

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 for a revision to the recordkeeping and reporting requirements in the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) dated January 23, 2017 (82 FR 7920) and using Oral Fluid (OFMG) dated October 25, 2019 (84 FR 57554), which include the Federal Drug Testing Custody and Control Form (Federal CCF); the National Laboratory Certification Program (NLCP) application forms for urine laboratories, urine Instrumented Initial Test Facilities (IITFs), and oral fluid laboratories; and the NLCP information checklists for urine laboratories, urine IITFs, and oral fluid laboratories. These requirements and forms are currently approved under OMB No. 0930-0158, which expires on August 31, 2020.

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 C). 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 (Mandatory Guidelines). The Mandatory Guidelines were first published on April 11, 1988, (53 FR 11979), with the latest revision, the UrMG, published on January 23, 2017 (82 FR 7920) (Attachment D) and the first version of the OFMG published on October 25, 2019 (84 FR 57554) (Attachment E).

The UrMG and OFMG require chain of custody procedures to document the integrity and security of a 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 UrMG and OFMG require using an OMB-approved Federal CCF (Federal CCF -

Attachment F). To facilitate ease of use and uniform reporting, the UrMG and OFMG will use a combined format to streamline the Federal CCF. The combined form will collect all information required by both Mandatory Guidelines and minimize duplication and cost to the users.

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. The Federal CCF may be used as a paper or electronic form.

The UrMG and the OFMG 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 G, I, or K) 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 H, J, and L). 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 UrMG and OFMG that are summarized below:

Recordkeeping Sections		
Summary of Sections	UrMG	OFMG
Collector is given name and phone of federal agency point of contact	Section 4.6(c) <i>What must a federal agency do before a collector is permitted to collect a specimen?</i>	Section 4.5(c) <i>What must a federal agency do before a collector is permitted to collect a specimen?</i>
Collector completes Federal CCF for specimen collected	Section 8.3 <i>What are the preliminary steps in the urine specimen collection procedure?</i>	Section 8.3 <i>What are the preliminary steps in the oral fluid specimen collection procedure?</i>
	Section 8.4 <i>What steps does the collector take in the collection procedure before the donor provides a urine specimen?</i>	Section 8.4 <i>What steps does the collector take in the collection procedure before the donor provides an oral fluid specimen?</i>
	Section 8.5 <i>What steps does the collector take during and after the urine specimen collection procedure?</i>	Section 8.5 <i>What steps does the collector take during and after the oral fluid specimen collection procedure?</i>
	Section 8.6 <i>What procedure is used when the donor states that they are unable to provide a urine specimen?</i>	Section 8.6 <i>What procedure is used when the donor states that they are unable to provide an oral fluid specimen?</i>
	Section 8.8 <i>How does the collector prepare the urine specimens?</i>	Section 8.8 <i>How does the collector prepare the oral fluid specimens?</i>
Materials to submit to become an HHS inspector	Section 9.12(a)(3) <i>Who can inspect an HHS-certified laboratory or IITF and when may the inspection be conducted?</i>	Section 9.10 <i>Who can inspect an HHS-certified laboratory and when may the inspection be conducted?</i>
Laboratory submits qualifications of new responsible persons (RP) and alternate RPs to HHS	Section 11.4(c) <i>What happens when the RP is absent or leaves an HHS-certified laboratory?</i>	Section 11.4(c) <i>What happens when the RP is absent or leaves an HHS-certified laboratory?</i>
Specifications for laboratory semi-annual statistical report of test results to each federal agency	Section 11.22(a) <i>What statistical summary reports must an HHS-certified laboratory provide for urine testing?</i>	Section 11.20(a) <i>What statistical summary reports must an HHS-certified laboratory provide for oral fluid testing?</i>
Information on drug test that laboratory must provide to donor through the Medical Review Officer (MRO)	Section 11.23(b) <i>What HHS-certified laboratory information is available to a federal agency?</i>	Section 11.21(b) <i>What HHS-certified laboratory information is available to a federal agency?</i>

