Mandatory Guidelines for Federal Workplace Drug Testing Programs

SUPPORTING STATEMENT

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting OMB approval of the recordkeeping and reporting requirements in the Mandatory Guidelines for Federal Workplace Drug Testing Programs dated November 25, 2008 and for the revision to the Federal Drug Testing Custody and Control Form (Federal CCF), the National Laboratory Certification Program (NLCP) application form for laboratory or Instrumented Initial Test Facility (IITF), and Sections B and C of the NLCP inspection checklist for laboratory or IITF. These requirements and forms are currently approved under OMB No. 0930-0158, which expires on November 30,2011.

A. Justification

1. Circumstances of Information Collection

The Federal Workplace Drug Testing Program was 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). As a result of the Executive Order and Public Law, the Department of Health and Human Services (HHS) published the Mandatory Guidelines for Federal Workplace Drug Testing Programs in the Federal Register on April 11, 1988 (53 FR 11979), which were revised on November 25, 2008 (73 FR 75122) (Attachment B) and a subsequent change to the effective date on April 30, 2010 (75 FR 22809) (Attachment C), to establish comprehensive standards for a Federal workplace drug testing program. Additionally, employers regulated by the Department of Transportation (DOT) are required to use the Federal CCF when collecting urine specimens and to have their specimens tested by HHS-certified laboratories.

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

The Mandatory Guidelines also establish the standards for a National Laboratory Certification Program, which include requirements for a laboratory or IITF to become 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 IITF is complete and indicates that the laboratory IITF is prepared to test specimens using forensically and scientifically supportable procedures, the laboratory or IITF can begin the initial certification process which consists of testing three sets of performance testing samples and undergoing an inspection. The laboratory or IITF is certified by HHS and enters the NLCP after successfully completing this initial certification process.

Certified laboratories or IITF are inspected every six months. Prior to each maintenance inspection, the laboratory IITF receives a copy of Sections B and C of the NLCP inspection checklist (Attachment F or H). The information submitted by the laboratory or IITF allows the members of the inspection team to become familiar with the laboratory=s or IITF procedures before arriving at the laboratory or IITF to conduct the inspection, thereby, facilitating the completion of the inspection.

Subpart F, K and L of the Mandatory Guidelines requires certified laboratories and IITF to maintain and document the security and chain of custody procedures used, the quality assurance and quality control procedures used, and the analytical procedures used. Additionally, laboratories or IITF are required to report test results in accordance with the specifications and to participate in a performance testing and inspection program. Subpart P describes the procedures that are used to review the suspension or proposed revocation of a certified laboratory.

The recordkeeping and reporting requirements contained in the Mandatory Guidelines are listed 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
Lab or IITF required to submit application for certification

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

Section 11.4(c) - Recordkeeping
Lab submits qualifications of new RPs and alternate RPs to HHS

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

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

Section 11.23(b) - Recordkeeping
Information on drug test that lab must provide to donor through MRO

Section 12.4(c) - Reporting
IITF submits qualifications of new RTs 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 (proposed revised Federal CCF-Attachment D)

The Federal CCF is a five-copy, carbonless form used to identify a specimen and to document its handling at the collection site. It can be used to collect a split specimens (i.e., a split specimen collection procedure is when the collector takes a single specimen and transfers it into two specimen bottles). The 5 copies are 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 reverse side of Copy 5 gives instructions on completing the Federal CCF. There is also a privacy act statement on the reverse side of copy 5 that explains the donor=s rights relative to the release of information found on the form. A new Federal CCF is used each time a urine

specimen is collected. All of the information on the Federal CCF is necessary to ensure that the specimen can be forensically proven to be collected from a specific donor, yet the privacy of the donor=s identity is maintained (i.e., the laboratory or IITF is not given the donor=s name).

The NLCP Urine Laboratory and IITF Application Form and NLCP Laboratory and IITF Inspection Checklist sections B and C are kept secure and private at the NLCP contractor facility. All the records maintained at the certified laboratories or IITF are kept secure and private in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

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).

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 information that the NLCP contractor can review to determine if the laboratory or IITF is prepared to begin the initial certification process.

