PTA / PIA: FDA - RPS - QTR3 - 2025 - FDA4949596

Created Date: 8/5/2025 12:43 PM Last Updated: 8/29/2025 4:42 PM

General Information

PTA / PIA Name:	FDA - RPS - QTR3 - 2025 - FDA4949596	**PTA / PIA ID:**	3604203
Component Name:	FDA - OII Resource Planning System	**ATO Boundary Name:**	OII Regulatory Business Information Services
Overall Status:	Complete	**# of Days - Open:**	36
Submitter:		**Submit Date:**	8/8/2025
Next Assessment Date:	N/A	**Expiration Date:**	1/1/2100
Office:		**OpDiv:**	FDA
Security Categorization:	Moderate		
Make PIA available to Public?:	Yes	**PIA Required:**	Yes

General 01:	Identify the Enterprise Performance Lifecycle Phase of the system.	Operations and Maintenance
General 02:	Is this a FISMA-Reportable system?	No
General 03:	Does the system have or is it covered by a Security Authorization to Operate (ATO)?	No
General 04:	ATO Date or Planned ATO Date.	6/30/2025
General 05:	Is the system or electronic information collection, agency or contractor operated?	Agency
History Log:	View History Log	

Privacy Threshold Analysis

Privacy Threshold Analysis

PTA 01:	Point of Contact (POC) Name	Rosemarina Sather
PTA 01A:	POC Title and Organization	POC Title: IT Project Manager POC Organization: ODT/OIMT/OTD/DAS/ORCFB
PTA 01B:	POC Email Address	Rosemarina.Sather@fda.hhs.gov
PTA 01C:	POC Phone Number	240-461-7132
PTA 02:	Indicate the following reason(s) for this PTA. Choose from the following options.	New
PTA 03:	Is the data contained in the system owned by the agency or contractor?	Agency

PTA 04:	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.	The purpose of Resource Planning System (RPS) is to automate the Office of Inspection and Investigations' (OII's) field work planning and resource allocation process, in addition to providing key capabilities to summarize annual plan targets for field operations, e.g., inspections, sample collections and laboratory analysis, and import regulatory activities. The relationship of this component to other Food and Drug Administration (FDA) systems/components/information collections is: RPS is a downstream system that ingests work plan and work accomplishment data from source systems within the Regulatory Business Information Systems (RBIS) boundary, specifically the Online Reporting Analysis Decision Support System (ORADSS) and Field Work Force Planning System (FWFPS). The RPS does not have connectivity with other upstream or downstream systems. RPS is a standalone application residing in the enterprise Digital Solutions Partners (DSP) Appian platform, which provides synchronization with FDA Active Directory (AD) for user account management. The key functional elements of the system include user management and module time workflows to support OII work planning analytics branch (WPAB) business processes, supported by Amazon Web Services (AWS) Postgres Relational Database Service (RDS) and AWS Glue jobs for the data pipeline. System "users" consist of RPS administrators, Work Plan Managers, Work Plan Analysts, and Center/ Inspectorate Stakeholders.
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.	The types of information collected into the system are employee/direct contractor name, Email (Business), Employee ID, OII work plan data (planning fiscal year, center, program area, Full-Time Equivalent (FTE) type, group process area code (PAC), operation code, problem area flag (PAF), reporting PAC); work accomplishment data (accomplishment fiscal year, center, program area, FTE type, group PAC, operation code, PAF, reporting PAC), recommended and final module times, and user comments including comment-by user name and role. The types of data that are maintained in and/or shared from the system is/are related to module time analysis reports for each program area and FTE type, which can be exported. This includes all the data listed as collected above. The amount of time the Personally Identifiable Information (PII) (e.g., comment-by user and role) is stored in the system is permanent until storage is needed but must be at least 5 years.

PTA 05A:	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.
PTA 05C:	Please identify the system that maintains the user credentials or controls access to this system.	The system providing credentials is through Digital Solution Partners (DSP) Appian Cloud platform which uses Single Sign-On (SSO) and Active Directory.
PTA 06:	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.	The information is collected as a snapshot for the purpose of supporting future work planning activities (i.e., next fiscal year operations) based on FDA historical operational accomplishment data (e.g., hours, mean value, median value) and work plans. It is maintained for record keeping (archival) purposes. The information is not shared with other systems. PII from the component is not shared with other systems. The module time analysis reports generated will be exported using data queries and saved in a file to a shared drive accessible only by RPS Administrators and Managers for record keeping (archival) purposes, as part of the quality management. Exports will not be disseminated. The export may contain names with their roles, associated to comments input using the component.
PTA 07:	Does the system collect, maintain, use, or share PII?	Yes
PTA 08:	Does the system include a website or online application?	Yes
PTA 08A:	Provide the URL(s).	URL is expected to be: https://appian-dsc.fda.gov/suite/sites/rps/page/home
PTA 08B:	Are any of the website or online applications accessible by the public (including publicly accessible log in pages)?	No
PTA 09:	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.	The RPS website provides OII business workflows for entering module times. Individuals who have access to the application are FDA internal staff or FDA-badged contractor support having the roles: RPS administrators, OII Work Planning and Analytics Branch (WPAB) Work Plan Managers, WPAB Work Plan Analysts, and Center/ Inspectorate Stakeholders. Users access the website using an intranet URL and single sign-on (SSO).
PTA 10:	Does the website have a posted privacy notice?	No
PTA 11:	Does the website contain links to non-federal government websites external to HHS?	No
PTA 12:	Does the website use web measurement and customization technology?	No
PTA 13:	Does the website have any information or pages directed at children under the age of thirteen?	No
PTA 14:	Does the system have a mobile application?	No
PTA 20:	Are any third-party websites or applications (TPWA) associated with the system?	No
PTA 21:	Does this system use artificial intelligence (AI) tools or technologies?	No

