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QUALIFICATION OF EQUIPMENT
ANNEX 8: QUALIFICATION OF BALANCES

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ANNEX 8 OF THE OMCL NETWORK GUIDELINE
"QUALIFICATION OF EQUIPMENT"

QUALIFICATION OF BALANCES

1. INTRODUCTION

This document is the 8th Annex to the core document "Qualification of Equipment", which together should be used when planning, performing and documenting the qualification process of balances.
The core document contains the introduction and general forms for Level I and II of qualification, which are common to all types of instruments.
Annex 8 contains instrument-related recommendations on parameters to be checked at Level III and IV of qualification and the corresponding typical acceptance limits, as well as practical examples on the methodology that can be used to carry out these checks.

2. AIM AND SCOPE OF THE GUIDELINE

This guideline describes the requirements for balances (electronic - digital) used in chemical and biological tests in OMCLs.

The following types of balances are considered in this guideline (Table 1):

Table 1

Type	Ordinary name	Number of digits after decimal position (g)	Accuracy Class
1.	Ultra Micro Balances	7	I
2.	Micro Balances	6	I
3.	Semi-micro Balances	5	I
4.	Analytical Balances	4	I
5.	Precision Balances	1 to 3	II
6.	Technical Balances	0 to 1	III

The classifications are based on the OIML R 76-1 International Recommendation document (see Table 2).

Table 2: The verification scale interval, number of verification scale intervals and minimum capacity in relation to the accuracy class of an instrument.

Accuracy class	Verification scale interval (*e*)	Number of verification scale intervals (n = Max/*e*)		Minimum capacity (Min) (Lower limit)
		minimum	maximum	
Special (I)	0.001 g ≤ *e* (*)	50 000 (**)	-	100 *e*
High	0.001 g ≤ *e* ≤ 0.05 g	100	100 000	20 *e*
(II)	0.1 g ≤ *e*	5 000	100 000	50 *e*
Medium	0.1 g ≤ *e* ≤ 2 g	100	10 000	20 *e*
(III)	5 g ≤ *e*	500	10 000	20 *e*
Ordinary (IIII)	5g ≤ *e*	100	1 000	10 *e*

* It is not normally feasible to test and verify an instrument to *e* < 1 mg due to the uncertainty of the test loads.
** For an instrument of class I with d < 0.1 mg, *n* may be less than 50000. The minimum capacity is reduced to 5 *e* for grading instruments, *i.e.* instruments that determine a transport tariff or toll (*e.g.* postal scales and instruments weighing waste material).
On multiple range instruments, the verification scale intervals are *e*1, *e*2, …, *e*r with *e*1 < *e*2 < … < *e*r. Similar sub-scripts are also used with the terms Min, *n* and Max.
On multiple range instruments, each range is treated as if it were an instrument with one range.
For special applications that are clearly marked on the instrument, an instrument may have weighing ranges in classes I and II, or in classes II and III. The instrument as a whole shall then comply with the more severe requirements of *3.9 Variations due to influence quantities and time* applicable to either of the two classes (see OIML R76-1 International Recommendation document)

Max = Maximum capacity of the balance
e = verification scale interval
e_1, e_i, e_r = verification scale interval, rules for indices

3. CONSIDERATIONS FOR LEVEL I AND II OF EQUIPMENT QUALIFICATION

At Level I of the qualification of balances (selection of instruments and suppliers), it is recommended to select a manufacturer of balances that can satisfy the needs of the laboratory and works under ISO 9001 certification.
At Level II of the qualification of balances (installation and release for use), it is recommended to check all the requirements set during the selection of the instrument and calibration should be performed before putting into service by an accredited external service supplier, or internally by appropriately qualified personnel, using certified reference weights according to an approved procedure.

4. REQUIREMENTS FOR BALANCE USE

Location of the Balance
The accuracy and precision of weighing results are closely associated with the location of the balance. OMCLs should ensure that the balance can work under optimal conditions (weighing room/laboratory, weighing bench, temperature, light, air, *etc*.).

It is recommended that balances of types 1 to 6 (see Table 1 above) are located in a specially designed weighing room that is vibration-proof, dust-free and has an anti-static floor. For substances that are sensible to static electricity it is also possible to use an ionising unit.

