OCIO Office of the DOT Chief Information Officer

U.S. Department of Transportation

Privacy Impact Assessment

Office of the Secretary (OST)
Office of Drug and Alcohol Policy and Compliance (ODAPC)
Supplemental Statement to Support the Use of Electronic Custody and Control Forms

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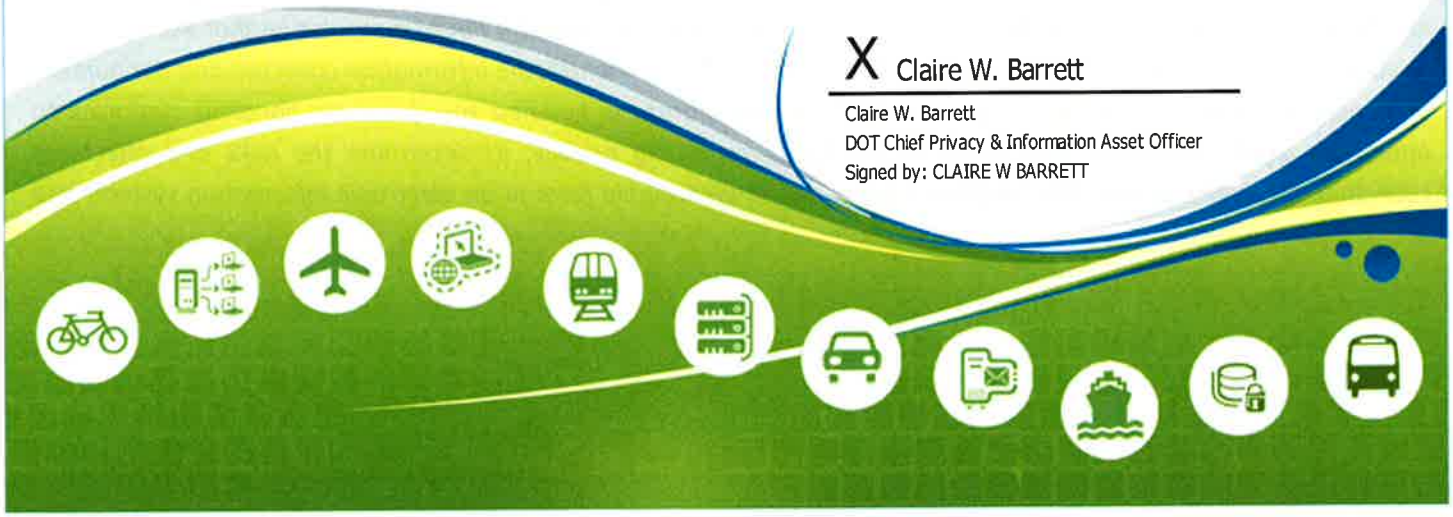

Executive Summary

The Federal Workplace Drug Testing Program was established by Executive Order 12564 on September 15, 1986, and further mandated by Congress in section 503 of Public Law 100-71 (July 11, 1987). The Department of Health and Human Services (HHS), in developing the program, created a comprehensive set of standards for the Federal Workplace Drug Testing Program, including chain of custody procedures designed to ensure the integrity and security of specimens from the time the specimen is collected until the time the testing results are reported by the laboratory. To satisfy this mandate, HHS first issued its Mandatory Guidelines on April 11, 1988, and in doing so, created the uniform Federal Drug Testing Custody and Control Form, otherwise known as the Federal CCF. The Federal CCF is the tool by which agencies and participants in the testing process are assured that the specimen collected is actually that of the tested employee.

Following the HHS' mandate, Congress passed The Omnibus Transportation Employee Testing Act (OTETA) of 1991 (Pub. L. 102-143, 105 Stat. 952, (Oct. 28, 1991)), which mandated that DOT develop a controlled substance and alcohol testing program for its regulated entities. In developing the DOT program, Congress directed that the Department "incorporate the [HHS] scientific and technical guidelines dated April 11, 1988, and any amendments to those guidelines, including mandatory guidelines establishing ... strict procedures governing the chain of custody of specimens collected for controlled substances testing." As a result of this mandate, DOT has required its regulated entities to use the Federal CCF, as developed by HHS and approved by the Office of Management and Budget (OMB). Historically, the Federal CCF has only been available for use in paper form. Recently, however, OMB approved the use of both a paper form Federal CCF and an electronic Federal CCF (eCCF). DOT is issuing this statement as a supplement to the Privacy Impact Assessment issued by HHS regarding the eCCF, to further explain how the eCCF may be used by DOT-regulated entities and the measures that have been put into place to ensure not only the integrity and security of the testing process, but the privacy of the individuals who are subject to testing. This PIA does not address the DOT's internal employee-testing program nor the collection and use of drug testing samples of DOT employees maintained in the Department's Drug & Alcohol Testing Management Information System (DATMIS). Information about the DOT program and system may be found in the DATMIS PIA published on the DOT privacy program website www.dot.gov/privacy.

