1. PURPOSE

This guideline describes the technical policy established by NAC on estimating the uncertainty of measurements made within the scope of services provided by calibration and testing (including medical) laboratories and on the assessment and reporting of measurement uncertainty in the statement of measurement uncertainty estimation. The applicable requirements of this guideline also apply to internal calibration.

2. SCOPE

This guideline covers the estimation of measurement uncertainty in laboratory activities of conformity assessment bodies accredited by NAC, meeting the requirements of relevant international standards.

3. DEFINITIONS

Quantity: A property that belongs to a phenomenon, object, or substance, and the amount of which can be expressed as a number and reference.

Measurand: The quantity intended to be measured.

International System of Units (SI): A system of units based on the International System of Quantities, which is accepted in the General Conference on Weights and Measures (CGPM). It includes the names and symbols of basic units, prefixes for these names and symbols, and their usage rules.

Measurement Accuracy: The closeness of agreement between a measured quantity value and a true quantity value of a measurand.

Measurement Precision: The closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions.

Measurement Error: The measured quantity value minus a reference quantity value.

Measurement Uncertainty: A non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.

Combined Standard Measurement Uncertainty: The standard measurement uncertainty obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model.

Expanded Uncertainty: The multiplication of the combined standard measurement uncertainty by a factor greater than one.

Coverage Factor: A number larger than one by which a combined standard measurement uncertainty is multiplied to obtain an expanded measurement uncertainty.

Calibration: A sequence of operations 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.

Verification: The provision of objective evidence that a given item fulfills specified requirements.

Validation: Verification where the specified requirements are adequate for an intended use.

Metrological Traceability: The 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.

4. RELATED DOCUMENTS

ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories
ISO 15189 Medical laboratories - Requirements for quality and competence
JCGM 200:2012: International vocabulary of metrology – Basic and general concepts and associated terms (VIM) - 3rd edition.
JCGM 100:2008 (GUM): Evaluation of measurement data — Guide to the expression of uncertainty in measurement.
EA-4/02 M:2022: Evaluation of the uncertainty of measurement in calibration
EA-4/16 G:2003: EA guidelines on the expression of uncertainty in quantitative testing
ILAC G17 Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025
ILAC G8: Guidelines on Decision Rules and Statements of Conformity
ILAC P14: ILAC Policy for Uncertainty in Calibration
ILAC P15: Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies
ILAC P10: ILAC Policy on Metrological Traceability of Measurement Results

5. IMPLEMENTATION
5.1 NAC Policy

Accredited calibration laboratories must estimate the relevant measurement uncertainty so that the results of all the calibrations they perform can be interpreted. Measurement uncertainties should generally be estimated and reported according to the method specified in the international document ISO/IEC Guide 98-3, published by BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP, and OIML under the title "Guide to the Expression of Uncertainty in Measurement (GUM)," or the method described in the EA documents referring to this document.

The calculated uncertainty estimation should be documented and supported by evidence. Calibration laboratories applying to become accredited must specify their "calibration and measurement capability" for calibration studies included in their accreditation scope. The meaning of "Calibration and Measurement Capability" and the expression "Best Measurement Capability," previously used in the accreditation system, is the same, and the detailed definition is given in the document ILAC P14:09/2020 "ILAC Policy for Uncertainty in Calibration." The complexity of the mathematical modeling used in estimating measurement uncertainty should be proportional to the desired degree of accuracy. At least the following information should be included in the presentation of measurement results:

A clear description of the measurand,
The value found as a result of measurement,
Expanded uncertainty at a confidence level of 95%,
Coverage factor (k), and

Unit of measurement for the measurement result and expanded uncertainty.

In determining the level of confidence for expanded uncertainty and the expansion coefficient corresponding to this level, different approaches may be required in some cases (including different distributions in the measurement uncertainty budget, type A uncertainty contributions obtained with less than 10 repetitions, etc.). For these cases, Section 5 of the EA 4-02 M: 2013 "Evaluation of the Uncertainty of Measurement in Calibration" document and the annexes it refers to should be considered.

