TECHNICAL ACCREDITATION REQUIREMENTS:

ISO/IEC 17025 CALIBRATION LABORATORIES (NON-FORENSIC) – SCALES AND BALANCES
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FOREWORD

This document defines mandatory requirements for ISO/IEC 17025 accreditation of scale and balance calibration laboratories. It is based on the current version of ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories. This document applies to all laboratories performing scale and balance calibrations.

For more information, contact the ANSI National Accreditation Board, 11617 Coldwater Road, Suite 101, Fort Wayne, IN 46845, USA, telephone 414-501-5494, www.anab.org.

INTRODUCTION

This document establishes specific technical requirements as defined by ANAB. Historically, there have been inconsistencies with the representation of uncertainties on scopes of accreditation, reported on calibration certificates, and in the development of uncertainty budgets. Sometimes inconsistencies occur because of the resolution of the unit under test. Resolution of the scale or balance being tested is often the largest contributing factor to the measurement uncertainty.

Many combinations of capacities and resolutions can occur in the field. It is difficult to properly represent a realistic view of these combinations while properly stating measurement uncertainties. There also are questions as to whether scales and balances should be listed in general terms (i.e., weighing systems) or listed specifically (i.e., weighing systems – analytical balances, bench scales, floor scales, etc.).

This technical requirement document addresses the contributors to be included in an uncertainty budget for the calibration of scales and balances, traceability, assuring quality/proficiency testing, and representation of the scope of accreditation.

REFERENCES

JCGM 100:2008, Evaluation of measurement data – Guide to the expression of uncertainty in measurement (GUM)


ILAC P9, ILAC Policy for Participation in Proficiency Testing Activities

ILAC P10, ILAC Policy on the Traceability of Measurement Results

ILAC P14, ILAC Policy for Uncertainty in Calibration

ISO/IEC 17043, General requirements for proficiency testing

EURAMET Calibration Guide No 18, Guidelines on the Calibration of Non-automatic Weighing Instruments

DEFINITIONS

Shall indicates a requirement, should indicates a recommendation, may indicates a permission, and can indicates a possibility or a capability.
Adjustment [VIM 3.11]: Set of operations carried out on a measuring system so that it provides prescribed indications corresponding to given values of a quantity to be measured.

Calibration [VIM 2.39]: Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication.

Calibration and measurement capability (CMC) [ILAC P14]: Calibration and measurement capability available to customers under normal conditions, as described in the laboratory’s scope of accreditation granted by a signatory of the ILAC Arrangement.

Interlaboratory comparison [ISO/IEC 17043 3.4]: Organization, performance, and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.

Metrological traceability [VIM 2.41]: 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.

National Metrology Institute (NMI): National Metrology Institutes (NMI) and Designated Institutes (DI) maintain standards in countries (or regions) all over the world. Throughout this document, the term "NMI" is used to cover both National Metrology Institutes as well as Designated Institutes.

Participation: (For proficiency testing) defined as completing the test and submitting the data for evaluation.

Proficiency testing [ISO/IEC 17043 3.7]: Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

Uncertainty of measurement [VIM 2.26]: Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.

Verification [VIM 2.44]: Provision of objective evidence that a given item fulfils specified requirements.

Example 1: Confirmation that a given reference material as claimed is homogeneous for the quantity value and measurement procedure concerned, down to a measurement portion having a mass of 10 mg.

Example 2: Confirmation that performance properties or legal requirements of a measuring system are achieved.

Example 3: Confirmation that a target measurement uncertainty can be met.

1. ASSURING QUALITY/PROFICIENCY TESTING (AQ/PT)

1.1. General Requirements

1.1.1. The laboratory shall participate in appropriate proficiency testing/inter-laboratory comparisons (PT/ILC) activities representing the parameters, ranges, measurements, test technologies, inspections, methods, and uncertainty of measurement described in the scope of accreditation.

1.1.2. The laboratory shall maintain a documented plan that ensures participation for the current year and at least the next three years covering a representative sampling of activities within each major field identified in the scope of accreditation.
a. The laboratory shall evaluate the risk of the calibrations associated with the scope of accreditation and incorporate that risk analysis as part of the PT plan.

1.1.3. The laboratory shall investigate any results found outside of predefined performance criteria, such as unsatisfactory results.

a. The laboratory shall promptly notify ANAB of unsatisfactory results.

b. When appropriate, corrective action shall be performed.

c. A record of the investigation summary and conclusion shall be retained.

1.1.4. The laboratory shall maintain records of its participation on a rolling four-year basis.

1.1.5. The laboratory shall ensure that PT activities are not always performed by the same person if other qualified personnel in the system perform accredited work.

