U.S. Department of Transportation

Privacy Impact Assessment

Federal Aviation Administration

FAA

Toxicology Database

ToxDB

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Executive Summary

As required by the Aviation Safety Research Act of 1988, Public Law 100-591 H.R. 4686 (or "H.R. 4686"), the Federal Aviation Administration (FAA) established the Civil Aerospace Medical Institute (CAMI) which conducts civil aeromedical research under section 312(e) of the Federal Aviation Act of 1958. CAMI is responsible for enhancing human safety, security, and survivability in civilian aerospace operations. The Aviation Safety Research Act of 1988, Public Law 100-591 H.R. 4686 also authorizes CAMI to conduct toxicological analyses on specimens from, and pathologic studies on, aircraft accident[1] and incident[2] fatalities and non-fatalities. To accomplish this mission, CAMI established an aerospace medical research database, Toxicology Database (ToxDB), used to determine which medical and human performance factors play a role in aviation accidents/incidents. In addition, under an inter-agency reimbursable agreement between the FAA and the National Transportation Safety Board (NTSB)[3], CAMI also conducts ad-hoc toxicological testing on individuals who were involved in transportation accidents/incidents in the rail, bus, maritime, and highway sectors.

The FAA developed this Privacy Impact Assessment (PIA) in accordance with the E-Government Act of 2002 because ToxDB collects Personally Identifiable Information (PII) on individuals[4] involved in transportation accidents/incidents, individuals conducting autopsies, and FAA employees and contractors accessing the ToxDB to conduct toxicological analyses and testing services for the FAA, NTSB and other external organizations[5] as needed. This PIA only addresses toxicological, pathological, and related analyses on individuals involved in an accident/incident and does not address records pertaining to the investigation of the accident/incident, which are maintained in other FAA systems. This PIA is being updated to reflect a revision to the System of Records Notice (SORN) covering these records as well as minor edits to clarify content.

[1] Based on 49 Code of Federal Regulations (CFR) 830.2, an accident means "an occurrence associated with the operation of an aircraft which takes place between the time any person boards the aircraft with the intention of flight and all such persons have disembarked, and in which any person suffers death or serious injury, or in which the aircraft receives substantial damage."

[2] Based on 49 CFR 830.2, an incident means "an occurrence other than an accident, associated with the operation of an aircraft, which affects or could affect the safety of operations". Examples might be under-shooting, over-running, or running off the side of runways.

[3] *Federal Reimbursable Agreement between Department of Transportation/Federal Aviation Administration and the National Transportation Safety Board*, December 2020.

[4] Privacy rights are not extended to the deceased; however, the FAA continues to protect and manage their PII nevertheless under DOT Order 1351.18, Privacy Risk Management Policy.

[5] These other organizations may include local law enforcement entities, other Department of Transportation modes, or foreign countries.

What is a Privacy Impact Assessment?

The Privacy Act of 1974 articulates concepts for how the federal government should treat individuals and their information and imposes duties upon federal agencies regarding the collection, use, dissemination, and maintenance of personally identifiable information (PII). The E-Government Act of 2002, Section 208, establishes the requirement for agencies to conduct privacy impact assessments (PIAs) for electronic information systems and collections. The assessment is a practical method for evaluating privacy in information systems and collections, and documented assurance that privacy issues have been identified and adequately addressed. The PIA is an analysis of how information is handled to—i) ensure handling conforms to applicable legal, regulatory, and policy requirements regarding privacy; ii) determine the risks and effects of collecting, maintaining and disseminating information in identifiable form in an electronic information system; and iii) examine and evaluate protections and alternative processes for handling information to mitigate potential privacy risks.[6]

Conducting a PIA ensures compliance with laws and regulations governing privacy and demonstrates the DOT's commitment to protect the privacy of any personal information we collect, store, retrieve, use and share. It is a comprehensive analysis of how the DOT's electronic information systems and collections handle personally identifiable information (PII). The goals accomplished in completing a PIA include:

- *Making informed policy and system design or procurement decisions. These decisions must be based on an understanding of privacy risk, and of options available for mitigating that risk;*
- *Accountability for privacy issues;*
- *Analyzing both technical and legal compliance with applicable privacy law and regulations, as well as accepted privacy policy; and*
- *Providing documentation on the flow of personal information and information requirements within DOT systems.*

Upon reviewing the PIA, you should have a broad understanding of the risks and potential effects associated with the Department activities, processes, and systems described and approaches taken to mitigate any potential privacy risks.