Specifies contents of IITF semi-annual statistical report to federal agencies served	Section 12.19(a) <i>What statistical summary reports must an HHS-certified IITF provide?</i>	Not applicable – IITFs prohibited from testing.
MRO documents donor’s request to have split specimen tested	Section 14.1(b) <i>When may a split (B) specimen be tested?</i>	Section 14.1(b) <i>When may a split (B) specimen be tested?</i>
Specifies that MRO must report verified split specimen test results to the federal agency	Section 14.7 <i>How does an MRO report a split (B) specimen test result to an agency?</i>	Section 14.6 <i>How does an MRO report a split (B) specimen test result to an agency?</i>

Reporting Sections		
Summary of Sections	UrMG	OFMG
Laboratory or IITF required to submit an application for certification	Section 9.2(a)(1) <i>What is the process for a laboratory or IITF to become HHS-certified?</i>	Section 9.2(a)(1) <i>What is the process for a laboratory to become HHS-certified?</i>
Laboratory completes Federal CCF upon receipt of specimen and before reporting result	Section 11.8 <i>What are the laboratory chain of custody requirements for specimens and aliquots?</i>	Section 11.8 <i>What are the laboratory chain of custody requirements for specimens and aliquots?</i>
	Section 11.19(a) and (o) <i>What are the requirements for an HHS-certified laboratory to report a test result?</i>	Section 11.17(a) and (k)(1) <i>What are the requirements for an HHS-certified laboratory to report a test result?</i>
IITF submits qualifications of new responsible technicians (RT) and alternate RTs to HHS	Section 12.4(c) <i>What happens when the RT is absent or leaves an HHS-certified IITF?</i>	Not applicable – IITFs prohibited from testing.
IITF completes Federal CCF upon receipt of specimen and before reporting result	Section 12.8(a) <i>What are the IITF chain of custody requirements for specimens and aliquots?</i>	Not applicable – IITFs prohibited from testing.
	12.15(a) and (f) <i>What are the requirements for an HHS-certified IITF to report a test result?</i>	Not applicable – IITFs prohibited from testing.
Drug test information that IITF must provide to donor through MRO	Section 12.20(b) <i>What HHS-certified IITF information is available to a federal agency?</i>	Not applicable – IITFs prohibited from testing.
MRO completes the Federal CCF before reporting result	Section 13.4(d)(4) <i>What are the responsibilities of an MRO?</i>	Section 13.4(d)(4) <i>What are the responsibilities of an MRO?</i>

MRO must inform donor of right to request split specimen test when a positive, adulterated, or substituted result is reported	Section 13.8(b) <i>Who may request a test of a split (B) specimen?</i>	Section 13.8(b) <i>Who may request a test of a split (B) specimen?</i>
---	--	--

2. Purpose and Use of Information

a. **Federal CCF** (current 2017 Federal CCF - Attachment M)-paper and electronic

The Federal CCF is used to identify a specimen and to document its handling at the collection site. The current 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 2-5 (which is distributed to the MRO, collector, employer, and donor). The same information is provided and noted on the paper Federal CCF and the ECCF; only the mechanism for collecting and transmitting that information differs.

With the allowance of the revised Federal CCF, HHS is not requiring collection of any new information. HHS has made minor content revisions to the current form as follows:

Copies 1-5

Revised Step 1

1. Added “CDL State and No” for donor identification types
2. Added “Collector Contact Info:” and “Other” line (e.g., email)

Revised Step 2

1. Put Urine and Oral Fluid checkboxes above Step 2 for collector to annotate
2. Expanded to 4 lines for collector entries:
 - General entry for Split, Single, or None Provided (same as current)

- Entries specific to urine collection (moved “Collector reads urine temperature within 4 minutes” here; other entries same as current)
- Entries specific to oral fluid collection: added “Split Type” with checkboxes for Serial, Concurrent, and Subdivided; “Each Device Within Expiration Date?” with checkboxes Yes or No; and Volume Indicator(s) Observed checkbox)
- Remarks (same as current)

Revised Step 3

1. Edited instruction to state “collector affixes seal(s) to bottle(s)/tube(s)”

Revised Step 4 (Collector section)

1. Edited “Specimen Bottle(s) Released To” box to state “Specimen Bottle(s)/Tubes(s) Released To”

Copy 1 (Test Facility Copy)

Revised Step 4 (Accessioner section)