The uncertainties estimated by the calibration laboratory should be correlated with the measurement results obtained during calibration. Expanded uncertainties should be reported with two significant figures. In cases where the uncertainty value needs to be known for subsequent calculations, it may be useful to also maintain rounded figures to reduce errors that may result from rounding. Where it is necessary to report with more than two significant figures (three significant figures, etc.), the technical grounds for the situation in question must be maintained.

The obtained and reported estimated value of the measurand must be rounded to have a number of digits equal to that of the associated uncertainty estimate. For example, if the value of the measurand is estimated as 9.05778 as a result of the measurement and the uncertainty is found to be 0.023, the estimated value of the measurand must be rounded to 9.058. Chapter 7 of the GUM document provides guidelines on how to round. Calibration certificates issued by accredited calibration laboratories must include measurement uncertainty values, and these values must not be smaller than the Calibration and Measurement Capability specified in the accreditation certificates.

Accredited testing/analysis laboratories:

Policies determined jointly by EUROLAB, EURACHEM, CLSI, and EA regarding measurement uncertainty for accredited testing/analysis laboratories are described in ILAC-G17.

The measurement uncertainty statement must contain the necessary information for comparison.

GUM, ISO/IEC 17025:2017, and ISO 15189:2022 are fundamental documents. However, sector-specific interpretations may be necessary.

Only the uncertainty of measurement in quantitative (quantified) tests will be considered. The strategy for using qualitative analysis results will be developed by the scientific committee.

There are three cases when the standard method is used by the laboratory:

- When the standard method containing information on how to calculate the measurement uncertainty is used, it is sufficient to apply the measurement uncertainty procedure given in the standard, provided that it fully complies with the testing method predictions.
- If a typical measurement uncertainty value is given in the standard for analysis results, the laboratory is allowed to use this value. However, in this case, it is necessary for the laboratory to show that it is fully compatible with the method.
- If the standard contains the exact measurement uncertainty value of the test results, no additional activity is required. However, in this case, it is also necessary for the laboratory to show that it is fully compatible with the method.

The detail of measurement uncertainty estimates may vary according to technical areas.

In certain situations, it may be sufficient to report reproducibility standard deviations studied at multiple levels as combined uncertainty.

In addition, it is also appropriate to use sources published on a national/international level that are relevant/sector specific.

5.2 Calibration Laboratory

GUM Approach:

Basic Concepts in Evaluation of Uncertainty

Standard Uncertainty: Uncertainty of a measurement result that can be calculated as a standard deviation.

Calculation of Type A Uncertainty: Statistical analysis method of uncertainty calculations of a series of observations.

Calculation of Type B Uncertainty: Other (non-statistical) methods of uncertainty calculations of a series of observations.

Combined Standard Uncertainty: The standard uncertainty of the result of a measurement obtained from many other values is equal to the positive square root of the sum of variances or covariances calculated by taking into account how changes in these values affect the measurement result.

An ideal method for calculating and expressing the uncertainty of a measurement result must have the following properties:

- **Universality:** The method should be applicable to any type of measurement and to any type of data used for each measurement.

The actual quantity used in the expression of uncertainty must also have the following properties:

- **Internal Consistency:** Measurement uncertainty should be attainable regardless of the components that contribute to the uncertainty, the way the components are grouped, or separated into sub-components.
- **Portability:** When it is necessary to use the result of one measurement in a second measurement, the uncertainty of the first measurement should be used directly in this second measurement.

In most cases, a measurand Y is not measured directly but is determined from N other quantities $X_1, X_2, \ldots, X_N$ through a functional relationship f.

$$Y=f(X_1,X_2,\ldots,X_N)$$

The set of input quantities $X_1, X_2, \ldots, X_N$ can be categorized as such:

- Quantities whose values and uncertainties can be determined directly in the measurement. These values and uncertainties can be obtained by making decisions as a result of a single observation, repeated observations, or a certain experience. These results may include corrections to instrument readings and the factors that influence the result, such as ambient temperature, pressure, and humidity.
- Quantities whose values and uncertainties are brought from external sources, such as calibrated measurement standards, certified reference materials, or reference data obtained from quality manuals.

