Statement of Work and Delivery Schedule

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work below:

A. Background Information:

Pursuant to Executive Order 12564 and Public Law 100-71 (Section 503), the Department of Health and Human Services (HHS) has been given the responsibility to establish the requirements for collecting and testing specimens and reporting results for the Federal Workplace Drug Testing Program. A key element of this effort has been the development of the scientific and technical requirements for the National Laboratory Certification Program as specified in the Mandatory Guidelines for Federal Workplace Drug Testing Programs (69 FR 19644, April 13, 2004) (Mandatory Guidelines), and as revised. The certification of laboratories is essential to ensure the forensic and scientific supportability of test results reported to the Federal agencies. In addition, the Department of Health and Human Services is proposing to establish scientific and technical guidelines for the testing of hair, sweat, and oral fluid specimens in addition to urine specimens; scientific and technical guidelines for using on-site tests to test urine and oral fluid at the collection site; requirements for the certification of instrumented initial test facilities; and added standards for collectors, on-site testers, and medical review officers. Detailed notice of this proposal was published in the Federal Register (69 FR 19673, April 13, 2004).

B. Objectives

The purpose of this contract is to provide the Division of Workplace Programs (DWP) with a Contractor that will satisfy all the requirements for the National Laboratory Certification Program (NLCP) as specified in the Mandatory Guidelines for Federal Workplace Drug Testing Programs (69 FR 19644, April 13, 2004) (Mandatory Guidelines), and any subsequent revisions. In addition, the Contractor must have the capacity to expand the NLCP to satisfy (1) the scientific and technical Guidelines for the testing of hair, sweat, and oral fluid specimens; (2) the scientific and technical Guidelines for onsite screening tests for urine and oral fluids at the collection site; and (3) the requirements for the certification of laboratories, and ongoing quality assurance and performance of NLCP-related activities at collection sites, laboratories, and by medical review officers (MROs).

The Contractor shall operate the National Laboratory Certification Program (NLCP) as described in the Mandatory Guidelines. The Contractor shall independently furnish the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government to perform the tasks described below. A copy of the Public

Law 100-71 (Section 503), Executive Order 12564, the NLCP Laboratory Application Form, the NLCP Laboratory Information Checklist, the NLCP Inspection Checklist, the NLCP Records Audit Checklist, and the NLCP Manual for Laboratories and Inspectors. These references total more than 350 pages. For ease of review, these references are located in Room 2-1033 for review if necessary. The first three references above can also be found on our website at http://www.workplace.samhsa.gov .

All costs associated with Tasks A through J, and Task O (Option 4, Year 5), are reimbursed by the Government. All costs associated with Tasks K through N are recovered as fees charged to the laboratories participating in the NLCP, unless specifically noted as an exception or by direction of the GPO.

The Contractor awarded the contract shall propose a fee schedule that will be reviewed and approved by the Government at time of contract award. The proposed fee schedule must describe all the different fees that laboratories will pay to participate in the NLCP.

C. Specific Requirements

Year 1

Task A. Management

1. Contractor Meetings

The Contractor and Government project staff will meet on a quarterly basis to discuss all tasks contained in the contract. This may be accomplished by either a site visit or webcast capability. Each meeting will be at least a 2-day meeting to be held at the Contractor's site or by a webcast from the Contractor's site.

The Contractor shall submit an agenda to the Government Project Officer (GPO) listing the items to be discussed during the meeting.

2. Drug Testing Advisory Board

The Contractor shall send a maximum of 4 individuals to attend each meeting of the SAMHSA Drug Testing Advisory Board (DTAB). DTAB meetings are held in the Washington, D.C., area. The Contractor will assist the GPO in developing the agenda for each DTAB meeting and will prepare materials for presentation as requested by the GPO.

The Contractor shall submit all materials being presented at the DTAB meeting no later than one week prior to the meeting to the GPO for review and approval.

3. Foreign Program Activities

The Contractor shall send 2 individuals to participate in meetings and travel to border countries, subject to approval by the GPO, that are developing drug testing programs under the North American Free Trade Act (NAFTA).