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). Section (a)(5) of div. H of the Fiscal Year 2005 Omnibus Appropriations Act, Pub. L. 108-447, 118 Stat. 3268 (Dec. 8, 2004) requires DOT to conduct a PIA of a regulation that will affect the privacy of individuals. The PIA shall identify the type of personally identifiable information collected and the number of people affected. 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.[1]

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.

Overview of the Federal CCF:

The current Federal CCF is a five-part paper form that consists of the following copies:

- Copy 1: Test Facility Copy
- Copy 2: Medical Review Officer (MRO) Copy
- Copy 3: Collector Copy
- Copy 4: Employer Copy
- Copy 5: Donor Copy

Each testing activity/specimen collection requires the use of an OMB-approved form on which the following information is collected: the employer's name, address, I.D. number; the donor's birthdate, SSN or employee I.D. number, private driver's license number or Commercial Driver's License number (CDL); the MRO's name, address, phone and fax numbers; the collector's name, phone and fax numbers as well as the address of the collection site. In addition, information about the test itself is provided, such as the reason for the test (i.e. whether it is a pre-employment test, random test, reasonable suspicion test, etc.); any remarks from the collector regarding the testing process; the test result, as well as any notes of the MRO. The process for completing the Federal CCF is provided on the back of Copy 5.

In 2013 Department of Transportation, regulated parties conducted approximately 6 million drug tests resulting in approximately 30 million individual pieces of paper (one copy each for each of the parties involved in the testing process). The most common mode of transmitting Federal CCF copies is via fax. However, some faxes are better quality than others and not all collection facilities have fax machines. As a result, Federal CCF copies must be mailed, thus affecting the timeframes for the testing verification and the reporting of results to employers. The paper-based process also increases the risk of lost or illegible forms, increasing the likelihood of adverse effect to

[1]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).

the individual through loss of control of PII and unauthorized use, or inaccurate testing outcomes leading to the loss of employment. In addition, employers, laboratories and medical review officers must retain the paper copies for inspection purposes. This requires additional time and expense for the physical filing, storage and retention of the paper copies. All of this places unnecessary cost and storage burdens on parties in the DOT-regulated drug testing process.

On August 29, 2010, in approving the last version of the Federal CCF (ICR 201007-0930-002), OMB noted in its terms of clearance that "[p]rior to the next approval of this package, the Agency shall provide a progress update on adoption of electronic forms in an effort to reduce burden. SAMHSA is encouraged to explore ways to convert the Federal Drug Testing Custody and Control Form (Federal CCF) into an electronic form."[2]

When the parties to the DOT-regulated process are permitted to use an eCCF, the actual collection process will not change, but will improve. The parties will continue to follow established drug testing collection protocols. They will enter identical information to what is being collected on paper. The parties will be able to leverage "Print on Demand" capabilities to improve efficiencies in the testing process. Specifically, the accuracy and legibility of the information recorded on the eCCF is expected to improve tremendously because the employer will be preprinting the information and the testing donor will be able to verify the PII within this clearly printed information. When an employer changes service agents (collection site, lab or medical review officer), the Federal eCCF will allow for the up-to-date and most accurate information and employers and collection sites will no longer need to discard forms preprinted with outdated information.

The eCCFs need to be transmitted securely to the appropriate parties. With the electronic transmission of the appropriate copies to the parties, the timeframes for the verifications and reporting of results should also improve. In addition, we believe that use of the eCCF by the parties will reduce costs and environment impact of stocking pre-printed CCFs, and reduce or eliminate the need to file and pay for physical storage space for and retrieval of the paper copies.

We anticipate that there will be eCCFs that facilitate the use of wet signatures and others that facilitate the use of digital signatures of individuals involved in the testing process (primarily donors and collectors). The use of digital signatures is well accepted throughout the domestic and international business communities. Any digital signatures would need to meet industry standards to insure their integrity and viability.

As discussed above, in transitioning to the eCCF, HHS and DOT are not requiring collection of any new information. The same information that is currently provided and noted on the paper Federal CCF will be provided on the eCCF; only the mechanism for collecting and transmitting that information will change. For instance, in some cases, some employers may choose to use a web portal system that would allow the employer, or a designated employer representative to order a test online by entering the employee's information, which would then be transferred to the collection site. The collection site, after verifying the employee's identity, would be able to retrieve the test order and generate the eCCF. Once the necessary information from the collection site is entered and the actual specimen collection is completed, the specimen is labeled with a tracking code that matches the tracking code assigned to the eCCF, the specimen would be sent to the laboratory for analysis. Upon arrival, the laboratory could

[2] CCF Information Collection Request Approval (Aug. 29, 2010), *available at* http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201007-0930-002

scan the code on the specimen and retrieve the eCCF to document the lab results. The same process would then be followed by the MRO to review the laboratory results. This is just one method that those who are involved in the testing process could use as an alternative to the current paper Federal CCF.

