1**. Purpose:**

This document specifies the DPA policy for the calculation of measurement uncertainty and the reporting of uncertainty in conformity documents (certificates/evidence) issued by calibration laboratories.

2. Scope:

In the context of this document, "calibration laboratory" refers to all bodies that carry out calibration activities, for example: testing laboratories, calibration laboratories and medical laboratories; inspection bodies; PT providers, biobanking, reference material producers. While this policy covers the calibration of reference materials, it does not cover the assignment of uncertainty to the value of a reference material in any field. Bodies that are not calibration laboratories are not expected to assess their own CMC, but should pay attention to the CMCs covered by the ILAC Agreement and the CIPM MRA. Also, where applicable, these bodies must carry out an assessment of the measurement uncertainty in accordance with the requirements of the relevant reference standards.

3. Responsibilities:

This procedure is implemented by all lead assessors, technical assessors, the director of the Directorate of Testing/Calibration/Medical Laboratories/the director of the Directorate of Certification and Inspection Bodies and the conformity assessment bodies. The director of the Directorate of Testing/Calibration/Medical Laboratories/the director of the Directorate of Certification and Inspection Bodies is responsible for controlling the implementation of this procedure.

4. References:

S SH EN ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories;

Policy DA-PO-002, "Accreditation policy"

5. Glossary and Abbreviations:

For the purposes of this document, the terms and definitions given in the International Vocabulary of Metrology - Basic and General Concepts and Related Terms, VIM (JCGM 200:2012) are used.

VIM - International Vocabulary of Metrology - Basic and General Concepts and Related Terms, (JCGM 200:2012)

Uncertainty (of measurement) – Parameter, associated with the result of a measurement, that characterizes the distribution of values, which can reasonably be attributed to the quantity being measured.

Expanded Uncertainty – The quantity defining an interval around the measurement result that can be expected to encompass a large part (fraction) of the distribution of values that can reasonably be attributed to the measurand.

Coverage Factor – A numerical factor used as a multiplier of the combined standard uncertainty to obtain an expanded uncertainty.

Calibration and Measurement Capability (CMC) is the calibration and measurement capability available to users of services under normal circumstances: (a) as expressed in a laboratory's accreditation program provided by signatories to the Multilateral Agreement on Mutual Recognition, or (b) as published in the International Bureau of Weights and Measures' Comparison Database (BIPM-KCDB).

CAB: Conformity Assessment Body

GUM - Guide to the Expression of Uncertainty in Measurement, JCGM 100:2008

6. Rules for the assessment of measurement uncertainty:

During the assessment and accreditation of calibration laboratories, the DPA applies the principles set out in the binding documents: EA 4/02 M:2022 Assessment of Measurement Uncertainty in Calibration (https://european-accreditation.org/information-center/ea-publications/) and ILAC P14:09/2020 ILAC Policy on Measurement Uncertainty in Calibration (https://ilac.org/publications-and-resources/). Calibration laboratories must carry out the assessment of measurement uncertainty in accordance with EA 4/02 M:2022 and report it in the prescribed manner. However, other approaches proposed by the GUM and its supplements (such as the Monte Carlo method) may also be acceptable.

The assessment of measurement uncertainty in calibration is also specified in several EURAMET guidelines available at www.euramet.org. A measurement result statement is only complete if it contains the value attributed to the measured value and the measurement uncertainty associated with that value. Calibration laboratories shall provide documented evidence of measurement uncertainty assessment procedures carried out in accordance with the principles of document EA 4/02 M:2022 and shall define and document their calibration and measurement capabilities (CMC).

Confirmation that the requirements of the reference standards are met are:

a) the existence and implementation of a measurement uncertainty assessment document (e.g. procedure or manual) containing the result of the measurement uncertainty assessment (calculation) carried out for a specific calibration case (as an example). In case of multiple calibration methods, the measurement uncertainty is estimated for each method individually, i.e., for each calibration object

or

b) the existence and implementation of a document (e.g., work instructions) describing the method of performing the calibration, within which the procedure for estimating the measurement uncertainty will be described, as well as a section containing the results of the estimation (calculation) of the measurement uncertainty obtained by the described procedure for a specific calibration case (as an example).

he accreditation program of an accredited calibration laboratory shall include the calibration and measurement capability expressed in terms of:

- the measured or reference material;

- the calibration/measurement method/procedure and/or the type of instrument/material to be calibrated or measured;

- the measurement range and additional parameters, if applicable;

- the measurement uncertainty.