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

A laboratory or IITF must submit Sections B and C of the NLCP inspection checklist before each semi-annual maintenance inspection. The information submitted helps the inspectors become familiar with the laboratory=s or IITF operations before arriving at the laboratory or IITF. Two inspectors are used for the initial inspections of applicant laboratories and IITF. Two to nine inspectors are used for each semi-annual inspection of a certified laboratory or IITF, depending on the size of the laboratory or IITF. Each certified laboratory or IITF submits Sections B and C of the NLCP inspection checklist twice each year because there are two inspections per year. Laboratories or IITF must be certified before they are permitted to test urine specimens under Executive Order 12564.

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.

e. Changes to the Federal CCF

The changes are as followed:

The first change was to add a new item in Step 1 of Copy 1, which lists the acronyms for the Federal testing authorities under which the specimen is collected. The new Step 1 (d) would read

as follows: “D. Specify Testing Authority: HHS, NRC, DOT – Specify DOT Agency: FMCSA, FAA, FRA, FTA, PHMSA, USCG” with a checkbox beside each agency name.

The second change was to revise the Federal CCF Copy 1 to permit use by IITFs, in addition to laboratories.

The third change was to add the new drug analytes required by the revised Guidelines to the Primary Specimen Report section in Step 5(a) on Copy 1. The new drug analytes are methylenedioxymethamphetamine (MDMA), commonly known as “ecstasy”; methyleneamphetamine (MDA), and methylenedioxyethylamphetamine (MDEA). MDA and MDEA are both close chemical analogues of MDMA.

The fourth change was to revise the Medical Review Officer (MRO) reporting sections on Copy 2 for primary specimens (Step 6) and for split specimens (Step 7) to facilitate reporting in accordance with the Guidelines.

3. Use of Information Technology

In the Notice for Proposed Revision to the Federal CCF (74 FR 59196) there was no discussion or suggestion that the final Federal CCF would allow the use of software applications for entering data and printing the Federal CCF at the collection site. All of the discussion addressed the printed form and the slight modifications allowed to the printed form. We also mentioned that “other required information may be printed on the Federal CCF during the original printing and assembly process or added by overprinting the five-part printed form after assembly”. Having acknowledged this requirement to the printing process for the Federal CCF, many public

comments were submitted suggesting that there should be an allowance to an "on-demand Federal CCF".

Two commenters agreed with continuing to require the printed Federal CCF and not allowing on-demand Federal CCF in the regulated workplace drug testing program. One hundred and twenty-eight commenters were in favor of an on-demand Federal CCF. The commenters listed problems with the pre-printed Federal CCF. Some of the listed problems included: untimely distribution of the Federal CCF copies, poor legibility of pre-printed Federal CCF, incorrect/outdated information printed on the Federal CCF, required storage of hardcopy forms, and problematic impact (dot-matrix) printers needed to print information on the 5-part Federal CCF. Some of the same commenters also listed the benefits of an on-demand Federal CCF. They included: employers and C/TPA can enter information electronically and improve the accuracy of information; software systems governing the collection process improve collector compliance; the Federal CCF printed at the collection site will have the most up-to-date employer, laboratory, and MRO information; the Federal CCF produced with collection site software and laser printers are more legible than handwritten carbonless forms; the Federal CCF copies can be distributed electronically from the collection site; electronic archival and retrieval systems are superior to paper-based; and a Federal CCF printed at the collection site reduces the likelihood that the Federal CCF will be lost or labels/seals damaged in transit to the collection site brought by the donor or shipped by the C/TPA/employer.

All of these concerns expressed in the public comments surrounding the allowance of an on-demand CCF have been reviewed by SAMHSA. Standards adopted for the security of electronic forms, and the use of an electronic signature have been addressed in various HHS regulations

and have been published as final rules. In the Food and Drug Administration (FDA), 21 Code of Federal Regulations (CFR), Part 11 (62 FR 13430) on March 20, 1997, Electronic Records, Electronic Signatures, Final Rule, the final rule provides criteria under which FDA would consider electronic signatures to be equivalent to full handwritten signatures, initials, and other general signings required by agency regulations. Another publication is the Office of the Secretary for HHS 45 CFR Part 160, 162, and 164 (68 FR 8334) on February 20, 2003, Health Insurance Reform, Security Standards, Final Rule. This final rule sought to adopt national standards for safeguards to protect the confidentiality, integrity, and availability of electronic-protected health information.