Task B. Administration

1. Standard Operating Procedure (SOP) Manual

The Contractor shall maintain a standard operating procedure (SOP) manual that describes in detail how the Contractor will carry out all aspects of the NLCP. The SOP manual must be kept current as program requirements change.

2. Security System

The Contractor shall have procedures to maintain the security of the workplace and the security of all current and archived NLCP records.

3. Distributing Documents

The Contractor shall prepare cover letters and make copies of program documents that will be sent electronically or mailed to inspectors and laboratories after receiving the request from the GPO. The final letters and documents must be approved by the GPO before they are distributed.

4. Freedom of Information Act (FOIA) Requests

The Contractor shall assist the GPO to prepare and assemble materials in response to Freedom of Information Act (FOIA) requests for disclosure of NLCP records. A list of the documents and copies of the documents must be provided to the GPO after receiving the request.

5. NLCP Documents

The Contractor shall prepare and revise, as needed, the following NLCP documents: Laboratory Inspection Checklist, Records Audit Checklist, Manual for Laboratories and Inspectors, Specimen Collection handbook, Medical Review Officer manual, NLCP application, education and training documents (e.g., professional scientific workshop presentations), and other related NLCP Program Documents. All NLCP documents prepared and revised by the Contractor must be approved by the GPO before they are distributed.

6. Mandatory Guidelines

The Contractor shall assist the Division of Workplace Programs to periodically revise the Mandatory Guidelines.

Task C. **Training**

1. Inspector Training Workshop

The Contractor shall prepare materials and provide the staff to train individuals as inspectors for the NLCP. The annual workshop to train new inspectors shall take place within the contractor's local geographic area. Final training materials must be submitted to the GPO for approval before the workshop is scheduled.

Training materials are needed to train individuals to inspect laboratories testing urine, hair, sweat, and oral fluid specimens. The Contractor shall select the individuals who will be trained as inspectors from those having the appropriate education and experience and interest in becoming inspectors. The individuals selected for training are subject to approval by the GPO. Individuals attending qualified training session will pay their own travel expenses.

2. Inspector Continuing Education/Laboratory Director Workshop

The Contractor shall present a workshop for trained inspectors and laboratory directors to ensure that they are kept current with all changes in the NLCP. A workshop is presented annually before, after, or during the annual meeting of the Society of Forensic Toxicologists, Inc.. The Contractor shall make arrangements to distribute workshop materials to those inspectors who were unable to attend the workshop. Final presentation materials must be submitted to the GPO for approval before the workshop is scheduled. Inspectors and laboratory directors attending the workshop will pay their own travel expenses.

With the consent and approval of the GPO, the Contractor establishes the requirements for trained inspectors to acquire continuing education credits to remain in an active inspector status.

3. Contractor Staff Professional Development

The Contractor may send each NLCP contract-dedicated professional staff member to one professional meeting (such as, the annual meeting of the American Academy of

Forensic Sciences or the annual meeting of the Society of Forensic Toxicologists) or to one professional training course per year. The subject material of a professional training course must have relevance to the NLCP. The reimbursement for the attendance of the contractor's professional staff at a meeting or training course is subject to prior approval by the GPO. **Note to offeror for budget purposes, the contractor shall propose eight (8) staff for this training.**

Task D. Special Projects

The Contractor conducts special research studies and performance testing evaluations as requested by the GPO. Interim progress reports are submitted to the GPO at various times. A draft final report is submitted to the GPO after completing the project. The final report for each project is submitted to the GPO within 2 weeks after the GPO reviews the draft report.

The Contractor may use subcontractors to conduct the special projects if the Contractor does not have the capability to complete the project in the specified time.

There will be approximately 12 special projects during the first year of the contract. Each special project may continue or be modified/reduced in subsequent years.