Introduction & System Overview

As an integral part of the FAA's comprehensive safety mission, the Office of Aerospace Medicine (AAM) conducts medical investigations of fatal and non-fatal aircraft accidents/ incidents to determine the relationship of medical and human factors to accident/incident

[6] Office of Management and Budget's (OMB) definition of the PIA taken from guidance on implementing the privacy provisions of the E-Government Act of 2002 (see OMB memo of M-03-22 dated September 26, 2003).

cause, aircraft design, crash injury or occupant survival. This includes conducting forensic toxicology analyses of victims involved in fatal and non-fatal aviation accidents. AAM's purpose in collecting and maintaining information within this system includes mitigation of human factors-related accidents/incidents, improving survival, and minimizing crash related injuries. Investigative findings inform and improve aviation safety through regulatory and research activities. Autopsy and toxicological information is recorded from fatal accidents and compiled with information in airman medical records to identify possible contributions of medical conditions and toxic agents to accidents/incidents. Airman medical information is also compiled and analyzed to assess the potential contribution of medical factors to serious non-fatal airman incapacitations and injuries. CAMI also conducts ad-hoc toxicological testing on individuals who have been involved in transportation accidents/incidents in the rail, bus, maritime, and highway sectors.

FAA employees and contractors manage the activities, products, and services for the laboratories, facilities and related assets, including the Toxicology Database (ToxDB). Within AAM, the Bioaeronautical Sciences Research Branch (BSRB) uses the ToxDB for the consolidation and analysis of toxicology, autopsy, and medical information related to individuals involved in transportation accidents/incidents.

However, the ToxDB only collects analytical and investigative toxicological results, medical, and autopsy information from accidents/incidents and does not serve as the FAA's repository of information concerning the *investigation* of the actual accident/incident. The NTSB and/or FAA conducts an on-scene investigation of the accident/incident gathering information relating to the accident/incident for input into the FAA's Accident/Incident System (AIDS)[7]. While the AIDS and ToxDB systems are separate, the FAA Investigator-in-Charge (IIC) might cite autopsy and toxicological information obtained from ToxDB in their final report as possible contributions of medical conditions and toxic agents to accidents/incidents. Such information would then be included in AIDS via the FAA IIC's final report.

After a report of a fatal or non-fatal aircraft accident/incident, the FAA's Regional Operations Center immediately notifies CAMI. CAMI coordinates with the NTSB IIC or FAA IIC and local authorities in arranging for autopsies, if necessary, and obtaining toxicological specimens. For accidents/incidents where there are living victims, the NTSB IIC coordinates with local hospitals and law enforcement to obtain toxicological specimens from living victims.

***Typical Transaction within the ToxDB*:**

Access to ToxDB:

[7] The PIA for AIDS can be found on DOT's Privacy Impact Assessments page.

Access to ToxDB applications is granted by a manager requesting permission to add a user to the application. That request is routed through a ticketing system to the ToxDB system owner who approves user additions and removals. Users are added and/or removed by system and application administrators as there is no self-registration. Users must be FAA employees or contractors and must have a legitimate need for system access. Users who no longer have a legitimate need are removed from each application. Account creation requires name and business email from FAA employees and contractors who access ToxDB using their Personal Identification Verification (PIV) card.

