

**Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Prevention**

National Laboratory Certification Program (NLCP)

HHS-Certified Laboratory and Instrumented Initial Testing Facility Notice

Date: August 1, 2011

Subject: Fee Schedule

This notice provides the new fee schedule for laboratories and instrumented initial testing facilities (IITFs) participating in or applying for certification in the Department of Health and Human Services' (HHS) National Laboratory Certification Program (NLCP). **The new fee schedule is effective December 1, 2011.**

The NLCP is a self-supporting program and each participant test facility (i.e., laboratory or IITF) is required to pay fees. To maintain this self-supporting certification program, the Substance Abuse and Mental Health Services Administration (SAMHSA) Division of Workplace Programs (DWP) periodically reviews all costs associated with the inspection and performance testing (PT) programs. Every effort is made to ensure that the NLCP is a self-supporting program and that each test facility pays fees commensurate with the costs of each part of the program.

NLCP application fees have been established for each phase of the program. As set forth on the fee schedule published with this memo, the NLCP application fee for an IITF is \$2,000, consistent with the current laboratory application fee. The current NLCP application requires an applicant IITF to submit an extensive amount of information. NLCP contractor staff review the information and work with the applicant IITF to revise, correct, or resubmit information when required. These fees are necessary for the contractor to provide detailed guidance to the applicant IITF on the information that needs to be submitted or revised before the applicant can proceed to the next steps in the certification process.

An NLCP inspection fee of \$11,200 has been established for IITFs and is required for each IITF inspection (i.e., initial inspection, 3-month inspection, maintenance inspection) in each phase of the program. This amount is consistent with the current inspection fees for the initial and 3-month inspections of a laboratory and with the maintenance inspection fee for a Category I HHS-certified laboratory. The current NLCP inspection process for IITFs requires two inspectors to perform an onsite inspection, as well as contractor effort in pre- and post-inspection activities. This fee is necessary for the contractor to provide the services to the IITF for the certification process. An NLCP inspection fee for a special inspection of an HHS-certified IITF will be actual cost, the same as for current HHS-certified laboratories

NLCP pre-inspection and post-inspection remedial action fees associated with the IITF have been established for each phase of the program. The NLCP pre-inspection and post-inspection

remedial action fees for an IITF are \$1,000 and \$3,000, respectively. These fees are consistent with the current fees for HHS-certified laboratories. The pre-inspection fee will encourage an IITF to submit the accurate and timely information and in the required format. The post-inspection fee is appropriate for contractor staff to review records and documentation that must be submitted by the IITF for post-inspection remedial action.

NLCP PT fees associated with IITFs have been established for each phase of the program. The NLCP initial and maintenance performance testing (PT) fee for an IITF is \$3,000. The contractor's costs for activities associated with the IITF PT program (e.g., preparing and shipping the sets of PT samples, analysis of results) are the same as for the current laboratory PT program.

SAMHSA's Division of Workplace Programs has evaluated the NLCP remedial action fees associated with minor PT errors for the current HHS-certified laboratories and for IITFs. Accordingly, SAMHSA has determined that NLCP PT remedial action fees are no longer required for minor PT errors unless the error reoccurs on the next PT occasion. The efforts expended in the PT remedial process for one-time minor PT errors can be covered by the maintenance PT fees. DWP continues to attempt to minimize the remedial fees associated with errors on PT samples; however, the costs associated with reoccurring minor PT errors can become significant. These errors can affect test facility performance and, therefore, must be appropriately corrected and costs for efforts involved must be appropriately charged to the laboratory or IITF. A PT remedial action fee of \$3,000 will be charged when an HHS-certified laboratory or IITF reports a major PT error. These fees are consistent with the current fees for HHS-certified laboratories. The costs associated with remediation of major PT errors can become significant and affect test facility performance and, therefore, must be corrected and costs for efforts involved must be appropriately charged to the laboratory or IITF.

The Division of Workplace Programs has reviewed the NLCP withdrawal fee for the current HHS-certified laboratories and for IITFs. The NLCP withdrawal fee has been revised from \$9,900-16,300, with the final fee charged to be based on actual cost for the final audit inspection. The actual cost of the HHS-certified laboratory or IITF withdrawal fee is appropriate for an onsite inspection and auditor for contractor staff to review records and documentation prior to a HHS-certified laboratory or IITF withdrawing from the program.

The new fee schedule is as follows for Laboratories and Instrumented Initial Testing Facilities:

Event	Fee (\$)
Application	2,000
Inspections	
Initial	11,200
3-month Second Initial	11,200
Maintenance	
IITF	11,200
Laboratory:	
Category 0	9,000
Category 1	11,200
Category 2	16,300
Category 3	24,800
Category 4	38,000
Category 5 – Inspection	38,000
Category 5 – Audit	24,800
Special	Actual cost
Remedial Action	
Pre-inspection	1,000
Post-inspection	3,000
Performance Testing	
Initial Set	3,000
Maintenance Set	3,000
Remedial Action	
Major	3,000
Reoccurring Minor	1,000
Withdrawal – final audit inspection	Actual cost

The fee schedule will continue to be evaluated periodically to ensure fees accurately reflect the costs associated with each activity.

If you have any questions regarding these changes, please contact my staff at (240) 276-2600 or by email: Ron.Flegel@samhsa.hhs.gov.

/SIGNED/

Carol Rest-Minberg
Acting Director
Division of Workplace Programs