Privacy Impact Assessment (PIA): FDA - RAFT-MAP - QTR4 - 2024 - FDA4323888

Created Date: 10/17/2024 12:24 PM Last Updated: 11/13/2024 12:44 PM

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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 - RAFT-MAP - QTR4 - 2024 - FDA4323888	**PIA ID:**	2328692
Name of Component:	FDA - HFP Real-Time Application for Tracking and Mapping	**Name of ATO Boundary:**	CDRH Scientific and Research General Support Systems
Overall Status:		**PIA Queue:**	
Submitter:		**# Days Open:**	28
Submission Status:	Submitted	**Submit Date:**	10/17/2024
Next Assessment Date:	11/13/2027	**Expiration Date:**	11/13/2027
Office:		**OPDIV:**	FDA
Security Categorization:		**OpDiv PIA ID:**	FDA4323888
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)?	Yes
4:	ATO Date or Planned ATO Date.	8/18/2023
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.	PIA Validation (PIA Refresh)
PTA - 2A:	Describe in further detail any changes to the system that have occurred since the last PIA.	RAFT-MAP has added several survey forms including wastewater treatment plant, farm, marina, animal, septic system, and FSMA annual inspection to support data gathering and adding other features to visually display these data. It will continue to support Produce Rule's provision for irrigation water quality, EU-US bilateral trade agreement for shellfish export, and the National Shellfish Sanitation Program (NSSP). RAFT-MAP has been focused on improving functionalities and adding dispersion model/analytical tools based on collected environmental data since 2020. No additional forms/data are gathered.
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 FDA Center for Food Safety and Nutrition (CFSAN) Geographical Information System (GIS) infrastructure consists of one component: Real-Time Application for Tracking and Mapping (RAFT-MAP). RAFT-MAP is a data collection and analytics tool that CFSAN engineering team built to support the regional and state shellfish specialists to investigate contamination level of the shellfish growing areas to protect food safety. RAFT-MAP is a client-piece software which needs be installed on the client owned laptop or Toughbook to be used to collect data during the field studies. To accomplish this, CFSAN uses RAFT-MAP to gather environmental data via a variety of scientific instruments and create a real-time map of dye-tagged effluent or raw sewage in relation to growing areas for shellfish. The real-time data will be displayed on the Toughbook/laptop to identify contamination severity of the sampled areas. By expanding the functionalities, the system will also be used to investigate the level of irrigation water contamination to ensure the produce safety.
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.	FDA employees use the CFSAN GIS during field studies to collect and store technical information including metrics questions relating to the current water conditions of public waterways being studies such as temperature, depth, and conductivity, etc. FDA does not collect, store, or maintain PII, RAFT-MAP surveys are conducted and only accessed by the state users. Developers (FDA Direct Contractors) may access PII for system development purposes. The developer is in charge of the daily Operations and Mangement (O&M) support and continues the system development tasks. FDA created the survey forms for state user use. The state users are capturing points of contacts (POCs) of the wastewater treatment plant, farm, marina, animal, and septic system info, which includes (a) first and last name of the wastewater plant manager or operator, (b) business phone number and (c) address of the commercial facility and/or public data in conjunction with the professional/scientific research standpoint. The PII collected is consistent with professional capacity. The PII is destroyed upon verification of successful creation of the final document or file, or when no longer needed for business use, whichever is later.
PTA - 5A:	Are user credentials used to access the system?	No
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 RAFT-MAP system collects and stores all raw field data gathered or created by FDA employees during field studies via the manual data entry of information or real time capture of data from field instruments into RAFT-MAP. As described in questions 11 and 12, the tool is used to support the FDA engineering team technical assistance and training with States as well as shellfish specialists to investigate the contamination level of the shellfish growing areas. The POC information of the commercial/public are collected for pollution sources verification. There will be no POC data collected or stored from the residential area. The forms in RAFT-MAP were primarily developed for the State users use.
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?	No
PTA - 8A:	Are any of the URLs listed accessible by the general public (to include publicly accessible log in and internet websites/online applications)?	
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.	
PTA - 10:	Does the website have a posted privacy notice?	
PTA - 11:	Does the website contain links to non-federal government websites external to HHS?	
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?	
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?	
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.	Name Phone numbers Mailing Address
PIA - 2:	Indicate the categories of individuals about whom PII is collected, maintained or shared.	Members of the public
PIA - 3:	Indicate the approximate number of individuals whose PII is maintained in the system.	51 - 200
PIA - 4:	For what primary purpose is the PII used?	The primary purpose is to be able to contact the facility and discuss the information collected. The PII is in conjunction with professional status. This is a tool developed for the State shellfish users. FDA does not internally collect the data.
PIA - 5:	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 - 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.	RAFT-MAP collects/stores the stated data to keep supporting Produce Rule's provision for irrigation water quality, EU-US bilateral trade agreement for shellfish export, and the National Shellfish Sanitation Program (NSSP) RAFT-MAP includes data that support post market food safety through inspection, analyses, and control of biological, chemical, and physical hazards from production to product consumption, in accordance with 21 CFR Part 123 as authorized under provisions of Title 21 of the U.S. Code including 21 U.S.C. 321 and 350g.
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 Non-Government Sources Other
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.	FDA developed the survey form in RAFT-MAP for the state users use, the information is owned and maintained by the client.
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.	RAFT-MAP users enter the PII relevant to the POC in the system manually if provided by the external POCs (wastewater treatment plant, farm, marina, animal and septic system. Since all data collected is voluntary, there is no method to opt out.
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 changes the collection, use, or sharing of PII data in RAFT-MAP, FDA will notify affected individuals by the most efficient and effective means available and appropriate to the specific change(s). This notice may include a phone call, a mail notification, a notice on a web site, or e-mail notice to the individuals.
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.	Individuals who suspect their PII has been inappropriately obtained, used or disclosed in any FDA system have several avenues available to resolve the situation. These individuals may contact the office or division where they have determined that their information is held. Individuals may then make further requests for their information to be corrected or amended. FDA considers these requests and, if appropriate, makes the requested changes.

