

Privacy Impact Assessment

for the

Select Agent Inventory (SAI)

DHS Reference No. DHS/S&T/PIA-031(a)

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Abstract

The Select Agent Inventory (SAI) is a database and workflow system used by Department of Homeland Security (DHS) Science & Technology Directorate (S&T) Plum Island Animal Disease Center (PIADC) to house and automate requirements in support of the Federal Select Agent Program. The Federal Select Agent Program oversees the possession, use, and transfer of biological select agents and toxins that have the potential to pose a severe threat to public, animal, or plant health or to animal or plant products. S&T is updating the Privacy Impact Assessment (PIA) to document additional PIADC health clinic data in the SAI system, in conjunction with efforts to automate manual processes within the PIADC Occupational Health Clinic, and the integration of a PIADC Training Database. This Privacy Impact Assessment update documents the privacy risks associated with the additional collection and use of personally identifiable information (PII) to support the implementation of the new Occupational Health Clinic Medical Database and the integration of a PIADC Training Database, which are accessible only to S&T, into the SAI system.

Overview

The DHS S&T PIADC houses animal biological agents and toxins and automates the process of managing these agents in support of the Federal Select Agent Program. The Federal Select Agent Program is a federal regulatory program that protects the nation from the accidental or intentional introduction of foreign animal diseases that can threaten livestock industries, food safety, and the economy. The PIADC is a biosafety-level 3 laboratory and the only one in the nation that can conduct diagnostic testing, research, and vaccine development for foreign animal diseases, such as foot-and-mouth disease. A select agent is a biological agent or toxin that has the potential to pose a severe threat to public health and safety, animal or plant health, or animal or plant products. Select agent regulations require increased security for PIADC personnel and address the reliability of an individual for access to Tier 1 biological select agents and toxins, but not for employment in general.

In addition to using the SAI system to track select agents and toxins, the PIADC uses the SAI system to manage and automate Federal Select Agent Program reporting, including facility access. The SAI system will consist of three databases:

1. Select Agent Database: This database contains information on biological agents and toxins that have the potential to pose a severe threat to public health and safety, animal

¹ A biosafety-level 3 laboratory is one in which work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure.

² Tier 1 biological select agents and toxins are biological agents and toxins that present the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure, or public confidence, and pose a severe threat to public health and safety.



health, or animal products.

- 2. PIADC Training Database: This database contains information regarding individuals who have been cleared for access to the PIADC facility and to the biological agents and toxins deemed select agents.
- 3. Occupational Health Clinic Medical Database: This database contains information regarding an individual's continued suitability to enter the PIADC facility.

The SAI system contains personally identifiable information regarding individuals who have access to the PIADC facility and to the biological agents and toxins deemed select agents. To access both the PIADC facility and select agents, the Federal Select Agent Program requires individuals to undergo a Bioterrorism Security Risk Assessment, performed by the Federal Bureau of Investigation (FBI).³ The PIADC uses the SAI system to store information that identifies individuals that have been cleared for access following the regulation-required security assessment.

To ensure general health and safety within the PIADC, all individuals with access to the facility are required to maintain suitability for entry. Suitability includes clearance via multiple routine medical evaluations that track specific health information for individuals and fulfillment of certain training requirements. The information from the Occupational Health Clinic Medical Database, in combination with information from the PIADC 's Training Database, is used to identify and create profiles for individuals to ensure compliance with Title 9 of the Code of Federal Regulations, Section 121.⁴

Reason for PIA Update

S&T is updating the Privacy Impact Assessment to address privacy risks and mitigation measures associated with the SAI system's addition of the PIADC Training Database, which is accessible to credentialed S&T staff at PIADC, and the Occupational Health Clinic Medical Database, which is only accessible to the PIADC Occupational Health Clinic staff. The purpose of these databases is to automate the current manual processes used by the PIADC staff to perform routine activities such as facility entry suitability, appointment scheduling and tracking, reporting, training management, and metrics tracking. The addition of these databases will aid the PIADC staff in determining an individual's suitability to access and perform duties at the PIADC.