Collection of Specimens and Airman Information:

In the case of accident/incident fatalities, local medical examiners or coroners conduct an autopsy. Completed autopsy reports are sent to the FAA by mail, fax, or as attachments in encrypted emails. Upon receipt, ToxDB personnel verify and manually input the following PII from the autopsy report (if provided) into ToxDB:

- DOB
- Social Security Number (SSN)
- Autopsy results

During the autopsy, the local medical examiner or coroner collects specimens (i.e., tissues, blood, fluids) from the deceased and sends them to the FAA for toxicological analysis. For living victims, hospital personnel and/or law enforcement personnel collect specimens while providing initial medical care or as part of investigatory procedure at a hospital. The NTSB may subsequently subpoena the hospital or law enforcement entity for specimens and records concerning the victim if impairment is suspected. Such specimens are sent directly to the FAA Toxicology Laboratory. The FAA provides specimen collection kits (commonly referred to as a ToxBox) to the FAA Flight Standard District Offices for distribution to medical examiners, coroners, or hospitals[8] for the collection of specimens when an accident/incident occurs. Alternatively, the Forensic Sciences laboratory may send a ToxBox directly to those in need upon request. The ToxBox is a custom-built evidence container that provides all necessary instructions and materials for standardized toxicological collection and processing. Included in ToxBox is FAA Form AC 8025-3 "Accident Information and Change of Custody" which the medical examiner, coroner, or hospital personnel complete, using the victim's credentials or ID. The FAA Form AC 8025-3 collects the following PII about the victim:

- Name of victim

[8] On occasion, specimens for living victims may be collected using other standardized specimen collection boxes other than the ToxBox. In those cases, accompanying documentation varies from the FAA Form AC 8025-3.

- Date of Birth (DOB)
- Sex

Included also is information about the accident/incident:

- Accident/incident Date
- Time
- Location
- Role of Victim

In addition, for fatalities, FAA Form AC 8025-3 collects the following PII from the medical examiner/coroner performing the autopsy:

- Medical Examiner Case Number
- Medical Examiner/Coroner:
    - Name
    - Email Address
    - Phone Number

Once specimen collection is complete, the medical examiner or coroner personnel places specimen containers (labeled with information such as name of collector, type of sample, and name of victim) into the ToxBox and secures the ToxBox with tape and a security seal. In the case of hospital or law enforcement specimens, shipping takes place following a subpoena from the NTSB. The person packing the ToxBox inserts the date and his/her initials on the security seal. The completed and signed copy of the FAA Form AC-8025-3 is also placed in the ToxBox. The medical examiner, coroner, or hospital personnel ship the ToxBox to CAMI using a carrier (such as FedEx).

In the case of non-fatal serious injuries and incapacitations, CAMI contacts the appropriate Flight Standards District Office or Certificate management Office to identify the airman who suffered the injury or incapacitation, and then forward that information, along with information regarding the event, to the certifying Regional Medical Division (RMD) using FAA Form 8020-27 "Regional Flight Surgeon Information Sheet". The Regional Medical Division conducts an inquiry and may require the airman to obtain a new medical examination to permit the RMD to make a proper airman disposition. The disposition, along with medical conditions observed in the examination, are documented on FAA Form 8020-27 and sent to CAMI for entry into ToxDB.

The FAA Form 8020-27 collects the following PII about the victim:

- Name of victim
- Medical Certification Applicant Identification Number
- Medical Conditions Identified

Included also is information about the accident:

- Accident/incident Date
- Time
- Location
- Role of Victim

In addition, for fatalities, FAA Form AC 8025-3 "Accident Information and Chain of Custody" collects the following PII from the medical examiner/coroner performing the autopsy:

- Regional Medical Division POC name
- Regional Medical Division Reviewer Name

Receipt of the ToxBox at CAMI:

Upon receipt of the ToxBox at CAMI, FAA ToxDB personnel videotape the opening of each ToxBox and its contents as documentation of what came from the medical examiner, coroner, or hospital. ToxDB personnel index these videotape records by case number only and not by any identifier associated with the FAA employee opening the box or the accident/incident victim. ToxBox contents documentation is also conducted manually for purposes of entering into ToxDB. If civil litigation ensues from the accident/incident, ToxDB personnel share the internal chain of custody and other pertinent documents, along with the screen shots from the videotape records, if requested, with the FAA's Office of Chief Counsel for use in civil litigation matters involving investigations.

ToxDB personnel manually input the PII and other information contained on FAA Form AC 8025-3 into ToxDB.

