# ASCLD/LAB-*International*

# ASCLD/LAB Policy on Measurement Uncertainty

ASCLD/LAB-*International* is a program of the
American Society of Crime Laboratory Directors / Laboratory Accreditation Board
ASCLD/LAB



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**This document replaces AL-PD-3051**



**NOTE** Guidance documents are available from ASCLD/LAB to assist customers with better understanding and implementing ASCLD/LAB policies. While customers are encouraged to review and consider information from the guidance documents, guidance documents issued by ASCLD/LAB do not contain or create any additional accreditation requirements. Currently, the companion guidance documents for this policy are:

- AL-PD-3061 *ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty - Overview*
- AL-PD-3062 *ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty – ANNEX A - Details on the NIST 8-Step Process*
- AL-PD-3063 *ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty – ANNEX B - Drug Chemistry Discipline*
- AL-PD-3064 *ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty – ANNEX C - Firearms/Toolmarks Discipline*
- AL-PD-3065 *ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty – ANNEX D - Toxicology Discipline - Testing (Example – Concentration of Ethanol in an Ante-Mortem Blood Specimen)*

The following companion guidance document is under development:

- *ANNEX E – Toxicology Discipline - Calibration (Breath Alcohol)*

## Document History / AL-PD-3060

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| October 4, 2012 | Draft | Initial review and adoption by the ASCLD/LAB Board of Directors | ASCLD/LAB Board of Directors | N/A |
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## 1 Purpose

Estimation of measurement uncertainty[1] is an element of measurement traceability,[2] a requirement for ISO/IEC 17025:2005[3] accreditation and an important tenet of the laboratory's management system.[4] The purpose of this document is to state how ASCLD/LAB will interpret, apply and assess estimation of measurement uncertainty requirements from ISO/IEC 17025:2005.

## 2 Scope and Concept

This policy is intended for laboratories that are accredited or that are seeking accreditation under either the ASCLD/LAB-*International* Testing or Calibration Program, and that provide quantitative (i.e., numerical) measurement results to customers.

This policy is not intended to apply to situations where test results are not numerical (e.g., pass/fail, positive/negative, or other qualitative examinations).

It is ASCLD/LAB's intention to conform to the principles set forth in the Guide to the Expression of Uncertainty in Measurement (GUM),[5] including applicable GUM supplements. The GUM, internationally recognized and widely accepted, describes standardized methods for evaluating, estimating and expressing measurement uncertainty.



## 3 General Requirements

The general requirements in ISO/IEC 17025:2005 for the estimation of uncertainty of measurement are:

> *5.4.6.1 A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.*
>
> *5.4.6.2 Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.*
>
> *5.4.6.3 When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.*

Based on these general requirements:

3.1 ASCLD/LAB applicant and accredited laboratories shall have and shall apply a procedure to estimate the uncertainty of measurement when values are reported for: 1) the quantity (weight or volume) of controlled substance evidence or the quantity of a controlled substance when reported as a weight or volume fraction (purity) of the whole; 2) the concentration (weight or volume fraction) of a drug in a toxicology sample, including values reported for blood alcohol; 3) the barrel

length of a firearm and/or the overall length of a firearm; and 4) the calibration of breath alcohol measuring instruments and calibration of breath alcohol reference materials.

Additionally, a testing laboratory shall estimate the measurement uncertainty for a measurement other than those listed above when required to meet the needs of a customer.

3.1.1 The procedure for estimation of measurement uncertainty shall include the process of rounding the expanded uncertainty.

3.1.2 The coverage probability[6] of the expanded uncertainty shall be a minimum of 95.45 % (often referred to as approximately 95 %).

## 4 Record Requirements

Laboratory records will be assessed by ASCLD/LAB as a part of determining conformance with Clauses 5.4.6.1, 5.4.6.2 and 5.4.6.3 of ISO/IEC 17025:2005 (cited above) and the provisions of this policy.

