

National Laboratory Certification Program

Updated: March 2013

Under the authority of Section 503 of Public Law 100-71, 5 U.S.C. Section 7301, and Executive Order No. 12564, the Department of Health and Human Services (HHS) establishes the standards for Federal Workplace Drug Testing Programs. As required, HHS published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the Federal Register on April 11, 1988 [53 FR 11979]. HHS subsequently revised the Guidelines on June 9, 1994 [59 FR 29908], September 30, 1997 [62 FR 51118], November 13, 1998 [63 FR 63483], April 13, 2004 [69 FR 19644], and November 25, 2008 [73 FR 71858]. The Guidelines establish the scientific and technical standards that are used to certify the laboratories that test specimens collected by federal agencies. When the Guidelines were first published in the Federal Register in 1988, HHS awarded a contract, known as the National Laboratory Certification Program (NLCP), to develop a laboratory certification program that satisfied the requirements specified in the Guidelines.

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

The Guidelines' Subpart C, "Drug and Specimen Validity Tests," Subpart K "Laboratory," and Subpart L "Instrumented Initial Test Facility (IITF)" describe requirements that laboratory/IITF personnel must satisfy, the procedures laboratories/IITFs must follow to test specimens, quality assurance and quality control requirements that a laboratory/IITF must use when testing specimens, and requirements for reporting results to a Medical Review Officer.

Subpart I of the Guidelines, "HHS Certification of Laboratories and IITFs," establishes the specific certification requirements that a laboratory/IITF must meet in order to test urine specimens for federal agencies. This subpart specifies the requirements for an applicant laboratory/IITF to become certified under the NLCP and specifies the requirements for an HHS-certified laboratory/IITF to maintain its certification.

In accordance with the Guidelines, the NLCP includes comprehensive performance testing (PT) and inspection programs. To become HHS-certified, an applicant laboratory must successfully complete three rounds of PT and an inspection occurring concurrent with the third set of PT. In addition, a laboratory/IITF must undergo another inspection 3 months after becoming HHS-certified. To maintain HHS certification, a laboratory/IITF must participate in and satisfy the requirements for the quarterly maintenance PT program and achieve successful performance on every semiannual maintenance inspection.

HHS notifies federal agencies of the laboratories/IITFs that are currently certified by publishing a notice, which is updated monthly, in the Federal Register during the first week of each month. Changes to the list include adding newly certified laboratories, removing 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 conducted for federally-regulated workplace drug testing programs under the NLCP is exempt from the requirements under the Clinical Laboratory Improvement Amendments (CLIA).

NLCP Fee Schedule

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

NLCP Application

A laboratory/IITF that is interested in becoming HHS-certified under the NLCP is required to submit an application. Information concerning the NLCP application process may be obtained from the DWP (240.276.2600).