Gathering of Additional Information for Input into ToxDB:

If the accident/incident victim is an airman, ToxDB personnel also search another FAA medical database called the Medical Support Systems – Document Imaging Workflow System (MSS-DIWS) for additional information concerning the airman relevant to the toxicological analysis. The following information from MSS-DIWS is manually entered by ToxDB personnel into ToxDB:

- Airman certificate number (which could be their SSN)
- Date of last physical
- Class of airman
- Medications
- Self-reported pathologies

ToxDB personnel also access the Safety Performance Analysis System (SPAS) to pull these PII and non-PII elements of information for input into ToxDB to further round out the ToxDB case file:

- Demographic information of the victim
- Aircraft specifications
- Airman certification information

The purpose of this extraction is to provide necessary aircraft-related information which is useful in determining aircraft certification and aircraft maintenance history.

Finalizing the ToxDB Case and Report:

FAA toxicologists perform toxicological analyses in the BSRB's Forensic Sciences laboratory. The analysis determines the drugs present in tissues and fluids of fatally injured and non-fatally injured victims. The FAA utilizes the toxicological results for individual aircraft and select transportation accident/incidents investigations to determine the contribution, if any, of chemical agents on the cause(s) of a particular accident/incident and to gather data for research purposes. The toxicological results for each accident/incident also provide essential information for medical certification specialists in terms of ensuring airman compliance with medical requirements.

ToxDB analysts enter results of toxicological analyses conducted on specimens into ToxDB. For each toxicological test, the analyst enters the type of test performed, the time the specimen was logged out for testing, and time the specimen was logged in from testing. The results of the testing, which includes the quantitative or qualitative amounts of drug and/or chemicals, is then recorded in ToxDB by the analyst. Toxicological analyses are not performed using ToxDB itself; but rather ToxDB only records and maintains the analyses results. Final ToxDB reports are digitally signed and encrypted. Toxicology reports are shared externally, via email, with medical examiners/coroners for their files on the relevant autopsy investigations performed by them.

CAMI provides NTSB with a final report at the conclusion of the testing, which contains the victim's name, CAMI case number, the results of the toxicology analysis of the individual(s) involved in an accident/incident, and the NTSB number. ToxDB personnel manually upload the final autopsy and toxicology reports to NTSB's MEDICS system.

Fair Information Practice Principles (FIPPs) Analysis

The DOT PIA template is based on the fair information practice principles (FIPPs). The FIPPs, rooted in the tenets of the Privacy Act, are mirrored in the laws of many U.S. states, as well as many foreign nations and international organizations. The FIPPs provide a framework that will support DOT efforts to appropriately identify and mitigate privacy risk. The FIPPs-based analysis conducted by DOT is predicated on the privacy control families

articulated in the Federal Enterprise Architecture Security and Privacy Profile (FEA-SPP) v3, sponsored by the National Institute of Standards and Technology (NIST), the Office of Management and Budget (OMB), and the Federal Chief Information Officers Council and the Privacy Controls articulated in Appendix J of the NIST Special Publication 800-53 Security and Privacy Controls for Federal Information Systems and Organizations.

Transparency

Sections 522a(e)(3) and (e)(4) of the Privacy Act and Section 208 of the E-Government Act require public notice of an organization's information practices and the privacy impact of government programs and activities. Accordingly, DOT is open and transparent about policies, procedures, and technologies that directly affect individuals and/or their personally identifiable information (PII). Additionally, the Department should not maintain any system of records the existence of which is not known to the public.

FAA uses the information collected and maintained in the ToxDB to process toxicological analysis and testing on individuals who have been involved in transportation accidents/incidents, most of which are fatal. PII is collected using FAA Form AC 8025-3, individual medical examiner's/coroner's autopsy reports, or sometimes in the instance of living victims, from copies of their hospital records. In instances of fatalities, the medical examiner or coroner collects the information using the deceased victim's credentials or ID. In the case of a non-fatality, local law enforcement or hospital personnel collect information directly from the individual, verifying it against their credentials or ID, or from the victim's credentials or ID in case the individual is incapacitated.

DOT and FAA System of Records Notices (SORNs) provide transparency about privacy practices regarding the collection, use, sharing, safeguarding, maintenance, and disposal of information about individuals covered under the Privacy Act of 1974, as amended.

