

ASCLD/LAB-*International's* Forensic Science Breath Alcohol Calibration Program

ASCLD/LAB-*International* offers accreditation to forensic science breath alcohol calibration programs that provide services in the categories of breath alcohol instrument calibration and breath alcohol calibration reference materials.

To assist a laboratory in determining if the work that they perform is applicable to this accreditation program it is helpful to start with the definition of calibration.

- The *International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM)* defines calibration as: the operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication.¹

To simplify, calibration:

- Uses traceable standards or reference materials
- Follows a specified procedure
- Determines if the performance of the item being calibrated meets the required specifications

Importantly, calibration is **not** adjustment or verification of calibration.

- VIM - Adjustment is a set of operations carried out on a measuring system so that it provides prescribed indications corresponding to given values of the quantity to be measured.¹
 - The process performed to “fix” the calibration item if it did not meet the required specifications.
- VIM - Verification is the provision of objective evidence that a given item fulfils specified requirements.¹
 - The “check” performed to ensure the item still meets the required specifications.

Verification of calibration can also be called a calibration check, or an accuracy check.

A calibration laboratory is **not** required to perform adjustments or verifications of calibrations.

There are other sections of ISO/IEC 17025:2005 that are important to be aware of. Section 5.4.2 states that “the laboratory shall use calibration methods which meet the needs of the customer and which are appropriate for the calibrations it undertakes.” Section 5.4.6.1 requires that “a calibration laboratory shall have and shall apply a procedure for estimating the uncertainty of measurement for all calibrations...”. Measurement traceability is a required aspect of a calibration method. Section 5.6.2.1.1 states that “a calibration laboratory establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary realizations of the SI units of measurement” and again speaks of traceability in Section 5.6.3.2 saying that “reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials.”

In addition to the definition of calibration, ASCLD/LAB-*International* specifies that the calibration program must be an organizational unit of a crime laboratory or the calibration operation must be a

¹ *International Vocabulary of Metrology – Basic and General Concepts and Associated Terms*, VIM, 3rd edition, JCGM 200:2008. Available at <http://www.bipm.org/en/publications/guides/vim.html>

laboratory (however named) with at least one analyst (however named) and the calibration program's customers must be conducting breath alcohol testing for criminal justice purposes.

Looking first at these terms and concepts and the category of breath alcohol measuring instruments -

Calibration is:

the procedure(s), using traceable reference standards and reference materials, which confirm the accuracy and precision of the breath alcohol measuring instrument across a range of ethanol values that meets the needs of the customer. The uncertainty of measurement for the calibration procedure(s) in use will have been calculated. A calibration certificate or report is prepared for each calibration. The calibration certificate or report must meet all applicable requirements.

A laboratory will qualify for participation in the program if they establish a calibration procedure that meets these criteria and if the calibrated breath alcohol instruments are used in evidential, quantitative breath alcohol tests where a sanction or a penalty is involved.

Note: a laboratory may additionally perform calibrations on measuring instruments that are not evidential, quantitative breath alcohol measuring instruments.

Adjustment is:

the process of altering the breath alcohol instrument when the instrument does not pass the accuracy and precision specifications. In some programs this may be called a "repair or maintenance activity" and may always be performed. NOTE: If a breath alcohol instrument is adjusted, it must then be calibrated. Calibration laboratories **are not** required to perform adjustments.

Verification is:

typically a subset of the calibration method involving a less rigorous procedure than the calibration method itself. It is common for a verification to be a single concentration of ethanol but it may include more than one ethanol concentration. The ethanol concentration(s) used in a verification procedure may be the same as those used in the calibration method or the ethanol concentration(s) may be different. The verification procedure may use the same medium, wet-bath simulator or dry gas, as used in the calibration method or the verification may use the alternative medium. Calibration laboratories **are not** required to perform verifications of calibration. Conversely, laboratories that only perform calibration verifications **do not** meet the definition of a calibration laboratory.