Measurement Uncertainty and Sources of Error

Error Types

Different types of errors that occur regularly in measurement results:

- Systematic Errors
- Random Errors
- Shift
- Outliers

All errors are systematic by nature. When errors are not systematically detected, it is because either the cause of the error has not been investigated or the level of decision making is not sufficient. Systematic errors can be characterized by their magnitude and sign (positive or negative).

ER = MR - TV

- ER: Error
- MR: Measurement result
- TV: True value

Possible Uncertainty Components in Measurement:
- Environment
- Reference of measurement equipment
- Measurement equipment
- Measurement setup
- Software and calculations
- Personnel
- Measured object
- Description of characteristic
- Measurement procedure
- Physical constants

Other possible uncertainty components include temperature, time variance, spatial gradient, gravity, vibration/noise, electromagnetic interference, humidity, transients in the power supply, contamination, lighting, thermal radiation, air flow, device thermal balance, ambient pressure, etc.

The calculation of uncertainty components can be done with two parameters: Type A evaluation and Type B evaluation.
- **Type A Evaluation:** Requires repeated measurement data. The standard deviation of the distribution or the standard deviation of the average value can be calculated using their formula.
- **Type B Evaluation:** Involves other (non-statistical) methods of uncertainty calculations of a series of observations. Judgments should be made scientifically, using all available information, and taking into account all possible different values. Possible uncertainty components include data obtained from previous measurements, experience and previously acquired information on relevant materials and devices used, specifications specified by the manufacturer, data contained in calibration and other certificates, and data in user manuals.

Calculation of Measurement Uncertainty Components:
The contribution of all measurement uncertainty components to combined uncertainty is not equal. In practice, only a small number of uncertainty components are expected to contribute significantly. If the components that contribute to the measurement uncertainty are less than 1/3 of the largest measurement uncertainty and the number of these components is not too many, they do not need to be included in the measurement uncertainty calculations. However, these components must be proven to be insignificant. For this purpose, the contribution of each component must be estimated by preliminary studies, or the uncertainty components must be combined. As a result, the trivial ones

should be eliminated. Following the calculation of all standard uncertainties, the combined uncertainty u_c (y) is calculated as follows:

$$u_c(y) = (u_1^2 + u_2^2 + u_3^2 + \quad)^{1/2}$$

Expanded uncertainty U is obtained by multiplying the combined standard uncertainty $u_c(y)$ by the coverage factor k.

$$U = k.u_c(y)$$

The measurement result normally includes the measured magnitude value y and the associated expanded uncertainty U. In calibration certificates, the measurement result must be reported as Y ± U, along with units of of y and U. Tabular representation of the measurement result can be used and, if appropriate, also the relative expanded uncertainty U / | y | can be provided. The coverage factor and distribution must be declared in the calibration certificate. For this, an explanatory note should be added as shown below.

$$y-U \leq Y \leq y+U$$

The declared expanded measurement uncertainty is the value found by multiplying the standard uncertainty with the coverage factor taken as k = 2, providing a confidence level of approximately 95%.

Decision rules must comply with customer, regulatory, or standard requirements. They must be decided and documented before work begins. It should be clearly stated that the tolerance limits are consistent with the requirements and that all measurement uncertainties and other calculations are performed consistently with the requirements of ISO/IEC 17025:2017. The agreed decision rule used for statements of conformity should be clearly documented in the measurement report.

Understanding customer needs related to the statement of conformity requested by customers and approving them at the test/calibration request stage. At the request review stage, the statement request is taken into consideration and an agreement must be reached with the customer regarding the decision rules to be applied based on the risk to be accepted by the customer. Inclusion of the decision rule in reports containing statements of conformity (if not included in the rule, specification, or standard) is required.

Basic Requirements of ILAC P14:
In the context of the CIPM MRA and ILAC Arrangement, and in compliance with the CIPM-ILAC Common Statement, the following definition is agreed upon:

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

a) As described in the laboratory's scope of accreditation granted by a signatory to the ILAC Arrangement; or

b) As published in the BIPM key comparison database (KCDB) of the CIPM MRA.

ILAC Policy on Scopes of Accreditation of Calibration Laboratories:
The scope of accreditation of an accredited calibration laboratory shall include 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.

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.