Based on these requirements:

4.1 ASCLD/LAB-*International* applicant and accredited testing and calibration laboratories shall record the following elements for each estimation of measurement uncertainty:

(a) Statement defining the measurand,[7]
(b) Statement of how traceability is established for the measurement,
(c) The equipment (e.g., measuring device[s] or instrument[s]) used,
(d) All uncertainty components considered,
(e) All uncertainty components of significance[8] and how they were evaluated,
(f ) Data used to estimate repeatability and/or reproducibility,
(g) All calculations performed,
(h) The combined standard uncertainty, the coverage factor,[9] the coverage probability and the resulting expanded uncertainty,
(i ) The schedule to review and/or recalculate the measurement uncertainty.

4.2 All of these records may be assembled in any format chosen by the laboratory and the records may be maintained in one or more locations.

## 5 Reporting Requirements

The applicable requirements in ISO/IEC 17025:2005 regarding reporting estimated measurement uncertainty are:

> *5.10.3.1 … test reports shall, where necessary for the interpretation of the test results, include the following:*
>
> *c) where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the uncertainty affects compliance to a specification limit;*

*5.10.4.1 … calibration certificates shall include the following, where necessary for the interpretation of calibration results:*

*b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof;*

## 5.1 Reporting for testing laboratories:

Clause 5.10.1 of ISO/IEC 17025:2005 requires that a test report be accurate, clear, unambiguous and objective. Further Clause 5.10.3.1 (c) of ISO/IEC 17025:2005 addresses the situations when uncertainty of measurement is required to be reported.

Based on these requirements:

5.1.1 For all required estimations of measurement uncertainty (See Section 3.1 of this policy), the laboratory shall have a policy and procedure to implement Clause 5.10.3.1 (c) of ISO/IEC 17025:2005 for that test result.

At a minimum, the laboratory shall report the estimated uncertainty when it impacts evaluation of a specification limit stated by a regulatory body, a statute, case law or other legal requirement. A legal requirement is created, imposed and enforced by a third party external to the laboratory agency.

5.1.2 When measurement uncertainty is reported, the value shall be reported in the test report or in an attachment to the report, and shall be expressed as an expanded uncertainty and include the coverage probability.

This measurement result shall include the measured quantity value, $y$, along with the associated expanded uncertainty, $U$, and this measurement result shall be reported as $y \pm U$ where $U$ is consistent with the units of $y$.

NOTE 1 For asymmetrical uncertainties, it may be inappropriate to quote a single result for the uncertainty and presentations other than $y \pm U$ may be needed.

NOTE 2 When the measurement is expressed as a fraction, the uncertainty may be reported as a fraction.

5.1.3 If a regulatory body, statute, case law or other legal requirement specifies the format for the reporting of a test result, which causes a conflict with this measurement uncertainty policy, then the laboratory shall report the test result in the specified format.

5.1.3.1 The laboratory shall have objective evidence of the regulation, statute, case law or other legal requirement readily available for review during an ASCLD/LAB assessment.

5.1.3.2 When specifically prohibited from including measurement uncertainty in the test report, the laboratory shall have a policy and procedure for applying the estimated uncertainty at the laboratory's established level of confidence prior to reporting the test result.

5.1.3.3 The existence of such a regulation, statute, case law or other legal requirement to limit the testing laboratory's reporting of measurement uncertainty does not excuse the laboratory from estimating the measurement uncertainty of the test method in accordance with all provisions of this policy.

5.2 Reporting for calibration laboratories:

Clause 5.10.1 of ISO/IEC 17025:2005 requires that a calibration report be accurate, clear, unambiguous and objective. Further Clause 5.10.4.1 (b) of ISO/IEC 17025:2005 addresses reporting requirements for uncertainty of measurement on calibration certificates.

Based on these requirements:

5.2.1 The estimated measurement uncertainty shall be reported in the calibration certificate, report, label, or in an attachment to the report (however named), and shall be expressed as an expanded uncertainty and include the coverage factor and the coverage probability.

5.2.1.1 This measurement result shall include the measured quantity value, *y*, along with the associated expanded uncertainty, *U*, and this measurement result shall be reported as $y \pm U$ and be consistent with the units of *y*.

NOTE For asymmetrical uncertainties, it may inappropriate to quote a single result for the uncertainty and presentations other than $y \pm U$ may be needed.

5.3 Reporting for both testing and calibration laboratories:

5.3.1 The rounded expanded uncertainty shall be reported to at most two significant digits, unless the laboratory has a documented rationale for reporting additional significant digits.

