

# EXHIBIT C



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## ESTIMATING UNCERTAINTY of MEASUREMENT POLICY

Updated March 2007  
December 2008 established as full conformance date

The application of ISO/IEC 17025 estimated uncertainty of measurement requirements in forensic science testing laboratories continues to develop. The ASCLD/LAB Board of Directors has determined that a continued period of transition is needed prior to expecting or achieving full conformance in forensic science testing laboratories. To allow for this transition period, the ASCLD/LAB Board of Directors has adopted the following policy for estimating uncertainty of measurement and will phase in full conformance between now and December 31, 2008.

### Introduction

The ASCLD/LAB-*International* accreditation program currently accredits forensic science laboratories to the ISO/IEC 17025:2005 and the 2006 ASCLD/LAB-*International* Supplemental Requirements. The requirements for estimating uncertainty of measurement appear in **Section 5.4.6** of the ISO/IEC 17025 accreditation document:

***Clause 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.***

NOTE 1 The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:

- the requirements of the test method;
- the requirements of the customer;
- the existence of narrow limits on which decisions on conformity to a specification are based.

NOTE 2 In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions.

The important concepts in this clause include:

- The uncertainty of measurement is based on an estimate.
- In many cases, forensic laboratories need not concern itself with rigorous, metrologically and statistically valid calculations of uncertainty.
- The laboratory shall attempt to identify all components of uncertainty.
- The laboratory shall ensure that reported measurements do not give the wrong impression of uncertainty.

- The estimate of uncertainty must be based on those parameters which will significantly impact the reported value.
- The estimate of uncertainty must have an empirical basis.

Uncertainty of measurement is defined by the *International Vocabulary of Basic and General Terms in Metrology*:

***“A parameter associated with the result of a measurement that characterizes the dispersion of values that could reasonably be attributed to the measurand.”***

At this time, the ASCLD/LAB requirement for estimating uncertainty of measurement applies only to a numerical value in quantitative analysis which appears in a test report.

Qualitative tests (identifications) do not currently require estimates of uncertainty.

Examples of when uncertainty of measurement is not applicable include but are not limited to:

- identifying a drug in a controlled substance analysis;
- identifying a latent fingerprint as originating from a specific person;
- identifying a document as originating from a specific person as the writer.

### **Estimating the Uncertainty of Measurement**

ASCLD/LAB does not prescribe a specific formula for estimating uncertainty of measurement.

Laboratories should consider available references and consult with their own statistician or metrology expert to determine the most applicable method for developing an estimation of uncertainty of measurement. Any generally accepted method may be used as long as the laboratory complies with the following section.

### **Complying with ASCLD/LAB-*International* Requirements**

To comply with ASCLD/LAB-*International* accreditation requirements, a laboratory shall include the following elements when estimating of uncertainty of measurement:

- Specify what is being measured.
- Specify the measurement method (what measuring device or instrument is used).
- Construct and document an appropriate measurement uncertainty budget, identifying and listing all potential sources of uncertainty. Consult with your own statistician or metrology expert when setting up the budget.
- Laboratories may then dismiss any potential sources which discipline experts within the laboratory know from previous experience do not impact the uncertainty of measurement to any significant degree.



- Gather sufficient measurement data. Consult with your own statistician or metrology expert to determine the most appropriate process for gathering data and to determine the amount and type of data to be gathered.

Alternatively, a laboratory may identify existing recent analytical data on replicate measurements which is available in the laboratory. Sources could include but is not limited to: method validation, QC, proficiency testing, replicate-testing data. Other sources of data may include calibration certificates or scientific literature.

- Estimate the uncertainty of the measurement method in accordance with an appropriate formula selected by your own statistician or metrology expert.
- Document the estimated uncertainty of the measurement method and have the result and supporting data available in the laboratory.
- Maintain or recalculate the estimated uncertainty of measurement as the need arises (i.e. when a significant change occurs in the budget). Consult with your own statistician or metrology expert to determine when this action is necessary.

