

ASCLD/LAB-*International*

Final Assessment Report

Washington State Patrol Breath Test Program Seattle, Washington

(Satellite premises located in the following cities within Washington State: Burlington, Marysville, Poulsbo, Tumwater, Tacoma, Vancouver, Wenatchee, Yakima, Kennewick, and Spokane)

PART 1 – GENERAL INFORMATION

INTRODUCTION

This is the ASCLD/LAB-*International Final Assessment Report* of the Washington State Patrol - Breath Test Program (Measuring Instruments). The on-site assessment was conducted during the period October 7 - 10, 2014.

The ASCLD/LAB-*International* assessment team consisted of the following members:

Lead Assessor:

C. Glen Johnson - Staff Assessor, ASCLD/LAB / Round Rock, TX

Technical Assessors:

Emily Esquivel - Jefferson County Sheriff's Department / Beaumont, TX
W. Mark Fondren - Tarrant County Medical Examiners Office / Fort Worth, TX
Karin Kierzek - Minnesota Bureau of Criminal Apprehension / St. Paul, MN
Alka B. Lohmann - Virginia Department of Forensic Science / Richmond, VA

OBJECTIVES OF ASSESSMENT

The assessment was conducted to evaluate the management and technical operations of the laboratory in accordance with the accreditation requirements specified below, and to report the findings of the assessment in a fair and impartial manner to the laboratory and to the ASCLD/LAB Board of Directors for the purpose of accreditation in accordance with the scope of the assessment.

ACCREDITATION REQUIREMENTS

The assessment was performed using the requirements of *ISO/IEC 17025:2005*, the *2007 ASCLD/LAB-International Supplemental Requirements for Breath Alcohol Calibration Laboratories*, the *ASCLD/LAB Policies on Measurement Traceability and Measurement Uncertainty* and the laboratory's own documented management system.

SCOPE OF ASSESSMENT

The laboratory is seeking accreditation in and was assessed in the following areas:

Field	
Forensic Science Calibration	
Discipline(s)	Categories of Calibration
Toxicology	Breath Alcohol Measuring Instruments

LABORATORY OVERVIEW

The Washington State Patrol - Breath Test Program is a state government laboratory that provides services and assistance to law enforcement agencies throughout Washington State. The main laboratory is located at 811 E. Roanoke, Seattle, Washington. The satellite facilities are located in Washington at the following addresses: 10945 Chuckanut Drive, Burlington; 2700 116th Street NE, Marysville; 22065 Viking Way NW, Poulsbo; 222 Tumwater Blvd, Bldg 16, Tumwater; 2502 112th Street East, Tacoma; 11018 NE 51st Circle, Vancouver; 2822 Euclid Avenue, Wenatchee; 2715 Rudkin Road, Union Gap (Yakima); 143302 E Law Lane, Kennewick and West 6403 Rowand Road, Spokane.

Lt. Robert Sharpe is the Impaired Driving Section Commander, and at the time of the assessment the laboratory had a staff of 18 proficiency tested personnel and 4 non-proficiency tested personnel.

ASSESSMENT TEAM FINDINGS

The laboratory was found to be in conformance with all ASCLD/LAB-*International* accreditation requirements except for those requirements cited in Part 2 of this report, or the assessment team found that the requirement was not applicable to the operations of this laboratory.

Each requirement for which the assessment team found the laboratory to not be in total conformance was initially marked "No." For each requirement marked "No," the laboratory was provided with a Corrective Action Request (CAR) following the on-site assessment. A copy of each CAR provided to the laboratory is included in Part 2 of this report.

As reflected on the CAR documents in Part 2 of this report, the laboratory has now appropriately resolved all CARs issued.

COMMENTS

Comments include recommendations, suggestions, or other observations documented by the assessment team that are not supported by sufficient objective evidence of non-compliance. The laboratory is not required to respond to comments. The following comment(s) were documented by the assessment team during the on-site assessment: **None**

OTHER CONSIDERATIONS

Other Considerations may include any topic, issue or information of which the ASCLD/LAB Board of Directors needs to be aware in order to make a more fully informed decision regarding the accreditation decision.

In accordance with ASCLD/LAB policy and procedures the following information was provided by the ASCLD/LAB headquarters office immediately prior to the accreditation decision:

Proficiency Testing

On-site the assessment team found the laboratory to be in conformance with all applicable proficiency testing requirements. A follow-up check with the ASCLD/LAB Proficiency Program Manager immediately prior to this final report, reveals that the laboratory is currently in conformance with all applicable, ASCLD/LAB external proficiency testing requirements.

Complaints against the Laboratory

None known to ASCLD/LAB

REPORT AUTHORIZATION

This *Final Assessment Report* of the Washington State Patrol - Breath Test Program is issued by Lead Assessor Glen Johnson. As Lead Assessor, Mr. Johnson has reviewed the contents of this report and affirms that the report represents a true and accurate accounting of the findings of the ASCLD/LAB-*International* assessment team.

