Mandatory Guidelines for Federal Workplace Drug Testing Programs

SUPPORTING STATEMENT

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting an extension from OMB for approval of the recordkeeping and reporting requirements in the Mandatory Guidelines for Federal Workplace Drug Testing Programs dated April 13, 2004, and for the continued use of the Federal Drug Testing Custody and Control Form (Federal CCF), the National Laboratory Certification Program (NLCP) application form, and Sections B and C of the NLCP inspection checklist. These requirements and forms are currently approved under OMB No. 0930-0158, which expires on 9/30/09.

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 April 13, 2004 (69 FR 19644) (Attachment B), 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 (Attachment C).

The Mandatory Guidelines also establish the standards for a National Laboratory Certification Program, which include requirements for a laboratory to become certified and to maintain certification. Prior to the initial certification process, each interested laboratory is required to submit an application (Attachment D) to the NLCP contractor for review and evaluation. If the NLCP application form submitted by the laboratory is complete and indicates that the laboratory is prepared to test specimens using forensically and scientifically supportable procedures, the laboratory can begin the initial certification process which consists of testing three sets of performance testing samples and undergoing an inspection. The laboratory is certified by HHS and enters the NLCP after successfully completing this initial certification process.

Certified laboratories are inspected every six months. Prior to each maintenance inspection, the laboratory receives a copy of Sections B and C of the NLCP inspection checklist (Attachment E). The information submitted by the laboratory allows the members of the inspection team to

become familiar with the laboratory=s procedures before arriving at the laboratory to conduct the inspection, thereby, facilitating the completion of the inspection.

Subpart C of the Mandatory Guidelines requires certified laboratories 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 are required to report test results in accordance with the specifications and to participate in a performance testing and inspection program. Subpart D 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 2.2(c) - Recordkeeping
Requires a collector to complete a Federal CCF for each specimen collected

Section 2.2(f)(19) - Recordkeeping
Collector writes the date of the collection on the specimen labels/seals

Section 2.2(f)(20) - Recordkeeping
Donor initials the specimen labels/seals

Section 2.2(f)(22) - Recordkeeping
Donor signs statement on Federal CCF certifying that the specimen is his or her specimen

Section 2.2(h)(6) - Reporting
Describes how Medical Review Officer (MRO) reports result for a split specimen

Section 2.3(a)(4) - Recordkeeping
Responsible Person (RP) for laboratory must document training of personnel

Section 2.3(a)(5) - Recordkeeping
RP must maintain the Standard Operating Procedure (SOP) manual and review, sign, and date it when procedures are first placed into use or changed

Section 2.3(a)(6) - Recordkeeping
RP must document validity, reliability, accuracy, precision, and performance characteristics of each test and test system

Section 2.3(f) - Recordkeeping
Describes contents of laboratory personnel files

Section 2.4(a) - Recordkeeping
Document access and internal chain of custody procedures

Section 2.4(h) - Reporting
Describes how a laboratory reports tests results

Section 2.4(h)(15) - Reporting
Laboratory provides a semi-annual statistical summary report to Federal agency

Section 2.4(h)(17) and 2.4(p) - Recordkeeping
Laboratory must retain records for two years

Section 2.4(q)(1) - Recordkeeping
Laboratory must have a procedures manual

Section 2.4(q)(4) - Recordkeeping
Laboratory must document corrective actions

Section 2.5(a) - Recordkeeping
Laboratory must document validation of test methods

Section 2.6(c) - Reporting
Medical Review Officer reports test result to the agency

Section 2.6(e)(2) - Disclosure
Medical Review Officer informs donor of the right to request a retest

Section 2.6(g) - Reporting
Describes how the Medical Review Officer reports retest results to the agency

Section 2.6(h) - Reporting
Describes how the Medical Review Officer reports final results to the agency

Section 2.8 - Disclosure
Describes the information that the laboratory must provide to the donor

Section 3.4 - Disclosure
Laboratories must inform private-sector clients when testing specimens using different procedures

Section 3.15(a) - Disclosure
HHS will notify laboratory of proposed suspension or revocation of certification

Section 3.17(f) - Reporting
Laboratory must report results for the performance testing (PT) samples

Section 3.19(b)(11) - Reporting
Laboratory must provide an explanation for errors made on PT samples

Section 3.20 - Recordkeeping and Reporting
Document all aspects of the laboratories procedures and to correct deficiencies that are identified during inspections

Section 3.22 - Reporting
HHS publishes a monthly list of certified laboratories in the Federal Register

Sections 4.1(b), 4.4, and 4.5(a) - Reporting
Request for official review of suspension/proposed revocation

Section 4.6 - Reporting
Request for abeyance agreement

Section 4.7(a) - Reporting
Preparation of the review file and written argument

Section 4.9(a) and (c) - Reporting
Request for expedited review

2. Purpose and Use of Information

a. Federal CCF (Attachment C)

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 either a single specimen or 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	Laboratory 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 confidentiality of the donor=s identity is maintained (i.e., the laboratory is not given the donor=s name).

The NLCP Application Form and Sections B and C of the NLCP inspection checklist are kept secure and confidential at the NLCP contractor facility.

All the records maintained at the certified laboratories are kept secure and confidential 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 D)

A laboratory 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 is prepared to begin the initial certification process.

c. Sections B and C of the NLCP Inspection Checklist (Attachment E)

A laboratory 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 operations before arriving at the laboratory. Two inspectors are used for the initial inspections of applicant laboratories. Two to nine inspectors are used for each semi-annual inspection of a certified laboratory, depending on the size of the laboratory. Each certified laboratory submits Sections B and C of the NLCP inspection checklist twice each year because there are two inspections per year. Laboratories 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 will be forensically and scientifically supportable.