### **Comments**

The purpose of specific tests and use of the test results should be considered when estimating uncertainty of measurement. Consideration must be given to the impact of the process on the laboratory's time and resources. However, good science and the needs of the customer(s) will be the determining factors in how many resources the laboratory uses in estimating the uncertainty.

Only those components under the control of the laboratory need to be considered when estimating the uncertainty of measurement.

### **Records**

Records must be maintained to describe the process used to develop the estimation of uncertainty. These records must include the elements of the budget, data gathered, calculations to arrive at the estimate, and the estimated uncertainty associated with the measurement method. The records must be available at the laboratory during on-site assessments and, when requested, made available to a customer.

### **Reporting**

Estimated uncertainty of measurement need not be reported unless specifically requested by the customer.

### **Policy Implementation**

**Immediate Compliance:** All laboratories assessed for ASCLD/LAB-*International* accreditation prior to December 31, 2008 must have available and produce objective evidence that a reasonable effort is being made to estimate uncertainty of measurement for all measurements that matter which are being reported.

**Effective January 1, 2009:** Laboratories assessed for ASCLD/LAB-*International* on and after January 1, 2008<sup>9</sup> must have available and produce objective evidence (in accordance with this policy) that estimated uncertainty has been determined for all measurements that matter which are being reported.

NOTE 1: The term “critical measurement” is purposefully avoided in this policy due to community disagreement on the meaning. The term “measurements that matter” is used instead. A “measurement that matters” is one that is used, or may reasonably be expected to be used, by an immediate or extended customer (anyone in the judicial process) to determine, prosecute or defend the type or level of criminal charge(s).

NOTE 2: Implementation is based upon the date of on-site assessment, not on the date of application for accreditation.



## ASCLD/LAB

# Updated Approach to Uncertainty of Measurement Requirements in the ASCLD/LAB-*International* Accreditation Program for Testing Laboratories

### Introduction

The current ASCLD/LAB estimated uncertainty of measurement policy requires all applicant and accredited laboratories in the ASCLD/LAB-*International* program to have completed estimating uncertainty of measurement for all reported “*measurements that matter*”<sup>1</sup> by December 31, 2008.

As ASCLD/LAB representatives continue to communicate with existing and potential customers, it is clear that the level of awareness and understanding of ISO/IEC 17025 estimated uncertainty of measurement requirements is not yet at a sufficient level in the U.S. crime laboratory community to continue with the December 31, 2008, full conformance date. Analysis by ASCLD/LAB management suggests that a revised policy, additional clarification and interpretation from ASCLD/LAB, and efforts to facilitate or support greater access to customer training will all be necessary to assist the crime laboratory community in appropriately implementing estimated uncertainty of measurement requirements.

Therefore, to facilitate a more meaningful transition to conformance with estimated uncertainty of measurement accreditation requirements, the ASCLD/LAB Board of Directors has authorized the following updated approach to estimated uncertainty of measurement requirements in the ASCLD/LAB-*International* accreditation program for testing laboratories.

### Scope

The following program and policy provisions apply only to the ASCLD/LAB-*International* accreditation program for testing laboratories.

Laboratories accredited or seeking accreditation in the ASCLD/LAB-*International* Breath Alcohol Calibration accreditation program shall be in compliance with all applicable ISO/IEC 17025:2005 and any applicable ASCLD/LAB estimated uncertainty of measurement and traceability requirements at the time of initial accreditation and consistently maintain on-going conformance once accredited.

There are no requirements for estimated uncertainty of measurement in the ASCLD/LAB Legacy accreditation program.

### Updated Approach

The previously published December 31, 2008 date for full conformance associated with the current ASCLD/LAB policy on estimating uncertainty of measurement is rescinded. All other elements of the

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<sup>1</sup> A “measurement that matters” is one that is used, or may reasonably be expected to be used, by an immediate or extended customer (anyone in the judicial process) to determine, prosecute or defend the type or level of criminal charge(s).