Privacy Impact Assessment

Privacy Impact Assessment

PIA 22:	Indicate the type(s) of personally identifiable information (PII) that the system will collect, maintain, or share.	Biographical Information Name Contact Information Email Address (Business) Other Other
PIA 22A:	Identify the "other" type(s) of personally identifiable information (PII) not mentioned in the above list.	Employee ID username role
PIA 23:	Indicate the categories of individuals about whom PII is collected, maintained, or shared.	Employees/HHS Direct Contractors
PIA 24:	Indicate the approximate number of individuals whose PII is maintained in the system.	100 – 499
PIA 25:	For what primary purpose is the PII used?	The FDA uses the PII for the primary purposes of user management, where a role is assigned to each RPS user, providing audit information on comments entered as part of business workflows, and sending workflow status notifications to user email addresses.
PIA 26:	Describe any secondary uses for which the PII will be used (e.g., testing, training, or research).	The FDA makes no secondary use of the PII.
PIA 28:	Identify legal authorities, governing information use and disclosure specific to the system and program.	The legal authorities that govern information use and disclosures specific to the system and program are: Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 374; Public Health Service Act, 42 U.S.C. 262-264.
PIA 29:	Are records in the system retrieved by one or more PII data elements?	No
PIA 30:	Identify the sources of PII in the system.	Government Sources Within the OPDIV
PIA 31:	Is there an Office of Management and Budget (OMB) information collection approval number?	No
PIA 31B:	Explain why an OMB information collection approval number is not required.	Not applicable. Per 5 CFR 1320.3(c), RPS is not a "collection of information" as the information maintained in the system is not obtained by means of identical questions posed to, or identical reporting, recordkeeping, or disclosure requirements imposed on, ten or more persons.
PIA 32:	Is the PII in the system shared directly with other organizations outside the system's Operating Division?	No
PIA 33:	Is the submission of PII by individuals voluntary or mandatory as defined in the Privacy Act?	Voluntary

PIA 34:	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.	There is no option to opt-out of the information collection since PII is necessary for system user account creation and management. Username is required for authentication to gain access to the system via FDA single single-on (SSO). Opting out would prohibit individuals from performing assigned duties. There are no external users of the system.
PIA 35:	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.	If FDA practices change with regard to the collection or use of PII in RPS, the agency will provide any required notice and obtain consent from individuals. Notice 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 36:	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.	The processes in place to resolve an individual's concerns when they PII has been inappropriately obtained, used or disclosed are defined for the FDA wide organization. Individuals may raise concerns through supervisory channels, reach out to the Privacy Office, follow procedures to report a PII breach, and/or use FDA's Employee Resource and Information Center (ERIC) or the Customer Service Portal (CSP) to submit specific service requests. All suspected or known breaches may be reported to the FDA Privacy Office or the FDA Cybersecurity and Infrastructure Operations Coordination Center (CIOCC).
PIA 37:	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.	All PII is relevant because point of contact information is necessary to communicate with internal FDA users. PII (name, email, employee ID) is provided via FDA Active Directory which is vetted through FDA's security processes. Accuracy is ensured by individual review of User Access Review (UAR) reports and correcting data during OII's use of the system/information, e.g., updating user's role or organization. Integrity and availability are ensured by security controls selected and implemented in the course of providing the system with an authority to operate (ATO). Controls are selected based on 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 38:	Identify who will have access to the PII in the system.	Users Administrators Developers Contractors
PIA 38A:	Select the type of contractor.	HHS/OpDiv Direct Contractors

