IECEx OD 012

Edition 3.0 2021-10

IECEx OPERATIONAL DOCUMENT

IEC System for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres (IECEx System)

ExTAG Guide for application of measurement uncertainty to conformity assessment activities in the IECEx System

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

IECEx Operational Document OD 012 –

ExTAG Guide for application of measurement uncertainty to conformity assessment activities in the IECEx System

FOREWORD

This document is to provide guidance for the application of measurement uncertainty to conformity for laboratory tests carried out under the IECEx System.

Document history

Date	Summary
2003-11	Version 1 as original version.
2009-03	Edition 2 published to provide information regarding compliance with IEC 17025:2005. ExCB comments included and comments from IECEx members addressed.
2021-10	Edition 3 published to: • update content to IEC 17025:2017, • clarify information on decision rules and simple acceptance, • remove content in clauses 5,6 and Annex A, • introduce advice for IECEx assessors (Annex B) and • introduce guidance for calibration certificates (Annex C).

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ExTAG Guide for application of measurement uncertainty to conformity assessment activities in the IECEx System

1 Scope

This Guide presents a practical approach to the application of measurement uncertainty to conformity assessment activities in the IECEx System.

2 Reference documents

ISO/IEC 17025:2017 (Edition 3), *General requirements for the competence of testing and calibration laboratories*

ISO/IEC Guide 98-3:2008, *Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

ISO/IEC Guide 98-4:2012, *Uncertainty of measurement - Part 4: Role of measurement uncertainty in conformity assessment*

IEC Guide 115:2021, *Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector*

3 General

3.1 Requirements of ISO/IEC 17025:2017

ExTLs in the IECEx are required to comply with ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories.

ISO/IEC 17025: 2017, Clause 7.6.3 states:

> *A laboratory performing testing shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the test method.*
>
> NOTE 1 In those cases where a well-recognised test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, the laboratory is considered to have satisfied 7.6.3 by following the test method and reporting instructions.
>
> NOTE 2 For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result if the laboratory can demonstrate that the identified critical influencing factors are under control.

ISO/IEC 17025: 2017, Clause 7.8.2.2 states

> *The laboratory shall be responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer shall be clearly identified. In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results…*

ISO/IEC 17025: 2017, Clause 7.8.3.1 item c) states:

> *"In addition to the requirements listed in 7.8.2, test reports shall, where necessary for the interpretation of the test results, include the following:"*

"c) where applicable, the measurement uncertainty……when:

- *it is relevant to the validity or application of the test results*
- *a customer's instruction so requires, or*
- *the measurement uncertainty affects conformity to a specification limit"*

ISO/IEC 17025: 2017 Clause 7.8.6 states the following where measurement uncertainty is defined within the decision rule if the ExTL is requested to make conformance statements in the test report:

"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."

NOTE for the purposes of certification, where the ExCB is providing the client with a decision on certification, the ExCB is the client of the ExTL and the ExCB is making the judgement on conformity.

3.2 Application of ISO/IEC 17025:2017 in the IECEx Equipment Scheme

ISO/IEC 17025: 2017 was written as a general use document, for all industries. Measurement uncertainty principles are applied to laboratory testing and presentation of test results to provide a degree of assurance that decisions made about conformance of the products tested according to the relevant requirements are valid. Procedures and techniques for measurement uncertainty calculations are well established.

The standards used by the IECEx do not contain any specifications for measurement uncertainty or requirements for decision rules for test results at the time of publication of this OD. Therefore, there are no established specification limits that can be used to determine whether a particular measurement uncertainty for a result is in conformance or that measurement uncertainty is to be used in determining conformance. The standards contain significant safety factors, which have been used in lieu of requiring measurement uncertainty for test results.

Therefore, this document is written to provide some more background, give some references to IEC guides that can be used. Reference is also made to the 'Simple acceptance' decision rule that is commonly used in IECEx.