Lead Assessor C. Glen Johnson



Signature

November 3, 2014

Date

DISTRIBUTION LIST

Lt. Robert Sharpe, Impaired Driving Section Commander
Larry Hebert, Bureau Director
Erik Neilson, Standards and Accountability Manager
John K. Neuner, ASCLD/LAB Executive Director
Pamela L. Bordner, ASCLD/LAB Senior Accreditation Program Manager
Laurel J. Farrell, ASCLD/LAB Accreditation Program Manager-Calibration

PART 2 – CORRECTIVE ACTION REQUESTS

CORRECTIVE ACTION REQUEST (CAR) Number 1 of 7

Laboratory Name: Washington State Patrol- Breath Alcohol Measuring Instruments
 Laboratory Location: Seattle, WA
 Laboratory Contact Name: Erik Neilson
 Contact Number: 206-262-6113
 Summation Conference Date: October 10, 2014

FINDING

Clause No.:	5.2.6.1.2	Source:	2007 Supplemental-BAC	Level:	1
Requirement:	Calibration technicians (however named) performing duties under the supervision of a qualified laboratory employee shall meet the educational requirement(s) specified in the job description.				
Finding:	The two supervisors of the instrument calibration technicians do not meet the educational requirements of a qualified laboratory employee. Neither of the supervisors possess a baccalaureate or advanced degree in a natural science, toxicology, criminalistics, or a closely related field. These two individuals supervise ten of twelve calibration technicians who do not meet the educational requirements to issue a calibration certificate.				
Corrective Action Plan Due:	November 14, 2014				
Implementation of Corrective Action Due:	January 13, 2015				

CORRECTIVE ACTION

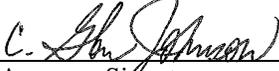
Summary of Laboratory Response:	An individual with a previous educational exemption has been assigned as the Technical Leader/Calibration Activities Supervisor. This new position has supervisory responsibility over all calibration and technical functions of the instrument calibration technicians. The two supervisors of the instrument calibration technicians will have administrative responsibilities only.
Supporting Documentation Provided by Laboratory:	The qualifications for the selected Technical Leader/Calibration Activities Supervisor have been reviewed and an educational waiver from 2009 was provided and is maintained as confirmation of qualifications for this analyst. The Operations Manual of the Breath Test Program was amended to include the job title and duties for the new Technical Leader/Calibration Activities Supervisor with total oversight of the technical functions within the measuring instruments calibration activities. The organization chart was also revised to reflect this new technical supervisor while maintaining the two administrative supervisors. The revisions were effective October 23, 2014. A single job description for the Breath Test Program supervisors was updated on October 28, 2014. The job description includes the general

	<p>administrative duties of all three supervisors with reference to the Operations manual for the duties of the Technical Leader/ Calibrations Activities Supervisor.</p> <p>The laboratory is now in compliance with the requirement.</p>
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ACCEPTANCE

Revisit required to verify effective implementation prior to surveillance:

No Yes



Assessor Signature

October 28, 2014

Date Accepted

CORRECTIVE ACTION REQUEST (CAR) Number 2 of 7

Laboratory Name: Washington State Patrol- Breath Alcohol Measuring Instruments
 Laboratory Location: Seattle, WA
 Laboratory Contact Name: Erik Neilson
 Contact Number: 206-262-6113
 Summation Conference Date: October 10, 2014

FINDING

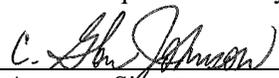
Clause No.:	4.13.2.6	Source:	2007 Supplemental-BAC	Level:	1
Requirement:	The laboratory's unique calibration record identifier and the analyst's handwritten initials (or secure electronic equivalent of initials or signature) shall be on each page of the calibration documentation in the record.				
Finding:	The analyst's handwritten initials or secure electronic equivalent of initials or signature are not on each page of the calibration documentation in all measuring instruments calibration records.				
Corrective Action Plan Due:	November 14, 2014				
Implementation of Corrective Action Due:	January 13, 2015				

CORRECTIVE ACTION

Summary of Laboratory Response:	The Technical Manual was revised to require the analyst (technician reviewing and issuing certificate) to print and initial and date each page of the calibration documentation. These initialed measuring instrument calibration records will then be electronically scanned and maintained as the original records after the quality of the electronic record has been confirmed.
Supporting Documentation Provided by Laboratory:	The Technical Manual revisions were reviewed and now indicate the requirement for the analyst (technician reviewing and issuing certificate) to initial and date each page of the calibration documentation prior to electronically scanning these measuring instrument calibration records which are maintained as the original records. These revisions were effective on October 28, 2014. A sample record set of the initialed measuring instrument calibration records were also reviewed and demonstrate compliance with the revised procedure.