The information in ToxDB is covered by SORN DOT/FAA 857, "*Accidents/Incidents and Investigations*", 88 FR 73070 (October 24, 2023) because the information stored in the ToxDB may be retrieved by name of the individual. Records covered by this Notice were previously covered under DOT/FAA 856, Airmen Medical Records, 88 FR 37301, June 7, 2023.

The FAA retrieves system access records in ToxDB by name and protects those Privacy Act records in accordance with Department published SORN DOT/ALL 13, "*Internet/Intranet Activity and Access Records,*" 67 FR 30757 (May 7, 2002).

The publication of this PIA further demonstrates the DOT's commitment to provide appropriate transparency into the ToxDB system.

Individual Participation and Redress

DOT provides a reasonable opportunity and capability for individuals to make informed decisions about the collection, use, and disclosure of their PII. As required by the Privacy Act, individuals should be active participants in the decision-making process regarding the collection and use of their PII and they are provided reasonable access to their PII and the opportunity to have their PII corrected, amended, or deleted, as appropriate.

In the case of an accident/incident not involving fatalities, local law enforcement or hospital personnel collect information directly from the individual (or use the victim's credentials or ID in the case of incapacitation) and place the information on FAA Form AC 8025-3 or in other hospital or law enforcement records.

Under the provisions of the Privacy Act, living accident/incident victims may request searches to determine if any records pertain to them. Individuals wishing to know if their records appear in a system may inquire in person or in writing, as follows:

Notification Procedure (for access to records):
Aviation Data Systems Branch, AFS-620
Federal Aviation Administration
Mike Monroney Aeronautical Center
P.O. Box 25082
6500 South MacArthur Blvd.
Oklahoma City, Oklahoma 73125

The request must include the following information:

- Full Name
- Mailing address
- Phone number and/or email address
- A description of the records sought, and if possible, the location of the records
- A statement under penalty of perjury that the requester is the individual who he or she claims to be.

Contesting Record Procedures (for redress/amendment of records):

An individual who wants to contest information about themselves that is contained in this system should make their request in writing, detailing the reasons the records should be corrected and addressing their letter to the following address:

Aviation Data Systems Branch, AFS-620
Federal Aviation Administration
Mike Monroney Aeronautical Center
P.O. Box 25082
6500 South MacArthur Blvd.
Oklahoma City, Oklahoma 73125

Purpose Specification

DOT should (i) identify the legal bases that authorize a particular PII collection, activity, or technology that impacts privacy; and (ii) specify the purpose(s) for which it collects, uses, maintains, or disseminates PII.

Legal Bases:

The Aviation Safety Research Act of 1988, Public Law 100-591 H.R. 4686, authorizes the FAA to conduct toxicological analyses on specimens from, and pathologic studies on, aircraft accident/incident fatalities and non-fatalities. In addition, pursuant to 49 U.S.C. § 106(l) and 106(m), the FAA signed a federal inter-agency reimbursable agreement with the NTSB for the FAA to provide toxicological testing services to the NTSB for selected surface transportation accidents/incidents.

Regulations granting the FAA's authority and, therefore, its processes for investigating transportation related accidents/incidents are in the Code of Federal Regulations (CFR) as listed below:

- 49 CFR 800 Part 1. 49 CFR 800 Appendix, *Request to The Secretary of The Department of Transportation to Investigate Certain Aircraft Accidents C-2*;
- 49 CFR 830, *Notification and Reporting of Aircraft Accidents or Incidents and Overdue Aircraft, and Preservation of Aircraft Wreckage, Mail Cargo, and Records C-3*;
- 49 CFR 831, *Accident/Incident Investigation Procedures*; and
- 49 CFR 845, *Rules of Practice in Transportation: Accident/Incident Hearings and Reports*.

ToxDB collects and maintains airmen certificate numbers (under authority 49 U.S.C. § 44703(b) (B)) which, in some cases, could be an airman's SSN.

ToxDB data will be used by the FAA consistent with the purposes for which it was collected as described in SORNDOT/FAA 857, *"Accidents/Incidents and Investigations"*, 88 FR 73070 (October 24, 2023). System access data will be used by the FAA consistent with the purposes for which it was collected as described in SORN DOT/ALL 13, "*Internet/Intranet Activity and Access Records,*" 67 FR 30757 (May 7, 2002).