1.2. Types of Participation

1.2.1. If other factors are similar, the laboratory shall select, when available and appropriate, PT/ILC providers that are accredited to ISO/IEC 17043 by ANAB or another accreditation body that is a signatory of the APLAC or IAAC MRA for PTP.

1.2.2. When ISO/IEC 17043 accredited PT/ILC providers are not used and the laboratory develops its own ILC, the laboratory shall seek written ANAB approval for each PT/ILC scheme. This written ANAB approval shall be documented prior to participation.

1.2.3. When ensuring the validity of results internally, a plan and procedure shall be applied to meet the requirements of ISO/IEC 17025. The plan and procedure will be evaluated by the assessor(s) during assessment activities for the effectiveness of the results.

1.3. Frequency of Participation

1.3.1. The laboratory shall participate in at least one approved PT/ILC activity or alternative each calendar year.

1.3.2. The laboratory shall perform a PT/ILC activity or alternative covering a representative sampling of activities within each major field in the scope of accreditation for each rolling four-year period.

1.4. Initial Accreditation Requirements

1.4.1. Before accreditation can be granted, the applicant laboratory shall have performed satisfactorily in at least one approved PT/ILC within the previous 12 months. The applicant laboratory shall provide reported results as evidenced by either a preliminary or final report issued by an approved provider. Evidence of PT participation and submission of data may be sufficient for initial accreditation. In such cases, failure to submit to ANAB an official report of results within six months of accreditation will risk suspension of accreditation by the laboratory.

1.4.2. Major fields with related parameters for calibration scopes can be found in PR 2351, Preparing a Draft Scope of Accreditation for Calibration Laboratories.

2. METROLOGICAL TRACEABILITY

2.1. The laboratory shall ensure that all testing and calibration results are traceable to the International System of Units (SI Units) wherever possible. This may be accomplished through NIST or another National Metrology Institute (NMI). A hierarchy of acceptable sources of traceability is available in procedural rules.
2.1.1. Applicant and accredited labs may use a national, state, or provincial weights and measures laboratories that are recognized and/or traceable to the country NMI. Evidence of recognition and/or traceability shall be available during the assessment.

2.1.2. Metrological Traceability from an NMI: Applicant and accredited laboratories may submit appropriate physical standards and measurement and test equipment (M&TE) directly to NIST or, when appropriate, to another NMI to the SI units. Accredited organizations may obtain certified reference materials from NIST [called Standard Reference Materials (SRM) under trademark] or another NMI. Use of an NMI other than NIST must be documented as the appropriate NMI relevant for the scope of accreditation and stated uncertainties.

2.1.3. Traceability from an ISO/IEC 17025 Accredited Calibration Laboratory: Applicant and accredited laboratories may use ISO/IEC 17025 accredited calibration laboratory services wherever available. ISO/IEC 17025 accredited calibration laboratories are those accredited by ANAB or another accreditation body that is recognized as a signatory of the International Laboratory Accreditation Cooperation (ILAC) MRA. A list of ANAB accredited ISO/IEC 17025 laboratories is available at www.anab.org. When using accredited calibration laboratory services, the calibration certificate shall include a recognized accreditation body symbol or otherwise refer to accredited status to be considered satisfactory for traceability purposes.

2.2. When an ANAB applicant or accredited laboratory submits physical standards or M&TE to a calibration provider that is not covered by the traceability hierarchy referenced in procedural rules, that traceability chain shall be submitted for approval.

2.3. The laboratory shall maintain a list of off-scope calibrations documenting the traceability of the measurements associated with the scope technologies.

2.4. Calibration certificates and/or reports for reference standards shall provide indication of metrological traceability:
   - Uncertainty of measurement associated with a specified range of measurement for a specified measurement parameter (e.g., force, mass, temperature),
   - Symbol of an ILAC-recognized accreditation body that has recognized the competence of the laboratory through accreditation or equivalent, and
   - Information regarding traceability through an NMI or intrinsic standard and/or a statement of compliance with an identified metrological specification to the SI unit.

2.5. Calibration certificates and/or reports provided for customers shall contain a traceability statement indicating traceability to the International System of Units (SI).

   Example: The calibrations within the certificate or report are traceable through NIST or another National Metrology Institute to the International System of Units (SI).

2.6. Calibration certificates and/or reports shall provide evidence of actual traceability. NIST numbers shall not be reported unless traceability has been achieved directly from NIST.

