Guidelines on the Reporting of Compliance with Specification

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PREAMBLE

These guidelines have been prepared to assist testing and calibration laboratories worldwide in stating and reporting compliance with specification of quantitative measurements. In order to satisfy the requirements of ISO/IEC 17025, laboratories should provide customers with statements of measurement results, their uncertainty, and the assessment of compliance with specification when requested to do so, in accordance with these guidelines. Other internationally agreed documents are available to be used for detailed evaluations of uncertainty and calculations for compliance with specification in the general case as well as in more complex situations. See references in section 4.

The guidance offered in this document is based on the assumption that the measurement result has a substantially normal distribution. In some testing and calibration activities this assumption may not be valid. In such cases, the guidance enclosed may not be appropriate, and the laboratory should refer to other guidelines for calculations concerning compliance with specification. See references in section 4.

PURPOSE

This document provides guidelines for testing and calibration laboratories (and their customers) in relation to the decision and reporting of compliance or non-compliance with specified requirements. Legal or regulatory requirements for the reporting of compliance override these guidelines.

AUTHORSHIP

These guidelines were prepared by the Accreditation Committee of ILAC.

1. STATEMENTS OF COMPLIANCE ACCORDING TO ISO/IEC 17025

1.1 For testing laboratories, ISO/IEC 17025:2005 (clause 5.10.3.1 b) requires that "the test report shall, where necessary for the interpretation of the test results include…, where relevant, a statement of compliance/non-compliance with requirements and/or specification".

1.2 For calibration laboratories, ISO/IEC 17025:2005 (clause 5.10.4.2) requires that "if a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met". It is permissible to omit the measurement result and its uncertainty from the report as long as they are retained for possible future reference.

2. STATING COMPLIANCE WITH SPECIFICATION FOR A SINGLE QUANTITY

2.1 When a specification describes an interval with an upper and lower limit, a statement of compliance or non-compliance should only be made where the ratio of the expanded uncertainty interval to the specified interval is reasonably small and fit for purpose (meaning that the laboratory should be able to meet the needs of the customer).

2.2 When compliance with a specification is made it should be clear to the customer which coverage probability for the expanded uncertainty has been used. In general the coverage probability will be 95 % and the reporting shall include a remark such as *"The statement of compliance is based on a 95% coverage probability for the expanded uncertainty."* This means that the probability that the measurement is below the upper specification limit is higher than 95 %, i.e. approximately 97.5 % for symmetrical distributions. A lower limit is treated similarly. Other values for the coverage probability for the expanded uncertainty should be agreed between the laboratory and the customer. Coverage probabilities for the expanded uncertainty higher than 95 % might be chosen while lower values should be avoided.

2.3 The following approach for a certain upper specification limit is recommended. (A lower limit is treated similarly.):

(a) **Compliance:** If the specification limit is not breached by the measurement result plus the expanded uncertainty with a 95% coverage probability, then compliance with the specification can be stated (See Case 1 of Fig.1). This can be reported as "*Compliance*" or "*Compliance – The measurement result is within (or below) the specification limit when the measurement uncertainty is taken into account*". In calibration this is often reported as "*Pass*";

(b) **Non-compliance:** If the specification limit is exceeded by the measurement result minus the expanded uncertainty with a 95% coverage probability, then non-compliance with the specification can be stated. (See Case 4 of Fig.1) This can be reported as "*Non-compliance*" or "*Non-compliance – The measurement result is outside (or above) the specification limit when the measurement uncertainty is taken into account*". In calibration this is often reported as "*Fail*";

(c) If the measurement result plus/minus the expanded uncertainty with a 95 % coverage probability overlaps the limit (See Case 2 and 3 of Fig.1), it is not possible to state compliance or non-compliance. The measurement result and the expanded uncertainty with a 95 % coverage probability should then be reported

together with a statement indicating that neither compliance nor non-compliance was demonstrated. A suitable statement to cover these situations would be "*It is not possible to state compliance*". In Case 2 of Fig.1 it is possible to indicate, that the measurement is below the limit, which can be done using a similar statement "*It is not possible to state compliance using a 95 % coverage probability for the expanded uncertainty although the measurement result is below the limit*". If shorter statements are reported it should not give the impression that the result complies with specification.