These two documents provide a roadmap for an on-demand Federal CCF. SAMHSA is prepared to consider the use of an on-demand Federal CCF after the publication of the final Federal CCF. We will seek public comment specifically on the standards to be established concerning electronic signature, non-repudiation agreement for digital signatures, third party software for managing Federal CCF information, unique specimen identification number, the legally-binding equivalent of traditional hand-written signatures in a forensic arena, the security data transmission over telecommunications systems/networks, and the integrity of document content.

4. Efforts to Identify Duplication

The information on the Federal CCF is unique and is collected to satisfy forensic requirements.

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, only used by inspectors for conducting an inspection, and not available elsewhere.

The recordkeeping and reporting requirements in the Mandatory Guidelines are unique and are essential to reporting the correct drug test results on the Federal CCF.

To avoid duplication, employers regulated by the Department of Transportation are required to use the Federal CCF and HHS-certified laboratories or IITF for their workplace drug testing programs rather than using different custody and control forms or establishing alternative laboratory certification programs.

5. Involvement of Small Entities

The Federal CCF is used only by Federal agencies and employers regulated by DOT. The requirement to use the Federal CCF has no special impact on small businesses regulated by DOT. 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 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 would collect and maintain 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 a drug test, 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 requires a laboratory to submit specific information regarding the procedures it uses to handle and test specimens. 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. A laboratory would not receive the positive feedback it needs to assess the forensic and scientific acceptability of its testing procedures if this information is not collected at the time a laboratory applies to the NLCP.

The requirement for each laboratory to update Sections B and C of the NLCP inspection checklist before each inspection ensures that the inspectors have the latest information on the procedures used by the laboratory since the last inspection. Collecting the information from each laboratory less frequently would require the inspectors to spend a great deal of time determining what the laboratory is currently doing and what changes were made since the last

inspection rather than spending the time they have for the inspection reviewing all aspects of the laboratories operations.

The recordkeeping and reporting requirements are continuous for all aspects of a laboratory=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 November 17, 2009 (74 FR 59196).

SAMHSA received a total of 161 responses from individual commenters with multiple comments on the proposed changes to the Federal CCF from HHS-certified laboratories, third party administrators (TPA), collection sites, MROs, printing firms, employers, organizations, and interested individuals. In addition, another 427 letters with identical content were sent by one central submitter and postmarked on or before the closing date of the comment period (January 19, 2010). All comments are posted on the website at http://www.drugfreeworkplace.gov/. The majority of the commenters supported the proposed changes to the Federal CCF, and a similar majority also commented on the desired availability

for an “On-Demand CCF”. All comments were reviewed and taken into consideration in preparing the final Federal CCF.

The recordkeeping and reporting requirements in the Mandatory Guidelines were developed by the government when the original Guidelines were published in the Federal Register on April 11, 1988. Minor changes were made when the revised Guidelines were published in the Federal Register on June 9, 1994, on April 13, 2004 and November 25, 2008. In addition, there was a public comment period before the changes were adopted before each final notice of the Guidelines.

Laboratories and Inspectors

The NLCP application form was developed by the NLCP contractor and has been used for several years with only minor changes in format. Sections B and C of the NLCP inspection checklist were developed by the government and the NLCP contractor.

Prior to making changes in these documents, the NLCP contractor requests the certified laboratories and NLCP inspectors to submit suggested changes to the documents on a regular basis. After the final changes are made, the NLCP contractor reviews any feedback from the laboratories and inspectors to ensure that the changes were appropriate.

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 laboratory that completes an NLCP application form or Sections B and C of the NLCP inspection checklist.

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 agency=s administrator of the Employee Assistance Program, and a supervisor with authority to take adverse personnel action. The information on each copy of the Federal CCF was developed to protect the identity of the individual being tested.

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 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. The individual tested must initial the specimen label and sign the Federal CCF acknowledging that it is his or her urine specimen. Upon notification by the testing laboratory that a specimen has tested positive, the MRO must contact the individual to determine if there is a valid medical explanation for the positive test. The medical information given to the MRO must be kept private to the extend of the law.