PIADC Training Database

³ For more information on the Bioterrorism Security Risk Assessment, see the original Privacy Impact Assessment, U.S. DEPARTMENT OF HOMELAND SECURITY, SCIENCE & TECHNOLOGY DIRECTORATE, PRIVACY IMPACT ASSESSMENT FOR THE SELECT AGENT INVENTORY, DHS/S&T/PIA-031 (2016), available at https://www.dhs.gov/privacy-documents-st.

⁴ Title II, Subtitle B of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188.



The PIADC Training Database system contains training records and personally identifiable information regarding PIADC employees and contractors who have access to the PIADC facility and to the biological agents and toxins deemed select agents. The Federal Select Agent Program requires any individual who accesses select agents to undergo a Bioterrorism Security Risk Assessment performed by the FBI. After an individual undergoes the assessment and is cleared to access select agents, the PIADC Training Database in the SAI system maintains that clearance information. After undergoing the Bioterrorism Security Risk Assessment, PIADC requires cleared PIADC employees and contractors to take certain role-based trainings, such as handling hazardous materials, biocontainment, and select agents. The PIADC Training Database maintains the following personally identifiable information on PIADC employees and contractors accessing the PIADC facility and select agents:

- Name (first, middle, and last);
- Birth month;
- System username and password;
- Job title;
- Role;
- DOJ/FBI Number;⁵
- Medical evaluation expiry date;
- U.S. citizenship status;
- Country of origin; and
- Plum Island Badge identification code.

The PIADC Training Database maintains PIADC employees and contractors' contact and personnel information and training course data, including training requirements and completion dates, which make up the employee or contractor's base record. The PIADC requires the completion of certain job-related trainings to grant onsite PIADC access to its employees and contractors.

Only approved PIADC staff will have access to the PIADC Training Database. The PIADC Training Database allows Occupational Health Clinic Staff to view the above-mentioned base record to verify PIADC employee profiles. However, approved users of the PIADC Training

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⁵ The DOJ/FBI Number is generated by the FBI and provided to the PIADC Select Agent Program after an applicant's information is submitted to the FBI to conduct the Bioterrorism Security Risk Assessment. For more information, see the original Privacy Impact Assessment, U.S. DEPARTMENT OF HOMELAND SECURITY, SCIENCE & TECHNOLOGY DIRECTORATE, PRIVACY IMPACT ASSESSMENT FOR THE SELECT AGENT INVENTORY, DHS/S&T/PIA-031 (2016), available at https://www.dhs.gov/privacy-documents-st.



Database will not have access to the Occupational Health Clinic Medical Database unless they receive additional approval for access.

Occupational Health Clinic Medical Database

PIADC health clinic staff access to the PIADC Training Database and Occupational Health Clinic Medical Database will aid their decisions on each individual's continued suitability to enter the PIADC. The Occupational Health Clinic automates the current manual processes in performing routine activities, such as maintaining medical examinations and medical clearance information. The PIADC's Occupational Health Clinic Medical Database will pull some of the above listed data elements from the PIADC Training Database records for individuals that have been cleared to access select agents. These records will be viewable and editable for individual profiles in the Occupational Health Clinic Medical Database where they will remain according to their record retention schedule and disposition authority.

PIADC Occupational Health Clinic staff collect medical information on forms during the intake process and from physical exams, which are administered by the PIADC's Occupational Health Clinic staff, for any new or continuing employees or contractors requiring lab access. The forms are completed on-site at PIADC, collected by the DHS medical contractor within the Occupational Health Clinic, and stored onsite at PIADC in a double-locked file storage cabinet system. Only a limited number of Occupational Health Clinic staff with a need to know have access to the forms.

The Occupational Health Clinic staff will use the intake forms to update the Occupational Health Clinic Medical Database with dates corresponding to when the forms were completed and dates or selections identifying completion of specific exams, tests, or requirements for work related personal protective equipment (PPE). No forms will be uploaded to the Occupational Health Clinic Medical Database. Some health clinic data will be used in conjunction with data existing in the SAI system's PIADC Training Database to determine whether an individual will be granted access to a laboratory, or in some instances for specific jobs outside of the laboratory that may require access approval. Currently, all collected health information is stored on paper at the PIADC Occupational Health Clinic, while limited information is stored in the Occupational Health Clinic Medical Database. The PIADC's Occupational Health Clinic Coordinator will manually enter the information into the health clinic database and prepare it to be reviewed by the PIADC's Operational Health Clinic Medical Review Officer. The PIADC Operational Health Clinic Medical Review Officer will review the information and determine suitability.

