National Laboratory Certification Program

Updated: April 2024

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 scientific and technical guidelines for Federal workplace drug testing programs and established standards for certification of laboratories engaged in drug testing Federal agencies.

HHS originally published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the Federal Register on April 11, 1988 [53 FR 11979]. The Substance Abuse and Mental Health Services Administration (SAMHSA) 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]. SAMHSA published the revised Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) on January 23, 2017 [82 FR 7920] and the first Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) on October 25, 2019 [84 FR 57554]. SAMHSA subsequently revised the UrMG (88 FR 70768) with an effective date of February 1, 2024, and the OFMG (88 FR 70814) with an effective date of October 10, 2023.

Using data obtained from the Federal Workplace Drug Testing Programs and HHS-certified laboratories, the Department estimates that 275,000 urine specimens are tested annually by Federal agencies.

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 for the development of the National Laboratory Certification Program (NLCP), the laboratory accreditation program based on 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 Department certifies three types of laboratories. Urine laboratories and oral fluid laboratories conduct all tests and report all specimen results. For urine only, instrumented initial test facilities (IITFs) conduct the initial drug and first specimen validity tests for urine specimens and report only the negative and negative dilute results. IITFs forward specimens requiring further testing to a certified urine laboratory.

The UrMG Subpart C, “Urine Specimen Tests,” Subpart K, “Laboratory,” and Subpart L, “Instrumented Initial Test Facility (IITF)” describe requirements that laboratory and IITF personnel must satisfy, the procedures laboratories and IITFs must follow to test urine specimens, quality assurance and quality control requirements that a laboratory and IITF must use when testing urine specimens, and requirements for reporting urine test results to a Medical Review Officer. The OFMG Subpart C, “Oral Fluid Specimen Tests” and Subpart K, “Laboratory” describe requirements that laboratory personnel must satisfy, the procedures laboratories must follow to test oral fluid specimens, quality assurance and quality control requirements that a laboratory must use when testing oral fluid specimens, and requirements for reporting oral fluid test results to a Medical Review Officer. The OFMG Subpart L, “Instrumented Initial Test Facility (IITF)” describes the restriction that only HHS-certified laboratories are authorized to test oral fluid specimens for Federal agency workplace drug testing programs.

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

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)