Privacy Impact Assessment (PIA): FDA - AMS - QTR1 - 2025 - FDA4900705

Created Date: 1/10/2025 7:24 PM Last Updated: 2/11/2025 4:17 PM

Copy PIA (Privacy Impact Assessment)

Do you want to copy this PIA ?

Please select the user, who would be submitting the copied PIA.

Instructions

Review the following steps to complete this questionnaire:

1) Answer questions. Select the appropriate answer to each question. Question specific help text may be available via the icon. If your answer dictates an explanation, a required text box will become available for you to add further information.

2) Add Comments. You may add question specific comments or attach supporting evidence for your answers by clicking on the icon next to each question. Once you have saved the comment, the icon will change to the icon to show that a comment has been added.

3) Change the Status. You may keep the questionnaire in the "In Process" status until you are ready to submit it for review. When you have completed the assessment, change the Submission Status to "Submitted". This will route the assessment to the proper reviewer. Please note that all values list questions must be answered before submitting the questionnaire.

4) Save/Exit the Questionnaire. You may use any of the four buttons at the top and bottom of the screen to save or exit the questionnaire. The button allows you to complete the questionnaire. The button allows you to save your work and close the questionnaire. The button allows you to save your work and remain in the questionnaire. The button closes the questionnaire without saving your work.

Acronyms
ATO - Authorization to Operate
CAC - Common Access Card
FISMA - Federal Information Security Management Act
ISA - Information Sharing Agreement
HHS - Department of Health and Human Services
MOU - Memorandum of Understanding
NARA - National Archives and Record Administration
OMB - Office of Management and Budget
PIA - Privacy Impact Assessment
PII - Personally Identifiable Information
POC - Point of Contact
PTA - Privacy Threshold Assessment
SORN - System of Records Notice
SSN - Social Security Number
URL - Uniform Resource Locator

General Information

PIA Name:	FDA - AMS - QTR1 - 2025 - FDA4900705	**PIA ID:**	2628958
Name of Component:	FDA - OII Assignment Management Services	**Name of ATO Boundary:**	OII Case and Workload Management
Overall Status:		**PIA Queue:**	
Submitter:		**# Days Open:**	32
Submission Status:	Submitted	**Submit Date:**	1/10/2025
Next Assessment Date:	N/A	**Expiration Date:**	2/11/2028
Office:		**OPDIV:**	FDA
Security Categorization:		**OpDiv PIA ID:**	FDA4900705
Legacy PIA ID:		**Make PIA available to Public?:**	Yes

1:	Identify the Enterprise Performance Lifecycle Phase of the system.	Operations and Maintenance
2:	Is this a FISMA-Reportable system?	No
3:	Does the system have or is it covered by a Security Authorization to Operate (ATO)?	No
4:	ATO Date or Planned ATO Date.	
5:	Is the system or electronic information collection, agency or contractor operated?	Agency

PTA

PTA

PTA - 2:	Indicate the following reason(s) for this PTA. Choose from the following options.	New
PTA - 2A:	Describe in further detail any changes to the system that have occurred since the last PIA.	
PTA - 3:	Is the data contained in the system owned by the agency or contractor?	Agency

PTA - 4:	Please give a brief overview and purpose of the system by describing what the functions of the system are and how the system carries out those functions.	The purpose of OII Assignment Management Services (AMS) is to provide modern technical functionality to replace many manual tasks performed by investigative and supervisory staff. AMS allows the Work Planners (Center and District) and District Supervisors to create, update, clone and delete an assignment, with corresponding operation blocks and subsequently create operations from these operation blocks. AMS also allows the above roles i.e., Work Planner & District Supervisor as well as investigators, consumer complaint coordinators and compliance officers to create ad-hoc assignments with one or more related operations. AMS allows users to release work into operational systems to have the work completed. AMS is a holistic solution for both end-users working with OII and future integrating systems (internal OII systems and external Center and/or State-facing systems). Work Control Planners can perform a variety of tasks using AMS such as: • Create, Update, Clone, and Delete an Assignment. • Perform Keyword and Advanced Search of Assignments. • Create, Update, Clone, and Delete an Operation. • Perform Keyword and Advanced Search of Operations. • Releasing Single or Multiple Operations. • Create, Update, Clone, Divide and Forward Operation Block. • Perform Keyword and Advanced Search of Operation Block. • Data Analysis using Dashboards.