The use of an electronic chain of custody form is currently widely used in non-Federal drug testing. The transportation industries have seen the tremendous increase in accuracy, efficiency, integrity, security and a significant decrease in cost coming from their use of the electronic chain of custody forms currently in the marketplace. Currently, in non-Federal testing, industry standards on accuracy, integrity, and security control the electronic medium with great success. The majority of non-Federal testing occurs on DOT look-alike forms that have the same data field, and are employed in collection and verification procedures modeled after those of the DOT or HHS. The non-Federal chain of custody forms are seen as more accurate because the employers populate the data fields that are theirs, while the employees can verify and correct inaccuracies in data fields that pertain to them. These forms are currently seen as having integrity at least as good as, if not better than, the paper copies because it is possible for a collector to go back and alter a paper copy after the donor has left the collection site, but this is not possible with an electronic chain of custody form.

Fair Information Practice Principles (FIPPs) Analysis

The DOT PIA template 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[3], 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[4].

Transparency

Sections 522a(e)(3) and (e)(4) of the Privacy Act[5] and Section 208 of the E-Government Act[6] 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.

In accordance with the Paperwork Reduction Act, HHS published a notice[7] in the Federal Register seeking public comment on its proposed transition from paper to an electronic version of the Federal CCF, as well as the data necessary to complete the testing process. As stated in the Notice, the information collection activity under the paper and electronic versions of the CCF is identical.

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[3] http://www.cio.gov/documents/FEA-Security-Privacy-Profile-v3-09-30-2010.pdf
[4] http://csrc.nist.gov/publications/drafts/800-53-Appdendix-J/IPDraft_800-53-privacy-appendix-J.pdf
[5] 5 U.S.C. 552a(e)(3) and (e)(4).
[6] 44 U.S.C. 3501 note.
[7] 78 FR 42092 - http://www.gpo.gov/fdsys/pkg/FR-2013-07-15/pdf/2013-16794.pdf

As is required today, employers remain responsible for notifying individuals that they are subject to the OTETA's testing requirements and that the Federal eCCF will be used to facilitate the management of that process. DOT expects employers to inform their employees about changes to the testing process, including its conversion to the eCCF so that employees are adequately informed about the information that will be collected, why that information must be collected, and how the information will be secured.

DOT does not retain any PII of individuals employed by regulated parties provided on a paper Federal CCF, nor would it retain any PII collected using the eCCF.

Individual Participation and Redress

DOT should provide 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 be provided reasonable access to their PII and the opportunity to have their PII corrected, amended, or deleted, as appropriate.

Submission of the information required on the eCCF is voluntary, however incomplete or inaccurate information may result in an inability to process test specimens and report accurate results. Employers may collect the information directly from individuals or may use existing data repositories to populate the data in the form. Individuals should be provided an opportunity to review and verify their PII listed on the eCCF to ensure the accuracy of the information.

The DOT regulation 49 CFR section 40.321 prohibits an employer or a service agent (who implements the drug testing requirements on behalf of an employer) from releasing individual test results or medical information about an employee to third parties without the employee's specific written consent, unless the release is authorized under Subpart P of 49 CFR Part 40. Examples of releases that the regulation allows without an employee's consent include releases to the actual individual tested, releases to DOT inspectors and auditors, limited categories of state or local safety personnel, and the National Transportation Safety Board. 49 CFR section 40.321(b) prohibits blanket releases, in which an employee agrees to release a category of information, such as all of his or her test results, or to release information to a category of third parties not contemplated in Subpart P of 49 CFR Part 40, are not permitted; rather, the written consent must be signed by the employee authorizing the release of particular information to an identified person or organization at a particular time.

Statutory Authority and 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 its collects, uses, maintains, or disseminates PII.

As discussed above, OTETA, mandated that DOT develop a controlled substance and alcohol testing program for its regulated entities and that the Department, "incorporate the [HHS] scientific and technical guidelines dated April 11, 1988, and any amendments to those guidelines, including mandatory guidelines establishing ... strict procedures governing the chain of custody of specimens collected for controlled substances testing." HHS' Mandatory Guidelines require chain of custody procedures to document the integrity and security of a urine specimen from the time it is collected until specimen results are reported to the Medical Review Officer (MRO) by the laboratory. To

ensure uniformity among all federally-regulated workplace drug testing programs, the Mandatory Guidelines require using an OMB-approved Federal CCF.