12. Estimates of Annualized Hour Burden

a. Federal CCF

	Hours per Response	**Number of Responses**	**Total Burden**
Donor	0.08 (5 min)	7,096,000	567,680 hr
Collector	0.07 (4 min)	7,096,000	496,720 hr

Laboratory	0.05 (3 min)	7,066,000	339,800 hr
IITF	0.05 (3 min)	30,000	15,000 hr
MRO Review	0.05 (3 min)	7,096,000	354,800 hr

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.

Note: The above number of responses is an estimate of the total number of specimens collected annually (96,000 Federal agency specimens; 7,000,000 DOT regulated specimens).

b. NLCP Application Form

Laboratory	3 hr	3	9 hr
IITF	3 hr	1	3 hr

Note: The estimate of three applications per year is based on receiving only 3 applications for a laboratory application during the past year and only 1 IITF application in after October 1, 2010.

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.

c. Sections B and C of the NLCP Inspection Checklist

Laboratory	3 hr	38	76 hr
IITF	3 hr	0	0 hr

Note: There are currently 38 certified laboratories undergoing 2 maintenance inspections each year and there are no IITF.

Note: The estimate of 3 burden hours to complete sections B and C of the NLCP Inspection Checklist has not changed even though additional information is requested. The original burden hours were generous to begin with and are still appropriate.

d. Recordkeeping

Laboratory	250 hr	38	9,500 hr
IITF	250 hr	0	0 hr

Total Annualized Burden **1,783,588 hr**

Estimates of Annualized Hourly Cost to Respondents for Collections of Information

	Total Burden	Wage Rate	Annualized Cost
a. Federal CCF			
Donor	567,440 hr	$25/hr	$14,186,000
Collector	496,510 hr	$15/hr	$7,447,650
Laboratory	339,800 hr	$35/hr	$11,887,750
IITF	15,000 hr	$35/hr	$525,000
MRO	354,650 hr	$150/hr	$53,197,500

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

a. NLCP Application Form			
Laboratory	9 hr	$35/hr	$315
IITF	3 hr	$35/hr	$105
a. Sections B and C of the Inspection Checklist			
Laboratory	300 hr	$35/hr	$10,500
IITF	0 hr	$35/hr	$0
b. Recordkeeping			
Laboratory	12,500 hr	$35/hr	$437,500
IITF	0 hr	$35/hr	$0

Total Annualized Hourly Costs $74,924,815

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 or DOT-regulated employer pays for collecting and testing specimens and for the MRO review of results as part of its workplace drug testing program.

2. Laboratory

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 becoming a certified laboratory and maintaining certification.

The following fee schedule applies to laboratories or IITF participating in the NLCP:

	Fee
Application	$2,000
Performance Testing (PT)	
Initial Set	$3,000
Maintenance Set	$3,000
Inspections	
Initial	$11,200
Maintenance*	$9,000; $11,200; $16,300; $24,800; $38,000; $62,800

* Inspection Fee depends on the size of the laboratory or IITF

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

Application Fee	$2,000
3 initial sets of PT Samples	$9,000
Initial inspection	$11,200

Total Applicant Cost/Lab = $22,200

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

4 Sets of Maintenance PT Samples	$12,000
2 Maintenance Inspections/year	$43,300 (*)

(*)Using a $21, 650 average fee for all current categorized labs

Total Annual Cost/Lab = $55,300

Total Annual Cost to Labs or IITF to participate in the NLCP (40 labs x $55,300) = $2,212,000

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):

96,000 specimens/yr x $60/specimen = $5,760,000

(2) Estimated Administrative Costs:

96,000 specimens/yr x $60/specimen = $5,760,000

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 (Project Office)**

2 FTEs + Travel Costs to NLCP contractor site = $225,000

Total Annual Government Cost (a1+a2+b) = $11,745,000

15. Changes in Burden

There is no hourly burden change. The revision is due to the minor Federal CCF modification (see section 2.e, Changes to the Federal CCF).

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

because it was submitted using a form past a stated expiration date. SAMHSA 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