NOTE It is rarely, if ever, necessary to report the rounded expanded uncertainty to more than two significant digits.

5.3.2 The specific measuring device or instrument used for a reported test or calibration result must have been evaluated in the estimation of measurement uncertainty for that test or calibration method.

5.3.3 The measurement result and the rounded expanded uncertainty shall be reported to the same level of significance.

NOTE Reducing or simplifying a fraction is not a change in level of significance.



NOTES – All links last confirmed on April 30, 2013

[1] VIM Definition – 2.26 measurement uncertainty: non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

JCGM, *International vocabulary of metrology – Basic and general concepts and associated terms* (VIM), 3rd ed. (Sèvres, France: BIPM-JCGM 200, 2012) (2008 version with minor corrections). Available for download at http://www.bipm.org/en/publications/guides/vim.html.

[2] "Measurement traceability" refers to "metrological traceability."

VIM Definition - 2.41 metrological traceability: property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty

Source: Joint Committee for Guides in Metrology (JCGM), *International vocabulary of metrology – Basic and general concepts and associated terms* (VIM), 3rd ed. (Sèvres, France: International Bureau of Weights and Measures [BIPM]-JCGM 200, 2012) (2008 with minor corrections).

[3] International Organization for Standardization (ISO), *ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories* (Geneva, Switzerland: ISO, 2005). Available for purchase at http://www.iso.org/iso/home/store/catalogue_ics.htm or from other authorized distributors.

Additional information about ISO is available at http://www.iso.org/iso/home.html

[4] ISO, *ISO/IEC 17025:2005 – Clause 1.4 – Note 1: "The term 'management system' in this International Standard means the quality, administrative and technical systems of a laboratory."*

[5] Joint Committee for Guides in Metrology (JCGM), *Evaluation of measurement data – Guide to the expression of uncertainty in measurement* (GUM) (GUM 1995 with minor corrections). (Sèvres, France: International Bureau of Weights and Measures [BIPM]-JCGM 100], September 2008). Available at http://www.bipm.org/en/publications/guides/gum.html.

Even though the electronic version of the 2008 edition of the GUM is available free of charge on the BIPM's website, copyright of that document is shared jointly by the JCGM member organizations (BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP and OIML).

[6] VIM Definition – 2.37 coverage probability: probability that the set of true quantity values of a measurand is contained within a specified coverage interval

Note 1 This definition pertains to the Uncertainty Approach as presented in the GUM.
Note 2 The coverage probability is also termed "level of confidence" in the GUM.

Source: Joint Committee for Guides in Metrology (JCGM), *International vocabulary of metrology – Basic and general concepts and associated terms* (VIM), 3rd ed. (Sèvres, France: International Bureau of Weights and Measures [BIPM]-JCGM 200, 2012) (2008 with minor corrections).

[7] VIM Definition – 2.3 measurand: quantity intended to be measured

Source: Joint Committee for Guides in Metrology (JCGM), *International vocabulary of metrology – Basic and general concepts and associated terms* (VIM), 3rd ed. (Sèvres, France: International Bureau of Weights and Measures [BIPM]-JCGM 200, 2012) (2008 with minor corrections).

[8] NIST, *NIST Policy on Traceability – Supplementary Materials for NIST Policy Review: I Frequently Asked Questions: I.B Questions about Establishing Metrological Traceability*:

I.B.5 - As a practical matter, the contribution of an input quantity to a measurement result is ***significant*** if a change in the value or uncertainty of the input quantity corresponds to a change in the significant figures of the stated value or uncertainty of the measurement result.

Available at: http://www.nist.gov/traceability/suppl_matls_for_nist_policy_rev.cfm

[9] VIM Definition – 2.38 coverage factor: number larger than one by which a combined standard measurement uncertainty is multiplied to obtain an expanded measurement uncertainty

Note A coverage factor is usually symbolized *k* (see also GUM:1995, 2.3.6).

Source: Joint Committee for Guides in Metrology (JCGM), *International vocabulary of metrology – Basic and general concepts and associated terms* (VIM), 3rd ed. (Sèvres, France: International Bureau of Weights and Measures [BIPM]-JCGM 200, 2012) (2008 with minor corrections).