As a result of this mandate, DOT has required its regulated entities to use the Federal CCF, as developed by HHS and approved by the Office of Management and Budget (OMB). Once the Office of Management Budget (OMB) approves the use of the Federal eCCF, the Department will update 49 CFR Part 40 (Drug and Alcohol Regulations) to authorize the use of the same by regulated parties.

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. DOT should retain PII for only as long as necessary to fulfill the specified purpose(s) and in accordance with a National Archives and Records Administration (NARA)-approved record disposition schedule. Forms used for the purposes of collecting PII shall be authorized by the Office of Management and Budget (OMB)

Submission of your SSN is not required by law and is voluntary. If you opt not to submit your SSN, DOT will allow employers to assign other unique identifiers, such as private driver's license number CDLs or employee identification numbers, to process the specimen. Your refusal to furnish your SSN will not result in the denial of any right, benefit, or privilege provided by law. To accommodate DOT needs, the HHS-developed eCCF allows for the continued collection of information regarding the reason for the test (pre-employment, random, reasonable suspicion/reasonable cause, post-accident, return-to-duty, and follow-up testing), as well as information regarding which DOT agency regulates the employee's safety-sensitive duties HHS-developed Federal eCCF

Employers covered under DOT drug and alcohol-testing regulations must maintain records that document their testing program consistent with 49 CFR Part 40 and other industry specific regulations. Industry specific regulations requiring record keeping are listed in the following:

Industry	ation
FAA - Airline	R part 120, Subpart E, section 120.111 R part 120, Subpart F, section 120.219
FMCSA – Motor Carrier	R part 382.401
FRA - Railroad	R part 219.901 and 219.903
FTA - Transit	R part 655.71
PHMSA - Pipelines	R part 199.227
USCG - Maritime	R Part 16.260

Table 1 - Employers coverered under DOT drug and alcohol-testing regulations must maintain records that docuemtn their testing program.

Depending on the regulated industry and the type of test, entities would be required to retain testing records between one and five years subject to specific DOT agency requirements. Specific requirements for each DOT agency may be found on the DOT's Office of Drug & Alcohol Policy & Compliance (www.dot.gov/odapc).

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.

The use of the Federal CCF for DOT-regulated drug testing is currently required by 49 CFR section 40.13(f). In addition, 49 CFR section 40.13 does not allow employers or other parties to the collection process to delete or include additional information or data fields on the CCF.

Employers and service agents participating in the testing process are not allowed to release test results or medical information about an employee to any third party, unless the information falls under one of the exceptions to 49 CFR Part 40, Subpart P, referenced above, without the employee's written consent. Blanket releases, in which an employee agrees to release a category of information, such as all of his or her test results, or to release information to a category of third parties, are explicitly prohibited under 49 CFR section 40.321(b). To be valid, the written consent must be signed by the employee authorizing the release of particular information to an identified person or organization at a particular time.

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).

Federal eCCF systems must comply with applicable HHS information quality standards, include data checks to ensure that information collected conforms to formatting requirements (i.e., nnn-nn-nnnn for SSN), and require completion of certain fields as a condition of proceeding to the next section of the testing process where appropriate. Employers who are responsible for accuracy of information populated in the Federal eCCF and are strongly encouraged to have employees validate personal information prior to its use.

The redress process described in the Individual Participation and Redress section is a mechanism to maintain and improve accuracy of information.

Security

DOT shall implement administrative, technical, and physical measures 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.

The Department has neither created nor contracted for the development of a system in support of Federal eCCF. Employers choosing to use a Federal eCCF, as opposed to the paper process, are responsible for ensuring that systems and vendors used for this process establish adequate security measures to ensure that confidential employee records are not available to unauthorized persons and ensure the integrity of the records. This includes protecting the physical security of records, access controls, and computer security measures to safeguard confidential data in electronic data bases. Regulated parties must comply with HHS and DOT issued guidance addressing standards concerning electronic signature, non-repudiation agreement for digital signatures, third party software for managing Federal eCCF information, unique specimen identification number, the legally-binding equivalent of traditional hand-written signatures in a forensic arena, the security of data transmission over telecommunications systems/networks, and the accuracy and integrity of document content.

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.

As discussed above, DOT has not created nor contracted for the development of a system in support of a Federal eCCF. Any employer that wishes to use the eCCF must ensure that documents stored electronically are easily accessible to authorized individuals, legible, formatted, and stored in an organized manner, and that records are maintained in such a manner or location that ensures controlled access. DOT inspectors and auditors, as well as state and local government partners who conduct audits and inspections on behalf of DOT, will continue to monitor and assess the use of all Federal CCFs, including the Federal eCCF, as part of their on-going auditing and inspecting processes.

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