3. Use of Information Technology

The Federal CCF must be a hard copy form to properly document chain of custody at the collection site and each form must have a preprinted specimen identification number to ensure that the form and the information on it can be directly associated with a specific specimen. After collection, one copy of the form accompanies the specimen to the laboratory while the other copies of the form are distributed as required. To reduce cost and burden, SAMHSA permits the Federal CCF to be printed by anyone as long as it conforms to the specifications.

In response to the previous terms of clearance specified by OMB, SAMHSA has initiated an effort directed toward the electronic collection, reporting, and maintenance of information in accordance with the requirements of the Government Paperwork Elimination Act.

Upon receiving the specimen, a laboratory generally documents all aspects of its drug testing and administrative procedures using paper copies that document the handling of specimens from receipt until final disposal. However, with the increasing acceptance of electronic devices to accurately scan information and the use of computers to maintain and archive information, most laboratories are attempting to replace paper copies with electronic records.

The Mandatory Guidelines dated April 13, 2004, permit all certified laboratories to report drug testing results electronically to MRO. This policy has eliminated requiring each laboratory to send or fax a paper copy of the Federal CCF for each negative specimen to the MRO. This policy accounts for approximately 95% of the specimens tested (i.e., those reported negative). This change, by itself, has eliminated millions of paper copies of reports.

Although the electronic reporting of results from the laboratory to the MRO has become a standard procedure, the format for the electronic reports has not been standardized. However, the laboratories are doing an excellent job in ensuring that the reports are accurate and consistent with the results that appear on the Federal CCF. SAMHSA will continue evaluating the requirements for other paperless laboratory procedures.

A paper copy of the NLCP application form is sent to prospective laboratories because only a few laboratories actually decide to apply. A computer disk containing the form as a word processing file is available if requested by an applicant laboratory.

In January 2006, the NLCP contractor started requiring laboratories to enter the information for Sections B and C of the NLCP inspection checklist using a secure website. This allows laboratories to easily update Sections B and C prior to each inspection. The NLCP contractor can then print copies for distribution to the inspectors before the inspection. The use of the

secure website has reduced the burden on the laboratories for completing and revising Sections B and C of the NLCP inspection checklist.

The recordkeeping and reporting requirements in the Mandatory Guidelines are normally satisfied by using computer laboratory information management systems and maintaining paper copies of many records. The NLCP encourages the use of laboratory-based computer systems to document various laboratory records and information collection procedures.

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 on the NLCP application form is not available from any other source because the procedures used by each laboratory are unique.

The information provided by each laboratory 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 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 April 22, 2009 (Vol. 74, p. 18388) and SAMHSA received no comments in response to this notice.

a. Drug Testing Advisory Board (DTAB)

The Drug Testing Advisory Board (DTAB) advises the Administrator, SAMHSA, based on an ongoing review of the direction, scope, balance, and emphasis of the Agency's urine drug testing activities and the urine drug testing laboratory certification program. The Board reviews the Agency's program for national laboratory certification for Federal workplace drug testing programs as required by Public Law 100-71 and as described in the Mandatory Guidelines for Federal Workplace Drug Testing Programs. It recommends areas for emphasis or de-emphasis, new or changed directions, and mechanisms or approaches for implementing recommendations. Periodically, the Board reviews specific science areas on new drugs of abuse and the methods necessary to detect their presence in urine.

The DTAB consists of the Director, Division of Workplace Programs, Center for Substance Abuse Prevention, as Chair, and 10 members selected by the Administrator, SAMHSA. The 10 members appointed to the Board are recognized as experts in either analytical forensic toxicology, in urine collection procedures for regulated drug testing programs, or in interpreting drug testing results. The individuals appointed represent a variety of disciplines related to forensic drug testing such as experience in a forensic drug testing laboratory, related academic research, toxicological research, the MRO specialty, or technical expertise from other government agencies involved with drug testing issues, including military drug testing programs.

DTAB meetings are held approximately four times a year. Meetings are open to the public except as determined otherwise by the Secretary or other official to whom the authority has been delegated. Notice of all meetings is given to the public. Meetings are conducted and records of the proceedings kept as required by applicable laws and Departmental regulations. The current DTAB members are:

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The NLCP contractor presents proposed changes to the NLCP documents at DTAB meetings. The DTAB members then make recommendations regarding the final changes.

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, and on April 13, 2004. The DTAB made recommendations and reviewed the proposed changes. In addition, there was a public comment period before the changes were adopted before each final notice of the Guidelines.

b. 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 confidentiality 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 confidential.

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)	7,096,000	354,800 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

Note: The estimate of three applications per year is based on receiving only 3 applications during the past year.

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	100	300 hr

Note: There are currently 40 certified laboratories undergoing 2 maintenance inspections each year.

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	50	12,500 hr
	Total Annualized Burden		**1,786,809 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	354,650 hr	$35/hr	$12,412,750
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.

b. NLCP Application Form

Laboratory	9 hr	$35/hr	$315

a. Sections B and C of the Inspection Checklist

Laboratory	300 hr	$35/hr	$10,500

b. Recordkeeping

Laboratory	12,500 hr	$35/hr	$437,500
	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 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

The cost for an applicant laboratory 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 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 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 not burden change.

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 (April 13, 2004)

C. Federal CCF

D. NLCP Application Form

E. Sections B and C of the NLCP Inspection Checklist