access the web site (via public URL, log in, etc.). Please address each element in your response.	<p>The CDRH Export Certificate and Tracking System (CECATS) module in OC FURLS provides a means for an automated certificate processing, and for FDA personnel to monitor domestic product status. FDA personnel can also identify facilities not in compliance with FDA laws and regulations for firm's manufacturing medical devices in the U.S.</p> <p>FDA Employees, Direct Contractors and industry users (members of the public) have access to the FURLS website.</p> <p>Users access the CECATS module through OC FURLS. Access to OC FURLS is managed by the OAA application. OAA is the OC FURLS user account database and user authentication module. Internal FDA users authenticate using Single Sign On (SSO). All modules require that the external users log into the system for authentication to determine which modules within OC FURLS the user can access per the users' access request. External users (Industry users) login in using access credentials (username/password).</p>
<b>PTA 10:</b>	Does the website have a posted privacy notice?	Yes
<b>PTA 11:</b>	Does the website contain links to non-federal government websites external to HHS?	No
<b>PTA 12:</b>	Does the website use web measurement and customization technology?	No
<b>PTA 13:</b>	Does the website have any information or pages directed at children under the age of thirteen?	No
<b>PTA 14:</b>	Does the system have a mobile application?	No
<b>PTA 20:</b>	Are any third-party websites or applications (TPWA) associated with the system?	No
<b>PTA 21:</b>	Does this system use artificial intelligence (AI) tools or technologies?	No

## Privacy Impact Assessment

### Privacy Impact Assessment

<b>PIA 22:</b>	Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share.	<p>Identifying Numbers</p> <ul style="list-style-type: none"> <li>Taxpayer ID Number (TIN)</li> <li>DUNS</li> </ul> <p>Biographical Information</p> <ul style="list-style-type: none"> <li>Name</li> <li>User Credentials</li> </ul> <p>Contact Information</p> <ul style="list-style-type: none"> <li>Email Address (Personal)</li> <li>Mailing Address (Business)</li> <li>Phone Numbers (Business)</li> </ul> <p>Other</p> <ul style="list-style-type: none"> <li>Other</li> </ul>
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<b>PIA 22A:</b>	Identify the “other” type(s) of personally identifiable information (PII) not mentioned in the above list.	Fax Number (business); job title (where combined with other unique identifier); email addresses also include State email addresses.
<b>PIA 23:</b>	Indicate the categories of individuals about whom PII is collected, maintained, or shared.	Business Partners/Contacts (Federal state, local agencies) Employees/HHS Direct Contractors Members of the public
<b>PIA 24:</b>	Indicate the approximate number of individuals whose PII is maintained in the system.	100,000 – 999,999
<b>PIA 25:</b>	For what primary purpose is the PII used?	The primary purpose of the PII in OC FURLs modules is to create, manage, and communicate regarding registrations/listings/certificates and associated industry users registering through FURLs. For example: username/password is used to ensure controlled, secure access; email and mailing address are used to communicate with industry users regarding any actions taken on submissions including new account creation, account deactivation or reactivation, temporary passwords for password reset, new submissions, status changes, return for action, and other actions.
<b>PIA 26:</b>	Describe any secondary uses for which the PII will be used (e.g., testing, training, or research).	The are no secondary uses.
<b>PIA 27:</b>	Describe the function of the SSN, Truncated SSN, and/or Taxpayer ID. If the Taxpayer IDs collected are only for businesses include that in your response.	Taxpayer IDs collected are only for businesses.
<b>PIA 27A:</b>	Cite the legal authority to use the SSN, Truncated SSN, and/or Taxpayer ID. If the Taxpayer IDs collected are only for businesses, you may respond N/A.	N/A
<b>PIA 28:</b>	Identify legal authorities, governing information use and disclosure specific to the system and program.	FDA issues export certificates under Sections 801(e) or 802 under the Export Reform and Enhancement Act of 1996. Sections 510 and 905 of the Food, Drug and Cosmetic Act (FD&C, codified at 21 U.S.C. 360 and 387e) require establishments (e.g., manufacturers, re-packers, and re-labelers) to register with FDA upon engaging in the manufacture, preparation, propagation, compounding, or processing of FDA regulated products including food, drugs, medical devices, poultry, tobacco and biological products, with certain exceptions.  Statutory citations: 21 U.S.C. 321, 331, 342, 344, 351, 352, 355, 360, 360b, 371, 374, 381, 387e, 393; 42 U.S.C. 262, 264, 271.
<b>PIA 29:</b>	Are records in the system retrieved by one or more PII data elements?	No

