Information regarding decision rule

# Introduction

IECEx ExCBs and ExTLs will need to address the requirements on “decision rule” that have been introduced in the latest edition of IEC 17025. This will be necessary to ensure that the IECEx 02 Scheme and our ExTRs are meeting the requirements of IEC 17025 and to also meet the expectations of national accreditation bodies.

# Background

While the term “decision rule” appears to be new, the concept it addresses has been around for a long time.

The following are the relevant parts of IEC 17025 Third edition, 2017-11.

**3 Terms and definitions**

3.7

decision rule

rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

**7 Process requirements**

**7.1 Review of requests, tenders and contracts**

**7.1.3** When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer.

NOTE For further guidance on statements of conformity, see ISO/IEC Guide 98-4.

**7.8 Reporting of results**

**7.8.6 Reporting statements of conformity**

**7.8.6.1** 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.

NOTE Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.

**7.8.6.2** The laboratory shall report on the statement of conformity, such that the statement clearly identifies:

a) to which results the statement of conformity applies;

b) which specifications, standards or parts thereof are met or not met;

c) the decision rule applied (unless it is inherent in the requested specification or standard).

NOTE For further information, see ISO/IEC Guide 98-4.

**Annex A**

(informative)

**Metrological traceability**

**A.2.3** Measurement standards that have reported information from a competent laboratory that includes only a statement of conformity to a specification (omitting the measurement results and associated uncertainties) are sometimes used to disseminate metrological traceability. This approach, in which the specification limits are imported as the source of uncertainty, is dependent upon:

— the use of an appropriate decision rule to establish conformity;

— the specification limits subsequently being treated in a technically appropriate way in the uncertainty budget.

The technical basis for this approach is that the declared conformance to a specification defines a range of measurement values, within which the true value is expected to lie, at a specified level of confidence, which considers both any bias from the true value, as well as the measurement uncertainty.

EXAMPLE The use of OIML R 111 class weights to calibrate a balance.

At present the IECEx approach to implementing the above has not been agreed and it is likely there will be varying interpretations by ExCBs/ExTLs, possibly influenced by their local accreditation body.

ILAC has published a document ILAC G8:09/2019 Guidelines on *Decision Rules and Statements of Conformity* that is of relevance to this topic. A copy of this is provided separately.

# IECEx groups affected

The following groups within IECEx are likely to have some interest and responsibility for this issue:

ExAG: IECEx Assessment Group

ExTAG WG01: Preparation of assessment and test report forms ExTRs

ExTAG WG04: Uncertainty of measurement

# Likely outcomes

To achieve a consistent outcome for this matter, it is likely appropriate text will need to be introduced for the Cover Page for ExTRs. However, this will need to be underpinned by how uncertainty of measurement is addressed in IECEx, which is currently covered by OD 012. OD 012 includes some the information relevant to “decision rule” but does not use that terminology and still refers to the old edition of the standard.

The following wording includes an example, showing how SGS Baseefa is applying this for the ExTRs that they are issuing:

A laboratory accredited to ISO/IEC 17025:2017 is required to publish its “Decision Rule” in respect of the application of uncertainty of measurement to the results of tests. The SGS Baseefa Ltd. decision rule is published in document BAS-PS-026, available from the SGS Baseefa web site. In summary: Where an indicated value lies close to a limit value, such that the uncertainty of measurement is greater than the difference between the two, it is not possible to state unequivocally that either compliance or non-compliance has been demonstrated. The SGS Baseefa Ltd. Decision Rule is to take the indicated value as the true value, based on the principle of “Shared Risk”.

NOTE The above document BAS-PS-026 can be accessed via the following link: <https://www.sgs.co.uk/en-gb/searchresults?s=BAS-PS-026&dc=http&d=4294967073>

# Way ahead

A way ahead needs to be planned to ensure all IECEx ExTLs are meeting the decision rule requirements and to come up with a consistent way of achieving this.

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29 September 2020