1. Edited “Primary Specimen Bottle Seal Intact” to state “Primary Specimen Seal Intact”
2. Edited “Specimen Bottle(s) Released To” box to state “Specimen Bottle(s)/Tubes(s) Released To”
3. Added “Primary/Single Specimen Device Expiration Date” and “Split Specimen Device Expiration Date” fields for accessioner to annotate expiration dates of oral fluid collection devices

Revised Step 5a (Certification and Reporting section)

1. Removed analyte names and checkboxes
2. Repositioned results and checkboxes: moved REJECTED FOR TESTING, ADULTERATED, SUBSTITUTED and INVALID RESULT checkboxes; moved POSITIVE checkbox to be under DILUTE
3. Added line for certifying scientist to record positive analytes and concentrations, and added “Analyte(s) in ng/mL” instruction (aligned under “POSITIVE for:”)

Copy 2 (Medical Review Officer Copy)

Revised Step 5 (Donor section)

1. Edited donor certification statement to state “specimen bottle/tubes”

Revised Step 6 (MRO section – Primary Specimen)

1. Put Urine and Oral Fluid checkboxes above Step 6 for MRO to annotate

Bottom of Copies

Revised Copy 1:

1. Edited label/seal at bottom of Copy 1 to allow for modification (e.g., perforations, label with transparent seal on one side, and separate label and seal)

Revised Copy 5:

1. Removed Instructions for Completing the CCF from the back. SAMHSA will post instructions for completing the Federal CCF for urine and oral fluid on their website.

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 G, I, or K)

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 H, J, or L)

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 UrMG and OFMG

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 UrMG and OFMG. 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, the Federal CCF may be used in either paper or electronic form.

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.

Duplication has been identified in the requirement of each Mandatory Guideline to have a Federal CCF. A combined CCF will eliminate the duplication of having two separate forms with identical information for the two specimen types.

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 information checklist is unique, is necessary for inspectors conducting an inspection, and is not available elsewhere.

The recordkeeping and reporting requirements in the UrMG and OFMG 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). The Federal CCF format addresses UrMG and OFMG requirements on the same CCF to eliminate the need for two forms.

5. Involvement of Small Entities

The Federal CCF is used only by federal agencies, employers regulated by DOT, and certain 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.

The information provided on the NLCP application form or in Sections B and C of the NLCP information 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 UrMG and OFMG 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 or oral fluid specimen that is collected. A 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 information 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 changes 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 information checklist, and the recordkeeping and reporting requirements in the UrMG and OFMG 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 February 11, 2020 (85 FR 7776).

SAMHSA received 32 comments from 7 commenters.

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 information checklist, or meets the other recordkeeping and reporting requirements in the UrMG and OFMG.

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, commercial driver's license state and number) may be 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 www.hhs.gov/pia, and the DOT privacy impact assessment at <https://www.transportation.gov/privacy>.

Completed NLCP application forms and Sections B, and C of the NLCP information checklists are kept secure and private at the NLCP contractor facility.

All records transmitted and maintained by the certified laboratories and IITFs are kept secure and private in accordance with the UrMG and OFMG.

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. Any 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)	Hourly Wage Rate (\$)	Total Cost (\$)³
Custody and Control Form¹:							
Donor	6,726,610	1	6,726,610	0.08	538,129	25	13,453,220
Collector	6,726,610	1	6,726,610	0.07	470,683	15	7,062,940.50
Laboratory	6,726,610	1	6,726,610	0.05	336,331	35	11,771,567.50
IITF	1	0	0	0.05	0	35	0

Form/Respondent	Number of Respondents	Responses per Respondent	Total Number of Responses	Burden per Response (hours)	Annual Burden (hours)	Hourly Wage Rate (\$)	Total Cost (\$)³
Medical Review Officer	6,726,610	1	6,726,610	0.05	336,331	150	40,500,000
NLCP Application Form²:							
Laboratory	5	1	5	3	15	35	525
IITF	0	0	0	3	0	35	0
Sections B and C - NLCP Information Checklist:							
Laboratory	29	1	29	1	29	35	1015
IITF	0	0	0	1	0	35	0
Record Keeping:							
Laboratory	29	1	29	250	7,250	35	253,750
IITF	0	0	0	250	0	35	0
Total	6,726,673		26,906,503		1,688,948		73,043,018

¹Note: 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).

