

**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 29, 2019

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 October 1, 2019.**

The NLCP is a self-supporting program and each participant test facility (i.e., laboratory or IITF) is required to pay fees. To maintain the 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.

The following summarizes the changes that are to be effective on October 1, 2019:

1. RTI has added a new laboratory category, Category 7. Since SAMHSA established Categories 0 through 6, the workloads of some certified laboratories have increased such that the current inspection format is not sufficient to enable review of the target percentage (i.e., about 10%) of the laboratory's non-negative specimens. Laboratories will continue to be notified of their category changes.

We are not making changes to other NLCP fees. However, the following describes additional changes to some NLCP inspections/audits:

2. Increase the number of audited non-negative specimens for laboratories in Categories 1, 4, 5 (inspections), and 6 (inspection and audit). The addition of four prescription opioids to the regulated drug testing panel was effective Oct. 1, 2017 for federal specimens and Jan. 1, 2018 for Department of Transportation regulated specimens. The added drugs led to increased numbers of non-negative specimens which, in turn, reduced the percent audited to less than the program's 10% target. Current inspection resources should enable review of additional specimens in these categories without increasing fees. With these changes, the percentage audited remains below, but closer to, the 10% target in these laboratories.
3. Add to criteria for changing Category 0 inspections to Category 1. Category 0 was established to reduce fees for very small laboratories in the NLCP with 1.5-day inspections. When additional inspection resources are required, the inspections for Category 0 laboratories are extended to 2 days and the laboratory is charged a Category 1 inspection fee. Current criteria are: when the inspection includes a Responsible Person (RP)/Alternate RP interview; when the laboratory's previous

inspection was unacceptable; when a major PT error was incurred/remediated since the previous inspection; and when the laboratory is in the process of mergers, acquisitions, moves within a facility, or relocation. RTI is adding two additional criteria: when the laboratory has validated more than one assay or new instrument model since the previous inspection; and when the laboratory has remediated multiple errors during the last two NLCP PT cycles.

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

Ron Flegel

Ron Flegel

Director

Division of Workplace Programs

The NLCP Fee Schedule, effective October 1, 2019 is as follows for Laboratories and Instrumented Initial Testing Facilities:	
Event	Fee (\$)
Application	\$3,000
Inspections	
Initial	\$12,900
3-month Second Initial	\$12,900
Maintenance	
IITF	\$12,900
Laboratory:	
Category 0	\$10,400
Category 1	\$12,900
Category 2	\$18,800
Category 3	\$28,500
Category 4	\$43,700
Category 5 - Inspection	\$43,700
Category 5- Audit	\$28,500
Category 6 - Inspection	\$54,600
Category 6- Audit	\$39,400
Category 7 - Inspection	\$65,500
Category 7- Audit	\$50,300
Special Inspection	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 Inspection/Audit	Actual Cost

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