Mandatory Guidelines for Federal Workplace Drug Testing Programs

SUPPORTING STATEMENT

A. Justification

1. Circumstances of Information Collection

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting Office of Management and Budget (OMB) approval of the recordkeeping and reporting requirements in the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) dated November 25, 2008 (73 FR 71858), which include the Federal Drug Testing Custody and Control Form (Federal CCF), the National Laboratory Certification Program (NLCP) application forms for laboratories and Instrumented Initial Test Facilities (IITFs), and the NLCP information checklists for laboratories and IITFs. These requirements and forms are currently approved under OMB No. 0930-0158, which expires on May 31, 2014.

The Federal Workplace Drug Testing Programs were established by Executive Order 12564 on September 15, 1986 and legislatively mandated in Section 503 of Public Law 100-71 dated July 11, 1987 (Attachment A). The Department of Health and Human Services (HHS) provides comprehensive scientific and technical standards to satisfy this mandate in the Mandatory Guidelines for Federal Workplace Drug Testing Programs. The Mandatory Guidelines were first published on April 11, 1988, (53 FR 11979), with the latest revision published on November 25, 2008 (73 FR 75122) (Attachment B) and with a subsequent change to the effective date published on April 30, 2010 (75 FR 22809) (Attachment C).

The Mandatory Guidelines require chain of custody procedures to document the integrity and security of a urine specimen from the time it is collected until disposal by the test facility (i.e., laboratory or IITF). To ensure uniformity among all federally-regulated workplace drug testing programs, the Mandatory Guidelines require using an OMB-approved Federal CCF (Federal CCF - Attachment D).

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. In addition to the Federal Workplace Drug Testing Programs, other federal agencies, such as the U.S. Department of Transportation and the Nuclear Regulatory Commission, also use the Federal CCF in drug testing programs required of their regulated industries and federal contractors. To date, the Federal CCF only has been authorized for use in paper form. Through this request, HHS seeks authorization to allow the use of both paper and electronic copies of the Federal CCF.

The Mandatory Guidelines also establish the standards for the NLCP, including requirements for a laboratory or IITF to become HHS-certified and to maintain certification. Prior to the initial certification process, each interested laboratory or IITF is required to submit an application (Attachment E or G) to the NLCP contractor for review and evaluation. If the NLCP application form submitted by the laboratory or IITF is complete and indicates that the test facility is prepared to test specimens using forensically and scientifically supportable procedures, the applicant test facility begins the initial certification process which consists of testing three sets of performance testing samples and undergoing an inspection. After successfully completing this initial certification process, the laboratory or IITF is certified by HHS and enters the NLCP. Through this request, HHS seeks authorization to continue using the NLCP application form in the certification process.

Once certified, laboratories and IITFs must undergo NLCP inspections every six months to maintain their certification. Prior to each inspection, the laboratory or IITF is required to update Sections B and C of the NLCP information checklist (Attachment F or H). The submitted information allows the members of the inspection team to become familiar with the laboratory's or IITF's procedures before arriving at the test facility to conduct the inspection, thereby, facilitating the timely completion of the inspection. HHS seeks continued approval to collect the information on the information checklist in support of the NLCP inspection program.

In addition to these three areas, HHS seeks approval to continue requiring the recording and reporting requirements specified in the Mandatory Guidelines that are summarized below:

Section 4.5(c) - Recordkeeping
Collector is given name and phone of federal agency point of contact

Section 8.3, 8.4, 8.5, 8.6, and 8.7 - Recordkeeping
Collector completes Federal CCF for specimen collected

Section 9.2(a)(1) - Reporting
Laboratory or IITF required to submit an application for certification

Section 9.10(a)(3) - Recordkeeping
Materials to submit to become an HHS inspector

Section 11.4(c) - Recordkeeping
Laboratory submits qualifications of new responsible persons (RP) and alternate RPs to HHS

Section 11.8 and 11.19(a) and (o) - Reporting
Laboratory completes Federal CCF upon receipt of specimen and before reporting result