If a balance of type 1 to 6 is located in a laboratory outside of the weighing room, then the weighing bench on which it is placed should be in a separate part of the laboratory that is vibration-proof and dust-free. For balances of types 1 to 4, a stable bench should be used.

It should be ensured that the weighing bench is stable, no matter from what material it is made. The weighing bench should not deform when work is carried out on it and it must be vibration-proof or the transfer of vibrations must not influence the weighing process. If there is a risk of instability, the balance should be equipped with a stability indicator so that the weight is only registered or printed after stabilisation of the balance.
The weighing bench should be non-magnetic (*i.e*. no steel plates) and protected against electrostatic charges (no plastic or glass).

Temperature
As weighing results are influenced by temperature, OMCLs should ensure a constant temperature is maintained in weighing rooms/laboratories. The typical drift of balances of types 1 and 2 is 1-2 ppm/°C. The deviation should not exceed more than 5 °C per hour.

Atmospheric humidity
The optimum relative humidity (% RH) during a weighing process is between 40 % to 60 % for balances of class I and II (see Table 1). The relative humidity may be expanded to 20 % to 80 % in cases where the accuracy and linearity of measurements are not affected.

Light
Balances should be protected from direct sunlight (heat).

Air
OMCLs should not place balances in the airflow of air conditioners or devices with ventilators (such as computers or large laboratory equipment), next to doorways or in areas of high traffic. This is because in addition to the potential temperature drift, strong air currents can interfere with the functioning of balances. If a balance is placed in a laminar flow workstation, e. g. for weighing of toxic material, the cabinet should be suitable for the intended use.

Weighing vessel
OMCLs must ensure that:

- the smallest possible weighing vessels are used.
- if the materials that the weighing vessel is made of have a high degree of electrical insulation (such as glass and plastic), they are not electrostatically charged.
- the weighing vessel and the sample it contains should have the same temperature as their surroundings.

- if the weighing vessel has been removed from a drying oven or dishwasher, it should be cooled to room temperature prior to being placed on the balance.
- depending on the type of balance, it is recommended to use cotton gloves.
- no magnets should be placed on the balance or into the weighing vessel.

5. REQUIREMENTS FOR WEIGHTS USED IN THE QUALIFICATION

Weights used for qualification should:

- be clean and, if necessary, wiped with ethanol. In the latter case a waiting time must be taken into account before the weight is used
- be stored in a dust-free environment.
- be handled with care; the use of cotton gloves or forceps/tweezers is especially recommended.
- have a suitable accuracy, depending on the type of balance.
- be calibrated by an accredited external service provider.
- be re-calibrated periodically.
- be clearly marked after each calibration.
- not be made of magnetisable material.
- the verification (in use control, see Table 3) may be done with non-calibrated weights.

6. FREQUENCY OF QUALIFICATION

OMCLs must ensure that qualification/calibration of balances is done on receipt (*i.e.* immediately after delivery) or prior to their first use and after any repair or move.

The frequency of qualification/calibration depends on the extent of use of the balances and is at the discretion of individual OMCLs.

Qualification/calibration must be performed in accordance with a pre-determined protocol in which acceptance criteria are defined. An external calibration should be performed by organisations accredited as calibrating laboratories according to ISO/IEC 17025 or, if performed internally, the laboratory should satisfy the same requirements in terms of measurement standards, calibration procedure, use of certified weights and qualification of personnel.

Table 3 prescribes the parameters, typical frequencies and tolerance limits for the qualification of balances for periodic and motivated instrument checks (Level III) and in-use instrument checks (Level IV)

Table 3

Parameter to be checked	Frequency	Typical tolerance limit
Levelling	every day before weighing begins	Acceptance limits of the balance
Internal calibration (adjustment) (automatic or manual)	every day before weighing begins	Automatic acceptance limits of the balance
Verification (in use control)	At least once a week	OMCLs shall define their own acceptance criteria
Accuracy	Frequency to be defined by OMCL, typically once a year	OMCLs shall define their own acceptance criteria
Linearity	Frequency to be defined by OMCL, typically once a year	OMCLs shall define their own acceptance criteria *(k* = 1±0.0001)
Precision	Frequency to be defined by OMCL, typically once a year	OMCLs shall define their own acceptance criteria (SD = maximum 5**d)*
Eccentricity	Frequency to be defined by OMCL, typically once a year	OMCLs shall define their own acceptance criteria (RSD = 0.05%)

k = correlation coefficient
SD = standard deviation
RSD = relative standard deviation