PII Collected, Used, Maintained, or Disseminated and for What Purpose:

ToxDB contains PII on individuals involved in transportation accidents/incidents (living or deceased), FAA employees and contractors, and local/state medical examiners/coroners.

The data produced or collected by each ToxDB user is used for the conduct of toxicological analyses on specimens from, and pathologic studies on, aircraft accident/incidents fatalities and non-fatalities and selected surface transportation accidents/incidents. The PII collected, used, maintained, and retained is listed below:

Individuals involved in a fatal or non-fatal accident/incident:

- Name
- Airman certificate number (which in some instances might be the airman's SSN)
- DOB
- Gender
- Medical information of individuals (contained in autopsy or toxicology reports)
- Physical specimens/remains (received in ToxBox kits)
- Date of last physical for airmen
- Medical findings from reports or medical certification examinations
- Class of airmen
- Airmen medications
- Airmen self-reported pathologies
- ToxDB case number

Local/State Medical Examiners/Coroners who submit specimens for analysis:

- Name
- Business contact information: telephone number, email addresses
- ME numbers

For account administration purposes, ToxDB also maintains PII on ToxDB personnel, who are FAA employees or FAA contractors:

- Name
- Business contact information: email address
- User IDs and passwords

FAA's ToxDB also shares PII and non-PII information both internally and externally as listed below:

Internal Sharing with Other FAA Systems and Offices:

The FAA's Office of Information Technology's Enterprise Data Center automatically receives all data elements from ToxDB daily for the purpose of system backup.

The FAA's Directory Services receives the full name and user ID of FAA ToxDB personnel for the purpose of user authentication.

From the FAA's Safety Performance Analysis System, ToxDB personnel manually extract (and manually input into ToxDB) the following PII from this system: demographic information about the airman, airman certificate number, and airman ratings. Non-PII information extracted from SPAS relates to aircraft registry information, including aircraft type, class, category, make, model, and year. The purpose of this extraction is to provide necessary aircraft-related information, which is useful in determining aircraft certification and aircraft maintenance history.

From the FAA's Medical Support Systems – Document Imaging Workflow System**,** ToxDB personnel manually extract (and then manually enter into ToxDB) PII of airmen who are victims of fatal or non-fatal aviation accidents/incidents, which may include items such as airman certificate number, date of last physical, class of airman, medications, and self-reported pathologies. The purpose of the extraction is to provide airman medical certification data for consideration by the FAA Medical Case Review Officers for the specific accident/incident, and to provide medical data for research purposes. In turn, ToxDB personnel email the final toxicology reports to MSS-DIWS personnel for manual upload into that system for integration with the respective airman's medical case files.

In the event of civil litigation, ToxDB personnel may provide, if requested, the final toxicology report, the litigation packet, along with screenshots from video footage of the opening of each ToxBox and its contents to the Office of Chief Counsel personnel for use in civil litigation matters involving investigations.

In addition to studying causative factors for individual accidents/incidents, FAA safety researchers may request ToxDB data sets spanning multiple accidents/incidents containing identifying or de-identified data for research purposes. Autopsy data is requested by filling out an Autopsy Program Team Data Sharing Agreement and Toxicology data is requested by consulting Toxicology Team management. The FAA sends all data sets containing PII in encrypted email while de-identified data sets are sent via regular email.

External Sharing:

ToxDB personnel upload autopsy and toxicology reports to the NTSB's MEDICS System. These reports may contain the following information: victim information (name, DOB, age, sex, toxicological data, and injury data), accident/incident date, accident/incident location, and medical examiner name. The purpose of the sharing is to update the NTSB's accident/incident investigation records with toxicological data on victims.

Toxicology reports on deceased victims are shared externally, via email, with medical examiners/coroners with the purpose of allowing them to complete their files on the relevant autopsy investigations performed by them.

External entities, such as universities, can also request aviation accident/incident data sets from the FAA that will be used solely for research purposes. External researchers must complete an AUT Confidentiality Statement Form[9] for autopsy data or consult with Toxicology Team management for toxicology data and will not receive any PII in the data sets.