Section 11.22(a) - Recordkeeping
Specifications for laboratory semi-annual statistical report of test results to each federal agency

Section 11.23(b) - Recordkeeping
Information on drug test that laboratory must provide to donor through the Medical Review Officer (MRO)

Section 12.4(c) - Reporting
IITF submits qualifications of new responsible technicians (RT) and alternate RTs to HHS

Section 12.8(a) and 12.15(f) - Reporting
IITF completes Federal CCF upon receipt of specimen and before reporting result

Section 12.19(a) - Recordkeeping
Specifies contents of IITF semi-annual statistical report to federal agencies served

Section 12.20(b) - Reporting
Drug test information that IITF must provide to donor through MRO

Section 13.3(c)(4) - Reporting
MRO completes the Federal CCF before reporting result

Section 13.7(b) - Reporting

MRO must inform donor of right to request split specimen test when a positive, adulterated, or substituted result is reported

Section 14.1(b) - Recordkeeping

MRO documents donor's request to have split specimen tested

Section 14.7 - Recordkeeping

Specifies that MRO must report verified split specimen test results to the federal agency

2. Purpose and Use of Information

a. Federal CCF (current 2010 Federal CCF - Attachment D)-paper and electronic

The Federal CCF is used to identify a specimen and to document its handling at the collection site. The paper Federal CCF is a carbonless form consisting of 5 copies as follows:

Copy 1	Test Facility Copy
Copy 2	Medical Review Officer Copy
Copy 3	Collector Copy
Copy 4	Employer Copy
Copy 5	Donor Copy

The electronic Federal CCF (eCCF) has the same format as the paper form. Because Copies 2-5 are identical, the eCCF consists of Copy 1 (Test Facility Copy) and Copy 2 (which is distributed to the MRO, collector, employer, and donor).

With the allowance of the eCCF, HHS is not requiring collection of any new or different 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, one option is 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 provided to the collection site. The collection site, after verifying the employee's identity, would be able to retrieve the test order and initiate the eCCF. After entering the necessary information on the eCCF and completing the specimen

collection, the collector would label the specimen bottles with a tracking code that matches the tracking code assigned to the eCCF, send the specimen to the test facility for analysis, and provide the eCCF to the test facility. Upon receipt of the specimen, the test facility would scan the tracking code on the specimen bottles and retrieve the eCCF. The test facility would complete the appropriate sections of the eCCF and report the drug test results by providing the eCCF to the MRO.

The Federal CCF is used by the following:

(1). **Federal Agencies**

Department of Agriculture
Department of Commerce
Defense Intelligence Agency
Department of Defense Dependent Schools
Defense Information Systems Agency
Defense Contract Audit Agency
Defense Security Service
Defense Logistics Agency
National Security Agency
National Imagery and Mapping Agency
Defense Special Weapons Agency
Office of Inspector General
Office of Sec. of Defense/Washington Headquarters Services
Department of the Navy
Uniform Services University of Health Science
Department of the Air Force
Department of Education
Department of Energy
Department of Health and Human Services
Department of Housing and Urban Development
Department of the Interior
Department of Justice
United States Marshals Service
Department of Labor
Department of State
Comptroller of the Currency, Treasury
Bureau of Engraving & Printing
Internal Revenue Service
Federal Law Enforcement Training Center
United States Mint
Bureau of the Public Debt
Financial Management Service
Environmental Protection Agency
Executive Office of the President