The following qualification tests may also be performed in addition to those described in Table 3 (recommended, not obligatory):

Parameter to be checked	Frequency (recommended)	Typical tolerance limit
Linearity error	once every six months	OMCLs shall define their own acceptance criteria (≤ accuracy of the balances)
Drift test	once every six months	OMCLs shall define their own acceptance criteria (RSD = 0.05%)
Minimum weight	once a year	OMCLs shall define their own acceptance criteria depending on the type of the balance
Measurement uncertainty	once a year	OMCLs shall define their own acceptance criteria depending on the type of the balance

7. QUALIFICATION PROCEDURE

Verification
Verification of the balance is performed by placing a suitable weight (depending on the type of balance) in the centre of the weighing pan once and comparing the result with pre-defined acceptance criteria. The same weight should always be used in these verifications.

The acceptance criteria shall be defined by each individual OMCL.

Accuracy
The accuracy of the balance is checked by weighing at least three different certified weights that cover the usual weighing range of the balance. It is recommended that the weights have approximately 5%, 50% and 100% of the maximum capacity of the balance (or of the maximum weight used on the balance), depending on the type of balance. It is recommended that the weighing is repeated at least 5 times for every weight, particularly, when the results shall also be used in the test for precision.

The acceptance criteria shall be defined by each individual OMCL.

Linearity
The results obtained from a series of accuracy checks can be used to calculate the correlation coefficient and to check for linearity. The correlation coefficient is calculated by comparing the nominal and measured masses of the weights.

The acceptance criteria for the correlation coefficient shall be defined by each individual OMCL.
(Proposed criterion: $k = 1 \pm 0.0001$).

Precision
The precision of the balance should be verified by weighing at least 5 times a weight that is equivalent to approximately 50% of the maximum capacity of the balance. It is recommended to repeat the test with a weight that is equivalent to approximately 5% of the maximum capacity of the balance, if the balance is used at the lower range.

The acceptance criteria shall be defined by each individual OMCL.
(Proposed criterion: SD = max 5**d, where d* = (actual) scale interval (*e.g.* d=0.1 mg)).

Eccentricity
The eccentricity test should be carried out using a weight equivalent to at least 30% of the maximum capacity of the balance (or of the maximum weight used on the balance). The weight should be placed between halfway to ¾ of the distance from the centre of the pan to its edge and be measured at each location in the following sequence: centre, front left, back left, back right, front right, and (optional) again centre.

The acceptance criteria shall be defined by each individual OMCL.
(Proposed criterion: RSD not more than 0.05%, calculated from all weighings at different locations on the pan).

Linearity error

Linearity error is tested at least 3 times using four weights of defined masses whose aggregate total mass is approximately equal to half of the maximum capacity, depending on the type of balance.
First, the combined mass of all four weights is weighed and recorded. Then, two sub-sets of weights are made and their masses are recorded.
The linearity error of the balance is an absolute value calculated by the difference between the combined mass of all four weights and the sum of the masses from the two sub-sets of weights, divided by 2.

The acceptance criteria shall be defined by each individual OMCL.
(Proposed criterion: linearity error ≤ accuracy of the balances).

Drift test
A drift test is only performed on 5, 6 or 7 decimal scale balances. It is carried out by repeated measurements (every 5 minutes for 30 minutes) of a control weight (depending on the type of balance) in the morning and afternoon.
The mean measurement, standard deviation and relative standard deviation can be calculated from the resulting data. The drift can also be extracted from the trend analysis of the verification test (Table 3).

The acceptance criteria shall be defined by each individual OMCL.
(Proposed criterion: RSD = 0.05%).

Minimum weight
The minimum weight value depends on the type of balance. It is determined from technical data and the external calibration certificate.

The acceptance criteria shall be defined by each individual OMCL.
(Proposed criterion: tolerance 0.5%, k=3 for class I balances and 1%, k=3 for class II and III balances).

Measurement uncertainty
The measurement uncertainty can be calculated according to GUM or other relevant documents or can be determined from the external calibration certificate.
A simplified procedure is proposed as follows:
A weight of approximately 50% of the maximum capacity of the balance (depending on the type of balance) is weighed at least 10 times and the mean measurement, standard deviation and relative standard deviation are calculated.