Data Minimization & Retention

DOT should collect, use, and retain only PII that is relevant and necessary for the specified purpose for which it was originally collected.

The FAA minimizes its data collection, maintenance, use, and retention in ToxDB to the information that is relevant and necessary to meet its authorized business purpose, which is to conduct toxicology analyses of all victims involved in fatal and non-fatal aviation accidents/incidents and personnel in other transportation accidents/incidents, with the goals of mitigating human factors-related accidents/incidents, improving survival, and minimizing crash related injuries. ToxDB maintains records in accordance with the National Archives and Records Administration (NARA) schedule DAA-0237-2023-0003: Forensic Toxicology Case Files. This schedule allows for a fifty-year retention period after cut-off, with cut-off occurring when the investigation closes. The business justification for the 50-year retention period is for research and trend analysis studies. System access records are governed by NARA General Records Schedule (GRS) 3.2, approved January 2023, Information Systems Security Records. Under that schedule, system access records are destroyed when business use ceases.

Use Limitation

DOT shall limit the scope of its PII use to ensure that the Department does not use PII in any manner that is not specified in notices, incompatible with the specified purposes for which the information was collected, or for any purpose not otherwise permitted by law.

DOT discloses ToxDB information outside DOT in accordance with DOT/FAA 857, *"Accidents/Incidents and Investigations"*, 88 FR 73070 (October 24, 2023). In addition to other disclosures generally permitted under 5 U.S.C. § 552a(b) of the Privacy Act, all or a portion of the records or information contained in ToxDB may be disclosed outside DOT as a routine use pursuant to 5 U.S.C. § 552a(b)(3):

- To the NTSB investigators and NTSB medical officers who use the data in their efforts to determine the cause of transportation accidents and incidents.
- To Medical Examiners or Coroners who use FAA toxicology results in their medical examiner's report.

[9] AUT Confidentiality Statement Forms are stored outside of the ToxDB system.

- To Federal, State, local and Tribal law enforcement and security agencies, information about airmen, when engaged in an official investigation or security threat assessment in which airmen are involved, or which affect the safety of transportation or national security.
- To Federal, State, local, Tribal, and foreign government agencies who use toxicology services provided by the FAA, information pertaining to the toxicology study requested by the agency.

The sharing of user account information in the ToxDB system is conducted in accordance with SORN DOT/ALL 13, "*Internet/Intranet Activity and Access Records*", 67 FR 30758 (May 7, 2002). In addition to other disclosures generally permitted under 5 U.S.C. §552(a)(b) of the Privacy Act, all or a portion of the records or information contained in the system may be disclosed outside DOT as a routine use pursuant to 5 U.S.C § 552a(b)(3) as follows:

- To provide information to any person(s) authorized to assist in an approved investigation of improper access or usage of DOT computer systems.
- To an actual or potential party or his or her authorized representative for the purpose of negotiation or discussion of such matters as settlement of the case or matter, or informal discovery proceedings.
- To contractors, grantees, experts, consultants, detailees, and other non-DOT employees performing or working on a contract, service, grant cooperative agreement, or other assignment from the Federal government, when necessary to accomplish an agency function related to this system of records.
- To other government agencies where required by law.

DOT may also disclose ToxDB information outside DOT pursuant to 15 additional routine uses applicable to all DOT Privacy Act systems of records. These routine uses are published in the Federal Register at 75 FR 82132 (December 29, 2010), 77 FR 42796 (July 20, 2012) and 84 FR 55222 (October 15, 2019).

Data Quality and Integrity

In accordance with Section 552a(e)(2) of the Privacy Act of 1974, DOT should ensure that any PII collected and maintained by the organization is accurate, relevant, timely, and complete for the purpose for which it is to be used, as specified in the Department's public notice(s).