### 3. Uncertainty of Measurement

3.1. The laboratory shall evaluate and/or calculate the uncertainty of measurement in the calibration of the scales and balances, whether in-house or accredited calibrations as defined on the scope of accreditation.
3.2. The basic formula for the calibration of a scale or balance is the error of indication of the device (E), equal to the device indication (I), minus the value of reference mass (mref). The uncertainty of the error of indication is dependent on uncertainty contributions due to the indication of the device (such as repeatability, resolution, eccentricity, etc.) and the reference mass used (such as errors, calibration, drift, buoyancy, etc.) during the calibration. The uncertainty budget in calibration of a scale or balance shall include but not be limited to the following contributions at a minimum:

- Repeatability of device
- Reproducibility for difference technician (if available)
- Resolution (round error of indication) due to no-load indication or setting the device to zero before any weighing
- Resolution (round error of indication) at load
- Specifications or tolerance of the mass standards, or long-term stability (drift) of the mass standard(s) and the uncorrected errors of the mass standards; if errors of the mass standards are applied to calibration results (errors), then the drift (long-term stability) of the mass standard need to be accounted for
- Contribution for the buoyance difference due to the air density during calibration being different than the air density used for the conventional reference mass values (please see EURAMET Calibration Guide No 18 for more details)
- Inherent uncertainty from the calibration of the mass standards

3.3. For the scope of accreditation, the contribution of the unit under test (UUT) resolution shall be identified appropriately depending on the option chosen by the laboratory to represent the capabilities within the scope of accreditation.

3.3.1. Resolution of the UUT shall be included within the uncertainty budget, or
3.3.2. Resolution excluded from the uncertainty budget and explanation provided on the scope of accreditation.

3.4. The contribution of the UUT resolution shall be included in the uncertainty budget when performing in-house calibrations.

3.5. The calibration laboratory shall report uncertainty of measurement on all certificates and reports unless it can be proved that the client does not want it reported.

3.5.1. Evidence that the client does not want the calibration uncertainty reported shall be available for review at the time of an assessment.
3.5.2. Regardless of whether the client wants the uncertainty of measurement reported, the laboratory shall retain documentary evidence of the measured quality values and the uncertainties of measurement and shall provide these immediately upon request.

3.6. A statement of the measurement result and the associated uncertainty must be accompanied by an explanation of the coverage probability and coverage factor (k).

Example: The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor \( k=2 \), which for a normal distribution corresponds to a coverage probability of approximately 95%.

3.7. When the measurement result is determined (or verified) to be within a specified tolerance or limits, the associated uncertainty of the measurement result shall be taken into account with respect to the tolerance or limits in accordance with a documented agreement established during the review of requests tenders and contracts.
3.8. As the definition of calibration and measurement capability (CMC) implies, the accredited calibration laboratory shall not report a smaller uncertainty of measurement than the uncertainty of the CMC for which the laboratory is accredited.

3.9. Uncertainties reported on calibration certificates and reports shall be appropriate to the measurement results and shall include the actual contributions that can be attributed to device under calibration and reference standards during the calibration.

3.10. The unit of the uncertainty reported on calibration certificates and reports shall always be the same as that of the measurand or in a term relative to the measurand.

3.11. Uncertainties reported on calibration certificates and reports shall be limited to two significant digits.

4. SCOPE OF ACCREDITATION

4.1. Scope of accreditation, Expanded Uncertainty Including Resolution

4.1.1. Parameter/Equipment: Weighing systems within the parameter of the scope of accreditation identify the resolutions based on the ranges identified. Because there are many types of scales and balances with their associated resolutions, the resolution is listed in the Parameter/Equipment column to specify at what resolution the CMC was figured. All resolutions that the laboratory tests shall be shown on the scope. Units of measure shown on the scope are based on the weight kits owned by the laboratory.

Examples in Appendix 1 indicate that the laboratory identifies the following resolutions on the scope of accreditation: 0.001 g, 0.01 g, 0.1 g, 0.1 lb, 1 lb, 10 lb, 20 lb.

Note: Weighing Systems also may be broken down into more specific types, for example, Balances, Bench Scales, Floor Scales, Truck Scales, Tanks and Hoppers, Rail Scales, etc.

4.1.2. Range: The range of the scales and balances shall be stated as a starting point of zero (0) to the capacity of the scale or balance. With the resolution stated in the Parameter/Equipment column, the overlapping of the ranges will not be questioned because the specific line item is based off of and identified by the resolution within the Parameter/Equipment column.

4.1.3. Expanded Uncertainty of Measurement: See section 3 above.

4.1.4. Reference Standard, Method, and/or Equipment: In this column of the scope of accreditation for scales and balances, identify the type of standard used to calibrate the scale or balance along with the method used to calibrate the scale or balance.

4.2. Scope of Accreditation, Expanded Uncertainty Excluding Resolution

4.2.1. Parameter/Equipment: Weighing systems within the parameter of the scope of accreditation identify the specific ranges based on the uncertainty budgets.

