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Guidelines to Recommendation K

A. Introduction

These Guidelines, which are complementary to UNECE WP.6 Recommendation K on *Metrological Assurance of Conformity Assessment and Testing*, are designed to provide additional detail and context to aid Governments in their implementation of Recommendation K and to provide information on the tools available for such implementation. Guidance is provided for each of the recommended practices.

B. Guidance for recommended practice

K.1: There are five key international organisations that issue international documents, standards, guides and recommendations which provide a framework to assist Governments when developing harmonized standards, guides and technical regulations promoting methods and means of metrological traceability. These are:

The **International Bureau of Weights and Measures (BIPM)** which has the mission of establishing worldwide uniformity of measurement and the General Conference on Weights and Measures has the authority of approving the definitions of the International System of Units (SI). The BIPM, under the responsibility of the International Committee for Weights and Measures (CIPM) publishes the "SI Brochure", which is an essential reference document for the application and correct use of the SI units. The national metrology institutes (NMIs) are tasked with the realization, maintenance, improvement and dissemination of the SI units via metrological traceable calibration and measurement services based on their calibration and measurement capabilities (CMCs). It should be noted that in many countries more than one laboratory holds national standards, and the term “designated institute” (DI) is used where this occurs. The CIPM, recognizing the need to demonstrate, unambiguously, the equivalence of such national realizations of the SI units, and therefore of the calibration and measurement certificates issued by NMIs/DIs, drew up a mutual recognition arrangement (CIPM MRA). The CIPM MRA provides a framework within which all participants validate and recognize the CMCs of other participants. These peer-reviewed CMCs are listed in the BIPM's key comparison database (KCDB). To provide the technical basis for this listing, participating NMIs are required to take part in comparisons of national measurement standards and have their CMC claims validated through

the peer review process of the CIPM MRA. This process includes the approval of a reviewed quality system, which conforms to appropriate internationally recognized standards (ISO/IEC 17025 for calibration and ISO 17034 for the production and certification of reference materials). The CIPM MRA is coordinated by the BIPM headquarters under the authority of the CIPM.

The **International Organisation of Legal Metrology (OIML)** promotes the global harmonization of legal metrology laws and procedures and provides its members with guidance with respect to their national legislation, including that measurements used for trade and regulatory purposes should be made using standards legally traceable to the SI. It has developed a set of International Recommendations which are intended as model regulations and which provide its members with the metrological and technical requirements for the alignment of national regulations concerning the manufacture and use of regulated measuring instruments. This infrastructure supports the legal traceability of measurements used in regulated measurements such as those used for trade, safety, health, and environmental monitoring. The OIML has also introduced the OIML Certification System (OIML-CS) which is intended to facilitate, accelerate and harmonize the work of national and regional bodies that are responsible for type evaluation and approval of measuring instruments subject to legal metrological control. Under the OIML-CS, signatories declare mutual confidence in the OIML type evaluation reports underpinning OIML certificates issued on the basis of the requirements described in an OIML Recommendation. OIML Issuing Authorities and their associated Test Laboratories who issue OIML certificates under Scheme A of the OIML-CS demonstrate their competence through compliance with International Standards on the basis of accreditation or peer assessment.

The **International Laboratory Accreditation Cooperation (ILAC)** is the global association for the accreditation of laboratories, inspection bodies, proficiency testing providers and reference material producers, with a membership consisting of accreditation bodies and stakeholder organizations throughout the world. ILAC facilitates trade and supports regulators by operating a worldwide mutual recognition arrangement – the ILAC Arrangement – among accreditation bodies (ABs) that are subject to regular peer reviews. Accredited laboratories and inspection bodies are required to comply with appropriate international standards including requirements for metrological traceability and measurement uncertainty.