General Services Administration
National Aeronautics and Space Administration
Small Business Administration
Department of Veterans Affairs
Army Center for Substance Abuse Programs
Bureau of Prisons
Federal Bureau of Investigation
Immigration and Naturalization Service
Drug Enforcement Administration
Department of Transportation
Bureau of Alcohol, Tobacco, and Firearms
U.S. Secret Service
U.S. Customs Service
Corporation for National Service
Advisory Council on Historic Preservation
American Battle Monuments Commission
USAID
Architectural and Transportation Board
Barry Goldwater Scholarship Foundation
U.S. Commission on Civil Rights
Commission of Fine Arts
Committee for Purchase from Blind/Disabled
Commodity Futures Trading Commission
Consumer Product Safety Board
Defense Nuclear Facilities Safety Board
Export-Import Bank of the United States
Farm Credit Administration
Federal Communication Commission
Federal Deposit Insurance Corporation
Federal Election Commission
Federal Emergency Management Agency
Federal Labor Relations Authority
Federal Energy Regulatory Commission
Federal Mediation and Conciliation Service
Federal Maritime Commission
Federal Mine Safety and Health Review Commission
Federal Reserve Board
Federal Retirement Thrift Investment Board
Federal Trade Commission
Foreign Claims Settlement Commission
Harry S. Truman Scholarship Foundation
Indian Arts and Crafts Board
Institute of Museum and Library Services
Inter-American Foundation
International Boundary Commission, U.S. and Canada
U.S. International Boundary and Water Commission, U.S. and Mexico
International Joint Commission

U.S. International Trade Commission
Surface Transportation Board
Japan-U.S. Friendship Commission
Marine Mammal Commission
U.S. Merit Systems Protection Board
National Archives and Records Administration
National Capital Planning Commission
National Commission on Libraries and Information Science
National Council on Disability
National Credit Union Administration
National Endowment for the Arts
National Endowment for the Humanities
National Labor Relations Board
National Mediation Board
National Science Foundation
National Transportation Safety Board
Office of Navajo and Hopi Indian Relocation
U.S. Nuclear Regulatory Commission
U.S. Office of Special Counsel
Office of Thrift Supervision
Occupational Safety and Health Review Commission
Overseas Private Investment Corporation
Peace Corps
Pension Benefit Guaranty Corporation
U.S. Railroad Retirement Board
Selective Service System
U.S. Soldiers' and Airmen's Home
Tennessee Valley Authority
Securities and Exchange Commission
U.S. Office of Government Ethics
Arctic Research Commission
Army and Air Force Exchange Service

(2). **Employers** regulated by the Department of Transportation under its drug and alcohol regulations and amendments (49 CFR Part 40) for the following:

Federal Aviation Administration
Federal Motor Carrier Administration
Federal Railroad Administration
Federal Transit Administration
Pipeline and Hazardous Materials Safety Administration
United States Coast Guard

(3) **Licensees and other entities** regulated by the Nuclear Regulatory Commission under its fitness-for-duty regulations (10 CFR Part 26).

b. NLCP Application Form (Attachment E or G)

A laboratory or IITF interested in participating in the National Laboratory Certification Program must submit an NLCP application form. The form contains the minimum information needed for a determination of the laboratory's or IITF's preparedness to begin the initial certification process.

c. Sections B and C of the NLCP Information Checklist (Attachment F or H)

A laboratory or IITF must submit Sections B and C of the NLCP information checklist before each semi-annual maintenance inspection. The information submitted is used by the inspectors to become familiar with the laboratory or IITF operations before arriving at the test facility for the onsite inspection.

d. Recordkeeping and Reporting Requirements in the Mandatory Guidelines

The recordkeeping and reporting requirements ensure that the information and records collected and maintained by a certified laboratory or IITF will be forensically and scientifically supportable.

3. Use of Information Technology

In accordance with the Government Paperwork Elimination Act (GPEA), the NLCP facilitates the use of automated, electronic submissions of any type of documentation required by the Mandatory Guidelines. All applications and NLCP information checklists may be submitted electronically to the NLCP. Drug testing service providers including collectors, test facilities, MROs, and third party administrators are allowed to transmit copies of the Federal CCF by secure electronic means. In addition, under this approval, the Federal CCF may now be used in either paper or electronic form. Although HHS expects that most service providers will choose to provide information electronically, paper submissions and reports will remain acceptable.

4. Efforts to Identify Duplication

The information on the Federal CCF is unique and is collected to satisfy forensic requirements and to facilitate reporting of drug test results.

The information provided by an applicant laboratory or IITF on the NLCP application form is not available from any other source because the procedures used by each laboratory or IITF are unique.