The acceptance criteria shall be defined by each individual OMCL.
Proposed criterion: measurement uncertainty is satisfactory if three times the standard deviation of not less than ten replicate weight measurements, divided by the amount weighed (approximately 50 % of the maximum capacity of the balance), does not exceed 0.001.

Alternatively to the above described qualification procedures the OMCL may use the guide OIML R76-1 from the International Organisation of Legal Metrology (current edition, see point 10. References).

8. QUALIFICATION REPORT

After the qualification procedure, OMCLs should appropriately record the results.
The following minimum information should be included:

- Title of the report
- Identification of the report
- Version number of the master copy.
- Entity that performed the qualification.
- Page numbering.
- Date.
- Unique identification of the weights used and their qualifications (unless specified in another quality document). Traceability to certificates must be provided.
- Unique identification of the balances.
- Qualification results and acceptance criteria.
- Conclusion (*e.g.* PASS/FAIL).
- Name and signature of the operator who performed the qualification.
- Name and signature of the person responsible for the release for use of the balances (preferably a different person from the operator who performed the qualification).

Note:
If an OMCL requests qualification/calibration from an external company, it must be ensured that this minimal information is contained in the external calibration report/certificate. The responsible person in the OMCL should evaluate and approve this report/certificate as a release for use of the balances.

9. GLOSSARY

Terms and definitions:

Accuracy
Accuracy is the degree of closeness of a measurement to the true value of the quantity being measured.

Calibration
Calibration is a demonstration that an instrument or a device produces results within specified limits when compared to those produced by a standard (or a reference standard that is traceable to a national or international standard) over an appropriate range of measurements. Calibration is a determination of the deviation between measurements and the true value under specified measuring conditions.

Drift (Sensitivity Drift)
Drift is a progressive (continuously upward or continuously downward) change in the display of the digital readouts of balances, which means that weight readings are not stable.
Environmental factors affect instrument stability (drift): e. g. temperature, static electricity, air flow and vibrations.

Eccentricity
Eccentricity is an error relating to variations in the positioning of weights on the weighing pan.

Levelling
Levelling is a procedure to ensure the balance is in the horizontal position.

Linearity
Linearity refers to the ability to deliver identical sensitivity throughout the weighing capacity of a balance.

Linearity error
Linearity error is the difference between the digital display for a weight that weighs 50% of the full weighing capacity of the instrument and its true mass.

Measurement uncertainty
Measurement uncertainty is a parameter, associated with the result of a measurement, that characterises the dispersion of the values that could reasonably be attributed to the measurement variable (VIM 3.9).
Measurement uncertainty is generally expressed by the standard uncertainty **u** or the expanded measurement uncertainty **U** (confidence interval). There are several ways of calculating the measurement uncertainty, one of them is given in the GUM.

Precision
Precision is a measure of the reproducibility of results from independent measurements.

Qualification
See OMCL Guideline "Qualification of equipment – Core document", *PA/PH/OMCL (08) 73 2R.*

Weights
Weights are objects, regulated in regard to their physical and metrological characteristics such as shape, dimensions, material, surface quality, nominal value, density, magnetic properties and maximum permissible error.

10. REFERENCES

OIML R 111-1(E), current edition (E), (OIML = International Organisation of Legal Metrology).

OIML R 76-1(E), current edition.

METTLER TOLEDO guidelines
- Proper Weighing with Laboratory Balances
- Good Weighing Practice™

ILAC G24 2007 (OIML D10 2007) GUIDELINES FOR THE DETERMINATION OF CALIBRATION INTERVALS OF MEASURING INSTRUMENTS

INTERNATIONAL VOCABULARY OF METROLOGY – BASIC AND GENERAL CONCEPTS AND ASSOCIATES TERMS (VIM), JCGM 100: 2008

EVALUATION OF MEASUREMENT DATA – GUIDE TO THE EXPRESSION OF UNCERTAINTY IN MEASUREMENT (GUM), JCGM 200: 2008

ILAC P10: 2013, ILAC POLICY ON THE TRACEABILITY OF MEASUREMENT RESULTS

ISO 9001

EURAMET cg-18, Version 3.0, 2011

US Pharmacopoeia <41 >

Internet pages:
http://www.msl.irl.cri.nz/sites/all/files/training-manuals/tg25-december2-2010.pdf

http://gmponblog.vinvarun.biz/2008/08/sop-calibration-of-balances.html