<b>PIA 30:</b>	Identify the sources of PII in the system.	<p>Directly from an individual about whom the information pertains</p> <ul style="list-style-type: none"> <li>Hard Copy Mail/Fax</li> <li>Email</li> <li>Online</li> </ul> <p>Government Sources</p> <ul style="list-style-type: none"> <li>Within the OPDIV</li> <li>Other HHS OPDIV</li> <li>State/Local/Tribal</li> <li>Foreign</li> </ul> <p>Non-Government Sources</p> <ul style="list-style-type: none"> <li>Members of the Public</li> <li>Private Sector</li> </ul>
<b>PIA 31:</b>	Is there an Office of Management and Budget (OMB) information collection approval number?	Yes
<b>PIA 31A:</b>	Provide the information collection approval number(s) and expiration date(s).	<p>OMB Approval Number 0910-0625</p> <p>OMB Expiration Date 08/31/2025</p>
<b>PIA 32:</b>	Is the PII in the system shared directly with other organizations outside the system's Operating Division?	No
<b>PIA 33:</b>	Is the submission of PII by individuals voluntary or mandatory as defined in the Privacy Act?	Voluntary
<b>PIA 34:</b>	Describe the method in place to notify and obtain consent from individuals whose PII will be collected. If no prior notice is given or consent cannot be obtained, explain why.	<p>There is no opt-out process for this system. Regulated entities are required by law to register and to submit information necessary to administer the registration process. FDA personnel and direct contractors consent to the submission and use of their information by HHS/FDA as a condition of employment.</p>
<b>PIA 35:</b>	Describe the process to notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of original collection). If they cannot be notified or have their consent obtained, explain why.	<p>If the FDA should change its privacy practices or its collection, use, or sharing of PII data in the OC FURLS CECATS module, the agency will notify the individuals whose PII is in the system in the most efficient and effective form available and appropriate to the specific change(s). This may include establishing a formal process involving written and/or electronic notice. Alternatively, the FDA will notify by informal processes such as e-mail to the affected individuals and/or FDA-wide e-mail blast.</p>
<b>PIA 36:</b>	Describe the process in place to resolve an individual's concerns when they believe their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate. If no process exists, explain why not.	<p>External submitters (e.g., registrant point of contact) may contact the FDA offices identified in the FDA's online web/privacy policy and elsewhere on FDA.gov. FDA personnel may raise concerns through the FDA Employee Resource and Information Center (ERIC) or contact FDA's Cybersecurity Infrastructure Operations Coordination Center (CIOCC) or Privacy Office.</p>

<b>PIA 37:</b>	Describe the process in place for periodic reviews of the system to ensure the integrity, availability, accuracy, and relevancy of the PII in the system. Please address each element in your response. If no processes are in place, explain why not.	Registrant point of contact PII is self-submitted and registrants/facilities certify accuracy of information. Registrant points of contact may correct or update their information using OC FURLS, the contact information provided on fda.gov and/or the specific fda.gov web pages associated with the FURLS program. Accuracy is ensured by individual review at the time of reporting. Users may correct/update their information themselves and their PII is relevant and necessary to be granted access to the system. Integrity and availability are protected by security controls selected and implemented in the course of providing the system with an authority to operate (ATO). Controls are selected based on the National Institute of Standards and Technology (NIST) guidance concerning the ATO process, appropriate to the system's level of risk as determined using NIST's Federal Information Processing Standards (FIPS) 199.
<b>PIA 38:</b>	Identify who will have access to the PII in the system.	Users Administrators Contractors
<b>PIA 38A:</b>	Select the type of contractor.	HHS/OpDiv Direct Contractors
<b>PIA 38B:</b>	Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices?	Yes
<b>PIA 39:</b>	Provide the reason why each of the groups identified in 38 needs access to PII.	Users: Require access PII about themselves and other users to make proper annual updates. The PII is self-submitted and registrants/facilities certify accuracy of information.  Administrators: Require access to PII about users to make proper annual updates.  Contractors: Some administrators are Direct Contractors.
<b>PIA 40:</b>	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Personnel who have access to PII are provided the information based on the need for access required to perform their duties. Personnel who require access to the system must obtain supervisor approval and sign off before access is granted.
<b>PIA 41:</b>	Describe the technical methods in place to allow those with access to PII to access only the minimum amount of information necessary to perform their job.	The requesting user's supervisor will indicate on the account creation form the minimum information system access that is required for the user according to their role. The agency reviews the system access list on a quarterly basis and adjusts users' access permissions and removes unneeded accounts from the system.