The information provided by each laboratory or IITF in Sections B and C of the NLCP inspection checklist is unique, is necessary for inspectors conducting an inspection, and is not available elsewhere.

The recordkeeping and reporting requirements in the Mandatory Guidelines are also unique.

To avoid duplication, employers regulated by the DOT are required by law to use the Federal CCF and HHS-certified laboratories for their workplace drug testing programs rather than using different custody and control forms or establishing alternative laboratory certification programs. The NRC also requires their regulated entities to use HHS-certified laboratories and to use the Federal CCF pursuant to §26.153(g).

5. Involvement of Small Entities

The Federal CCF is used only by federal agencies, employers regulated by DOT, and entities regulated by NRC. The requirement to use the Federal CCF has no special impact on small businesses. That is, some type of custody and control form must be used when a specimen is collected and submitted to a laboratory for a drug test. Use of an eCCF is optional; it is a business decision to implement use of the electronic form. Capital and start-up costs for a small business to implement an eCCF system may be balanced by marketable value and savings in time and labor (e.g., error reduction through use of computerized stepwise processes).

The information provided on the NLCP application form or in Sections B and C of the NLCP inspection checklist is information that any laboratory must have to show that it is capable of testing specimens and reporting results that are forensically and scientifically supportable.

The recordkeeping and reporting requirements in the Mandatory Guidelines describe procedures paralleling those employed in any laboratory that conducts forensic drug testing. In the normal course of business, a laboratory collects and maintains this same information to support the reported test results. The standards and certifying procedures represent the minimum burden consistent with the legislative intent of Executive Order 12564 and Public Law 100-71.

6. Consequences If Information Collected Less Frequently

A separate Federal CCF is used for each urine specimen that is collected. A urine specimen may be collected for one of the following reasons: pre-employment, random, reasonable suspicion/cause, post-accident, return to duty, or follow-up. Each federal agency and employer regulated by DOT establishes the frequency at which employees are randomly selected for drug testing, while the frequency for testing for the other reasons depends on the circumstances. The deterrence effect of a workplace drug testing program is related to the frequency that employees are tested.

The NLCP application form must be submitted only once as part of the process to become an HHS-certified laboratory or IITF. Without this information, it is impossible to assess whether a laboratory is capable of maintaining chain of custody and using reliable analytical procedures to test specimens and thus complete the certification process. The requirement for each laboratory or IITF to update Sections B and C of the NLCP inspection checklist before each inspection ensures that the inspectors have the information on changes since the last inspection and on current staffing and procedures. Collecting the information less frequently would require the inspectors to spend a great deal of time determining the current practices and what changes were instituted since the last inspection rather than spending the time allocated for reviewing all aspects of the laboratories operations.

The recordkeeping and reporting requirements are continuous for all aspects of a laboratory's or IITF's program. The collection of data and recordkeeping cannot be accomplished less frequently and still maintain the appropriate forensically acceptable minimum standards to ensure that all drug test results are supportable in a judicial or administrative proceeding.

7. Consistency with the Guidelines in 5 CFR 1320.5(d)(2)

The information collected on the Federal CCF, NLCP application form, Sections B and C of the NLCP inspection checklist, and the recordkeeping and reporting requirements in the Mandatory Guidelines comply with 5 CFR 1320.5(d)(2).

8. Consultation outside the Agency

A notice soliciting public comment on the collection of this information was published in the Federal Register on April 30, 2013 (78 FR 25282).

HHS received no responses on the Agency Information Collection Activities: Proposed Collection Comment Request. The public accepted the burden hour projection.

9. Payment to Respondents

There is no payment made or gift given to an individual who provides the required information on a Federal CCF or to any test facility that completes an NLCP application form or Sections B and C of the NLCP inspection checklist, or meets the other recordkeeping and reporting requirements in the Mandatory Guidelines.