In order to avoid ambiguity regarding the expression of the calibration and measurement capability (CMC) in the accreditation program, and consequently the smallest measurement uncertainty that can be expected to be achieved by a laboratory during calibration or measurement, where the measurand includes a value or range of values, one or more of the following methods for expressing the measurement uncertainty should be applied:

- a single valid value within the measurement range;

- the range of values of the measurement uncertainty. In this case, the laboratory must ensure that linear interpolation is suitable for determining uncertainty values within the measurement range;

- a specific function of the measurand or parameter on which the measurement uncertainty is determined;

- a matrix where the value of the measurement uncertainty depends on the value of the measurand and additional parameters;

- a graphical presentation form, ensuring that there is sufficient resolution on each axis to read the graph with at least two significant figures for the expanded measurement uncertainty. Open intervals (e.g. "0 < U < x") or e.g. for the resistance measurement range from 1 Ω to 100 Ω, the uncertainty declared as "less than 2 μΩ/Ω") are incorrect in the expression of the CMC.

The expressed CMC should include contributions from the "best" equipment available to be calibrated, in such a way that the confirmed measurement uncertainty can be achieved.

Note: The term "best available instrument" refers to the instrument being calibrated, which is commercially or otherwise available to the user, even if it has a particular performance (stability) or a long calibration history. Where the best available instrument can contribute to the measurement uncertainty due to repeatability equal to zero, this value may be used in the CMC assessment. However, other permanent components that contribute to the measurement uncertainty associated with the best available instrument should also be included. In exceptional cases, it is recognized that the "best available instrument" does not exist and/or the uncertainty contribution attributed to the instrument may significantly affect the uncertainty. If such contributions to the measurement uncertainty of the instrument can be separated from other contributions, then the contributions of the instrument may be excluded from the CMC statement. In such a case, however, it should be clearly identified in the accreditation scope that contributions to the instrument uncertainty are not included.

When laboratories provide services such as the provision of a reference value, the measurement uncertainty covered by the CMC should include factors related to the measurement procedure to be performed on the sample. The measurement uncertainty covered by the CMC usually does not include contributions arising from material instability and inhomogeneity. The CMC should be based on an analysis of the inherent properties of the method for characteristically stable and homogeneous samples. Note: The uncertainty described by the CMC for the measurement of the reference value is not identical to the uncertainty associated with the reference material provided by the reference material manufacturer. The expanded measurement uncertainty of a certified reference material will generally be greater than the uncertainty described by the CMC of the reference measurement on the reference material. The measurement result includes the measured value y and the expanded measurement uncertainty associated with U. In the calibration certificate/calibration certificate, the measurement result shall be presented as y±U, with the associated units for y and U. A tabular presentation of the measurement results may also be used, as well as the expanded relative measurement uncertainty U/|y|. In the calibration certificate/calibration certificate, the coverage probability and the coverage factor shall be stated, with the following explanation: "The expanded measurement uncertainty is expressed as the combined standard measurement uncertainty increased by a predefined coverage factor k for a coverage probability of approximately 95 %. The unit in which the measurement uncertainty is

expressed shall be the same as the unit of the measurand or a relative quantity in relation to the measurand, e.g. percentage or μV/V."

To avoid ambiguity in definitions, the use of the terms "ppm" (parts per million) and "ppb" (parts per billion) is not acceptable. The numerical value of the expanded measurement uncertainty is expressed to a maximum of two significant figures. Also, the numerical value of the measurement result is usually rounded to the decimal place where the least significant figure of the expanded measurement uncertainty is located. The procedure for rounding the numerical value of the measurement result is carried out in accordance with the rules for rounding numbers, after all calculations have been completed (in accordance with the instructions in Section 7 of the GUM).

Note: Details on rounding the numerical value of measurement results can be found in the GUM and ISO 80000-1:2022.

The contributions to the measurement uncertainty stated in the calibration certificate/calibration certificate should include relevant short-term influences during calibration and influences originating from the user equipment. Where applicable, the measurement uncertainty should include the same contributions that were included in the estimation of the uncertainty components of the CMC, except that the uncertainty components estimated for the best available equipment should be replaced by those associated with the user equipment. Therefore, the uncertainties reported in the calibration certificate/calibration certificate tend to be larger than the uncertainty covered by the CMC. Contributions that the laboratory cannot know, such as uncertainties arising from transport, should normally be excluded in the measurement uncertainty statement. However, if the laboratory anticipates that such contributions will have a significant impact on the measurement uncertainty, the user must be informed (review of requests, offers and contracts, S SH EN ISO/IEC 17025).

In the calibration certificate issued by an accredited calibration laboratory, the measurement uncertainty cannot be less than the uncertainty described in the CMC for the specific calibration method specified in the accreditation program.

Date :16.01.2026 **General Director**

Pranvera FAGU