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

It is recognized 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 cases, however, the scope of accreditation shall clearly identify that the contributions to the uncertainty from the device are not included.

5.3 Testing Laboratory

Approaches to Measurement Uncertainty Estimation

Testing/analysis laboratories must follow documents prepared by national or international organizations for the estimation of measurement uncertainty in test results. Resources that can be used for this purpose are given in the annexes. The Eurachem/CITAC and EA 4/16 guides state that there are two possible approaches to measurement uncertainty estimation:

- Defining Each Possible Source of Uncertainty: This approach involves defining what is measured, writing the model function, and calculating the contribution of each source to the measurement uncertainty. This approach is also defined as a "bottom-up" approach. In some cases, it is also defined as the "Classic GUM" or "Component-Component or Modeling Approach" method.
- Use of Method Performance Data: This approach is also called a "top-down approach" or "empirical approach."

GUM Approach

The GUM method is based on correct theory, requiring a consistent estimate of measurement uncertainty and metrological traceability. In the BIPM's recommendation document on Uncertainties (INC-1), it is recommended that the measurement uncertainty components be grouped into two categories: Type A (calculated by statistical methods) and Type B (obtained by

non-statistical methods). The components are then expressed in terms of variance and combined to give a single variance value according to mathematical probability theory. The resulting standard deviation value is an expression of the measurement uncertainty. Details of the uncertainty approach are given in GUM, where measurement uncertainty is handled mathematically through a direct measurement model, based on the assumption that the measurand can be expressed as a single value.

Method Validation and Use of Method Performance Data

The GUM approach can be quite useful if each uncertainty component can be detected or studied separately. However, many empirical measurements have indicated that this approach yields lower values than the actual measurement uncertainty because it is difficult to include all possible uncertainty components in the GUM approach. By using method validation and method performance data in measurement uncertainty calculations, the possibility of including all uncertainty components will be higher. In the GUM approach, due to the difficulty in determining and calculating all components that are the source of measurement uncertainty, the measurement uncertainties obtained by this method may be smaller than they should be.

Data on method performance can be obtained by:

- Method validation and confirmation studies (validation/verification)
- Inter-laboratory comparisons
- Internal quality control work (quality control cards, etc.)
- External quality assessment data (proficiency tests/inter-laboratory comparison)

Method Validation and Confirmation Studies (Validation and Verification)

Validating the method is carried out by conducting validation or verification studies in accordance with the principle of fitness for purpose. As a result of these studies, all necessary information and data on measurement uncertainty are collected. Parameters that can be considered for quantitative measurements include:

- **Precision:** Closeness of agreement between independent test results; expressed in terms of standard deviations obtained under repeatability, intermediate precision, or intra- and inter-laboratory reproducibility conditions. When measurement uncertainty is calculated from method validation studies, ideally, the standard deviation value obtained in the same laboratory using the same sample and method at different times, using different operators, different test equipment, etc., and called intermediate precision or intra-laboratory precision, should be used as precision data. In precision studies, the measurement range of the test method and the matrix it covers should be taken into consideration. In methods with a wide measurement range, matrix differences (if any) should be taken into account and studied at different levels (e.g., low, medium, and high concentration levels), and the relationships between standard deviations and test levels should be investigated. In low-level studies, the limit of quantitation (LOQ) and legal limit values, if any, should be included. According to the results, matrix and level differences should be considered while calculating the measurement uncertainties, if necessary. Precision data are the most fundamental component of the measurement uncertainty of the method.
- **Accuracy:** Closeness of agreement between the mean value obtained from a large series of test results and an accepted reference value. Accuracy can be named in different ways according to the material studied. An accuracy study is called "bias" when performed with reference material

and "recovery" when performed with a standard substance. Eliminating or reducing bias to insignificant levels is the most important goal. Bias/recovery data is also the most fundamental component of the measurement uncertainty of the method.