10. Assurance of Confidentiality

The information on the Federal CCF is collected under the authority in Executive Order 12564, 5 U.S.C. 3301 (2), 5 U.S.C. 7301, and Section 503 of Public Law 100-71, 5 U.S.C. 7301 note. Test results may only be disclosed to an MRO, the federal agency administrator of the Employee Assistance Program, and a supervisor with authority to take adverse personnel action. The

Federal CCF was developed to collect minimal personal identifying information of the individual being tested and to limit access only to the extent necessary to link the specimen and test results to the individual. The individual tested may object to the inclusion of his/her Social Security Number (SSN) on the CCF. Refusal to provide the SSN does not invalidate the drug test. Another identifier (e.g., employee identification number) is used in place of the SSN. For more information about the confidentiality and security of the information collected on this form, please review HHS privacy impact assessment at [insert link], and the DOT privacy impact assessment at www.dot.gov/privacy.

Completed NLCP application forms and Sections B and C of the NLCP inspection checklists are kept secure and protected at the NLCP contractor facility.

All records maintained by the certified laboratories and IITFs are kept secure and private in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

11. Questions of a Sensitive Nature

The certification standards and scientific and technical guidelines do not solicit information of a sensitive nature. The privacy inherent in the drug testing procedure itself requires adherence to applicable privacy and protection provisions. Upon notification by the testing laboratory that a specimen has tested positive, substituted, or adulterated, the MRO must contact the individual to determine if there is a valid medical explanation for the test results. The medical information given to the MRO must be kept private to the extent of the law.

12. Estimates of Annualized Hour Burden

a. Federal CCF

Form/Respondent	Number of Respondents	Responses per Respondent	Total Number of Responses	Burden per Response (hours)	Annual Burden (hours)	HourlyWage Rate ($)	Total Cost ($)[4]
Custody and Control Form[1]:							
Donor	6,150,000	1	6,150,000	0.08	492,000	25	12,300,500
Collector	6,150,000	1	6,150,000	0.07	430,500	15	6,457,500
Laboratory	6,150,000	1	6,150,000	0.05	307,500	35	10,762,500
IITF	0	0	0	0.05	0	35	0
Medical Review Officer	6,150,000	1	6,150,000	0.05	307,500	150	46,125,000
NLCP Application Form[2]:							
Laboratory	1	1	1	3	9	35	315
IITF	1	1	1	3	3	35	105
Sections B and C - NLCP Inspection Checklist[3]:							
Laboratory	35	2	70	1	70	35	2,450
IITF	0	0	0	1	0	35	0
Record Keeping:							
Laboratory	35	1	35	250	8,750	35	306,250
IITF	0	0	0	250	0	35	0
Total	24,600,072		26,600,107		1,546,332		75,954,120

[1]*Note: The time it takes each respondent (i.e., donor, collector, laboratory, and MRO) to complete the Federal CCF is based on an average estimated number of minutes it would take each respondent to complete their designated section of the form or regulated entities (e.g. HHS, DOT, and NRC).*

[1]*Note: The above number of responses is an estimate of the total number of specimens collected annually (150,000 federal agency specimens; and approximately 6,000,000 DOT regulated specimens).*

[2]Note: The estimate of three applications per year is based on receiving only 3 applications for a laboratory application in the past year (i.e., at the time of these calculations) and only 1 IITF application submitted after October 1, 2010.

[2]Note: The estimate of three burden hours to complete the application has not changed even though additional information is requested. The original burden hours were generous to begin with and are still appropriate.

[3]Note: At the time of these calculations, there were 35 certified laboratories undergoing 2 maintenance inspections each year and one certified IITF.

[3]Note: The estimate of 1 burden hour to complete Sections B and C of the NLCP Inspection Checklist has changed from the original 3 hours to the present 1 hour, even though additional information is requested. The original burden hours were generous to begin with and the 1 hour to provide new or updated information is an appropriate estimation.

[4]Note: The wage rates listed for each respondent are based on estimated average hourly wages for the individuals performing these tasks.

13. Estimates of Annualized Cost Burden to Respondents

1. Donors

There is no direct cost burden to a donor (i.e., employee/job applicant). Each federal agency, DOT-regulated employer, or NRC-regulated entity pays for collecting and testing specimens and for the MRO review of results as part of its workplace drug testing program.