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.	PII is provided voluntarily by the individual. Each individual is responsible for providing accurate information and may ensure accuracy by reviewing their submission content before submitting it. The relevancy of the PII is ensured by the design of this system which limits the PII collected to that which is necessary.
PIA - 17:	Identify who will have access to the PII in the system.	Users 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: To contact the POC to gather pollution sources details Developers: Developers have access to PII for system development purposes. The developer is in charge of the daily O&M support and continues the system development tasks. Contractors: RAFT-MAP developers are direct contractors
PIA - 19:	Describe the administrative procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.	Since the points of contacts (POCs) of the survey forms including wastewater treatment plant, farm, marina, animal, and septic system, which includes name, phone number and address of the commercial and/or public data in conjunction with the professional/scientific research standpoint, are captured on the individual forms, the RAFT-MAP users/developers/administrators will be able to view the POC data when accessing these survey forms.
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.	Role based access controls (RBAC) including Administrator controlled technical settings are employed to ensure that users have only the necessary access to perform their job duties. Management establishes roles for individual personnel, with role-based restrictions permitting access only to information that is required for each individual to perform his/her job.
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 personnel/users are required to complete FDA's IT Security and Privacy Awareness training annually. For additional privacy guidance, personnel may contact the agency's Privacy Office. Privacy program materials are provided to personnel on a central intranet page. Personnel may take advantage of information security and privacy awareness events and workshops held within FDA.

PIA - 22:	Describe the training system users receive (above and beyond general security and privacy awareness training).	The CFSAN RAFT-MAP engineers conduct field studies and collect data along with the regional and state shellfish specialists to train the users of the system.
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).	RAFT-MAP follows FDA and CFSAN retention policies and documented in the Project Management Plan. PII is maintained by the State users. RAFT-MAP records and data will be retained in accordance with FDA Records Control Schedule (RCS) - 9981 (Intermediary records) and General Records Schedule 5.2 Item 20, records are destroyed upon verification of successful creation of the final document or file, or when no longer needed for business use, whichever is later.
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 that PII entered via local access and shared with the FDA RAFT-MAP users only. Physical controls include that all system servers are located at FDA facilities protected by guards, locked facility doors, and climate controls. Since the PII data collected by RAFT-MAP are commercially/publicly accessible and RAFT-MAP follows the User Account Management SOP to grant access to the users. Only the approved users can view PII within the system, there is no additional controls required.

Review & Comments

Privacy Analyst Review

OpDiv Privacy Analyst Review Status:	Approved	**Privacy Analyst Review Date:**	10/17/2024
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:**	10/17/2024
		SOP Days Open:	0

Agency Privacy Analyst Review

Agency Privacy Analyst Review Status:	Approved	**Agency Privacy Analyst Review Date:**	10/21/2024
Agency Privacy Analyst Review Comments:	Reviewer: Nestor Villafuerte 10/21/2024 This PIA is ready for SAOP review and approval.	**Agency Privacy Analyst Days Open:**	4

SAOP Review

SAOP Review Status:	Approved	**SAOP Signature:**	Archer Signature_Bridget Guenther.docx
SAOP Comments:		**SAOP Review Date:**	11/13/2024
		SAOP Days Open:	23

Supporting Document(s)

Name	Size	Type	Upload Date	Downloads
CFSAN Real-Time Application for Tracking and Mapping_SOP Approved.pdf	161467	.pdf	10/18/2024 10:56 AM	0
PIAs in Queue (CFSAN Real-Time Application for Tracking and Mapping, CDER Site Selection Tool).pdf	432336	.pdf	10/18/2024 10:56 AM	0

Comments

Question Name	Submitter	Date	Comment	Attachment
PIA - 1	BLAND, CRYSTAL	10/18/2024	Per FDA Email, Question #3 of the general information. Q-3 “Does the system have or is it covered by a Security Authorization to Operate (ATO)? The FDA instance of Archer is reflecting “No” as the answer when the correct answer is “Yes.” The FDA Archer Team is aware of this occurrence and is working on a solution.	
PIA - 1	VILLAFUERTE, NESTOR	10/18/2024	On the next iteration of the PTA, please remove the reference to question numbers in PTA-6 as question numbers will not appear once they are published.	

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:	11/13/2024 12:44 PM	**History Log:**	View History Log