- **Linearity:** The most important indicator of the measurement range of the method. Correction should be made using nonlinear calibration functions when there is a significant deviation from linearity. Alternatively, the operating range can be limited. Data obtained from precision studies normally contain deviations from linearity. If the standard deviation caused by the deviation from linearity is negligible in addition to the measurement uncertainty from the calibration curve, it does not need to be considered as an additional measurement uncertainty.
- **LOD:** The LOD value is not directly related to measurement uncertainty. (This concept, namely "Detection Limit," is used by laboratories in different ways, such as observability limit, detection limit, measurement limit, etc. For this reason, it is preferred to use the abbreviation.)
- **Sensitivity (Selectivity):** Since these parameters, which are important for chemical analysis, do not provide direct information on measurement uncertainty, they do not need to be considered as a component of measurement uncertainty.

Inter-laboratory Studies

The ISO 5725 series standards, which are fundamental in inter-laboratory studies, make the necessary definitions regarding repeatability standard deviation s_r, reproducibility standard deviation S_R, and estimation of accuracy. When the repeatability and reproducibility values found in inter-laboratory studies based on these standards are given in the test method and the laboratory shows that the method is under control with the help of internal and external quality control studies, and if it fully complies with the method, it can use the reproducibility standard deviation given in the test method in measurement uncertainty calculations. The use of these data in the measurement uncertainty calculation is detailed in ISO 21748 and Eurachem/CITAC: 2012.

Internal Quality Control Studies

The laboratory should conduct internal quality control activities at regular intervals to check whether the performance it shows during validation studies continues. These activities can be carried out by the use of control charts and/or other internal quality control methods. The intermediate precision/within-laboratory reproducibility values and the results of the accuracy studies (bias/recovery) obtained from these studies are used in measurement uncertainty calculations.

External Quality Assessment Data (Proficiency Tests/Inter-laboratory Comparison)

In order to demonstrate its performance, the laboratory is required to regularly participate in external quality assessment programs. Results obtained from these programs can be used to calculate measurement uncertainty. For the systematic error revealed by external quality assessment results to be taken into account in the measurement uncertainty calculation, the laboratory must participate in at least six programs and obtain successful results. These six programs must be attended under the same conditions.

The laboratory should primarily rely on the standard method or the sources referred to by the standard method for the calculation of measurement uncertainty. However, if there is no definition of measurement uncertainty in the standard method, other sources that can be used are as follows:

- JCGM 200: 2012 VIM, International Vocabulary of Metrology - Basic and General Concepts and Associated Terms.
- ISO/TS 21749: 2005. Measurement Uncertainty for Metrological Applications - Repeated Measures and Nested Experiments. (www.iso.org)
- The Expression of Uncertainty and Confidence in Measurement, M3003, Edition 3, UKAS, 2012 (www.ukas.com)
- Policy on Estimating Measurement Uncertainty for Medical Testing Laboratories, (A2LA - the American Association for Laboratory Accreditation) (www.a2la.com)
- Technical Guide 4: A Guide on Measurement Uncertainty in Medical Testing (http://www.sac-accreditation.gov.sg)
- N. Majcen, P. Taylor, T. Marti≈°ius, A. Menditto, M. Patriarca, Practical Examples on Traceability, Measurement Uncertainty, and Validation in Chemistry Vol 2, 2011, (European Commission, Joint Research Centre)
- Measurement Uncertainty Revisited: Alternative Approaches to Uncertainty Evaluation, Technical Report no. 1/2007, EUROLAB, 2007 (www.eurolab.org)
- Guide to the Evaluation of Measurement Uncertainty for Quantitative Test Results, Technical Report no. 1/2006, EUROLAB, 2006 (www.eurolab.org)
- K. Jewell, Microbial Measurement Uncertainty: A Practical Guide, CCFRA, 2004, ISBN 0 905942 66 3 (www.campdenbri.co.uk)
- CLSI EP29-A. Expression of Measurement Uncertainty in Laboratory Medicine; Approved Guidance
- Uncertainty of Measurement in Quantitative Medical Testing, a Laboratory Implementation Guide, AACB Uncertainty of Measurement Working Group, November 2004
- ISO/TS 19036: 2006. Microbiology of Food and Animal Feeding Stuffs - Guidelines for the Estimation of Measurement Uncertainty for Quantitative Determinations
- ISO 14956: 2002. Air Quality - Evaluation of the Suitability of a Measurement Procedure by Comparison with a Required Measurement Uncertainty
- ISO 11222: 2002. Air Quality - Determination of the Time Average of Air Quality Measures
- ISO 20988: 2007. Air Quality - Guidelines for Estimating Measurement Uncertainty
- ISO/TR 12134: 2010. Rubber - Estimation of Uncertainty for Test Methods - Non-functional Parameters
- ISO/ASTM 51707: 2015. Guide for Estimation of Measurement Uncertainty in Dosimetry for Radiation Processing
- ISO/TR 24498: 2006. Paper, Board and Pulps - Estimation of Uncertainty for Test Methods
- ISO 29201: 2012. Water Quality - The Variability of Test Results and the Uncertainty of Measurement of Microbial Enumeration Methods
- ISO 3822-1: 1999. Acoustics - Laboratory Tests on Noise Emission from Appliances and Equipment Used in Water Supply Installations - Part 1: Method of Measurement. Amd 1: 2008. Measurement Uncertainty
- SANCO/12571/2013. Guidance Document on Analytical Quality Control and Validation Procedures for Pesticide Residues Analysis in Food and Feed

