THE ACCREDITATION SCOPE OF A CALIBRATION LABORATORY: GUIDELINES FOR FORMULATION AND EVALUATION

THIS PROCEDURE IS A SUPPLEMENT TO BELAC 2-002, " ACCREDITATION CERTIFICATE AND CORRESPONDING SCOPE OF ACCREDITATION: GENERAL GUIDELINES FOR FORMULATION AND EVALUATION "

Whenever it is relevant to a particular conformity assessment activity, the general principles described in this procedure are supplemented with specific provisions in a document from the series BELAC 2-405.

The versions of documents from the BELAC management system, available on the BELAC website (www.belac.be) are considered as the only valid versions.

English translation for information only.
Versions in French and Dutch remain the authoritative documents.

Applicable from: 27.10.2022

HISTORY OF THE DOCUMENT

Revision and date of approval	Reason for revision	Type of revision
0 CC 10.01.2019	New document	
1 CC 04.03.2021	- Addition of requirements to state measurement uncertainty on calibration certificates - Added possibility of flexible scope for calibration activity 1.19 (Reference Measurements) as referred to in BELAC 6-017 - Possibility to mention outdated versions of standardised calibration methods in the scope of accreditation. - Addition of a reference to the “SI Brochure: The International System of Units (SI)" of the BIPM. - Lay-out optimisation	4.2.5 4.1.2.3 4.1.2.2 4.1.2.2 Full document
2 Secretariat 15.12.2021	- Correction of an incorrect number when referring to a clause of ISO/IEC 17025	Point 4.1.2.2
3 Secretariat 18.05.2022	- Correction of typing errors and layout in the examples of measurement uncertainty	Point 4.1.2.2
4 Secretariat 27.10.2022	- The term 'critical location' is replaced by the term 'site of activity' by analogy with BELAC 2-002. - When measurement uncertainty is expressed in function of the relevant calibration quantity, care should be taken that the measurement uncertainty can never be equal to zero.	Points 3.2.and 3.3 from version 3 were deleted Point 4.1.2.2

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1 OBJECTIVES AND NORMATIVE REFERENCES

The present document is intended to supplement the document BELAC 2-002 «accreditation certificate and corresponding scope of accreditation: General guidelines for formulation and evaluation». This document defines specific guidelines for the description and evaluation of the scope of accreditation assigned to a calibration laboratory.

The provisions described in this document explicitly refer to the corresponding paragraphs of document BELAC 2-002.

This document refers to and is in accordance with the relevant parts of:

- the legal provisions that determine the functioning of BELAC;
- the standard EN ISO/IEC 17011 and EA and ILAC guidance, more specific document ILAC P14;
- the guidelines for the accreditation procedure (documents BELAC 3-11 and BELAC 3-12);
- the general guidelines for the accreditation of multi-site institutions (document BELAC 1-04).

2 RECIPIENTS

- The members of the Coordination Committees
- The members of the Accreditation Board
- The accreditation secretariat
- The assessors
- The accredited calibration laboratories

3 SPECIFIC PROVISIONS APPLICABLE FOR CALIBRATION LABORATORIES (SUPPLEMENT TO BELAC 2-002 § 3: DEFINITIONS)

- see paragraph 3 of the standard ISO/IEC 17025:2017;
- see JCGM 200 International vocabulary or metrology - Basic and general concepts and associated terms (VIM).

3.1 CMC (calibration and measurement capability):

CMC is a calibration and measurement capability available to customers under normal conditions:

(a) as published in the BIPM key comparison database (KCDB) or the CIPM MRA;
or
(b) as described in the scope of accreditation granted by a signatory to the ILAC Arrangement.

The calibration and measurement capability (CMC) is expressed in terms of:

- measurand or reference material;
- calibration/measurement method/procedure and/or type of instrument/material to be calibrated/measured;
- measurement range and additional parameters where applicable, e.g. frequency of applied voltage;
- The best achievable measurement uncertainty of an (almost) ideal measurement instrument under normal operational conditions from a calibration test facility.

When referring to measurement uncertainty further below in this document, this has to be interpreted as best achievable measurement uncertainty.

4 SPECIFIC PROVISIONS APPLICABLE FOR CALIBRATION LABORATORIES (SUPPLEMENT TO BELAC 2-002 § 4: GENERAL PROVISIONS

4.1 Content of the accreditation certificate and accreditation scope : principles and rules

4.1.1 Formulation of the accreditation certificate

The accreditation certificate includes the identification and address of the registered office of the accredited body. On the accreditation scope, in addition to the registered office, all sites of activities are specified.

4.1.2 Content of the accreditation scope

4.1.2.1 General

The accreditation scope for calibration laboratories shall clearly and unambiguously indicate the calibration activities covered by the accreditation. The description shall comply with the provisions described in § 4.1.2.2 below (fixed scope).

In the accreditation scope, the activities are grouped as much as possible by field and sub-field (see BELAC 6-017).