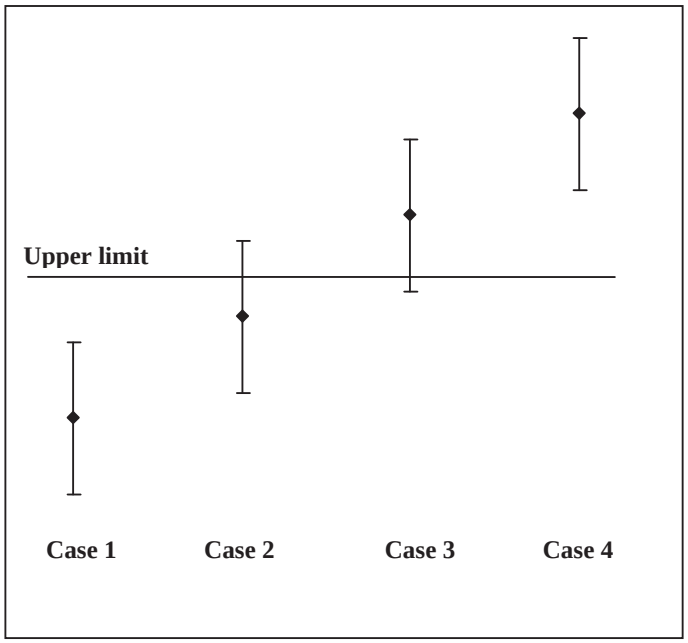

Fig.1 Compliance with specification for an upper limit. Compliance statements may be expanded to explicitly state whether compliance concerns an upper or a lower limit of specification using a coverage probability of 95 %.

2.4 A statement of compliance should not be reported in a way where it could be confused with inspection or product certification. For this purpose a remark can be added, such as "*The test results and the statement of compliance with specification in this report relate only to the test sample as analysed/tested and not to the sample/item from which the test sample was drawn*". In calibration a similar remark could be "*The measurement results and the statement of compliance with specification only relate to the instrument calibrated*".

2.5 If compliance with specification (for an upper limit) is defined as the measured value being less than the specification limit and the measurement result is equal to the specification limit, then non-compliance shall be stated. A lower limit is treated similarly.

2.6 In calibration, measurement uncertainty shall always be taken into account when compliance with specification is made. In testing, a specification or a documented code of practice may require a statement of compliance with specification in the test report,

which does not take into account the effect of measurement uncertainty. In this case, the specification usually holds an implicit assumption that the uncertainty of the agreed measurement method does not vary (i.e. due to prescribed classes of instruments used during test). It should be explicitly stated in the standard or specification that measurement uncertainty has been accounted for when setting the limits. The specification may also be set by national regulation to accommodate a reasonable amount of measurement uncertainty, (see 2.7). Whenever the measurement uncertainty is not taken into account, special care should be taken in the reporting. Laboratories should include notes and explanations in order to ensure unambiguous reporting.

2.7 If national or other regulations require a decision be made regarding rejection or approval, Case 2 of Fig. 1 can be stated as compliance, and Case 3 of Fig. 2 as non-compliance with the specification limit.

3. STATING COMPLIANCE WITH REQUIREMENTS OR WITH SPECIFICATION INVOLVING MULTIPLE QUANTITIES

3.1 If the evaluation of compliance with specification comprises more quantities (and/or measurands) each measurement value should be evaluated independently. The result of each evaluation should be reported as described in 2.3.

3.2 An overall evaluation of compliance with requirements or specification may be formulated in one of the following 3 ways, or by combining them, and may be reported to the customer in a summary according to:

(a) "*All measured values comply with the specification limit(s)*" or "*The item/sample complies with the requirements"*. This covers situations where all measurements comply with specification (Case 1 of Fig.1).
(b) "*For some of the measured values it is not possible to make a statement of compliance with specification*". This covers situations where some of the measurements demonstrate neither compliance nor non-compliance with specification (Case 2 and 3 of Fig.1).
(c) "*Some of the measured values do not comply with specifications*" or "*The item/sample does not comply with the requirements"*. This covers situations where one or more measurements are in non-compliance with specifications (Case 4 of Fig.1).

If an overall evaluation is made it should include a statement regarding the coverage probability for the expanded uncertainty such as *"The statement(s) of compliance with specification (or requirement) is based on a 95% coverage probability for the expanded uncertainty of the measurement results on which the decision of compliance is based"*. The statement should clearly indicate if other values for the coverage probability for the expanded uncertainty have been agreed between the laboratory and the customer as described in section 2.2, or refer to relevant regulations or codes of practice as described in section 2.6.

4. REFERENCES

1. ISO/IEC Guide 98-3:2008, *Uncertainty of Measurement – Part 3: Guide to the Expression of Uncertainty in Measurement.* (GUM:1995)

2. ISO/IEC Guide 99:2007, *International Vocabulary of Metrology - Basic and general concepts and associated terms (VIM),*

3. ISO 3534-1:2006, *Statistics - Vocabulary and symbols - Part 1: General statistical terms and terms used in probability.*

4. ISO 14253-1:1998, *Geometrical Product Specifications (GPS) - Inspection by measurement of workpieces and measuring equipment - Part 1: Decision rules for proving conformance or non-conformance with specifications.*

5. EURACHEM/CITAC Guide, *Use of uncertainty information in compliance assessment, 2007*

6. ASME B89.7.3.1-2001 *Guidelines for Decision Rules: Considering Measurement Uncertainty Determining Conformance to Specifications.*