For ToxDB, the FAA collects, uses, and retains data that is relevant and necessary for the purpose of conducing toxicological analyses on specimens from, and pathologic studies on, aircraft accident/incident fatalities and non-fatalities. For accidents/incidents involving a fatality, the coroner or medical examiner enters data on FAA Form AC-8025-3, using credentials or identification of the deceased. In the case of a non-fatality, local law

enforcement or hospital personnel obtain the information directly from the victim, and verification takes place during that point of collection. In the case of serious incapacitations or injuries, FAA investigators obtain the name and certificate number of the airman, and Regional Medical Division personnel receive airman medical examinations and make a disposition. Airman identifying and medical examination information is entered by CAMI and Regional Medical Divisions on FAA Form 8020-27. Only authorized individuals manually enter data into the ToxDB. Only a limited number of users can add, edit, or delete data in ToxDB. Only the ToxDB administrator can add new pharmaceuticals, types of tests, or other items that ToxDB will record and store.

To maximize accuracy, the FAA's Forensic Sciences Laboratory Manager created a rigorous data validation process for information entry and verification in the ToxDB, which all staff must follow. Verification of test result procedures include known positive and negative specimens (blind controls) in each batch to ensure accuracy of testing. Three separate reviews verify all final results, each of which authenticate the findings and then sign the final case review using pen signatures on hard copies. Cross-referencing of ToxDB information occurs with sources from medical investigators, coroners, investigators and other FAA personnel.

In addition, some fields in the system implement data validation techniques, e.g., date fields only accept dates in specific format or entries for some fields can only be selected from a drop-down menu.

Security

DOT shall implement administrative, technical, and physical measures to protect PII collected or maintained by the Department against loss, unauthorized access, or disclosure, as required by the Privacy Act, and to ensure that organizational planning and responses to privacy incidents comply with OMB policies and guidance.

FAA protects PII with reasonable security safeguards against loss or unauthorized access, destruction, usage, modification, or disclosure. These safeguards incorporate standards and practices required for federal information systems under the Federal Information Security Management Act (FISMA) and are detailed in Federal Information Processing Standards (FIPS) Publication 200, Minimum Security Requirements for Federal Information and Information Systems, dated March 2006, and National Institute of Standards and Technology (NIST) Special Publication (SP) 800-53, Revision 4, Security and Privacy Controls for Federal Information Systems and Organizations, dated April 2013.

ToxDB employs specific administrative, technical, and physical measures to protect PII against loss, unauthorized access, or disclosure. Personnel can only access ToxDB using their PIV card. All PII is encrypted in transit and at rest. Personnel receive guidance on their

duties as they relate to collecting, using, processing, and securing PII. This includes mandatory annual security and privacy awareness training, as well as a review of the FAA Rules of Behavior. The DOT and FAA Privacy Office conduct periodic privacy compliance reviews of ToxDB, as related to the requirements of OMB Circular A-130, Managing Information as a Strategic Resource.

The FAA has in place a privacy/security incident response plan which includes procedures for detection of a privacy/security incident, remediation and response if one occurs, and notification where appropriate to protect and inform impacted individuals. In addition, the FAA administrators, privacy personnel, and security personnel have conducted a privacy/security incident response exercise to evaluate the effectiveness of this plan.

ToxDB has a system security plan in place. The system was re-issued an Authority to Operate (ATO) on September 28, 2023, after completing the authorization and accreditation process that reviews security controls and procedures and that validates that ToxDB is compliant with appropriate information security processes and policies.

Accountability and Auditing

DOT shall implement effective governance controls, monitoring controls, risk management, and assessment controls to demonstrate that the Department is complying with all applicable privacy protection requirements and minimizing the privacy risk to individuals.

FAA Order 1370.121B, FAA Information Security and Privacy Program & Policy, implements the various privacy requirements of the Privacy Act of 1974 (the Privacy Act), the E-Government Act of 2002 (Public Law 107-347), DOT privacy regulations, Office of Management and Budget (OMB) mandates, and other applicable DOT and FAA information and information technology management procedures and guidance.

In addition to these practices, the FAA will implement additional policies and procedures as they relate to the access, protection, retention, and destruction of PII. Federal employees and contractors who work with the ToxDB are given clear guidance about their duties as related to collecting, using, and processing privacy data. Guidance is provided in mandatory annual security and privacy awareness training, as well as FAA Order 1370.121B. The FAA will conduct periodic privacy compliance reviews of the ToxDB with CAMI as related to the requirements of OMB Circular A-130, Managing Information as a Strategic Resource.

Responsible Official

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Approval and Signature

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