The **International Organization for Standardization (ISO)** is an independent, nongovernmental international organization with a membership of national standards bodies. Through its members, it brings together experts to share knowledge and develop voluntary, consensus-based, market relevant international standards that support innovation and provide solutions to global challenges. ISO publishes a range of standards that apply to manufacture and testing of various products, and the provision of services. In many cases, calibration and testing form an integral part of the requirements of the standards. ISO harmonizes its terminology with the International Vocabulary of Metrology (VIM) and frequently incorporates measurement-related clauses in these standards. ISO is responsible, together with the International Electrotechnical Commission (IEC) for ISO/IEC 17025, "General requirements for the competence of testing and calibration laboratories" the standard used by tens of thousands of testing and calibration laboratories worldwide. ISO works closely with the IEC, which has general responsibility for electrical standards, and the International Telecommunication Union (ITU), which has general responsibility for telecommunication standards. ISO, IEC and ITU work cooperatively through the World Standards Cooperation (WSC).

The **International Electrotechnical Commission (IEC)** is a non-profit, nongovernmental international standards organization with a membership of national electrotechnical committees that prepares and publishes its international standards for all electrical, electronic and related technologies – collectively known as "electrotechnology". IEC standards cover a vast range of technologies from power

generation, transmission and distribution to home appliances and office equipment, semiconductors, fibre optics, batteries, solar energy, nanotechnology and marine energy, as well as many others. The IEC also manages four global conformity assessment systems that certify whether equipment, systems or components conform to its international standards.

K.2: National technical regulations relevant to international trade and industrial cooperation should contain requirements for the technical competence of conformity assessment bodies and calibration and testing laboratories. This can be done by writing specific requirements; however, to do so is onerous and risks creating unintentional technical barriers to trade. There are a number of international documentary standards available related to conformity assessment tools to support public policy. By utilizing these documents, best practices can be embedded and technical barriers avoided. Most of these standards are developed and published jointly by the ISO and IEC. The "ISO 17000 family of standards" issued by the ISO committee for conformity assessment (CASCO) covers a wide range of topics including competence of accreditation bodies, testing laboratories, calibration laboratories and certification bodies. Most notably, in the context of Recommendation K, ISO/IEC 17011 establishes the requirements for accreditation bodies that accredit conformity assessment bodies and calibration and testing laboratories. The competency of calibration and testing laboratories is established in accordance with ISO/IEC 17025. ISO 17034 establishes the general requirements for the competence of reference material producers. ISO/IEC 17043 establishes the general requirements for the competence of proficiency testing providers.

There are other standards related to the "ISO 17000 family of standards" which address specific fields, such as medical testing laboratories (ISO 15189) and biobanking (ISO 20387). These standards are regularly updated to ensure that they remain current. These standards are typically published with their version number year (such as "ISO/IEC 17000:2020"). Generally, the standards can be referenced without citing their year of issue; when this is done, it means that the most recent version should be referenced. There are sometimes occasions where there is a desire to make reference to a specific version of the standard, in which case this must be done explicitly indicating the year of issue. When a new version of a standard is developed, the conformity assessment community usually agree to a defined timeframe for the transition from the old version to the new version of the standard.

K.3: When selecting conformity assessment bodies and test laboratories, it is important to take into account the final application, particularly when that application has elements related to safety, health, environment and consumer protection. A choice should be made as to whether the conformity assessment body or testing laboratories should be accredited or whether other measures are put in place. Irrespective of this choice, the bodies or testing laboratories should comply with appropriate international standards.

K.4: The choice of which decision rule (describes how measurement uncertainty is accounted for when stating conformity with a specified requirement) to follow will depend on the application for which the measurement is intended, and the decision rule should be clearly stated. Particular attention should be paid to the methods and means of obtaining measurement information used for the evaluation of the uncertainty of measurement which are the basis for conformity assessment decisions and test results.

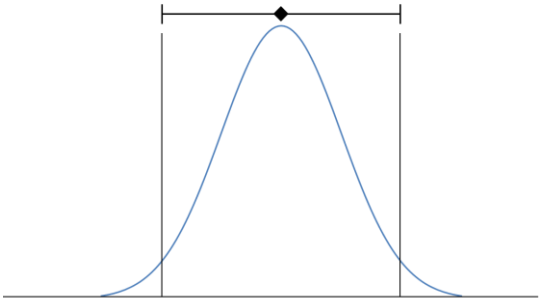

Figure 1 – Understanding of normal (bell curve) distribution.