The special projects must include, but are not limited to, the following:

1. New Technology, Instruments, and Analytes

The Contractor shall gather information on new technologies and new instruments being developed to test for drugs and additional analytes (e.g., MDMA, synthetic opiates) that may or could be included in drug testing programs. For technologies and instruments, the task includes evaluating the technologies and instruments and providing an assessment of their potential applicability to workplace drug testing programs.

2. Alternative Specimens

The Contractor shall evaluate other types of specimens (e.g., hair, sweat, oral fluid) for possible use in workplace drug testing programs. For alternative specimens and other analytes, the task may include establishing cutoff concentrations, estimating detection windows, and ability to develop and include performance testing samples in the NLCP performance testing (PT) program.

3. Demographic Analysis

The Contractor shall establish a process to gather non-negative drug test results to allow demographic analysis.

4. New Adulterants and Drug Culture Products

The Contractor shall purchase and identify adulterants and drug culture products that are sold with the intent of defeating a drug test. The effectiveness of the products to defeat a drug test shall be evaluated.

5. Collectors

The Contractor shall develop a quality assurance program to assess the specimen collection process and the compliance of collectors with NLCP requirements.

6. Medical Review Officers

The Contractor shall develop a quality assurance program to assess the review of drug test results by medical review officers and their compliance with NLCP requirements.

7. Bibliography of Scientific Journal Articles

The Contractor shall maintain a bibliography and copies of journal articles related to drug testing.

Task E. Specimen Investigations

Upon request from the GPO, the Contractor shall investigate potential problems with specimen test results that have been brought to the attention of the Division of Workplace Programs. An investigation may involve only reviewing documents provided by a laboratory or may include having the specimen tested by a reference laboratory. If additional testing by a reference laboratory is necessary to resolve the problem, the time allowed for the Contractor to report its findings to the GPO will be appropriately increased.

Task F. Special Inspections

The Contractor conducts, upon request of the GPO, a special laboratory inspection that is needed to investigate potential problems associated with a laboratory that may be withdrawing from the NLCP or for other special circumstances brought to the attention of the Division of Workplace Programs. The Contractor ensures that a special laboratory inspection is conducted within 3 weeks after receiving the request from the GPO. The Contractor submits a final inspection report to the GPO after a special inspection is completed. Generally, the cost for this type of inspection is reimbursed with government funds.

Task G. Reports and Accounting

1. Laboratory Inspection Schedule List

The Contractor prepares a list of the laboratories scheduled for inspections in a given month and provides the list to the GPO at least one month before that month of inspections begins. The list includes, at a minimum, the laboratory name and address, laboratory category, workload, previous inspection performance, and scheduled inspectors.

2. Performance Testing Report

The Contractor provides Performance Testing Status Reports that summarize the scores for each laboratory in the PT program, for each of the last two cycles, and the cumulative score for the last two cycles. In addition, each report provides a combined overall summary of performance for all laboratories similar to that provided for each laboratory.

The PT status report is submitted to the GPO after receiving all the test results from the laboratories for a PT cycle.

3. Laboratory Event History Report

The Contractor documents all interactions with applicant and certified laboratories and provides the information as an annual report to the GPO. Each annual report may contain only the updated information entered since the previous report.

4. Actual Inspection Cost Report

The Contractor provides a quarterly report that summarizes the actual inspection costs associated with each inspection. The report shall include: (1) bar graphs that give the average cost per month for each item (i.e., inspector airfares, hotel costs, meal costs, miscellaneous expenses, car rental costs) - the bar graphs indicate 12 months on a contract year basis, and (2) cost tables that list for each laboratory inspected the inspection date, name of inspectors that conducted the inspection, and for each inspector the airfare, hotel, meal, miscellaneous, and car rental costs.

5. Inspector List

The contractor maintains a database for the trained inspectors. The database includes, but is not limited to, the following information for each inspector: name, business address, home address, phone and FAX numbers, inspections conducted, and any other information that has been entered in the database that would affect an individual's selection for a particular inspection. A list of trained inspectors is provided to the GPO

quarterly.

