ASCLD/LAB-*International*
Surveillance Activity Report

Washington State Patrol - Breath Test Program

Premises visited:
811 E. Roanoke, Seattle, WA 98102
10945 Chuckanut Drive, Burlington, WA 98233
2700 116th Street NE, Marysville, WA 98271
22065 Viking Way NW, Poulsbo, WA 98370
222 Tumwater Blvd, Bldg 16, Tumwater, WA 98504
2502 112th Street East, Tacoma, WA 98445
11018 NE 51st Circle, Vancouver, WA 98682
2822 Euclid Avenue, Wenatchee, WA 98801
2715 Rudkin Road, Union Gap (Yakima), WA 98903
West 6403 Rowand Road, Spokane, WA 99224

Premises not visited:
N/A

Surveillance Activity: Expanded Surveillance Visit
Surveillance Activity Date: October 3-5, 2016

Surveillance Assessor(s):
Melissa Smrz
Technical Assessor(s):
Chris Fontenot – Poulsbo, Tumwater, Tacoma, and Vancouver
Melissa Kennedy – Seattle, Burlington, and Marysville
Lee Anne Spino – Wenatchee, Union Gap (Yakima), Spokane

ASSESSMENT OBJECTIVES

To conduct limited scope conformance monitoring of management and technical operations and to report the findings in a fair and impartial manner to the customer and to ASCLD/LAB for the purpose of continuing ASCLD/LAB-*International* accreditation in accordance with the scope of accreditation. Applicable requirements from ISO/IEC 17025:2005, the ASCLD/LAB-*International* Supplemental Requirements for the Accreditation of Forensic Science Calibration Laboratories – Breath Alcohol Measuring Instruments (version 1.0), applicable ASCLD/LAB-*International* policies and the documented management system were used for this assessment.

SCOPE OF ACCREDITATION

The premises located at 143302 E. Law Lane, Kennewick, WA, was recently closed due to a lack of staff. Calibration work from this location is being performed by the Union Gap premises. There are no other changes to the current scope of accreditation.

REVIEW OF CORE ACCREDITATION REQUIREMENTS

During the surveillance activity, the following were evaluated for conformance:

- Management organization
- Proficiency testing program and records
- Corrective action records

- Internal audit records
- Management review records
- Appropriate use of the ASCLD/LAB accreditation symbol

REVIEW OF TECHNICAL COMPETENCE

During the surveillance activity, personnel qualification records and technical records were evaluated for conformance and the performance of accredited services was witnessed.

CONCLUSIONS

Based upon a sampling of objective evidence during the surveillance activity, one or more nonconformities were required to be addressed (refer to the attached Nonconformities and Comments). All nonconformities have been appropriately resolved and operations are in conformance with applicable accreditation requirements. Comments are provided. Comments are an opportunity for potential improvement of a conforming practice.

REPORT AUTHORIZATION

As the surveillance assessor, I affirm that this report represents a true and accurate accounting of the findings of the ASCLD/LAB-*International* surveillance activity.

The next assessment activity is:

An Off-site Review scheduled for October 2017.
A Performance Declaration is required and due September 1, 2017.

Surveillance Assessor: Melissa Smrz

Melissa Smrz
Signature

January 30, 2017
Date

DISTRIBUTION LIST

Larry Hebert, Bureau Director
Lieutenant Robert Sharpe, Impaired Driving Section Commander
Erik Neilson, Standards and Accountability Manager
ASCLD/LAB Office

ASCLD/LAB-*International*
Nonconformities and Comments - Resolved

Washington State Patrol
Breath Test Program
Seattle, Tacoma, Tumwater, Vancouver, Poulsbo, Wenatchee, Union Gap/Yakima, Spokane, Burlington, Marysville premises
Surveillance Activity - Expanded
Dates: October 3 – 5, 2016
Assessor: Melissa Smrz

INSTRUCTIONS

FOR EACH NONCONFORMITY LISTED:
As applicable, a forensic service provider must follow requirements in ISO/IEC 17025:2005, 4.9 Control of nonconforming testing and/or calibration work and/or 4.11 Corrective action as well as the provider's own management system requirements for the resolution of all nonconformities identified during an assessment activity. Actions taken to resolve a nonconformity may include correction, corrective action based on root cause analysis or a combination of both. The type of action taken will be based on an evaluation of the significance of the nonconforming work (4.9) or the necessity to perform corrective action based on management system policy and procedure (4.11).

- Within 30 days of the assessment activity report date, a plan for resolution and a time schedule for implementation must be provided and accepted.
    - Describe the plan for achieving and documenting conformity which may include: correction, evaluation of significance, halting and resuming work, customer notification, corrective action, monitoring of effectiveness or additional audits.
- Within 90 days of the assessment activity report date, objective evidence of plan implementation to a level to ensure no negative impact to the work product or integrity of the evidence/item must be provided and accepted.
    - If corrective action is required by the plan, it is acknowledged that there will be instances where all aspects of the corrective action process may take more than 90 days to complete. However, within the 90 days, sufficient objective evidence must be provided to ensure that there is no longer a negative impact to the work product or integrity of the evidence/item.

FOR EACH COMMENT PROVIDED: There is no requirement to respond to a comment.

NC1

Premises Name (if more than one): All

REQUIREMENT: ASCLD/LAB-International 2016 Calibration Supplemental for Measuring Instruments
5.9.4 - "The laboratory shall establish a procedure for the technical review of calibration records and calibration certificates. The procedure shall: …
g) require that technical reviews not be conducted by the author or co-author(s) of the technical records or the calibration certificate under review."