<p><b>PIA 42:</b></p>	<p>Identify the general security and privacy awareness training provided to system users (system owners, managers, operators, contractors and/or program managers) to make them aware of their responsibilities for protecting the information being collected and maintained.</p>	<p>All users of the OC FURLS CECATS module take annual mandatory computer security and privacy awareness training. This training includes guidance on Federal laws, policies, and regulations relating to privacy and data confidentiality, integrity and availability, as well as the handling of data (including any special restrictions on data use and/or disclosure). The FDA Office of Digital Transformation (ODT) verifies that training has been successfully completed and maintains a record of certificates of training on all FDA employees and direct contractors.</p>
<p><b>PIA 43:</b></p>	<p>Describe the training system users receive above and beyond general security and privacy awareness training.</p>	<p>FDA personnel who use the OC FURLS CECATS module receive OC FURLS-specific training on how to use the system and adhere to agency security, privacy and other relevant policies. Privacy program materials are also available to personnel on a central intranet page. Personnel may take advantage of information security and privacy awareness events and workshops held within FDA. Privacy guidance is also available via the FDA's privacy office.</p>
<p><b>PIA 44:</b></p>	<p>Describe the process and guidelines in place for the retention and destruction of PII. Cite specific National Archives and Records Administration (NARA) records retention schedule(s) and include the retention period(s).</p>	<p>The agency continuously reviews the retention and destruction process associated with the information contained within OC FURLS modules to ensure it complies with FDA and NARA regulations. Applicable records control schedule: FDA file code 7210 and 7222 for Registration and Listing files and system database records; NARA approved citation N1-088-07-002, Items 6.1, 6.2, 6.2.2.</p> <p>Disposition: Temporary - Cutoff after establishment goes out of business or product is not commercially marketed. The certificate modules delete/destroy after 5 years. All other modules delete/destroy 10 years after cutoff or when no longer needed for legal, research, historical or reference purposes, whichever is the latest. If data are migrated into a new system or replaced by a successor system, delete/destroy it after the verification of successful data migration.</p> <p>FDA file codes 7220-7225 (NARA approved citation nos. N1-088-07-002, 6.2, 6.2.2, 6.2.4, and 6.2.5 and General Records Schedule GRS 5.2, Item 020) cover FDA's Registration and Listing Systems. These files are temporary and are destroyed when no longer needed, the establishment goes out of business, the product is no longer marketed, Destroyed 10 years after cutoff.</p>

<b>PIA 45:</b>	Describe how the PII will be secured in the system using administrative, technical, and physical controls. Please address each element in your response.	Administrative safeguards include user training; system documentation that advises on proper use; implementation of Need to Know and Minimum Necessary principles when awarding access, and others. Technical Safeguards include use of multi-factor access authentication, firewalls, and network monitoring and intrusion detection tools. Physical controls include that all system servers are located at facilities protected by guards, locked facility doors, and climate controls. Other appropriate controls have been selected from the National Institute of Standards and Technology's (NIST's) Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199.
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### Review and Comments

#### OpDiv Privacy Analyst Review

<b>Privacy Analyst Review Decision:</b>	Approved	<b>Privacy Analyst Review Date:</b>	7/18/2025
<b>Privacy Analyst Review Comments:</b>		<b># of Days - PA Review:</b>	0

#### SOP Review

<b>SOP Review Decision:</b>	Approved	<b>SOP Review Date:</b>	7/18/2025
<b>SOP Review Comments:</b>		<b># of Days - SOP Review:</b>	0

#### Agency Privacy Analyst Review

<b>Agency Privacy Analyst Review Decision:</b>	Approved	<b>Agency Privacy Analyst Review Date:</b>	7/21/2025
<b>Agency Privacy Analyst Review Comments:</b>	Reviewer: Nestor Villafuerte 7/21/2025 The following PIA is ready for SAOP review and approval.	<b># of Days - APA Review:</b>	3

#### SAOP Review

<b>SAOP Review Decision:</b>	Approved	<b>SAOP Review Date:</b>	7/21/2025
<b>SAOP Review Comments:</b>	Approved on behalf of the SAOP	<b># of Days - SAOP Review:</b>	0

#### SAOP Signature

Date	User	Type	Name	Original Value	New Value
7/21/2025 9:07 AM	BLAND, CRYSTAL	Signature	SAOP (Email PIN)		Content Signed

### Supporting Document(s)

Name	Size	Type	Upload Date	Downloads
No Records Found				

### Comments

Question Name	Submitter	Date	Comment	Attachment
PTA 01	BLAND, CRYSTAL	7/21/2025	Per FDA's Email, exported PIA is attached.	CDRH Export Certificate and Application Tracking System PIA_SOP Approved.pdf