It is also appropriate to use sources published on a national/international level which are

relevant/sector-specific but not defined in this guideline.

Microbiological Analysis

The distribution of differences between the reported values and the assigned values obtained in repeated rounds provides a basis for assessing the uncertainty arising from these parts of the measurement procedure under the scheme. Systematic deviations from traceable assigned values and other sources of uncertainty should also be considered. The GUM approach does not satisfactorily apply in the case of microbiological analysis of foods where it is difficult to create a truly comprehensive model of the measurement process.

There is a high risk of underestimating the true measurement uncertainty value due to the possibility of overlooking a significant source of uncertainty. Furthermore, it seems difficult to accurately measure the contribution of each stage of the analytical process to food microbiology, as the analyte is a living organism whose physiological state can be largely variable. The analytical target includes different strains, different species, or different genera.

In other words, microbiological analyses do not provide a metrologically rigorous and statistically valid estimate of measurement uncertainty. Therefore, the measurement uncertainty based on the standard deviation of the repeatability of the final result of the measurement process is more appropriately evaluated with a top-down or global approach. This is an approach based on test results (with replication of the same analysis) that, when it comes to microbiology, seems more meaningful than a step-by-step approach. ISO 19036 provides guidance for the estimation and expression of measurement uncertainty associated with quantitative results in food microbiology. It is applicable to the quantitative analysis of products intended for human consumption and feeding animals and environmental samples in the field of food production and food processing, typically performed by enumerating microorganisms using a colony counting technique, but also applies to quantitative analysis by alternative instrumental methods.

5.4 Decision Rule

The ILAC G8 provides the necessary guidance on the practical implementation of decision rules in the context of Testing and Calibration Laboratories. In conformity assessment, a measurement result is used to decide whether a related item meets a specific requirement. The requirement usually takes the form of one or two tolerance limits, which define a range of allowed values, called the tolerance range, of a measurable property of the substance.

If the true value of the property is within the tolerance range, it is considered appropriate; otherwise, it is unsuitable. These decisions normally play an important role in calculating the true values of the measurands (properties) and always determining the level of compliance against tolerances. Any decision competence is based on measurements taken with the Uncertainty of Measurement attributed to the result of any measurement made on the goods.

Pursuant to clause 7.8.6.1 of ISO/IEC 17025:2017: When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule. Therefore, the choice of decision rule (with or

without binary, non-binary, with/without guard bands) should be accompanied by an adequate explanation to ensure adequacy regarding compliance and disclosure of the nature of risk (e.g., in cases of strict acceptance, strict rejection, or common risks). The maximum PFA (probability of false acceptance) and/or PFR (probability of false rejection) should be agreed upon between the laboratory and its clients during the contract review phase. Other approaches to the application of decision rules may be acceptable if sufficient theoretical and empirical evidence of relevance is shown. ISO Guide 98-4 provides guidance on how to assess conformance possibilities and identify the main types of risk (specific and global consumer risk and producer risk).

6. REVISION TABLE

Date	Section	Amendment
19.03.2020	Header	Logo is changed.
22.03.2024	Header & all sections	New document code is used. Editorial changes are made.