Task H. Appeals

The Contractor assists the GPO in preparing documents to support an adverse action (such as, suspension or revocation) taken against a laboratory. An appeal of an adverse action by a laboratory may include scheduling a special inspection of the laboratory. The Contractor must provide a list and copy of the documents supporting the adverse action to the GPO after the request is received from the GPO. No more than 2 appeals are anticipated per year of the contract.

Task I. Requests for NLCP Applications

The Contractor documents all inquiries requesting information regarding the NLCP. When an application package is requested, the Contractor sends the requestor an OMB-approved application and associated program documents. The Contractor determines, with GPO approval, the program documents that are included to with the OMB-approved application. A complete application package shall specify all the information that must be submitted by an applicant laboratory as part of the application process.

Task J. Contract Tracking System/Database

The Contractor provides a monthly expenditures report that includes, at a minimum, a separate accounting for each task that is reimbursed with government funds and each task that is reimbursed by laboratory fees. The report shall conform to government accounting standards and the format shall include itemized charges, sub-totals, category totals, and sum totals.

The monthly expenditures report shall document all fees collected from each laboratory for the NLCP services provided.

1—The purpose of this task is to develop and implement an electronic contract and data management system to provide both tracking of the activities and analysis of the results of this procurement.

2—The Contractor shall construct and maintain a database for all information collected, and implement quality control including assurance of confidentiality, methods for cleaning the data, clarifying errors in information collecting and programming, appropriate analytical programs, and complete documentation.

3—Data and information related to this contract effort shall be collected, organized, and managed to develop a knowledge base for project management, analysis, and reporting to the Government on the progress of this effort.

4—The Contractor shall use off-the-shelf software to the extent possible to develop and implement such a system. All automated functions shall be compatible with SAMHSA's computer software and hardware [ref. to SAMHSA/DMS-IT Guidelines].

5—The Contractor shall efficiently plan, collect data, organize the database, and manage the automated contract management system, and shall use this information to track and monitor project activities, and to prepare reports.

6—Development of the system will begin immediately upon contract implementation to facilitate immediate and ongoing management of project data [subsequent to the Government approval of the IT Plan and the IT Security Plan].

7—Any changes to the SAMHSA/DMS-IT approved IT Plan and/or IT Security Plan shall be resubmitted to the Government for review and approval.

8—The size, scope, and complexity of the automated contract management system shall be commensurate with the size, scope, and complexity of the project and the information to be collected, managed, and reported.

SAMHSA/DMS-IT GUIDELINES: The Contractor shall use software that meets SAMHSA Guidelines. Specifically, the system (s) must be PC compatible, operate in a Windows environment, and use Microsoft Office Suit (Word; Excel; PowerPoint; and Access), PowerBuilder or other software consistent with SAMHSA/DMS-IT standards. The Contractor shall at all times maintain compliance with current DMS-IT standards, which may change over the duration of this contract. Any deviance from the SAMHSA standards should be negotiated with DMS-IT prior to contract award.

IT PROPOSED RESOURCES: The Offeror must submit, in addition to the IT Total Estimate Worksheets, a budget and a narrative for each of the IT resources proposed and an IT Technical Approach for accomplishing the tasks described in the SOW.

IT Plan: The Contractor shall prepare an IT Plan that will include the Design, Development, Implementation, and Maintenance for all IT Applications. The IT Plan should include functional requirements (e.g., data, workloads, user interface, reliability, security, and maintenance), technical requirements (e.g., hardware, software, and telecommunications) and operational and other requirements. It should also include major IT milestones and implementation dates of the project. The draft and final IT Plan will be submitted as a deliverable to the Government Project Officer (GPO) and the Division of Management Systems-Information Technology Team (DMS-IT) [through the GPO] for review and approval.

IT Security Plan: In compliance with OMB Circular A-130, "Management of Federal Information Resources," the Contractor shall prepare an IT Security Plan that will include a control process to ensure that appropriate management, operational and technical safeguards are incorporated into all SAMHSA IT Applications. The Contractor shall use the guidance provided in the documentation standards of the National Institute of Standards and Technology; NIST Special Publication 800-18 Rev. 1 "Guide for Developing Security Plans for Information Technology Systems" when developing the IT Security Plan.