PTA - 5:	List and/or describe all the types of information that are collected (into), maintained, and/or shared in the system regardless of whether that information is PII and how long that information is stored.	AMS is used by FDA investigators during an inspection to collect data about the FDA-regulated establishment they are inspecting as well as the FDA investigator's observations and findings during the inspection. The observations and findings are the narrative of the FDA investigator and may include any type of information entered by the investigator to support and describe their inspection, observations and findings at the firm. Information collected by the FDA investigators on the inspected FDA-regulated establishment includes: establishment (firm) name, firm address, firm type, FDA Establishment Identifier (FEI) number and inspection date as well as the firm's point-of-contact (POC) names and the POC's firm title, firm phone number, and firm email address. Additionally, AMS utilizes FDA investigators information as part of the inspection records and documentation (legal documentation): first name, last name, work phone number, and work email address. They access the system via a single-sign-on process using multi-factor authentication. AMS does not require, use, collect or maintain system-specific logon credentials (e.g., username and password).
PTA - 5A:	Are user credentials used to access the system?	Yes, but the user credentials are maintained in a separate system (e.g., AD, AMS) and not collected or maintained by this system. The system providing credentials is
PTA - 5B:	Please identify the type of user credentials used to access the system.	

PTA - 6:	Describe why all types of information is collected (into), maintained, and/or shared with another system. This description should specify what information is collected about each category of individual.	The AMS system enables the investigator or team of investigators to electronically coordinate and share their work together. The types of assignments that are being conducted include domestic and foreign assignments in support of compliance, consumer complaints, recalls and product safety surveillance. Establishments (firms) include any and all firms regulated by the FDA including firms responsible for the manufacturing and processing of foods, feeds, drugs, medical devices and in-vitro diagnostic devices. In using AMS, FDA inspection team members may assign one or more team members to an AMS inspection assignment by selecting from a pop-up list of values. The list of values (FDA investigator names) is generated by an internal query within the AMS system. Additionally, an FDA supervisor can enter an investigator's name into the AMS operation inbox user interface to further filter the view of inspection assignment records in the inbox. AMS does collect and maintain FDA-regulated establishment information and information about their main point of contact. The information includes establishment (firm) name, firm address, firm type, FDA Establishment Identifier (FEI) number and inspection date as well as the firm's point-of-contact (POC) names and the POC's firm title, firm phone number, and firm email address. AMS also maintains the first and last name of FDA investigators. The information collected via AMS is also shared internally within FDA for inspections, recalls, compliance and enforcement purposes.
PTA - 7:	Does the system collect, maintain, use or share PII?	Yes
PTA - 7A:	Does this include Sensitive PII as defined by HHS?	No
PTA - 8:	Does the system include a website or online application?	Yes
PTA - 8A:	Are any of the URLs listed accessible by the general public (to include publicly accessible log in and internet websites/online applications)?	No

