Guidance on Uncertainty for Testing Laboratories

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The purpose of this guidance document is to establish guidance on traceability and measurement uncertainty requirements for all testing laboratories accredited by ACLASS. Testing customers are required to demonstrate traceability and measurement uncertainty as defined within this document.

All laboratories assessed by ACLASS should and will be evaluated for measurement uncertainty appropriate to element 5.4.6 of ISO/IEC 17025, including all testing laboratories. While it is assumed that nearly all calibration laboratories will provide and display on their scopes of accreditation their CMCs (or best-case measurement uncertainties), it is often incorrectly assumed that testing laboratories will not need to provide measurement uncertainties. This guidance document will review relevant issues on this topic and will be updated as needed.

ACLASS wants first to acknowledge several related documents on this topic from a variety of sources including international regional co-operations and United States accreditation bodies. It is ACLASS' hope that practices, certainly in the United States, will be standardized as best as possible. We are committed to cooperating to this end and to revisions of this document as needed.

The main variability in requirements and practices for uncertainties regarding testing laboratories involves the amount of measurement precision that each test type provides. Thus, the first step for testing laboratories in the uncertainty arena involves placing each testing type into a key category based on precision and factors that may affect this precision.

ACLASS currently suggests five categories for ISO/IEC 17025 compliant uncertainty determinations for testing laboratories. We will review each of these categories and how they should be reviewed by ACLASS assessors.

The categories are as follows:

Category I – tests with qualitative measurements where no numerical measurements are made

Category II – tests with recognized methods that include defined uncertainty factors and ranges of results

Category III – tests with recognized methods, similar to metrology practice, often involving the same reference standards as calibration metrology

Category IV – tests with newly devised methods which require definition of the variability factors and their impact on results, and

Category V – "other" tests which simply require GUM determinations of the measurement variability. This last category is often the most frequently used by accredited testing laboratories

Those tests in Categories I and II typically would not require uncertainty budgets or significant review of uncertainty factors with the respective accredited laboratory. Those tests in Category III and V would require a review very similar to typical calibration laboratories. Those in Category IV would require even more review than the other categories to validate and verify the variability determinations affecting accuracy and precision of the tests. Those laboratories with testing in Categories III, IV, and V would therefore need a procedure drafted for calculating their uncertainties.

It might be noted that, while some testing laboratories may be calculating and utilizing uncertainty determinations, most of them will not be required or expected to report any uncertainties on test reports. In fact, the main reporting of uncertainties in test laboratory reports may actually be disguised. Laboratories that report an analytical result, often from a chemical or physical determination will report a value plus or minus a second value. This second number represents (but is not identified as) the test measurement uncertainty. The laboratory may only be required to demonstrate the capability to have uncertainties available to customers who specifically request such values from the laboratory.

Category I tests are typically qualitative tests that are pass/fail or go/no-go. They may be judgment calls with visual comparisons of patterns or colors or rough time exposures etc. Many ASTM methods are in this category, such as D-3359, A-247 and B-117. Similarly, many automotive and aerospace testing, many less-precise chemical methods, and even many microbial methods involve only qualitative identifications. It is not suggested that the laboratory can dismiss the responsibility to assess their uncertainty in this category. Rather the laboratory needs to identify all components of uncertainty, make a reasonable estimation and report the results in such a way that does not give a wrong impression of the uncertainty, where possible.

Category II tests are often represented as slightly more precise versions of the qualitative tests in the first category.[1] Several ASTM and automotive methods, including viscosity, gloss and haze, compression, tension and hardness testing of materials (not to be confused with calibrating hardness testers) are in this category. Here more measuring or analyzing devices may be used than in Category I tests. The laboratory is considered compliant to the uncertainty requirements and considerations as long as they follow the relevant official methods and formats in their reports.

Category III tests as described in this revision of the ACLASS guidance, represent a very narrowgroup. This set is restricted to those tests which are expected to require a CMC determination to be reported on the scope of accreditation. Much of what is termed dimensional inspection is included in this category. These would typically call for uncertainty budgets to calculate the relevant CMCs.The related MU uncertainties

[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 and/or the existence of narrow limits on which decisions on conformity to a specification are based.

reported on test reports for these tests also represents a piece of the traceability chain for these measurements.
Category IV tests are those that are often the most demanding for testing uncertainty consideration. These tests are often developed by reference standard manufacturers or specifiers or by laboratories with a flexible scope of accreditation. These tests may have new technologies or concepts that are used in their procedures. All factors that may influence variability of the measurements involved should be taken into consideration by such laboratories. These would then need to be described in uncertainty calculations and budgets.

Category V tests are those not covered above in the other sets. They involve quantitative measurements but are not expected to have CMC values reported on the scope of accreditation and are often not reported on test reports. They may or may not have MU values reported on their test reports, but they nonetheless need to be understood as to their variability of measurement, so that this could be provided to any customer who requests it. The mathematical practices outlined in the ISO GUM or NIST 1297 need to be understood here and demonstrated to the ISO/IEC17025 assessor for adequate determination of competence.

For many of these Category V analyses, laboratories may have historical tracking in the form of control charts or its equivalent. This tracking data may be utilized in some cases to generate an uncertainty value or averaged variability for a certain method or analysis. This may represent a repeatability or reproducibility study. Other potential factors that may affect the measurement variability need to be considered, though these factors very often are found insignificant to the overall variability. Often 30 or more repetitive analyses taken over time is used in the calculation of the standard deviation of these analyses. The uncertainty of the analysis or MU might then be represented as 2 standard deviations of this repeatability.

Regardless of the test category, all accredited testing labs are expected to have evidence that they have reviewed all significant factors that may contribute to the error or variability in their measurements. When possible, these factors should be converted so that all have the same units. Eventually these factors, expressed as standard uncertainties, should be combined and reported at approximately the 95% confidence level to provide an internationally-accepted expanded uncertainty. Only category III and a few category IV tests should have CMC determinations available. Category III, IV and V tests should have a procedure available and be able to demonstrate how they might generate MU values for testing customers.

Reference Documents:

UKAS LAB 12, “The Expression of Uncertainty in Testing, October 2000.
APLAC TC005 Interpretation and Guidance on the Estimation of Uncertainty of Measurement in Testing

ILAC-G17:2002 Introducing the Concept of Uncertainty of Measurement in Testing in Association with the application of Standard ISO/IEC 17025 ISO GUM, *Guide to the Expression of Uncertainty in Measurement*, also known as ISO Guide 98:2008

NIST Technical Note 1297. Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results - Available on the ACLASS website

EA-4/02 Expression of the Uncertainty of Measurement in Calibration

NCSL/ANSI Z-540-2-1997 *American National Standard for Expressing Uncertainty-U.S. Guide to the Expression of Uncertainty in Measurement* - This is a comprehensive publication and is the U.S. version of the *ISO Guide to the Expression of Uncertainty in Measurement (GUM) 1995*

Revision History

Date	Description
November 1, 2005	Initial Draft – B. Hirt
November 10, 2005	Review and approval – K. Greenaway
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November 22, 2008	Split out 5 rather than 4 test categories – B. Hirt
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