The Occupational Health Clinic Medical Database will track the status of intake forms and maintain limited information from the intake forms. No forms are uploaded to the Occupational Health Clinical Medical Database. The Occupational Health Clinic Medical Database will only be viewed or edited by approved PIADC Occupational Health Clinic staff. The Occupational Health



Clinic Medical Database is accessed by PIADC Occupational Health Clinic staff only. New users are evaluated, approved by the Medical Clinic Coordinator, and provided access after they are established as authorized employees of the PIADC Occupational Health Clinic. Several reports will be generated from the data for management purposes, including reports on physical exam completion dates, lab access clearance dates, physical exam status, and overdue physical exams. The Occupational Health Clinic Medical Database will only store digital medical data as entered from paper documents by PIADC Occupational Health Clinic staff. No medical data will be shared across any other databases. Medical records in paper form will be maintained onsite at the PIADC.

Privacy Impact Analysis

Authorities and Other Requirements

The authority to collect and use information does not change with this update. The authority to collect information is pursuant the Homeland Security Act of 2002 [Public Law 1007-296, §302(4)], Title 5 of the United States Code, Section 301 on Government Organizations and Employees; Executive Order 9397 as amended by Executive Order 13478; Executive Order 12968; Title 41, Subtitle C, Chapter 101 Federal Property Management Regulations, issued July 2002; Title 9 of the Code of Federal Regulations, Section 121;⁶ and Section 817 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001.⁷

The information collected, used, maintained, and stored in the SAI system is covered under the following System of Records Notices (SORNs):

- DHS/ALL-023 Department of Homeland Security Personnel Security Management⁸ covers processing records of personnel security-related clearance actions, to record suitability determinations, to record whether security clearances are issued or denied, and to verify eligibility for access to classified information or assignment to a sensitive position.
- DHS/ALL-024 Department of Homeland Security Facility and Perimeter Access Control and Visitor Management⁹ covers the collection and maintenance of records associated with DHS facility and perimeter access control, including access to DHS

⁶ Title II, Subtitle B of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188.

⁷ USA PATRIOT ACT of 2001, Pub. L. No. 107-56.

⁸ DHS/ALL-023 Department of Homeland Security Personnel Security Management, 75 FR 8088 (February 23, 2010), *available at* www.dhs.gov/privacy.

⁹ DHS/ALL-024 Department of Homeland Security Perimeter Access Control and Visitor Management, 75 FR 5609 (February 3, 2010), *available at* www.dhs.gov/privacy.



information technology and access to classified facilities, as well as visitor security and management.

• JUSTICE/FBI-009 The Next Generation Identification System¹⁰ covers the collection and maintenance of identification and criminal history records collected during background checks for persons who provide biographic and biometric data for the purposes of security clearances and suitability determinations.

The information collected, used, maintained, and stored as a result of adding the Occupational Health Clinic Medical Database to the SAI system is covered under the following System of Records Notices:

- OPM/GOVT-10 Employee Medical File System Records¹¹ covers the collection and maintenance of medical records, forms, and reports created on an employee during their period of employment to ensure that all relevant, necessary, accurate, and timely data are available to support any medically-related employment decisions affecting the subject of the records, including fitness-for-duty.
- DHS/OHA-001 Contractor Occupational Health and Immunization Records¹² covers the collection and maintenance of occupational health and immunization records of persons working in facilities where biological research involving potentially high-risk agents is being conducted. It is part of biological laboratory best practices to maintain contractor's occupational health and immunization records to ensure that appropriate and timely medical care is provided in the case of any potential risk of exposure.