PTA - 9:	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.	AMS's website enables the investigators or a team of investigators to electronically coordinate and share their work together. Work Control Planners can perform a variety of tasks using AMS such as: • Create, Update, Clone, and Delete an Assignment. • Perform Keyword and Advanced Search of Assignments. • Create, Update, Clone, and Delete an Operation. • Perform Keyword and Advanced Search of Operations. • Releasing Single or Multiple Operations. • Create, Update, Clone, Divide and Forward Operation Block. • Perform Keyword and Advanced Search of Operation Block. • Data Analysis using Dashboards. Users are provided a user interface to complete this work. Users can only access the website when connected to the FDA VPN. Any FDA user can visit the site, however, to be authenticated and access AMS, they must have the correct roles associated with their SSO account. URL: https://ora.fda.gov/ams
PTA - 10:	Does the website have a posted privacy notice?	Yes
PTA - 11:	Does the website contain links to non-federal government websites external to HHS?	No
PTA - 11A:	Is a disclaimer notice provided to users that follow external links to websites not owned or operated by HHS?	
PTA - 12:	Does the website use web measurement and customization technology?	No
PTA - 12A:	Select the type(s) of website measurement and customization technologies in use and if it is used to collect PII.	
PTA - 13:	Does the website have any information or pages directed at children under the age of thirteen?	No
PTA - 13A:	Does the website collect PII from children under the age thirteen?	
PTA - 13B:	Is there a unique privacy policy for the website and does the unique privacy policy address the process for obtaining parental consent if any information is collected?	
PTA - 14:	Does the system have a mobile application?	No
PTA - 14A:	Is the mobile application HHS developed and managed or a third-party application?	
PTA - 15:	Describe the purpose of the mobile application, who has access to it, and how users access it. Please address each element in your response.	
PTA - 16:	Does the mobile application/ have a privacy notice?	
PTA - 17:	Does the mobile application contain links to non-federal government websites external to HHS?	
PTA - 17A:	Is a disclaimer notice provided to users that follow external links to resources not owned or operated by HHS?	

PTA - 18:	Does the mobile application use measurement and customization technology?	
PTA - 18A:	Describe the type(s) of measurement and customization technologies or techniques in use and what information is collected.	
PTA - 19:	Does the mobile application have any information or pages directed at children under the age of thirteen?	
PTA - 19A:	Does the mobile application collect PII from children under the age thirteen?	
PTA - 19B:	Is there a unique privacy policy for the mobile application and does the unique privacy policy address the process for obtaining parental consent if any information is collected?	
PTA - 20:	Is there a third-party website or application (TPWA) associated with the system?	No
PTA - 21:	Does this system use artificial intelligence (AI) tools or technologies?	No

PIA

PIA

PIA - 1:	Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share.	Email Address Phone numbers Mailing Address Other - Free text Field
PIA - 2:	Indicate the categories of individuals about whom PII is collected, maintained or shared.	Employees/ HHS Direct Contractors Members of the public
PIA - 3:	Indicate the approximate number of individuals whose PII is maintained in the system.	Above 2000
PIA - 4:	For what primary purpose is the PII used?	The PII is used to accurately document an inspection for compliance, for business contact purposes, and in support of enforcement and analysis activities where inspection data is relevant.
PIA - 5:	Describe any secondary uses for which the PII will be used (e.g. testing, training or research).	There is no secondary use of PII
PIA - 6:	Describe the function of the SSN, Truncated SSN, and/or Taxpayer ID.	
PIA - 6A:	Cite the legal authority to use the SSN, Truncated SSN, and/or Taxpayer ID.	
PIA - 7:	Identify legal authorities governing information use and disclosure specific to the system and program.	Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 374; Public Health Service Act, 42 U.S.C. 262-264.
PIA - 8:	Are records in the system retrieved by one or more PII data elements?	No
PIA - 8A:	Please specify which PII data elements are used to retrieve records.	
PIA - 8B:	Provide the number, title, and URL of the Privacy Act System of Records Notice (SORN) that is being used to cover the system or indicate whether a new or revised SORN is in development.	
PIA - 9:	Identify the sources of PII in the system.	Directly from an individual about whom the information pertains In-person Government Sources Within the OPDIV