ASCLD/LAB uncertainty of measurement policy remain effective until or unless a revised policy is issued.

#### First Time Applicant Laboratories Assessed Between September 14, 2008 and December 31, 2008

Applicant laboratories assessed between September 14, 2008 and December 31, 2008 shall be expected to inform the assessment team of any documented progress made toward estimating uncertainty of measurement for measurements that matter which are reported.

A Level 1 corrective action request (CAR) from ASCLD/LAB shall be issued if the applicant laboratory cannot demonstrate some level<sup>2</sup> of documented effort toward addressing ISO/IEC 17025 and ASCLD/LAB estimated uncertainty of measurement requirements.

#### First Time Applicant Laboratories Assessed On or After January 1, 2009

Laboratories assessed on or after January 1, 2009 shall, as a minimum, provide a documented plan for coming into conformance with ISO/IEC 17025:2005 and ASCLD/LAB estimated uncertainty of measurement requirements for reported measurements that matter. The documented plan shall, at a minimum, contain the following elements:

- Identify the laboratory person(s) responsible for oversight or implementation of the plan.
- Identify the measurements that matter which are being reported by the laboratory.
- Summarize the laboratory's intended approach for estimating uncertainty of measurement.
- Provide a projected deadline for completion of the plan.<sup>3</sup>

A Level 1 CAR from ASCLD/LAB shall be issued if, as a minimum, the documented plan, adequately addressing all required elements, is not presented at or before the initial, on-site assessment.

#### Laboratories Granted Accreditation on or after September 14, 2008

ASCLD/LAB-*International* accredited laboratories are expected to continue efforts to come into conformance with ISO/IEC 17025:2005 and ASCLD/LAB estimated uncertainty of measurement requirements for reported measurements that matter. Progress shall be reported in each annual report to ASCLD/LAB and may be further assessed on-site at each surveillance visit. Accredited laboratories shall be able to demonstrate additional progress each year in completing and maintaining estimated uncertainty of measurement for measurements that matter which are reported. Annual, additional progress shall be expected until the laboratory has completed estimating uncertainty of measurement for all measurements

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<sup>2</sup> In this context, "some level" means any level more than total absence.

<sup>3</sup> When projecting a deadline for completion, keep in mind that once accreditation is granted ASCLD/LAB shall expect the laboratory to have completed estimating uncertainty of measurement for all reported measurements that matter by the third annual surveillance visit.



that matter which are reported. Appropriate maintenance of estimated uncertainties<sup>4</sup> shall also be expected.

A Level 1 corrective action request (CAR) shall be issued to any accredited laboratory which cannot demonstrate additional progress<sup>5</sup> and applicable maintenance during the first and second annual surveillance visits following initial accreditation.

ASCLD/LAB shall expect an accredited laboratory to have completed estimating uncertainty of measurement for all reported measurements that matter by the third annual surveillance visit. Appropriate maintenance is expected thereafter.

A Level 1 corrective action request (CAR) shall be issued to any accredited laboratory which cannot demonstrate completion by the third annual surveillance visit.

#### Laboratories Accredited Prior to September 14, 2008

Laboratories accredited in the ASCLD/LAB-*International* program prior to September 14, 2008 are expected to continue efforts to come into conformance with ISO/IEC 17025:2005 and ASCLD/LAB estimated uncertainty of measurement requirements for reported measurements that matter. Progress shall be reported in each annual report to ASCLD/LAB and may be further assessed on-site at each visit. Accredited laboratories shall be able to demonstrate additional progress each year in completing and maintaining estimated uncertainty of measurement for measurements that matter which are reported. Annual, additional progress shall be expected until the laboratory has completed estimating uncertainty of measurement for all measurements that matter which are reported. Appropriate maintenance of estimated uncertainties shall also be expected.

A Level 1 CAR shall be issued to any accredited laboratory which cannot demonstrate additional progress and applicable maintenance during the 2009, 2010 and 2011 surveillance visits, or during the first full assessment to renew accreditation if that occurs in one of these years.

