



Date: August 1, 2016

DQA Numbered Memo 16-009
Replaces DQA Memo 10-002

To: [Approved Laboratories and Analysts Performing Alcohol, Controlled Substance, and Controlled Substance Analog Testing for Implied Consent under Wis. Stat. § 343.305\(6\)\(a\)](#)

From: Crenear Mims, Director
Bureau of Health Services

Via: Otis Woods, Administrator
Division of Quality Assurance

**Approval of Laboratories and Analysts Performing Testing
under Wis. Stat. § 343.305(6)(a)**

Purpose

The Division of Quality Assurance (DQA), within the Department of Health Services (DHS), is responsible for approving laboratories and analysts performing testing under Wis. Stat. § 343.305(6)(a). This memo replaces DQA memo 10-002 adding Controlled Substances and Controlled Substance Analog Testing to applications.

Background

By statute, an approved laboratory or analyst must:

- Employ a blood or urine chemical analysis method approved by the Wisconsin State Laboratory of Hygiene (WSLH).
- Possess a valid permit to perform alcohol, controlled substance, or controlled substance analog testing which has been issued by DHS.
- Participate in a regular monitoring program administered by DHS.
- Submit to background checks performed by the Department of Revenue for use in collection of tax delinquencies, the Department of Children and Families for use in administration of child and spousal support programs, and the Department of Workforce Development for use in collection of delinquent unemployment insurance contributions.

The following are changes that have been made to the administration and oversight of this program:

- On an annual basis the WSLH will approve methods for alcohol and drug testing for laboratories under the Wis. Stat. § 343.305(6)(a) Implied Consent Law. These approvals will be provided to DHS.

- On an annual basis, DHS will approve and issue permits to laboratories and analysts. Previously, permits have only been issued for alcohol testing. New permits will be issued for approved laboratories and analysts for alcohol, controlled substance, and controlled substance analog testing.
- On an annual basis, laboratories will submit accreditation reports from their accrediting agency. This will constitute a monitoring program since accreditation approval encompasses many facets of laboratory operations such as personnel competency and qualifications, proficiency testing, pre-analytic, analytic, and post-analytic testing phases, quality assessment and assurance, quality control, and overall laboratory operations. Previously, laboratories were asked to participate in the WSLH Legal Alcohol Proficiency Testing Program for the monitoring program. With the change in how DHS will now monitor laboratories, this is no longer a requirement. Laboratories may choose to continue to participate in this external assessment.

Reporting Requirements

Approval and issuance of permits occurs on an annual basis at the beginning of each calendar year. Due to changes in program administration and the need to issue permits that are approved for controlled substances and controlled substance analogs in addition to alcohol, DHS will be implementing a one-time mid-year permit approval for laboratories and analysts. We will also be implementing the new monitoring program requirements. Please submit the following to DHS by **Friday, August 26, 2016**:

- Applications for your laboratory and each analyst.
 - Applications for laboratories and analysts can be found at the following DHS website link: <https://www.dhs.wisconsin.gov/library/F-62501.htm>
 - Applications for analysts can be found at the following DHS website link: <https://www.dhs.wisconsin.gov/library/F-62502.htm>
- Copy of your most recent accreditation report and current certificate of accreditation.

Submit all application forms by mail or secure/encrypted email to:

Division of Quality Assurance
Licensing, Certification, and CLIA Section
PO Box 2969
Madison, WI 53701-2969

Or DHSDQACLIA@dhs.wisconsin.gov

Questions

For questions regarding this memo, please contact the Licensing, Certification, and CLIA Section at 608-266-7485 or at DHSDQACLIA@dhs.wisconsin.gov