Note: Weighing systems may also be broken down into more specific types, for example, Balances, Bench Scales, Floor Scales, Truck Scales, Tanks and Hoppers, Rail Scales, etc.

4.2.2. Range: The range of the scales and balances shall be stated as a starting point of zero (0) to the capacity of the scale or balance.

4.2.3. Expanded Uncertainty of Measurement: ANAB requires the significant contributors of repeatability and specifications/tolerance of the mass standards and uncertainty from the calibration of the mass standards to be within an uncertainty budget at a minimum.
4.2.4. Reference Standard, Method, and/or Equipment: In this column of the scope of accreditation for scales and balances, identify the type of standard used to calibrate the scale or balance along with the method used to calibrate the scale or balance.

4.3. The expanded uncertainty of measurement (CMC uncertainty) values from the scope of accreditation shall never be reported on a calibration certificate, as they do not include the resolution of the unit under test. The laboratory must be able to prove to an assessor that it can calculate uncertainties for any combination of test load and resolution.

4.4. The resolution component of uncertainty will be mentioned in a footnote on the scope of accreditation.

<table>
<thead>
<tr>
<th>Revision Level</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>Original Release</td>
<td>Original release.</td>
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</table>
## Sample Scope: Expanded Uncertainty Including Resolution – With General Parameter Field

### Mass and Mass Related

<table>
<thead>
<tr>
<th>Parameter/Equipment</th>
<th>Range</th>
<th>Expanded Uncertainty of Measurement (+/-)</th>
<th>Reference Standard, Method, and/or Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weighing Systems</td>
<td>(0 to 100) g</td>
<td>3 mg</td>
<td>ASTM E617 Class 1 weights and NIST Handbook 44 utilized for the calibration of the weighing system.</td>
</tr>
<tr>
<td>(0.01 g resolution)</td>
<td>(0 to 1 000) g</td>
<td>0.03 g</td>
<td></td>
</tr>
<tr>
<td>(0.1 g resolution)</td>
<td>(0 to 2 000) g</td>
<td>120 mg</td>
<td>ASTM E617 Class 2 weights and NIST Handbook 44 utilized for the calibration of the weighing system.</td>
</tr>
<tr>
<td>(0.1 lb resolution)</td>
<td>(0 lb to 100) lb</td>
<td>0.3 lb</td>
<td>NIST Class F weights and NIST Handbook 44 utilized for the calibration of the weighing system.</td>
</tr>
<tr>
<td>(1 lb resolution)</td>
<td>(0 to 500) lb</td>
<td>2 lb</td>
<td></td>
</tr>
<tr>
<td>(10 lb resolution)</td>
<td>(0 to 100 000) lb</td>
<td>15 lb</td>
<td></td>
</tr>
<tr>
<td>(20 lb resolution)</td>
<td>(0 to 200 000) lb</td>
<td>30 lb</td>
<td></td>
</tr>
</tbody>
</table>

**Notes:**
1. Calibration and Measurement Capabilities (Expanded Uncertainties) are based on approximately a 95% confidence interval, using a coverage of $k=2$.
2. This scope is formatted as part of a single document including Certificate of Accreditation No. AC-xxxx.
### Sample Scope: Expanded Uncertainty Excluding Resolution – With General Parameter Field

**Mass and Mass Related**

<table>
<thead>
<tr>
<th>Parameter/Equipment</th>
<th>Range</th>
<th>Expanded Uncertainty of Measurement (+/-) ¹,²</th>
<th>Reference Standard, Method, and/or Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scales and Balances</td>
<td>(0 to 500) mg</td>
<td>0.12 mg</td>
<td>ASTM E617 Class 1 weights and NIST Handbook 44 utilized for the calibration of the weighing system.</td>
</tr>
<tr>
<td></td>
<td>(1 to 20) g</td>
<td>0.005 % applied load</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(21 to 60 000) g</td>
<td>0.003 % applied load</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(0.005 to 120 000) lb</td>
<td>0.013 % applied load</td>
<td>NIST Class F weights and NIST Handbook 44 utilized for the calibration of the weighing system.</td>
</tr>
</tbody>
</table>

**Notes:**

1. The expanded uncertainty of measurements is based on approximately 95% confidence interval, using a coverage of \(k=2\).
2. The CMC for scales and balances is highly dependent upon the resolution of the unit under test. The CMC presented here does not include the resolution of the unit under test. The resolution will be included in the reported measurement uncertainty at the time of calibration.
3. This scope is formatted as part of a single document including Certificate of Accreditation No. AC-xxxx.