All measurements have an uncertainty associated with them, albeit this uncertainty may be very small.

When measuring there is always a dispersion of measured values due to the imperfections of the instrument and/or the measurement process. This dispersion is usually in the form of a normal distribution (see Figure 1: normal / bell curve distribution). Often, this is described graphically with expanded measurement uncertainty, often referred to as error bars. The length of error bars in each direction is usually two standard deviations giving 95 % of confidence.

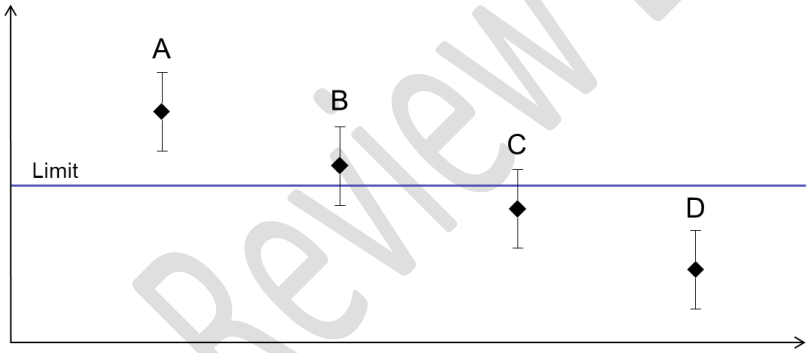

Figure 2 – Four possible outcomes for conformity assessment decisions.

With the single limit there are four possible outcomes for a measurement result when considering its associated measurement uncertainty (see Figure 2). In case A above, even taking into account the possible distribution of the measured result (the normal /bell curve distribution), the measurement result exceeds the limit; this is a clear “rejected”. In a similar way, case D is clearly “accepted” as it is well within the described limit. Whether cases B and C are “accepted” or “rejected” depends on the decision rule adopted. In the simplest decision rule, the nominal value would be compared with the limit, and thus case B would be “rejected” and case C would be “accepted”. However, it may be that accepting case C, where there is a probability that the true value is outside the limit, is not acceptable, for example for safety reasons. This can be addressed by introducing a guard band as shown below.

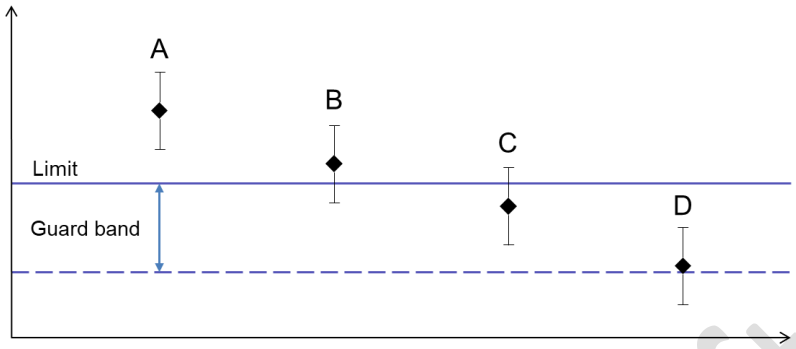

Figure 3 – Introducing guard band.

The introduction of a guard band as shown above would reduce probability for false acceptance. However, there is a significant risk of rejecting perfectly good outcomes with significant economic implications. Clearly, there is no single correct decision rule, the choice is likely to depend on the appetite for risk, and that will vary from one application to another application. For this reason, ISO/IEC 17025:2017 there is an explicit requirement that when the customer requests a statement of conformity to a specification or standard for a test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule should be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer. It is worth noting that many test procedures include how to do the test, how to interpret and report the results. In such cases a decision rule is often inherent.

A more detailed explanation regarding decision rules is given in the guide developed by the Joint Committee for Guides in Metrology (JCGM) and by ILAC[1].