4.1.2.2 Content of a "fixed" scope and associated conditions

The formulation of the fixed scope consists of a detailed list of the specific calibration activities for which the accreditation criteria are met. It is the representation of the situation at the moment of the assessment. Changes to a fixed scope are only possible after evaluation and approval by BELAC.

Where standardised calibration methods are used, the technical annex does not specify the date of issue of the calibration method used, assuming that the latest version is used. The calibration laboratory may apply for accreditation for an 'obsolete' version of the methods mentioned above, provided thorough justification is provided. In this case, reference may be made to the standardised calibration meth-od, explicitly mentioning the year or version number. In accordance with ISO/IEC 17025 §7.1.2, the laboratory will inform the customer that it concerns an obsolete method (contract review). The applicable calibration methods mentioned in the accreditation scope must be available at the calibration laboratory.

For each calibration (i.e. for each line in the accreditation scope), all relevant da-ta related to the CMC are specified :

- The subject of the calibration activity (quantity and measuring device);
- The description of the measuring device can be rather general in case the calibration procedure is the same for a range of measuring devices e.g. “current measuring devices” or “voltage generators”;
- Calibration / measuring range (including any additional relevant parameters e.g. frequency for electrical calibrations AC);
- The smallest uncertainty of measurement that laboratory can provide to its customers, expressed as the expanded uncertainty, having a coverage probability of approximately 95%. It is expressed in the same unit as the quantity involved or relative to the quantity involved;
- A reference to the calibration method/procedure used.

The measurement uncertainty is stated unambiguously, either as:

- one specific value that applies to the entire measuring range;
- an interval (where interpolation to intermediate values of the range is possible and open intervals are not allowed);
- a function of the relevant calibration quantity. In such a case, special care will be taken that the measurement uncertainty can never be equal to zero (e.g. if the measurement uncertainty is expressed as a percentage and the calibration range includes the zero value).

Measurement uncertainties should be referred to as "extended measurement uncertainty", corresponding to a coverage probability of about 95%.

Calibration activities that are carried out outside the calibration facilities of the calibration lab are identified as such in the accreditation scope.

Special care should be taken with the use of symbols and units:

- It is recommended that only units of the SI and those units recognised for use with the SI should be used to express the values of quantities and of the associated CMCs. Nevertheless, other commonly used units may be used where considered necessary. See also “SI Brochure: The International System of Units (SI)” which is available on www.bipm.org;
- The dash (-) should not be used to indicate a range of values, due to ambiguity with the negative operator (minus sign). The word “to” should be used instead;
  Example: “0.8 kg to 1.0 kg” instead of “0.8 kg - 1.0 kg”
- The unit should be repeated for each quantity value, either explicitly or by the use of parentheses;
  Example: “20 mV to 30 mV” or “(20 to 30) mV” instead of “20 to 30 mV”
- There should be a space between the numerical value and the unit symbol;
  Example: “100 ˚C” instead of “100˚C”
- Quantity symbols should be written in an italic font;
  Example: “$5 \times 10^{-4} \times I$” instead of “$5 \times 10^{-4} \times$ I”
- The letter "x" should not be used in place of the real multiplication sign (×);
  Example: “$5 \times 10^{-4} \times I$” instead of “5 x 10^{-4} x I”
- More guidelines and examples can be found in ISO 80000-1 (Quantities and units - Part 1: General)

4.1.2.2.1 Examples of presentation of a fixed scope:

Dimensional calibrations

	Calibration and Measurement Capabilities				
6-017	**DIMENSIONAL**				
1.5	**Length calibrations**				
1.5.6	**Measured quantity, instrument or gauge**	**Range**	**Expanded uncertainty (*)**	**Remarks**	**Calibration procedure**
	Ruler (all models)	0 mm to 200 mm	$1{,}5\ \mu m + 3 \times 10^{-6} \times l$		DIM_Rul01
		200 mm to 400 mm	$2{,}0\ \mu m + 3 \times 10^{-6} \times l$		
		400 mm to 3000 mm	$12\ \mu m + 3 \times 10^{-6} \times l$		
		3 m to 100 m	$6{,}0\ \mu m + 5 \times 10^{-6} \times l$		

(*) the smallest uncertainty of measurement the laboratory can provide to its customers, expressed as the expanded uncertainty having a coverage probability of approximately 95%.

Temperature related calibrations

	Calibration and Measurement Capabilities				
6-017	**TEMPERATURE**				
1.16	**Measured quantity, instrument or gauge**	**Measured quantity, instrument or gauge**	**Measured quantity, instrument or gauge**	**Measured quantity, instrument or gauge**	**Calibration procedure/ method**
1.16.2	Platinum resistance thermometers which meet the specifications of the ITS-90 or close to these specifications			Fixed points	P1-02-T.020
		-38,8344 °C	0,004 °C	triple point of mercury	
		0,01 °C	0,004 °C	triple point of water	
		29,7646 °C	0,004 °C	melting point of gallium	
		156,5985 °C	0,005 °C	freeze point of indium	
		231,928 °C	0,005 °C	freeze point of tin	
		419,527 °C	0,006 °C	freeze point of zinc	
		660,323 °C	0,015 °C	freeze point of aluminum	
1.16.1	Resistance thermometers	-196 °C	0,025 °C	By comparison with reference standards in liquid nitrogen at atmospheric pressure	P1-02-T.004
		-100 °C to -40 °C	0,05 °C	By comparison with reference standards	
		-40 °C to 0 °C	0,025 °C		
		0 °C to 280 °C	0,015 °C		

(*) the smallest uncertainty of measurement the laboratory can provide to its customers, expressed as the expanded un-certainty having a coverage probability of approximately 95%.

