ACCREDITATION COMMISSION FOR CONFORMITY ASSESSMENT BODIES

CAB Accreditation Policy Document

Document Title: **Policy On Measurement Uncertainty For Calibration & Testing Laboratories Including Medical Laboratories**

Document Number: **ACCAB-CAB- 2.0**

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Revision Number	Revision Date	Paragraph Number	Description of Revision	Revision Author

1.1	**Purpose:**
1.1.1	This policy ensures that calibration laboratories and testing laboratories in the ACCAB accreditation regime shall own and operate procedures for the estimation of uncertainty of measurement.
1.2	**Scope:**
1.2.1	This document lays down the ACCAB policy regarding the requirements for the evaluation of uncertainty in calibration and measurement, evaluation of the calibration and measurement capability (CMC), and the reporting of uncertainty on the certificates of calibration and measurement.
1.2.2	This policy is relevant to calibration laboratories, reference measurement laboratories for laboratory medicine, and producers of certified reference materials that offer calibration and measurement services that refer to their accredited status.
1.2.3	This policy also addresses requirements for The Estimation Measurement Uncertainty for Testing Laboratories and medical laboratories.
1.3	**Definition:**
1.3.1	The term “Best Existing Device” is understood as a device to be calibrated that is commercially or otherwise available for customers even if it has a special performance (stability) or has a long history of calibration.
1.3.2	For the purpose of this document the terms and definitions given in the “international Vocabulary of Metrology-Basic and General Concepts and Associated Terms” shall apply.
1.3.2.1	Calibration and Measurement Capability (CMC):- A CMC is a calibration and measurement capability available under normal conditions as described in the laboratory’s scope of accreditation granted by a signatory to the ILAC Arrangement; or BIPM key comparison database (KCDB – Appendix C) of the CIPM MRA.
1.4	**Details:**
1.4.1	**The Estimation of Uncertainty of Measurement for Calibration Laboratories:**
1.4.1.1	ACCAB accredited calibration laboratories shall require to assess uncertainties of measurement for all calibrations and measurements covered by the scope of accreditation.
1.4.1.2	ACCAB accredited calibration laboratories must estimate uncertainties of measurement in conformity with the “Guide to the Expression of Uncertainty in Measurement” (GUM), including its supplement documents and/or ISO Guide 35.
1.4.1.3	ACCAB accredited laboratories shall ensure that all measurement standards, measurement instruments and measurement equipment work which have a direct importance and consequence to the quality of measurement results must be calibrated by the national measurement standards laboratories or by an ISO/IEC 17025:2005 accredited laboratories or by

	other laboratories that validate traceability with the internationally accepted primary measurement standards.
1.4.1.4	ACCAB accredited laboratories shall ensure that traceability in chemical measurement shall be assured by the use (were appropriate) of Certified Reference Materials (CRMs) or Reference Materials (RMs).
1.4.2	**Scope of Accreditation of Calibration Laboratories:**
1.4.2.1	The scope of accreditation of an accredited calibration laboratory shall have the calibration and measurement capability (CMC)expressed in terms of:- a) measurand or reference material; b) calibration/measurement method/procedure and/or type of instrument/material to be calibrated /measured; c) measurement range and additional parameters where applicable, e.g., frequency of applied voltage; d) Uncertainty of measurement.
1.4.2.2	ACCAB accredited laboratories shall ensure that there is no scope of ambiguity on the expression of the CMC on the scopes of accreditation and, consequently, on the smallest uncertainty of measurement that can be expected to be achieved by a laboratory during a calibration or a measurement. Particular care should be ensured when the measurand covers a range of values. This could be generally achieved through employing one or more of the following methods for expression of the uncertainty: a) A single value, which is valid throughout the measurement range; b) A range. In this case a calibration laboratory should have proper assumption for the interpolation to find the uncertainty at intermediate values; c) An explicit function of the measurand or a parameter; d) A matrix where the values of the uncertainty depend on the values of the measurand and additional parameters; e) A graphical form, providing there is sufficient resolution on each axis to obtain at least two significant figures for the uncertainty.
1.4.2.3	The uncertainty covered by the CMC shall be expressed as the expanded uncertainty having a specific coverage probability of approximately 95 %. The unit of the uncertainty shall always be the same as that of the measurand or in a term relative to the measurand, e.g., percent. Usually the inclusion of the relevant unit gives the necessary explanation.
1.4.2.4	Calibration laboratories shall provide evidence that they can offer calibrations to customers in compliance with 7.5.1 b so that measurement uncertainties equal those covered by the CMC. In the formulation of CMC, laboratories shall take notice of the performance of the “best existing device” which is available for a specific category of calibrations.
1.4.2.5	A reasonable amount of contribution to uncertainty from repeatability shall be included and contributions due to reproducibility should be included in the CMC uncertainty component, when available. There should, on the other hand, be no significant contribution to the CMC