This Privacy Impact Assessment update does not affect the Authority to Operate for the SAI system. S&T issued the SAI system Authority to Operate on August 23, 2018. Since the SAI Privacy Impact Assessment was originally published, the National Archives and Records Administration (NARA) approved S&T's record retention schedule for "Biological Select Agent and Toxins Records."

• Records documenting the use, possession, and handling of biological agents and toxins are considered temporary and are destroyed six years after the cut off at the end of the calendar year in which biological select agents and toxins are removed from the Centers for Disease Control and Prevention (CDC) registration.

¹⁰ JUSTICE/FBI-009 The Next Generation Identification (NGI) System, 81 FR 27283 (April 26, 2016), *available at* https://www.federalregister.gov/documents/2016/05/05/2016-10120/privacy-act-of-1974-systems-of-records.

¹¹ OPM/GOVT-10 Employee Medical File System Records, 75 FR 35099 (June 21, 2010) as modified by 80 FR 74815 Federal Register, Volume 75 Issue 118 (Monday, June 21, 2010) (govinfo.gov).

¹² DHS/OHA-001 Department of Homeland Security Contractor Occupational Health and Immunization Records, 76 FR 21768-21772 (April 18, 2011), *available at* www.dhs.gov/privacy.



• The addition of the Occupational Health Clinic Medical Database updates the records schedule for the SAI system. PIADC Occupational Health Clinic staff are required to keep records maintained in the Occupational Health Clinic Medical Database for a minimum of 30 years, as governed by Occupational Safety and Health Administration Standard Title 29 Code of Federal Regulations 1910.1020. SAI system access information is deleted six years after the password is altered or a user account is terminated, pursuant to General Records Schedule 3.2 item 031.

This update does not implicate the Paperwork Reduction Act requirements for the SAI system. Each form has an existing Office of Management and Budget (OMB) Control number that covers the information collection.¹³

Characterization of the Information

PIADC Training Database

The PIADC Training Database updates the collection of information in the SAI system with the additional collection of medical evaluation expiration date and Plum Island Badge identification number. The data elements listed below from the PIADC Training Database will be linked to the Occupational Health Clinic Medical Database to eliminate rekeying and improve data integrity for the individuals on whom health data is collected and maintained within the Occupational Health Clinic Medical Database:

- Name (first, middle, last)
- Birth month
- Job title
- Medical evaluation expiry date

Occupational Health Clinic Medical Database

Information collected in the Occupational Health Clinic Medical Database on an individual's health status is used to update the SAI system. PIADC Occupational Health Clinic staff administer physical exams to lab personnel to determine their suitability for access to the lab. The completion of physical exams or tests, dates of the physical exams or tests, and requirement for work related personal protective equipment (PPE) will be collected by PIADC Occupational Health Clinic staff, maintained in the Occupational Health Clinic Medical Database, and updated as necessary.

¹³ See U.S. DEPARTMENT OF HOMELAND SECURITY, SCIENCE & TECHNOLOGY DIRECTORATE, PRIVACY IMPACT ASSESSMENT FOR THE SELECT AGENT INVENTORY, DHS/S&T/PIA-031 (2016), available at https://www.dhs.gov/privacy-documents-st.



Information collected and stored in the Occupational Health Clinic Medical Database does not include underlying medical documentation because this database only tracks medical examinations or tests completed and the dates on which they were completed, as well as the requirement for any PPE. Each record will be stored with a unique identifier that ties it to a unique PIADC Training Database staff record. This ensures information needed across database records is accurate. PIADC Occupational Health Clinic staff and management will maintain the confidentiality, integrity, and accuracy of medical data. In addition to the PIADC Training Database data elements, the Occupational Health Clinic Medical Database will collect the following data elements related to the individual's health status and store them within the SAI system. Some exams and/or tests are required to be administered at different time periods and will have a status of baseline, interim, or periodic to track medical fitness for facility access:

- Job Title
- Employer
- Supervisor
- Chemicals the worker was exposed to (Example: Asbestos/Silica/Formaldehyde)
- Physical Exam (baseline, interim)
- Respirator fit requirement (yes/no)
- Date fitted with Respirator (date)
- Hearing Conservation Program Enrollment (yes/no)
- Audiogram Exam Date (date)
- Audiogram Standard Threshold Shift Identified (yes/no)
- Repeat Audiogram (< 30 days) (yes/no)
- Standard Threshold Shift Confirmed (yes/no)
- Notification to examinee and Supervisor of confirmed Standard Threshold Shift (yes/no)
- Occupation Safety and Health Administration Recordable (yes/no)
- Notification to Industrial Hygienist (yes/no)
- Examinee Notification date(s) (date)
- Examinee Response Date (date)
- Occupational Health Clinic Exam Schedule Date (date)



- Occupational Health Clinic Physical Exam Completed (date)
- ONSITE Exam Components Pending (yes/no)
- OFFSITE Exam Components Pending (yes/no)
- Exercise Stress Test results received date (date)
- Chest X-ray results Received Date (date)
- Exercise Stress Test Scheduled Appointment (date)
- Chest X-ray Scheduled Appointment (date)
- B-Read Date of interpretation of Chest X-ray (date)
- Onsite Exam Turnaround Time (number of days)
- Offsite Exam Turnaround Time (number of days)
- Review Medical Officer's Medical Clearance Date (date)
- Notification of Review Medical Officer's Medical Clearance date (date)
- Medical Clearance Notification Turnaround time (number of days)
- Clinical Encounter Date (date)
- Components Pending Notes (reasons why components of physical exam could not be completed)
- Respirator Tools Needed (dust mask, neg pressure, powered air purifying, Self-Contained Breathing Apparatus)
- Biocontainment entry physical (baseline, periodic, interim)
- Animal contact physical (baseline, periodic)
- Fire brigade physical (baseline, periodic)
- Paramedic/EMT physical (baseline, periodic)
- Merchant mariner (baseline, periodic)
- Commercial driver (baseline, periodic)
- Asbestos exposure physical (baseline, periodic)
- Silica exposure physical (baseline, periodic)
- Formaldehyde exposure physical (baseline, periodic)



<u>Privacy Risk:</u> There is a privacy risk that information collected by PIADC and maintained in the SAI system may be inaccurate.

<u>Mitigation:</u> This risk is mitigated. PIADC Health Clinic Medical staff will ensure the accuracy of the data elements within the Occupational Health Clinic Medical Database through routine, manual quality check controls, such as verifying data elements and secondary review by PIADC Occupational Health Clinic staff.

Uses of the Information

PIADC Training Database

The addition of the PIADC Training Database and Occupational Health Clinic Medical Database introduces new uses of information for the SAI system. PIADC will use the PIADC Training Database to track and maintain required training data for PIADC personnel to gain access to the PIADC facility and select agents.

Occupational Health Clinic Medical Database

PIADC will use the Occupational Health Clinic Medical Database to automate PIADC personnel access record-keeping for the PIADC facility based on medical evaluations.

<u>Privacy Risk</u>: There is a privacy risk that unauthorized users may view information maintained in the PIADC Training Database and Occupational Health Clinic Medical Database or use the information for unauthorized purposes.

Mitigation: This risk is mitigated. Only authorized PIADC personnel with a need-to-know will have access to the PIADC Training Database and Occupational Health Clinic Medical Database. All SAI system users must complete training with the SAI System Administrator/database administrator to learn how to navigate the system's interface and agree to Rules of Behavior. After training completion, the SAI system users are granted access based on role-based permissions, which are authorized by the SAI System Administrator. Only approved PIADC staff will have access to the PIADC Training Database; however, PIADC Training Database users will not have access to the Occupational Health Clinic Medical Database unless they are approved for such access. Information in the Occupational Health Clinic Medical Database will only be viewed or edited by approved PIADC Occupational Health Clinic staff.

Notice

S&T provides general notice to the public about system changes through this Privacy Impact Assessment update. This update does not present any new privacy risks associated with providing notice before the point of collection.