Calibrations related to density/viscosity

	Calibration and Measurement Capabilities				
6-017	**DENSITY AND VISCOSITY**				
1.12	**TABLE I: VOLUME**				
1.12	**Measure quantity, instrument or gauge**	**Range**	**Expanded uncertainty (*)**	**Remarks**	**Calibration procedure**
1.12	Volume measuring devices, glass cups, recipients, …	50 ml to 100 ml	1 ml	Gravimetric method	KI / 02 / KC / V.51
		100 ml to 200 ml	1,5 ml		
		200 ml to 300 ml	2 ml		
		300 ml to 500 ml	2,5 ml		
		500 ml to 1000 ml	3 ml		
		1 l to 5 l	3,5 ml		

(*) the smallest uncertainty of measurement the laboratory can provide to its customers, expressed as the expanded uncertainty having a coverage probability of approximately 95%.

4.1.2.3 Content of a "flexible" scope and associated conditions

Flexible scope is not allowed for calibration activities, except for the calibration activity 1.19 (Reference Measurements) as referred to in BELAC 6-017.

4.2 Organization of assessments in case of a "fixed" scope

4.2.1 General procedure for evaluation

BELAC will ensure that all disciplines within an accreditation scope are covered during a full accreditation cycle. In addition it will be ensured that by means of well targeted sampling, the main calibrations within a discipline are evaluated, including aspects such as the competence of the personnel involved, the witnessing of calibrations, the review of records, interviews with the staff.

During an initial assessment or extension assessment, at least a sufficient number of calibrations for each discipline in the scope will be evaluated. During the subsequent surveillance and renewal assessments a selection of disciplines will be made on the basis of a previously drawn up planning. This planning can be changed at any time if deemed necessary, taking into account changes in activity volume, location, workload or organizational structure... Performance in interlaboratory comparisons and proficiency tests will also be taken into account. Specific attention will be paid to modified calibration methods.

The selection of methods, to be evaluated by the assessment team can be based on the experience of the laboratory, technical complexity of the calibration methods, risk assessment in case of errors or deviations. A balance is always sought between a full follow-up of the calibration performance and evaluating reports, measurement

uncertainty, lab infrastructure and equipment. This sampling method must be sufficiently adequate to gain confidence that all calibration activities in the accreditation scope lead to the release of reliable calibration results.

4.2.2 Maintaining the "fixed" scope

See also 4.2.1.

4.2.3 "Dormant" activities

Calibrations that are no longer performed in routine but for which a laboratory still participates on a regular basis (at least 1 / year) in quality checks are not regarded as dormant.

4.2.4 Extension of the accreditation scope with a fixed scope

In order to take account of the technological evolution within its activity domain or to respond to the wishes of its customers, the laboratory may at any time submit a formal application to BELAC in order to:

- adjust or expand calibration ranges and measurement uncertainties al-ready included in its accreditation scope, within a calibration discipline. Based on the proposed changes BELAC will investigate whether an evaluation (documentary or on site) is required;
- In the case of very limited adjustments, BELAC may also decide on an administrative update of the scope without prior evaluation. These activities will be a point of attention during the next assessment;
- add additional measuring devices or quantities within a calibration discipline already included in its accreditation scope. Based on the proposed changes BELAC will investigate whether an evaluation (documentary or on site) is required;
- Expand his permanent accreditation scope with completely new calibration disciplines.

In each of the abovementioned cases, the laboratory will submit a proposal of formulation for the new or modified calibrations to BELAC, based on the accreditation scope applicable at that time (a copy of which can be requested from the BELAC file manager at any time).

The information regarding the volume of activities (number of calibrations on an annual basis), participation in ring tests and results of ring tests for these modifications or extensions will also be mentioned in the relevant columns of the accreditation scope.

4.2.5 Measurement uncertainty on Calibration Certificates

Measurement uncertainties shall be reported in compliance with the GUM or equivalent documents such as EA4/02.

The measurement result shall include the measured quantity value y and the associated expanded uncertainty U. 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 measurement uncertainty is stated as the standard measurement uncertainty multiplied by the coverage factor k such that the coverage probability corresponds to approximately 95 %.”

The numerical value of the expanded uncertainty shall be given to, at most, two significant digits. Where the measurement result has been rounded, that rounding shall be applied when all calculations have been completed; resultant values may then be rounded for presentation. 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.

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.

As the definition of CMC implies, accredited calibration laboratories shall not report a smaller measurement uncertainty than the uncertainty described by the CMC for which the laboratory is accredited.