¹Note: The above number of responses is an estimate of the total number of specimens collected annually (150,000 federal agency specimens; approximately 6,500,000 DOT regulated specimens, and approximately 145,000 NRC regulates specimens).

²Note: The estimate of five applications per year is based on receiving only 5 requests 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.

²Note: The estimate of three burden hours to complete the application has not changed. The original burden hours are still appropriate.

³Note: At the time of these calculations, there were 30 certified laboratories undergoing 2 maintenance inspections each year and one certified IITF.

³Note: 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 an HHS-certified test facility and maintaining that certification.

NLCP Fee Schedule Effective October 1, 2019

**Initial Certification Payment Schedule
For Urine Laboratories and IITFs**

Event	Fee (\$)	Total Fee (\$)
Application		3,000
1 st Performance Test		3,000
2 nd Performance Test		3,000
3 rd Performance Test and Initial Inspection	3,000 12,900	15,900
		24,900
2nd Inspection (3 month)		12,900
TOTAL COST		37,800

**Initial Certification Payment Schedule
For Oral Fluid Laboratories**

Event	Fee (\$)	Total Fee (\$)
Application		3,000
1 st Performance Test		6000*
2 nd Performance Test		6000*
3 rd Performance Test and Initial Inspection	6000* 12,900	18,900
		33,900
2nd Inspection (3 month)		12,900
TOTAL COST		46,800

****The NLCP will provide three initial Oral Fluid PT sets at no cost to applicant laboratories until further notice.***

For an explanation of Laboratory Categories and Fees, please refer to NLCP Program Document #44.

Maintenance Inspection Program Payment Schedule

Certification	Fee Type	\$ (Each)	\$ (Annual)	
Single (OF or Ur)	Category 0 Maintenance Inspection	10,400	20,800	
	Category 1 Maintenance Inspection	12,900	25,800	
	Category 2 Maintenance Inspection	18,800	37,600	
	Category 3 Maintenance Inspection	28,500	57,000	
	Category 4 Maintenance Inspection	43,700	87,400	
	Category 5 Maintenance Inspection	43,700	144,400	
	Category 5 Maintenance Audit	28,500		
	Category 6 Maintenance Inspection	54,600	188,000	
	Category 6 Maintenance Audit	39,400		
	Category 7 Maintenance Inspection	65,500	231,600	
	Category 7 Maintenance Audit	50,300		
	Combined (OF and Ur)	Category 1 Maintenance Inspection	16,800	33,600
		Category 2 Maintenance Inspection	24,400	48,800
Category 3 Maintenance Inspection		37,000	74,000	
Category 4 Maintenance Inspection		56,800	113,600	
Category 5 Maintenance Inspection		56,800	187,600	
	Category 5 Maintenance Audit	37,000		

Category 6 Maintenance Inspection	71,000	244,400
Category 6 Maintenance Audit	51,200	
Category 7 Maintenance Inspection	85,200	301,200
Category 7 Maintenance Audit	65,400	
Pre-Inspection Remedial Action	1,000	
Post-Inspection Remedial Action	3,000	
Special Inspection	9,900 – 16,300	
Laboratory Withdrawal	9,900 – 16,300	

**Maintenance PT Payment Schedule
for Urine Laboratories**

Fee Type	\$ (Each)	\$ (Annual)
Quarterly Maintenance Performance Tests	3,000	12,000
Major PT Remedial Action	3,000	
Minor PT Remedial Action	1,000	

**Maintenance PT Payment Schedule
for Oral Fluid Laboratories**

Fee Type	\$ (Each)	\$ (Annual)
Quarterly Maintenance Performance Tests	6,000	24,000
Major PT Remedial Action	3,000	
Minor PT Remedial Action	1,000	

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):

$$150,000 \text{ specimens/yr} \times \$60/\text{specimen} = \$9,000,000$$

(2) Estimated Administrative Costs:

$$150,000 \text{ specimens/yr} \times \$60/\text{specimen} = \$9,000,000$$

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

Not Applicable

16. Time Schedule, Publication, and Analysis Plans

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

<u>Activity</u>	<u>Time (Elapsed Weeks)</u>
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.