In addition, the contractor shall comply with the IT Application(s) security requirements needed for the contract as set forth in the Statement of Work. The Contractor further agrees to include this provision in any subcontract awarded pursuant to the prime contract. The draft and final IT Security Plan will be submitted as a deliverable to the Government Project Office (GPO) and the Division of Management Systems-Information Technology Team (DMS-IT) [through the GPO] for review and approval.

Task K. Evaluation of Applications

The Contractor evaluates the application packages submitted by applicant laboratories that are interested in participating in the NLCP.

After an applicant laboratory satisfies the initial certification requirements, the Contractor sends a letter to the GPO indicating that the applicant laboratory is being recommended for certification. A certification letter is then issued by HHS.

Task L. Responsible Person Qualifications

The Contractor documents the review and recommendations for approval of each individual serving as a Responsible Person, co-Responsible Person, or alternate-Responsible Person. The Contractor shall develop instructions that describe what information is needed for an individual to be considered for these positions.

Upon completing an evaluation, the Contractor shall send a letter to the laboratory with its acceptance or rejection of the individual for that position and/or actions needed to make the individual acceptable.

Task M. Inspection Program

1. Pre-Inspection Activities

The Contractor maintains a laboratory inspection program that satisfies the requirements described in the Mandatory Guidelines.

The types of regular inspections needed include inspections of applicant laboratories, instrumented initial test laboratories (when included in the Mandatory Guidelines), and maintenance inspections. Additionally, a laboratory that withdraws from the NLCP may be inspected and charged a separate inspection fee depending on when the last regular inspection was conducted.

The Contractor shall establish a fee schedule that charges various size laboratories an appropriate cost recovery fee for each inspection and for other program activities (such as, the PT program activities described under Task N). The fee schedule is subject to approval by the GPO. The Contractor shall regularly assess the effectiveness of the inspection and PT programs and recommend changes to ensure the forensic nature of the NLCP and minimize costs to the laboratories. The Contractor shall evaluate fees regularly to ensure that the fees are appropriate.

The pre-inspection activities include selecting the trained inspectors that will be used for each inspection, arranging all the required travel for the inspectors, and requiring laboratories to submit information that will be used by the inspectors and the Contractor to prepare for the inspections.

2. Special Inspections

The Contractor schedules special laboratory inspections when requested by the GPO. The Contractor proposes how the special inspections will be conducted and the fees to be charged to the laboratories with approval by the GPO. Generally, a special inspection is conducted when the findings from a regular inspection indicate that a serious problem may exist at the laboratory and corrective action must be verified before the next regular inspection is scheduled. The Contractor may anticipate the need to schedule and conduct 6 special inspections per year.

3. Inspector Reimbursement

a. Consultants

The Contractor ensures that inspectors receive a consulting fee (to be established by the Government at the time of contract award) and reimbursement for hotel costs, meals, rental car costs, and miscellaneous travel expenses. The Contractor shall establish procedures to minimize and document all travel costs.

The funds collected through laboratory fees that are used to reimburse the inspector costs under this subtask (M3) are only subject to a Materials Support Expense (MSE) fee and the Contractor fee.

b. Contractor Staff

The Contractor staff will participate as inspectors on various types of laboratory inspections. The Contractor may anticipate that Contractor staff will participate in 25 inspections per year.

The Contractor staff receive regular wages (in lieu of a consulting fee) while inspecting laboratories and these wages are subject to fringe, overhead, G&A, and fee adjustments.

4. Post-Inspection Activities

a. Final Inspection Report

The Contractor reviews the reports submitted by the inspectors and prepares and sends a final inspection report to the laboratory. The final report may be sent electronically or mailed to the laboratory. A copy of the final report is sent to each of the inspectors who participated in the inspection.

b. Contractor Correspondence

The Contractor prepares a cover letter to accompany the final inspection report to the laboratory that provides an outcome of the inspection and comments on any deficiencies that need to be corrected. The final report and related materials may be sent electronically or mailed to the GPO when there is an unacceptable or failed inspection outcome.

