National Laboratory Certification Program (NLCP)

Updated: October 2007

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 the Federal Workplace Drug Testing Program. To accomplish this mission, HHS developed the Mandatory Guidelines for Federal Workplace Drug Testing Programs. The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11979), revised on June 9, 1994 (59 FR 29908), revised on November 13, 1998 (63 FR 63483), and revised on April 13, 2004 (69 FR 19644). The last revision on April 13, 2004, was implemented on November 1, 2004. The Mandatory Guidelines establish the scientific and technical standards that are used to certify the laboratories that test specimens collected by Federal agencies. When the Mandatory Guidelines were first published in the **Federal Register** in 1988, HHS awarded a contract to develop a laboratory certification program that satisfied the requirements specified in the Mandatory Guidelines. The contract awarded was called the "National Laboratory Certification Program," and this name has been used since that time.

The contractor that operates the NLCP contract for SAMHSA's Division of Workplace Programs furnishes the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the government to perform the tasks described in the contract and in accordance with the requirements specified in the Mandatory Guidelines.

Subpart B of the Mandatory Guidelines, "Scientific and Technical Requirements," describes requirements that laboratory personnel must satisfy, the procedures laboratories must follow to test specimens, quality assurance and quality control requirements that a laboratory must use when testing specimens, and requirements for reporting results to a medical review officer.

Subpart C of the Mandatory Guidelines, "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," establishes the specific certification requirements that a laboratory must meet in order to test urine specimens for Federal agencies. This subpart can be broken down into two areas. The first area specifies the requirements for an applicant laboratory to become certified. The second area specifies the requirements for a certified laboratory to maintain its certification.

In accordance with the Mandatory Guidelines, the NLCP includes comprehensive performance testing (PT) and laboratory inspection programs. To become certified, an applicant laboratory must successfully test 3 rounds of PT samples and successfully complete a laboratory inspection that occurs at the time the third set of PT samples are being tested by the laboratory. In addition, a newly certified laboratory must undergo an inspection 3 months after achieving certification. To maintain certification, a laboratory must participate in and satisfy the requirements for the "maintenance" PT program and achieve successful performance on every semiannual "maintenance" inspection. The "maintenance" PT program consists of sets of PT samples sent to each laboratory on a quarterly basis.

HHS notifies Federal agencies of the laboratories that are currently certified by publishing a notice in the **Federal Register** during the first week of each month. The list is updated each month. Typical changes to the list include adding the names and addresses of newly certified laboratories, deleting laboratories that have withdrawn from the NLCP, and indicating the suspension or revocation of a laboratory's certification.

In addition to the Federal agencies that use HHS-certified laboratories to test specimens for their workplace drug testing programs, the Department of Transportation, the Department of Energy, and the Nuclear Regulatory Commission require the industries they regulate to use HHS-certified laboratories for their workplace drug testing programs.

Note: The drug testing that a laboratory conducts for federally-regulated workplace drug testing programs under the NLCP is exempt from the requirements under the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88).

NLCP Fee Schedule

The fees paid by laboratories applying for or participating in HHS' National Laboratory Certification Program are posted on this website.

NLCP Application

A laboratory that is interested in becoming HHS-certified under the NLCP is required to submit an application. A copy of the NLCP application and other relevant information may be obtained from the NLCP contractor by calling 919-541-7457, sending an email to nlcp@rti.org, or sending a request by fax to 919-541-7042.