Data Retention by the Project

The records schedule for the SAI system changes with this update. Since the SAI Privacy Impact Assessment was originally published, NARA approved S&T's record retention schedule for "Biological Select Agent and Toxins Records." Records documenting the use, possession, and handling of biological agents and toxins are considered temporary and are destroyed six years after the cut off at the end of the calendar year in which the biological select agents and toxins were removed from the CDC registration, in accordance with NARA Disposition Authority Number DAA-0563-2019-0005. DHS deletes SAI system access information six years after a password is altered or the user account is terminated, pursuant to General Records Schedule 3.2 item 031.

Furthermore, the addition of the Occupational Health Clinic Medical Database updates the records schedule for the SAI system. PIADC Occupational Health Clinic staff are required to keep records maintained in the Occupational Health Clinic Medical Database for a minimum of 30 years, as governed by Occupational Safety and Health Administration Standard Title 29 Code of Federal Regulations 1910.1020.

<u>Privacy Risk</u>: There is a privacy risk that medical records in the SAI system may be maintained longer than necessary.

Mitigation: This risk is mitigated. The records maintained in the SAI system now have an approved records retention schedule and disposition authority; therefore, the records will be kept in accordance with that record retention schedule and disposition authority. Additionally, the records from the Occupational Health Clinic Medical Database are governed by Occupational Safety and Health Administration Standard Title 29 Code of Federal Regulation 1910.1020. PIADC is required to keep the records in the Occupational Health Clinic Medical Database for a minimum of 30 years. Medical records are manually reviewed and disposed of according to the PIADC Occupational Health Clinic's procedure.

Information Sharing

This Privacy Impact Assessment update does not affect information sharing related to the SAI system. The PIADC Training Database and the Occupational Health Clinic Medical Database do not share information outside of the SAI system, nor do individuals outside of PIADC have access to the databases. Only approved S&T staff have access to the databases.

Redress

This Privacy Impact Assessment update does not affect record access, redress, and correction. An individual seeking access to their information held by S&T may gain access to their records by filing a Freedom of Information Act or Privacy Act request. Individuals not covered by the Privacy Act may obtain access to records consistent with the Freedom of Information Act (FOIA) unless disclosure is prohibited by law or if the agency reasonably foresees that disclosure



would harm an interest protected by an exemption. Any individual seeking access to their information should submit a Freedom of Information Act or Privacy Act request to the DHS Freedom of Information Act Office to the address below, or electronically at https://www.dhs.gov/foia.

Chief Privacy Officer/Chief Freedom of Information Act Officer U.S. Department of Homeland Security 2707 Martin Luther King Jr. Avenue, SE Washington, D.C. 20528

Auditing and Accountability

S&T ensures that practices stated in this Privacy Impact Assessment update comply with federal, DHS, and S&T standards, policies, and procedures, including standard operating procedures, rules of behavior, and auditing and accountability procedures. Only approved SAI System Administrators, Responsible Officials, Information System Security Officers, and security officers will have access to the information in the SAI system, including the PIADC Training Database and the Occupational Health Medical Database. The Responsible Official conducts semiannual audits of the listing provided by the Federal Select Agent Program by comparing the official program's list with what exists in the local database.

System Administrators and security officers are required by DHS policies to abide by all privacy and information security regulations. The PIADC Information System Security Officer has access to the system to perform weekly audits.

All employees and contractors complete DHS Privacy and Information Security training annually. This is a mandatory requirement, and the training records are maintained by PIADC human resources staff and the Information System Security Officer. PIADC also requires all users to complete an SAI training session prior to being provided access to the system. In addition, all system users are required to read and agree to the Rules of Behavior prior to gaining access to the SAI system, PIADC Training Database, and Occupational Health Clinic Medical Database.

S&T employs technical and security controls to preserve the confidentiality, integrity, and availability of the data, which are validated during the security authorization process. These technical and security controls limit access to S&T users and mitigate privacy risks associated with unauthorized access and disclosure to non-S&T users. Further, DHS security specifications also require auditing capabilities that log the activity of each user to reduce the possibility of misuse and inappropriate dissemination of information. All user actions are tracked via audit logs to identify information by user identification, network terminal identification, date, time, and data accessed. The SAI system employs real-time, ongoing auditing measures and technical safeguards to prevent the misuse of data.



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Approval Signature

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