Looking next at the calibration category of breath alcohol reference materials –

Calibration is:

the procedure, using traceable reference materials, which establishes the concentration of ethanol in the breath alcohol reference material with a reported level of uncertainty. A calibration certificate or calibration label is prepared as the report of the calibration method. The calibration certificate or label must meet all applicable requirements.

A laboratory will qualify for participation in the program if they establish a calibration procedure that meets these criteria and if the laboratory supplies the certified reference material to customers who use it in evidential, quantitative breath alcohol tests where a sanction or a penalty is involved or in a calibration laboratory as previously defined in this document.

Note: a calibration laboratory may additionally supply the certified reference material to customers for uses that do not meet this requirement.

This category of calibration laboratory is less likely to use the processes of adjustment and verification.

The examples that follow are provided to illustrate the difference between calibration, adjustment and verification and are not intended for any other purpose.

1) A state has their breath testing instruments repaired and calibrated by the manufacturer. Each month, a member of the state breath program goes to the location of each instrument and analyzes a traceable ethanol solution using a wet-bath simulator. They have established an acceptable range for the result. They issue a report of this analysis and it is titled Calibration Check. If the instrument reading is within the acceptable range, the instrument remains in service. If the instrument reading is not within the acceptable range, the instrument is removed from service and sent back to the manufacturer for repair and calibration.

- This is a verification of calibration by the state and currently does not fit within the scope of the accreditation program.

2) A county agency is responsible for the 12 breath alcohol testing instruments in the county. Annually each instrument comes into the laboratory for maintenance. The county agency issues a certificate annually indicating that the instrument is capable of performing as required. The first step in the annual maintenance procedure is named “autocal” by the agency. A simulator containing a dilute ethanol reference material having a vapor concentration of 0.081g/210L is analyzed with the reference value being entered into the breath testing instrument at the required time in the automated procedure. The maintenance procedure continues with the analysis of dilute ethanol reference materials at 6 different concentrations each analyzed 10 times.

- The automated procedure “autocal” is actually an adjustment. In this county breath testing program, the laboratory chose to make an adjustment without first putting the breath testing measuring instrument through the calibration method.
- The analysis of the multiple levels of ethanol reference materials which provides both accuracy and precision performance data to determine if the breath alcohol testing instrument is capable of performing as required is the calibration method.
- This county laboratory is eligible for application to the accreditation program.

3) A county laboratory provides alcohol reference solutions to law enforcement agencies within their county. They do issue certificates with these solutions which provide the ethanol concentration. The solutions are used by staff administering quantitative preliminary breath tests which are not considered evidential.

- The laboratory is manufacturing breath alcohol reference materials but does not currently fit within the scope of the accreditation program because no customer of the laboratory uses the reference material for evidential, quantitative breath alcohol tests where a sanction or penalty is involved.
- If the results of the quantitative preliminary breath test were considered evidential, then the laboratory would be eligible for application to the accreditation program.

4) A state agency is responsible for the breath testing program within the state. This includes the training of instrument operators, the recertification of those operators, the promulgation of regulations on the breath testing sequence used in the state, and the repair and maintenance of over 200 breath alcohol testing instruments located in city, county, and state law enforcement agencies. The repair and maintenance program includes a procedure that evaluates the accuracy and precision of the instrument at 8 ethanol concentrations using dry gas reference material. This procedure is performed biannually – once in the laboratory and once at the instrument location. This evaluation has set criteria within which it must

perform or additional repairs will be required. A member of the lab staff also travels to the instrument locations monthly and analyzes three ethanol concentrations on each instrument one time each using wet-bath simulators. The same laboratory staff performs all of these functions. The agency issues certificates for each instrument operator after initial training as well as after each recertification, they issue certificates for the biannual evaluations in the lab and in the field as well as the monthly checks. They want to have their program accredited.