ACCEPTANCE

Revisit required to verify effective implementation prior to surveillance: No Yes


 Assessor Signature

November 3, 2014
 Date Accepted

CORRECTIVE ACTION REQUEST (CAR) Number 3 of 7

Laboratory Name: Washington State Patrol- Breath Alcohol Measuring Instruments
 Laboratory Location: Seattle, WA
 Laboratory Contact Name: Erik Neilson
 Contact Number: 206-262-6113
 Summation Conference Date: October 10, 2014

FINDING

Clause No.:	5.6.2.1.1	Source:	ISO/IEC 17025:2005	Level:	1
Requirement:	For calibration laboratories, the programme for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) (<i>Système international d'unités</i>).				
Finding:	The vendor for the external calibration of the Reference Barometers is appropriately accredited by a recognized accrediting body. However, the measuring instruments laboratory did not purchase an accredited calibration from this vendor and instead received the standard calibration as indicated on the calibration certificate.				
Corrective Action Plan Due:	November 14, 2014				
Implementation of Corrective Action Due:	January 13, 2015				

CORRECTIVE ACTION

Summary of Laboratory Response:	The Reference Barometer was shipped to the vendor for a calibration which meets the requirements of an accredited calibration service. This service will ensure that the calibrations and measurements made by the laboratory are traceable to the International System of Units (SI). It was shipped on October 16, 2014, and is expected to be returned within two weeks.
Supporting Documentation Provided by Laboratory:	A sample of the calibration certificate from the vendor was provided for review. This sample certificate clearly indicates that the vendor is accredited to ISO/IEC 17025:2005 by a recognized accrediting body with a scope of accreditation that includes this calibration service. The laboratory is now in compliance with the requirement.

ACCEPTANCE

Revisit required to verify effective implementation prior to surveillance: No Yes


 Assessor Signature

October 24, 2014
 Date Accepted

CORRECTIVE ACTION REQUEST (CAR) Number 4 of 7

Laboratory Name: Washington State Patrol- Breath Alcohol Measuring Instruments
 Laboratory Location: Seattle, WA
 Laboratory Contact Name: Erik Neilson
 Contact Number: 206-262-6113
 Summation Conference Date: October 10, 2014

FINDING

Clause No.:	5.4.1	Source:	ISO/IEC 17025:2005	Level:	1
Requirement:	The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope.				
Finding:	The calibration method did not include the replacement of the infrared lamp (IR source) as a component which required a calibration of the instrument prior to it being placed back into the field for evidentiary use.				
Corrective Action Plan Due:	November 14, 2014				
Implementation of Corrective Action Due:	January 13, 2015				

CORRECTIVE ACTION

Summary of Laboratory Response:	The manufacturer of the DataMaster breath test instruments has been contacted requesting an opinion on the need to recalibrate following IR lamp replacement. A senior engineer has responded and states that while there is no effect on alcohol measurement there may be some differences in the response to interfering substances, specifically acetone, and says that it is prudent to recalibrate. IR lamp replacement has been added to the list of component replacements that must be followed by recalibration in the Technical Manual. This finding is being treated as a nonconformance and is being reported to ASCLD/LAB. A review of the instrument work that initiated this finding has been conducted including the field breath tests performed between the time the lamp was replaced and calibration eight months later. We are also identifying all instruments that have had an IR lamp replaced in the past five years and a similar review will be conducted. Prosecutors will be contacted explaining the issue.
Supporting Documentation Provided by Laboratory:	The Technical Manual was revised to now include the infrared lamp (IR Source) to the list of components which require an instrument calibration prior to being placed back in the field for evidentiary use. A review of the "Notice of Nonconformance", dated October 20, 2014, was conducted. The notice indicated an investigation was conducted of the prior evidentiary use of all instruments having replacement infrared lamps and returned to service without a calibration for the past five years. The investigation concluded that there were five instruments with a total of 166 completed evidentiary breath tests conducted during the period of a lamp

	replacement until the next calibration. The calibration technicians assigned to these affected instruments were asked to contact the appropriate prosecutors and to report back to the supervisors when this had been completed. A laboratory record, reviewed on October 28, 2014, indicates that all the appropriate prosecutors had been notified and were provided with complete information on all potentially affected evidentiary tests. The laboratory is now in compliance with the requirement.
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ACCEPTANCE

Revisit required to verify effective implementation prior to surveillance:

No

Yes



Assessor Signature

October 28, 2014

Date Accepted

CORRECTIVE ACTION REQUEST (CAR) Number 5 of 7

Laboratory Name: Washington State Patrol- Breath Alcohol Measuring Instruments
 Laboratory Location: Seattle, WA
 Laboratory Contact Name: Erik Neilson
 Contact Number: 206-262-6113
 Summation Conference Date: October 10, 2014