K.5: A large number of relevant international documents, standards, guidelines and recommendations have been developed over the years by the key players, either individually or in joint committees. These capture a huge amount of knowledge and best practice. Furthermore, these documents are coherent in that they appropriately cross reference each other. Some of the most notable are:

- ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories;
- ISO 17034 General requirements for the competence of reference material producers;
- JCGM 200 International vocabulary of metrology – Basic and general concepts and associated terms (VIM);
- JCGM 100 Evaluation of measurement data – Guide to the expression of uncertainty in measurement (GUM) (also available as ISO/IEC Guide 98-3);
- JCGM 106 Evaluation of measurement data – The role of measurement uncertainty in conformity assessment;
- ILAC G8:09 Guidelines on Decision Rules and Statements of Conformity;

[1] specifically, in *JCGM 106 "Evaluation of measurement data – The role of measurement uncertainty in conformity assessment"* and in "*ILAC G8:09 - Guidelines on Decision Rules and Statements of Conformity"*

- OIML G 19 The role of measurement uncertainty in conformity assessment decisions in legal metrology;
- ISO 17020 Conformity assessment — Requirements for the operation of various types of bodies performing inspection;

There are also guides and standards for specific fields such as ISO 21748 *Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty evaluation*, EURACHEM/CITAC Guide *Setting and Using Target Uncertainty in Chemical Measurement, First Edition* and ISO 19036 *Microbiology of the Food Chain – Estimation of Measurement Uncertainty for Quantitative Determinations*. Further references can be found in ILAC-G17:01/2021 *ILAC Guidelines for Measurement Uncertainty in Testing.*

K.6: Metrological traceability is the backbone that ensures confidence in measurements results. It links measurements at the workplace to the SI or other international accepted references. There are various ways to demonstrate to other parties that internationally accepted paths have been followed. The importance of metrological traceability is reflected in the *"Joint BIPM, OIML, ILAC and ISO Declaration on Metrological Traceability",* which recommends that the following principles should be used whenever there is a need to demonstrate metrological traceability for international acceptability.

- In order to be able to rely on their international acceptability, calibrations should be performed
  - in national metrology institutes which should normally be signatories to the CIPM MRA and have CMCs published in the relevant areas of the KCDB or
  - in laboratories accredited to ISO/IEC 17025 by accreditation bodies that are signatories to the ILAC Arrangement.
- Measurement uncertainty should follow the principles established in the GUM.
- The results of the measurements made in accredited laboratories should be traceable to the SI.
- NMIs providing metrological traceability for accredited laboratories should normally be signatories to the CIPM MRA and have CMCs published in the relevant areas of the KCDB.
- In the framework of the OIML-CS, accreditation should be provided by bodies which are signatories to the ILAC Arrangement and which respect the above policies on metrological traceability to the SI.

The above is consistent with ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories* which however additionally deals with the instances where metrological traceability to the SI is not practical. The above is also consistent with the requirements of ILAC P10:07 *ILAC Policy on Metrological Traceability of Measurement Results* which additionally addresses the instances where NMIs provide services not included in the CIPM MRA and laboratories that provide services not included in their accredited scope.

K.7: Manufacturers, suppliers or customers submitting products for testing have the right to check the documentation of the test laboratory and/or its claim of being capable of achieving the desired level of technical competence required for measurement and testing. However, it should be noted that various international instruments exist to help ensure confidence and to reduce the burden of checking claims of competence related to measurement and testing:

- services offered by NMIs/DIs within the CIPM MRA are covered by calibration and measurement capabilities that have been published in the open access BIPM KCDB database (www.bipm.org/kcdb);
- scopes of accreditation in the field of calibration detail calibration and measurement capabilities while scopes of accreditation in the testing field specify parameters, objects and methods of tests. ILAC provides a link to the accreditation bodies who in turn list the calibration and testing laboratories all of whom publish their scopes of accreditation (www.ilac.org/signatory-search/);
- in the field of legal metrology, information regarding the OIML Issuing Authorities and Test Laboratories and their associated scopes under the OIML-CS is published (www.oiml.org/en/oiml-cs/oimlcsiasearch_view).