- The ASCLD/LAB-*International* accreditation program only addresses the calibration activity. The training and re-training of instrument operators is part of the state breath alcohol program and is outside the scope of the calibration accreditation program.
- The procedure the state agency has implemented to evaluate the accuracy and precision of the instrument is the calibration method. Per ISO/IEC 17025:2005 they would be required to estimate the uncertainty of this method.
- They perform the same calibration method both in the lab and in the field – the difference in locations does not matter, both are calibrations and they are correct to issue calibration certificates each time.
- The monthly analysis in the field using wet-bath simulators is a verification of the calibration. Even though they analyze three different ethanol levels, each one time, this procedure is a subset (less rigorous) than the calibration method they have determined is required to certify that the instrument is meeting their specifications. This monthly procedure is a quality control component that the state agency has decided to incorporate into their state breath testing program. The state agency certainly can issue a document at the completion of this procedure but needs to be thoughtful in the title of the document. Using the word “certificate” may be confusing to their customers.

5) A state agency toxicology laboratory is responsible for preparing an ethanol reference solution that is used by all law enforcement agencies in the breath tests given to subjects arrested for DUI. The toxicology laboratory bottles this reference material and labels the bottle providing the concentration of the material and the uncertainty in the value. The toxicology laboratory also provides this solution to the breath testing program located in the same state agency that performs the calibration of the breath alcohol measuring instruments used throughout the state. The breath testing program purchases certified ethanol reference material traceable to NIST and prepares dilute reference materials at vapor levels of 0.02%, 0.08%, 0.15%, 0.25% and 0.40% for use in their calibration method. The breath testing program has calculated an estimation of the uncertainty of measurement for this calibration method and issues a report of this calibration. After completing the calibration method and before returning the breath alcohol measuring instrument to field use, the breath program analyzes the reference material prepared by the toxicology laboratory. The calibration report for the instrument provides all analytical data from the instrument. The toxicology and breath testing programs are directed by two different people.

- Both programs fall within the scope of the accreditation program:
 - The customers of the toxicology laboratory, all state law enforcement agencies, are using the solution for evidential, quantitative breath alcohol tests.
 - The breath testing program calibration method is appropriate – multi-level, covering ethanol concentrations that meets the needs of their customers. The levels chosen are important statutorily and likely to be encountered in DUI subjects.
 - Both programs have calculated an estimation of uncertainty for their calibration methods.
 - The calibration report, the reference material label and all calibration records will be evaluated during the assessment to ensure that all accreditation requirements are covered.
- The use by the breath testing program of the reference material prepared by the toxicology laboratory prior to returning a breath alcohol measuring instrument to field use is a verification of calibration. This step in their protocol is outside the scope of the accreditation program.

- Because the two programs are directed by different people, each program will be required to submit an application for accreditation.

6) The city police crime laboratory is responsible for the 20 breath alcohol measuring instruments used at sub-stations throughout the city. The laboratory personnel perform no repairs to the breath alcohol measuring instruments. They send all instruments to the manufacturer for repair. The instruments return to the laboratory with a certificate of calibration. The city laboratory staff has decided that even though the manufacturer provides this certificate, they will put all instruments through their own calibration method prior to returning them to the field. In their calibration method they evaluate the performance of the breath alcohol instrument at 6 concentrations of ethanol and analyze each level ten times. The laboratory has chosen to use four levels of ethanol that are statute related. The levels include the concentrations for juvenile offenders, for both driving while ability impaired and driving under the influence and also the higher ethanol level that mandates enhanced sentencing. The last two ethanol levels included by the laboratory are higher in ethanol concentration to reflect impaired drivers in their city.

- A calibration laboratory is not required to perform repairs, adjustments or verifications.
- This laboratory meets the criteria for the program if along with this appropriate calibration method, they establish the uncertainty of the calibration procedure and prepare a calibration certificate or report for each calibration that meets all accreditation requirements.