The Contractor reviews information submitted by a laboratory in response to the final inspection report. After reviewing this additional information, the Contractor prepares a response that is sent electronically or mailed to the laboratory with its evaluation of the information and returns the information to the laboratory.

Task N. Performance Testing (PT) Program

1. PT Samples

The Contractor maintains a PT program that satisfies the requirements described in the Mandatory Guidelines. This includes preparing sets of initial PT samples to be sent to applicant laboratories and maintenance PT samples to be sent to certified laboratories.

The number and composition of PT samples used to prepare each year's sets of samples must be submitted to the GPO for review and approval.

2. PT Report

The Contractor electronically sends or mails a PT report to each laboratory. Each report shall include, at a minimum, the following: laboratory name and identification number, screening score, confirmation score, quantitation score (percent of results within ±20% or ±2 SD of mean and the number of drug challenges exceeding ±50% of the expected value), reporting score, and number of false positives. These scores shall be provided for the current PT cycle and cumulative scores for the last two cycles.

A similar PT report shall be sent to laboratories that are in the initial certification process.

3. PT Program Remedial Action

The Contractor notifies a laboratory when it has not satisfied all the requirements associated with the PT program and directs the laboratory to submit additional information and/or to take corrective action.

The Contractor reviews the information submitted by a laboratory in response to a remedial action request and prepares correspondence that provides an assessment of the corrective action or further action the laboratory must take to be in compliance with PT program requirements. After reviewing the information submitted by the laboratory, the Contractor shall return the information to the laboratory.

The Contractor prepares a final PT error notice report assessing the major and minor errors when laboratories have not satisfied all of the requirements of the PT program. The final PT error notice and related materials including assessed fees will be sent electronically or mailed to the GPO.

4. Reference Laboratory Testing

The Contractor shall use several reference laboratories to verify and determine the mean concentrations of the PT samples before they are sent to the laboratories as either initial or maintenance samples.

The Contractor shall recall a PT sample from a laboratory if there is any concern that the Contractor may have sent an incorrect PT sample to the laboratory. The recall procedure shall include using a reference laboratory to retest the PT sample in question.

Option 1 (Year 2)

Same tasks as Year 1.

Option 2 (Year 3)

Same tasks as Year 1.

Option 3 (Year 4)

Same tasks as Year 1.

Option 4 (Year 5)

Same tasks as Year 1 and the following new task as described:

Task O. Transition/Transfer Activity

Six months prior to the end of the contract, the Contractor provides a comprehensive 90-day plan that would detail the transfer of all relevant administrative and operational information associated with the NLCP to the incoming new contractor when the contract ends. The information to be transferred would include all computer maintained items, but is not limited to, the following essential functions: applications, certifications, proficiency testing performance data, inspection materials, inspection data/reports, program actions, administrative/ operational program devices, training materials, and trained inspector data base.

The Government will furnish the following property:

Widmer N-3 Automatic Numbering Machine (1)
Leica model 10400A TS meter refractometer (2)
Data Mate MC 1000 Microfiche reader/printer (1)

These items will be transferred from the current Contractor to the new Contractor after award of the contract, if necessary.

The cost for this task is reimbursed by the Government.

Special Contract Requirements

Conflict of Interest

Employees of the Contractor and any subcontractor who are involved in certifying, suspending, or revoking laboratories, as well as their spouses or minor children, shall not have a financial interest in a certified laboratory or a laboratory that seeks to be certified. A "financial interest" is any interest of monetary value that may be directly and predictably affected by the official action of an employee in carrying out the contract. There is no minimum amount of value or control that constitutes a financial interest, and it includes, among other things, the receipt of any salary or other payment from such laboratories, as well as stock in any such laboratory.