	uncertainty component attributable to physical effects that can be ascribed to imperfections of even the best existing device under calibration or measurement.
1.4.2.6	It is acknowledged that for some calibrations a “best existing device” does not exist and/or contributions to the uncertainty attributed to the device significantly affect the uncertainty. If such contributions to uncertainty from the device can be separated from other contributions, then the contributions from the device may be excluded from the CMC statement. For such a case, however, the scope of accreditation shall clearly identify that the contributions to the uncertainty from the device are not included.
1.4.2.7	Where laboratories offer services such as reference value provision, the uncertainty covered by the CMC should generally include factors related to the measurement procedure as it will be carried out on a sample, i.e., typical matrix effects, interferences, etc. shall be considered. The uncertainty covered by the CMC will not generally include contributions arising from the instability or in homogeneity of the material. The CMC should be based on an analysis of the inherent performance of the method for typical stable and homogeneous samples.
1.4.3	**Statement of Uncertainty of Measurement on Calibration Certificates:**
1.4.3.1	It is a requirement of ISO/IEC 17025:2005 that calibration laboratories must report the uncertainty of measurement and/or a statement, in the calibration certificate, in compliance with an identified metrological specification or clauses thereof.
1.4.3.2	ACCAB Accredited calibration laboratories shall report the measured quantity value and the uncertainty of measurement, in compliance with the requirements as detailed below in this section
1.4.3.3	Where it has been established during contract review and by exception that only a statement of compliance with a specification is required, then the measured quantity value and the measurement uncertainty may be omitted on the calibration certificate. The following shall however apply: • The calibration certificate is not planned to be used in support of the further distribution of metrological traceability (i.e. to calibrate another device); • As specified in ISO/IEC 17025:2005 clause 5.10.4.2, the laboratory shall determine the uncertainty and take that uncertainty into account when issuing the statement of compliance; and • The laboratory shall maintain documentary evidence of the measured quantity value and the uncertainty of measurement, as specified in ISO/IEC 17025:2005 clauses 5.10.4.2 and 4.13, and shall provide such evidence upon request.
1.4.3.4	The measurement result shall normally include the measured quantity value y and the associated expanded uncertainty U. In calibration certificates the measurement result should be reported as y ± U associated with the units of y and U. Tabular presentation of the measurement result may be used and the relative expanded uncertainty U / |y| may also be provided if appropriate. The coverage factor and the coverage probability shall be stated on the calibration certificate. To this an explanatory note shall be added, which may have the following content: “The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor k such that the coverage probability corresponds

	to approximately 95 %."
1.4.3.5	The numerical value of the expanded uncertainty shall be given to, at most, two significant figures. Further the following applies: a) The numerical value of the measurement result shall in the final statement be rounded to the least significant figure in the value of the expanded uncertainty assigned to the measurement result. b) b) For the process of rounding, the usual rules for rounding of numbers shall be used, subject to the guidance on rounding provided i.e in Section 7 of the GUM.
1.4.3.6	Contributions to the uncertainty stated on the calibration certificate shall include relevant short-term contributions during calibration and contributions that can reasonably be attributed to the customer's device. Where applicable the uncertainty shall cover the same contributions to uncertainty that were included in evaluation of the CMC uncertainty component, except that uncertainty components evaluated for the best existing device shall be replaced with those of the customer's device. Therefore, reported uncertainties tend to be larger than the uncertainty covered by the CMC. Random contributions that cannot be known by the laboratory, such as transport uncertainties, should normally be excluded in the uncertainty statement. If, however, a laboratory foresees such contributions will have significant effect on the uncertainties attributed by the laboratory, the customer should be notified according to the general clauses regarding tenders and reviews of contracts in ISO/IEC 17025:2005.
1.4.3.7	ACCAB accredited calibration laboratories shall not report a smaller uncertainty of measurement than the uncertainty of the CMC for which the laboratory is accredited as implied in the definition of CMC.
1.4.4	**The Estimation Measurement Uncertainty for Testing Laboratories Including Medical Laboratories:**
1.4.4.1	It is understood that the concept of measurement uncertainty is relatively new for the testing laboratory community and their clients. Therefore, ACCAB acknowledges that: 1. Measurement uncertainty budgets will not be required for qualitative or semi-quantitative tests; 2. If laboratory follows well recognized test methods that specify limits to the values of the major sources of uncertainty of measurement and specify the form of presentation of calculated results, then in such cases the laboratory is deemed to have satisfied the requirement by following the test method and reporting instructions; 3. For test methods that need identification of major components of uncertainty and reasonable estimate of measurement of uncertainty and for test methods that need identification of all components of uncertainty and detailed uncertainty budgets calculated or for test methods based on published regulatory or consensus methods for which the measurement uncertainty is not defined in the method, for such type of tests suitable ISO guide can be used to determine uncertainty estimates; 4. For test methods that have no significant sources of uncertainty other than random error then determine random error is deemed to have satisfied the requirement of ISO/IEC 17025:2005 clause 5.9 or ISO 15189:2012 clause 5.6. 5. In case of medical laboratories the relevant uncertainty components are those associated with actual measurement process, commencing with the presentation of the sample to

	the measurement procedure and ending with the output of the measured value. 6. In case of medical laboratories the measurement uncertainties may be calculated using quantity values obtained by the measurement of quality control materials under intermediate precision conditions that include as many routine changes as reasonably possible in the standard operation of a measurement procedure, e.g. changes of reagent and calibrator batches, different operators, scheduled instrument maintenance	
1.4.4.2	ACCAB accredited laboratories are required to validate the laboratory developed methods. As part of this validation, the significance of the measurement components or the significance of the modifications of the measurement components from the standard test method must be considered so that the appropriate measurement uncertainty category for the laboratory developed method can be identified.	
1.5	**References:**	
1.5.1	Details:	Document Number
1.5.1.1	ILAC Policy for Uncertainty in Calibration	ILAC-P14:01/2013
1.5.1.2	General Requirements for the competence of reference measurement laboratories	ISO Guide 34:2009
1.5.1.3	International Vocabulary of Metrology	ISO/IEC Guide 99:2007 (VIM)
1.5.1.4	Uncertainty of measurement	ISO/IEC Guide 98-3:2008