ASCLD/LAB shall expect a laboratory accredited prior to September 14, 2008, to have completed estimating uncertainty of measurement by the third ASCLD/LAB visit occurring after September 14, 2008. The three visits could be a combination of surveillance visits and a full assessment visit to renew accreditation. Appropriate maintenance is expected thereafter.

A Level 1 CAR shall be issued to any accredited laboratory which cannot demonstrate completion by the third visit.

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<sup>4</sup> If a significant change occurs with the laboratory which impacts the estimated uncertainty, the estimated uncertainty may need to be recalculated. Significant changes in personnel, instrumentation, measuring method, or facilities could all potentially be a reason for recalculating estimated uncertainty of measurement.

<sup>5</sup> In this context, "additional progress" means more progress than that demonstrated during the last ASCLD/LAB visit.



## **ASCLD/LAB Customer Support**

To facilitate a better understanding of estimated uncertainty of measurement, and its proper application to important measurements being reported in forensic science, the ASCLD/LAB Board of Directors has authorized ASCLD/LAB management to proceed with the following measures of customer support:

### Creation of Technical Advisory Sub-Committee on Uncertainty of Measurement

ASCLD/LAB will identify a manageable number of subject matter experts to serve as technical advisors to ASCLD/LAB in the area of uncertainty of measurement. The primary objectives of the Technical Advisory Sub-Committee on Uncertainty of Measurement (TAC-UM) shall be to:

- update or develop ASCLD/LAB UM and measurement traceability policy or guidance documents;
- formulate and/or review curriculum for the training and focused retraining of Lead and Technical assessors;
- formulate and/or review curriculum for general customer-focused training;
- provide ASCLD/LAB with technical input and advice on matters related to UM and measurement traceability.

### Facilitate General “How-To” Training for Customers

ASCLD/LAB does not currently offer consultation to accredited or applicant laboratories, therefore ASCLD/LAB shall not provide direct “how-to” training to customers. However, ASCLD/LAB can and will take action to increase the accessibility and affordability of suitable UM and traceability training for our customers at-large. Beginning in the spring of 2009, ASCLD/LAB shall identify appropriate, subject matter instructors; identify and secure training locations around the U.S.; and coordinate registration and logistics for general knowledge UM and traceability courses. The training shall be offered on a fee basis, calculated to cover the cost of training facilities, training materials, and competent instructors. The intent and purpose of the training shall be to increase participants’ general knowledge of UM and traceability and compliance with general ISO/IEC 17025 requirements.

### Rescind “full implementation” Date of Current ASCLD/LAB UM Policy

As already covered, the previously published December 31, 2008 date for full conformance associated with the previous ASCLD/LAB policy on estimating uncertainty of measurement is rescinded. Eliminating this “one size fits all” deadline will allow ASCLD/LAB customers greater flexibility in first understanding and then meeting UM and traceability accreditation requirements.

## **Critical Measurements Other Than Those Reported**

Beyond measurements that matter which are reported, most forensic laboratories routinely make and record measurements during analysis that impact the accuracy of the reported test result, but the measurement(s) is not reflected in the report. For the purposes of this discussion, ASCLD/LAB shall refer to such measurements as “critical measurements made during analysis.”

While the initial focus of ASCLD/LAB is to facilitate and require accredited laboratories to meet uncertainty of measurement requirements for reported measurements that matter, accredited laboratories will eventually be expected and required to have estimated uncertainty of measurement for appropriate “critical” measurements made during analysis.

Once an accredited laboratory has fully met the requirements for estimated uncertainty of measurement for reported measurements that matter, the laboratory shall then be required to continue efforts to meet ISO/IEC 17025 uncertainty of measurement requirements for other “critical” measurements which could impact a reported result. Demonstrating full conformance with uncertainty of measurement requirements for other “critical” measurements shall be expected by the sixth ASCLD/LAB visit which occurs after September 14, 2008.