PIA - 10:	Is there an Office of Management and Budget (OMB) information collection approval number?	No
PIA - 10A:	Provide the information collection approval number.	
PIA - 10B:	Identify the OMB information collection approval number expiration date.	
PIA - 10C:	Explain why an OMB information collection approval number is not required.	Forms are not used for information collection.
PIA - 11:	Is the PII shared with other organizations outside the system's Operating Division?	No
PIA - 11A:	Identify with whom the PII is shared or disclosed.	
PIA - 11B:	Please provide the purpose(s) for the disclosures described in PIA - 11A.	
PIA - 11C:	List any agreements in place that authorizes the information sharing or disclosure (e.g., Computer Matching Agreement (CMA), Memorandum of Understanding (MOU), or Information Sharing Agreement (ISA)).	
PIA - 11D:	Describe process and procedures for logging/tracking/accounting for the sharing and/or disclosing of PII. If no process or procedures are in place, please explain why not.	
PIA - 12:	Is the submission of PII by individuals voluntary or mandatory?	Voluntary
PIA - 12A:	If PII submission is mandatory, provide the specific legal requirement that requires individuals to provide information or face potential civil or criminal penalties.	
PIA - 13:	Describe the method for notifying individuals that their information will be collected and how they can opt-out of the collection or use of their PII. If there is no option to object to the information collection, provide a reason.	Establishment personnel provide PII voluntarily. They may object or discuss inspection observations with the FDA representative during the inspection or by contacting the FDA after the inspection. FDA personnel are required to provide their name and work contact information in order to get authorization to access the system.
PIA - 14:	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). Alternatively, describe why they cannot be notified or have their consent obtained.	If FDA practices change with regard to the collection or use of PII in AMS, the agency will provide any required notice and obtain consent from individuals. Procedures may include Federal Register notices, hard copy mail to individuals, adding or updating online notices and disclaimers, or using other available technological means for notification and consent.

PIA - 15:	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.	Personnel may raise concerns and/or submit data corrections through supervisory channels and FDA's Employee Resource and Information Center (ERIC). Individuals who are members of the inspected establishment may contact FDA through numerous email, phone and standard mail avenues (all listed on fda.gov). Additionally, there is a review process during the inspection that allows for a firm point of contact to review the final inspection reports and identify anything that they feel is inaccurate. All FDA personnel are required to report suspected or actual unauthorized access or other breaches of PII. External and internal individuals may contact the FDA Privacy Office and their OII contacts with privacy or PII handling concerns via information available on FDA.gov.
PIA - 16:	Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy. Please address each element in your response. If no processes are in place, explain why not.	All PII is relevant because FDA employee information and establishment POC information is necessary to conduct work and for communications between OII and regulated establishments. FDA employees provide their information and may update or correct it using internal resources whenever needed. POC PII (name and work contact data) is provided by the establishment or the individual establishment employee, and the individual and/or establishment is responsible for providing accurate information. Accuracy is ensured by individual review of inspection reports and correcting data in the course of OII's use of the system/information, e.g., updating name and phone number for entity point of contact. Firms/individuals may amend their submitted contact information by contacting FDA. FDA personnel may correct/update their information themselves. 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 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.
PIA - 17:	Identify who will have access to the PII in the system.	Users Administrators Developers Contractors
PIA - 17A:	Select the type of contractor.	HHS/OpDiv Direct Contractors
PIA - 17B:	Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices?	Yes

PIA - 18:	Provide the reason why each of the groups identified in PIA - 17 needs access to PII.	Users: Performing and documenting FDA Inspections. Administrators: Administrators have access to PII in the course of performing analysis of historical activities and to review work in process. Developers: Developers have access to PII to perform level 3 helpdesk support Contractors: Helpdesk direct contractors have access to PII to perform level 1 and 2 helpdesk support activities.
PIA - 19:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	System access requests are reviewed and approved by the system/business owner along with the AMS management team. System accounts are reviewed on a regularly basis to determine if access is still required for each user. Access is granted and restricted at the individual level as appropriate to the individual's duties (role-based access).
PIA - 20:	Describe the technical methods in place to allow those with access to PII to only access the minimum amount of information necessary to perform their job.	OII uses both technical and administrative methods to control access to PII in the system. Supervisors indicate when accounts are created to apply the minimum information system access that is required for the user to complete his/her job. The access list for the information system is reviewed on a quarterly basis and users' access permissions are reviewed/adjusted, and unneeded accounts are purged from the system. Users only have access to the minimum necessary information as needed to perform their job duties. Due to technical access permissions, the system will not allow users to access more than this minimum necessary information.
PIA - 21:	Identify the general security and privacy awareness training provided to system users (system owners, managers, operators, contractors and/or program managers) using the system to make them aware of their responsibilities for protecting the information being collected and maintained.	All users are required to complete FDA's annual Cybersecurity Awareness Training (CSAT). The Office of Digital Transformation (ODT) tracks completion.
PIA - 22:	Describe the training system users receive (above and beyond general security and privacy awareness training).	Users receive system-specific training, review and adhere to the Rules of Behavior, and may obtain additional privacy guidance from the agency's privacy officials. Users are provided with user guides and manuals and privacy guidance is available on the FDA intranet and from the FDA Privacy Office.
PIA - 23:	Describe the process and guidelines in place with regard to the retention and destruction of PII. Cite specific National Archives and Records Administration (NARA) records retention schedule(s) and include the retention period(s).	AMS records are maintained under the National Archives and Records Administration (NARA) Citation N1-088-09-1, FDA file code 7300 series, for Establishment Inspections and Compliance Action Files. Records are destroyed 10 years after classification of an inspection as "no action" or "voluntary action" indicated, and 30 years after close of a case where official action was indicated.