PIA 38B:	Do contracts include Federal Acquisition Regulation (FAR) and other appropriate clauses ensuring adherence to privacy provisions and practices?	Yes
PIA 39:	Provide the reason why each of the groups identified in 38 needs access to PII.	The reason the following groups need access to PII in RPS: Administrators and certain user roles (Work Plan Manager, Work Plan Analyst) create, update, and deactivate user access to the RPS application. Users can view names of FDA staff submitting comments in the system. Developers who are Contractors have access to PII data for developing, troubleshooting, and testing business workflows where name and email may be involved.
PIA 40:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Users who require access to the information system need to have supervisor approval and sign off before access is granted. Business Owners from the Office of Inspections and Investigations (OII) assign Work Planning and Analytics Branch (WPAB) staff to RPS roles (e.g., Work Plan Analyst) who will be performing the work using the business workflows and dashboards. The System Owner from the Office of Digital Transformation (ODT) manages system development and approves HHS/OpDiv contractors to access PII for implementation purposes.
PIA 41:	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 technical methods in place to determine which system users may access PII are users request access to the system by first requesting approval from the System Owner from the Office of Digital Transformation (ODT) or Business Owner from Office of Inspections and Investigations (OII). Once approved, system administrators can attain privileged access through FDA e3530, and Role Based Access Control (RBAC) processes which requires training and signing rules of behavior. Regular RPS users submit user account request to the DSP Appian platform through Service Now. RPS administrators, Work Plan Managers, or Work Plan Analysts then create a role in the RPS User Management module to limit the user's access.
PIA 42:	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.	IT Cybersecurity Awareness, Privacy, and Records Management training is conducted annually by FDA and is a requirement for all employees and direct contractors. System Administrators and those who have elevated privileges are required by FDA to complete specific role-based training (i.e., Information Security for IT Administrators), including signing HHS Rules of Behavior and Role Based.

PIA 43:	Describe the training system users receive above and beyond general security and privacy awareness training.	Limited system-specific training is received by users in the form of demonstrations and training during user acceptance testing. Users are also provided with a quick reference guide and privacy guidance is available on the FDA intranet and from Privacy staff.
PIA 44:	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).	RPS, under RBIS, records fall under National Archives and Records Administration (NARA) approved citation N-1-088-09-003 (a Record Control Schedule (RCS)) which calls for deletion of records 10 years after the final action or when no longer needed for operational, trend analysis, legal, or reference purposes, whichever is the latest. Data migrated to another system would be deleted after verification of migration.
PIA 45:	Describe how the PII will be secured in the system using administrative, technical, and physical controls. Please address each element in your response.	There is administrative control in place through existing formal processes such as: Certification & Accreditation, Authority to Operate, security plan, and contingency plans. Technical controls are employed through use of enterprise single sign-on and user identification, protective firewall, virtual private network, intrusion detection, encryption, and smart cards. Physical controls include that the system is maintained at a secure guarded facility, with camera monitoring and physical entry barriers.

Review and Comments

OpDiv Privacy Analyst Review

Privacy Analyst Review Decision:	Approved	**Privacy Analyst Review Date:**	8/8/2025
Privacy Analyst Review Comments:		**# of Days - PA Review:**	0

SOP Review

SOP Review Decision:	Approved	**SOP Review Date:**	8/13/2025
SOP Review 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.	**# of Days - SOP Review:**	5

Agency Privacy Analyst Review

Agency Privacy Analyst Review Decision:	Approved	**Agency Privacy Analyst Review Date:**	8/20/2025
Agency Privacy Analyst Review Comments:	Reviewer: Nestor Villafuerte 8/20/2025 All comments have been addressed. This PIA is ready for SAOP review and approval. 8/8/2025 Please see comments and update accordingly. PTA-5: 8/8/2025 Per PIA-22, please include the following PII elements Name, Email (Business), and Employee ID. PIA-22: PIA PTA-5, please include the following PII elements in the textbox "username and role."	**# of Days - APA Review:**	7

SAOP Review

SAOP Review Decision:	Approved	**SAOP Review Date:**	8/29/2025
SAOP Review Comments:		**# of Days - SAOP Review:**	9

SAOP Signature

Date	User	Type	Name	Original Value	New Value
8/29/2025 1:33 PM	BAUR, VANESSA	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	8/6/2025	Per FDA's Email: The PIA is experiencing an Archer error with the question General 03: “Does the system have or is it covered by a Security Authorization to Operate (ATO)?” The FDA instance of Archer is automatically entering the answer “No,” which is incorrect. The ATO date is 6/30/2025. At this time, we are unable to update Archer to reflect the correct answer “Yes.” The FDA Archer Team is aware of this occurrence and is working on a solution.	OII Resource Planning System_SOP approved.pdf 8-5-20205 EMAIL_FW_ PTA _ PIA 4949596 is ready for APA Review - Copy.pdf
PIA 22	VILLAFUERTE, NESTOR	8/6/2025	Please add the stated PII elements here into your response in PTA-5 (Name and e-mail address).	
PTA 05	BLAND, CRYSTAL	8/8/2025	8/8/2025 Per PIA-22, please include the following PII elements Name, Email (Business), and Employee ID.	
PIA 22A	BLAND, CRYSTAL	8/8/2025	PIA PTA-5, please include the following PII elements in the textbox "username and role."	
PTA 01	BLAND, CRYSTAL	8/19/2025	8-19-2025 FDA's Updated PIA and email: The ATO date is 6/30/2025.	8-13-2025_EMAIL_PIA in Queue (OII Resource Planning System) PTA _ PIA 4949596.pdf OII Resource Planning System_SOP Approved_8.13.2025.pdf