2. Test Facility (Laboratory or IITF)

There are no capital and start-up costs over and above the normal laboratory equipment required for maintaining a drug testing laboratory. However, there is a cost associated with a laboratory or IITF becoming a HHS-certified test facility and maintaining that certification. Use of an eCCF is optional; it is a business decision to implement use of the electronic form. Capital and start-up costs to implement an eCCF system may be balanced by marketable value and savings in time and labor (e.g., error reduction through use of computerized stepwise processes).

The cost for an applicant laboratory or IITF to achieve certification is as follows:

Event	Fee ($)
	2,000
Performance Testing:	
3 Initial Sets	9,000
Inspections:	
Initial	11,200
3-month Second Initial	11,200

Total Applicant Cost = $22,200

The annual cost for a laboratory or IITF to maintain certification is as follows:

Event	Fee ($)
Performance Testing:	
4 Maintenance Sets	12,000
Inspections:	
2 Maintenance Inspections*	
IITF	22,400
Laboratory**:	
Category 0	18,000
Category 1	22,400
Category 2	32,600
Category 3	49,600
Category 4	76,000
Category 5 – Inspection	76,000
Category 5 – Audit	49,600

* Inspection Fee depends on the size of the laboratory.

2 Maintenance Inspections/year = $43,300 (*)
(*)Using a $21, 650 average fee for all current categorized labs

Total Average Annual Cost = $55,300

Total Annual Cost to Laboratories or IITFs to participate in the NLCP (35 labs x $55,300) = $1,935,500

14. Estimates of Annualized Cost to the Government

(a) **Cost to Federal Agencies**

(1) Estimated Direct Testing Costs (i.e., collection, testing, and MRO costs):

150,000 specimens/yr x $60/specimen = $9,000,000

(2) Estimated Administrative Costs:

150,000 specimens/yr x $60/specimen = $9,000,000

Note: The above figures are estimates for the total number of specimens that were collected by the federal agencies (listed above) and for the direct testing and administrative costs, respectively, associated with each specimen.

(b) **Management Oversight of NLCP Contract (Contracting Officer Representative (COR))**

2 FTEs + Travel Costs to NLCP contractor site = $400,000

Total Annual Government Cost (a(1)+a(2))+b) = $18,400,000

15. Changes in Hourly Burden

Currently there are 1,786,809 burden hours in the OMB inventory. SAMHSA is requesting 1,546,329. The adjustment of -240,480 is due to the reduced number of respondents from 1 million

16. Time Schedule, Publication, and Analysis Plans

A typical process to become an HHS-certified laboratory is as follows:

Activity	Time (Elapsed Weeks)

NLCP Application Received		0		
Application Reviewed			2	
Application Accepted			4	
First Set of PT Samples		6		
Second Set of PT Samples		10		
Inspection and Third Set of PT Samples	14			
Evaluation of Laboratory's Performance	18			
Certification				20

The Division of Workplace Programs publishes the list of HHS-certified laboratories in the Federal Register on a monthly basis.

17. Display of Expiration Date

Approval is requested to not display the expiration date on the Federal CCF. A similar approval was granted three years ago. This avoids the possibility that millions of perfectly acceptable copies would be discarded or that a specimen would be rejected for testing by a laboratory or IITF because it was submitted using a form past a stated expiration date. HHS will notify users that they may continue using the current form until the new expiration date established by this approval request.

18. Exceptions to Certification Statement

This collection of information involves no exceptions to the Certification for Paperwork Reduction Act Submissions.

B. Collections of Information Employing Statistical Methods

This collection of information does not employ statistical methods.

LIST OF ATTACHMENTS

Attachment

A. Authorizing Legislation and Executive Order 12564

B. Mandatory Guidelines (November 25, 2008)

C. Mandatory Guidelines effective date change (April 30, 2010)

D. Federal CCF

E. NLCP Urine Laboratory Application Form

F. NLCP Urine Laboratory Information Checklist Form

G. NLCP Urine IITF Application Form

H. NLCP Urine IITF Information Checklist Form