PIA - 24:	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 uses of firewalls; access controls such as user names and passwords; and regular testing of information technology systems. Physical controls include that all system servers are located at FDA 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.

Review & Comments

Privacy Analyst Review

OpDiv Privacy Analyst Review Status:	Approved	**Privacy Analyst Review Date:**	1/10/2025
Privacy Analyst Comments:		**Privacy Analyst Days Open:**	

SOP Review

SOP Review Status:	Approved	**SOP Signature:**	
SOP Comments:	The FDA's Senior Official for Privacy (SOP) has: (a) approved the Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA) conducted for the subject system/component; (b) reviewed and approved the associated security categorization; and (c) reviewed and confirmed acceptable implementation status of the assigned privacy controls.	**SOP Review Date:**	1/10/2025
		SOP Days Open:	0

Agency Privacy Analyst Review

Agency Privacy Analyst Review Status:	Approved	**Agency Privacy Analyst Review Date:**	1/24/2025
Agency Privacy Analyst Review Comments:	Reviewer: Nestor Villafuerte 1/24/2025 Per FDA email (see Supporting Documentation), all comments have been addressed. This PIA is ready for SAOP review and approval. Does the system have or is it covered by a Security Authorization to Operate (ATO)? No Does the system have a planned ATO date? Yes The planned ATO date should be 1/31/2025	**Agency Privacy Analyst Days Open:**	14

SAOP Review

SAOP Review Status:	Approved	**SAOP Signature:**	Archer Signature_Bridget Guenther.docx
SAOP Comments:		**SAOP Review Date:**	2/11/2025
		SAOP Days Open:	18

Supporting Document(s)

Name	Size	Type	Upload Date	Downloads
1-24-2025 EMAIL_RE_ FDA PIAs_ FDA - GSRS - QTR1 - 2025 - FDA4900646.pdf	352999	.pdf	1/24/2025 4:17 PM	0
OII Assignment Management Services_SOP approved 1.10.2025.pdf	172154	.pdf	1/13/2025 9:00 AM	1

Comments

Question Name	Submitter	Date	Comment	Attachment
PIA - 1	VILLAFUERTE, NESTOR	1/13/2025	Does the system have a planned ATO date? On the PTA, please remove any instance of bullet points in the next iteration to ensure 508 compliance. On PTA-9 please write out VPN on the first instance.	
PIA - 1	BLAND, CRYSTAL	1/16/2025	Please note that Other is selected but the text field is empty, were these PII elements suppose to be in the text field "establishment (firm) name, firm address, firm type, FDA Establishment Identifier (FEI) number and inspection date as well as the firm's point-of-contact (POC) names and the POC's firm title." Also shouldn't "Name" be selected? Per PTA-5, AMS utilizes FDA investigators information as part of the inspection records and documentation (legal documentation): first name, last name.	

Admin Section

Is OpDiv Privacy Analyst Approved ?:	1	**Is OpDiv Privacy Analyst Return ? :**	0
		Is SOP Return ?:	0
Is Agency Privacy Analyst Approve ?:	1	**Is Agency Privacy Analyst Return ?:**	0
Is SAOP Approved?:	1	**Is SAOP Return ?:**	0
Total Approved:	4	**Total Return:**	0
Total Approval Required:	4		

Miscellaneous Fields

Last Updated:	2/11/2025 4:17 PM	**History Log:**	View History Log