FINDING

Clause No.:	5.10.2 (c)	Source:	ISO/IEC 17025:2005	Level:	2
Requirement:	Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so: c) unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate;				
Finding:	Amended measuring instrument calibration certificates contain additional information with regards to the purpose of amendment. However, this procedure now extends certificate length from the original one page certificate to two pages, and the unique identification of the calibration certificate is not included on the second page.				
Corrective Action Plan Due:	November 14, 2014				
Implementation of Corrective Action Due:	Prior to submission of the next Performance Declaration or the next on-site visit, whichever is scheduled to occur first.				

CORRECTIVE ACTION

Summary of Laboratory Response:	The amended certificate document has been modified to include the unique identification information on subsequent pages when the form length exceeds one page. The effective date of the revision was October 13, 2014.
Supporting Documentation Provided by Laboratory:	A sample form template for the amended certificate document was reviewed. If the information exceeds more than one page, the identifying data, including the unique identification, are now included on each page of the report. The laboratory is now in compliance with the requirements.

ACCEPTANCE

Revisit required to verify effective implementation prior to surveillance: No Yes

C. John Johnson
 Assessor Signature

October 24, 2014
 Date Accepted

CORRECTIVE ACTION REQUEST (CAR) Number 6 of 7

Laboratory Name: Washington State Patrol- Breath Alcohol Measuring Instruments
 Laboratory Location: Seattle, WA
 Laboratory Contact Name: Erik Neilson
 Contact Number: 206-262-6113
 Summation Conference Date: October 10, 2014

FINDING

Clause No.:	4.1.5 (h)	Source:	ISO/IEC 17025:2005	Level:	1
Requirement:	The laboratory shall: h) have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;				
Finding:	The measuring instruments laboratory has not clearly identified a technical manager with overall responsibility for the technical operations to ensure the required quality of laboratory operations.				
Corrective Action Plan Due:	November 14, 2014				
Implementation of Corrective Action Due:	January 13, 2015				

CORRECTIVE ACTION

Summary of Laboratory Response:	Language defining the role of a technical leader for the Breath Test Program has been added to the Operations Manual effective October 23, 2014. A technical leader has been appointed.
Supporting Documentation Provided by Laboratory:	The revised Operations Manual was reviewed. The duties and responsibilities of the new Technical Leader/Calibration Activities Supervisor have been clearly detailed in the procedures. Also the new position has been added to a revised Breath Test Program organizational chart. The laboratory is now in compliance with the requirements.

ACCEPTANCE

Revisit required to verify effective implementation prior to surveillance: No Yes


 Assessor Signature

October 24, 2014
 Date Accepted

CORRECTIVE ACTION REQUEST (CAR) Number 7 of 7

Laboratory Name: Washington State Patrol- Breath Alcohol Measuring Instruments
 Laboratory Location: Seattle, WA
 Laboratory Contact Name: Erik Neilson
 Contact Number: 206-262-6113
 Summation Conference Date: October 10, 2014

FINDING

Clause No.:	4.14.1	Source:	ISO/IEC 17025:2005	Level:	1
Requirement:	The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this International Standard. The internal audit programme shall address all elements of the management system, including the testing and/or calibration activities.				
Finding:	Although annual internal audits of the measuring instruments laboratory are being conducted, not all of the elements of the management system, including all the accreditation requirements and this International Standard, are being included in the internal audits. Examples of some, but not all, of the elements not included or records not maintained in the most recent 2014 internal audit: Management Requirements (organization, management system, document control, review of requests, tenders and contracts, purchasing services and supplies, service to the customer, complaints, control of nonconforming calibration work, improvement, corrective action, and management reviews).				
Corrective Action Plan Due:	November 14, 2014				
Implementation of Corrective Action Due:	January 13, 2015				

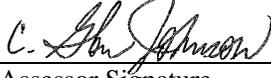
CORRECTIVE ACTION

Summary of Laboratory Response:	The Standards & Accountability Section, which has quality oversight of the Breath Test Program and conducts its internal audits, has elected to use the ASCLD/LAB - <i>International</i> Breath Alcohol 2007 Field Assessment Guide in addition to management system requirements in documenting all future internal quality audits.
Supporting Documentation Provided by Laboratory:	Use of the ASCLD/LAB- <i>International</i> Breath Alcohol 2007 Field Assessment Guide along with management system requirements will ensure all elements of the requirements for calibration activities are included in the internal audits. The laboratory is now in compliance with the requirement.

ACCEPTANCE

Revisit required to verify effective implementation prior to surveillance:

No Yes



Assessor Signature

October 24, 2014

Date Accepted