REQUIREMENT: ASCLD/LAB-International 2016 Calibration Supplemental for Measuring Instruments
5.9.5 - "The laboratory shall establish a procedure which requires administrative review of the calibration record and calibration certificate, prior to the release of each certificate or report. The laboratory procedure shall: …
f) require that administrative reviews not be conducted by the author or co-author(s) of the technical records or the calibration certificate under review."

DESCRIPTION OF THE NONCONFORMITY:
Calibration analysts who author reports and certificates are performing the technical and administrative reviews of the same reports and certificates.

DUE DATE for Resolution Plan: 11/16/16
DUE DATE for Resolution Completion: 1/15/17

SUMMARY OF PLAN AND OBJECTIVE EVIDENCE
Date: January 13, 2017
Summary of Plan:
The laboratory halted calibration work and then revised its procedures to ensure that the technical reviewer is not the same person as the calibration analyst or issuer of the calibration report/certificate.

Summary of Objective Evidence:
The laboratory submitted a directive which revised the technical review procedures. The directive requires that a technical reviewer be a different person than the author/issuer or the releaser of the certificate. The laboratory submitted five calibration records which include: 1) revised calibration certificate forms (three signature lines – author/issuer, reviewer, and releaser of the report) and, 2) the technical review checklist that includes two signature lines, one for the issuer/author of the report and one for the technical reviewer. The nonconformity is resolved.

NC2

Premises Name (if more than one): All

REQUIREMENT: ASCLD/LAB-International 2016 Calibration Supplemental for Measuring Instruments
5.4.1.2 - The source of material(s) used to calibrate a breath alcohol measuring instrument shall be different from that used to adjust a breath alcohol measuring instrument and that used to verify calibration status.

DESCRIPTION OF THE NONCONFORMITY:
The laboratory uses the same source solution to calibrate, to adjust and to verify the calibration status of breath alcohol measuring instruments. The laboratory uses the terms “linearity check”, “calibration” and “complete breath test” to reflect these steps (respectively).

DUE DATE for Resolution Plan: 11/16/16
DUE DATE for Resolution Completion: 1/15/17

SUMMARY OF PLAN AND OBJECTIVE EVIDENCE
Date: January 13, 2017
Summary of Plan:
The laboratory halted calibration work and then revised its procedures to ensure that the reference material used to adjust the instrument is different from the reference material used to calibrate the instrument and to verify the calibration. The laboratory clarified its use of terminology pertaining to adjusting and calibrating the instruments to be more consistent with accreditation requirements terminology.

Summary of Objective Evidence:
The laboratory submitted a directive that revises and clarifies the previous procedures pertaining to the use of different reference materials for the adjustment and calibration of instruments. It submitted five calibration records which demonstrate use of the appropriate and different reference materials during adjustment and calibration. The nonconformity is resolved.

NC3

Premises Name (if more than one): All

REQUIREMENT: ISO/IEC 17025:2005
5.10.4.3 - When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, shall be reported.

REQUIREMENT:ASCLD/LAB-International 2016 Calibration Supplemental for Measuring Instruments
4.13.2.1.2.1 - If an adjustment is performed due to a failed calibration procedure, pre and post adjustment data shall be retained.

DESCRIPTION OF THE NONCONFORMITY:
Pre-adjustment data is not being retained in instances where a calibration procedure fails and therefore these results are not available to be reported.

DUE DATE for Resolution Plan: 11/16/16
DUE DATE for Resolution Completion: 1/15/17

SUMMARY OF PLAN AND OBJECTIVE EVIDENCE
Date: January 13, 2017
Summary of Plan:
The laboratory halted calibration work until a revised policy was completed. A directive requiring that all calibration records, including those from failed or repeated calibrations, is retained.

Summary of Objective Evidence:
The laboratory submitted the cited directive, which includes the revised policy cited in the plan. The laboratory advised that it did not have any examples of failed calibrations during the last three months, but it submitted one calibration record that included a repeated and subsequently successful calibration. The nonconformity is resolved.

NC 4

Premises Name (if more than one): All

REQUIREMENT: ISO/IEC 17025:2005

5.2.5 - The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.

DESCRIPTION OF THE NONCONFORMITY:

The laboratory does not maintain a record of the successful completion of training in the presentation of evidence in court. Through interview, it was determined that each trainee is required to successfully complete a moot court. This training activity is not listed on the training checklist used by the laboratory to document completion of training tasks. An evaluation of the moot court is conducted verbally.

DUE DATE for Resolution Plan: 11/16/16

DUE DATE for Resolution Completion: 1/15/17

SUMMARY OF PLAN AND OBJECTIVE EVIDENCE

Date: January 13, 2017

Summary of Plan:

The laboratory revised its training policy and procedure to now include a written evaluation of the trainee's mock court testimony.

Summary of Objective Evidence:

The laboratory submitted its most current training procedure which includes the written evaluation requirement for mock court testimonies. The laboratory also submitted its corrective action form. The nonconformity is resolved.

CM 1

COMMENT:

To improve its existing proficiency test program, it is recommended that the laboratory consider the use of a dry gas proficiency test from an approved external test provider, as it continues to implement breath alcohol measuring instruments capable of analyzing a dry gas sample.