4 Background

4.1 Applying Measurement Uncertainty principles

A challenge to applying measurement uncertainty principles to conformity assessment activities is managing the cost, time, and practical aspects of determining the relationships between various sources of uncertainty. Some relationships are either unknown or would take considerable effort, time, and cost to establish. There are several proven techniques available to address this challenge. These techniques include eliminating from consideration those sources of variability, which have little influence on the outcome and minimizing significant sources of variability by controlling them.

4.2 Test methods used in the IECEx System

Test methods used under the IECEx System are in essence consensus standards. Criteria used to determine conformance with requirements are most often based on a consensus of judgement of what the limits of the test result should be. Exceeding the limit by a small amount does not result in an imminent hazard.

Test methods used may have a precision statement expressing the maximum permissible uncertainty expected to be achieved when the method is used. Historically, test laboratories have used state of the art equipment and not considered measurement uncertainty when comparing results to limits. Safety standards have been developed in this environment and the limits in the standards reflect this practice.

4.3 Test parameters that influence the results of testing in IECEx

Test parameters that influence the results of tests can be numerous. Nominal variations in some test parameters have little effect on the result while variations in other parameters may have an effect. However, limiting the variability of the parameter when performing the test can minimize the degree of influence.

An often-used way of accounting for the effects of test parameters on tests results is to define the acceptable limits of variability of test parameters. When this is done, any variability in results obtained due to changes in the controlled parameters is not considered significant if the parameters are controlled within the limits.

Examples of application of this technique are:

a) Input power source to be maintained: voltage ± 3,0%, frequency ± 2%, total harmonic distortion maximum 5,0%

b) Ambient temperature: 23 °C ± 5 °C, or 20 °C ± 5 °C

c) Relative Humidity: 50% ± 5%

d) Concentration of flammable gases in explosive mixtures ± 2%

e) Personnel: documented technical competency requirements for the test

f) Procedures: documented laboratory procedures

g) Equipment accuracy: instrumentation with accuracy per relevant standard or ExTL decision as an indication of a primary contributor to measurement uncertainty

NOTE The acceptable limits in items a through d are given as examples and do not necessarily represent actual limits established.

4.4 Decision based on simple acceptance ISO/IEC Guide 98-4

No decision rule is specified by the IEC standard, when comparing the measurement result with the applicable limit according to the specification in that standard. The decisions on conformity are made without applying the measurement uncertainty (“simple acceptance” decision rule, previously known as “accuracy method”).

Other rules may be used (for example when required by the standard or client)

An important and widely used decision rule is known as simple acceptance (ref: ISO/IEC Guide 98-4: 2012 section 8.2).

> *[The ExTL and the client] agree implicitly or explicitly, to accept as conforming (and reject otherwise) an item whose property has a measured value in the tolerance interval.*
>
> *In practice, in order to keep incorrect decisions to acceptable levels, there is usually a requirement that the measurement uncertainty has been considered and judged to be acceptable for the intended purpose.*

This confirms that measurement uncertainty should be addressed, but provided the uncertainty lies within acceptable limits, it is acceptable to use the measurement result without adjusting it to account for the uncertainty. A “simple acceptance” decision rule is employed in this case.

The question of what level of measurement uncertainty would be acceptable or unacceptable, is not addressed by this guide. Proficiency tests give an indication of the accuracy of results achieved by an ExTL, where the measurand is established by a consensus of the test data from participating laboratories. Precision can be determined by repeating measurements to establish the range of results obtained.

4.5 Decision rules

4.5.1 General

This section only provides information on simple acceptance. Other decision rules may be created and applied by ExTLs.

The uncertainties of measurement are calculated by the laboratory based on application of ISO/IEC Guide 98-4 and application of any relevant test methods, decision sheets and operational procedures of IECEx.

This guide assists ExTLs on the application of measurement uncertainty principles and applying the decision rule when reporting test results within IECEx Product Certification scheme, noting that the reporting of the measurement uncertainty for measurements is not necessary unless required by the test standard or customer.

Calculations of uncertainty leading to the reported values, when required by the test standard or customer, are on file with the ExTL that conducted the testing.

4.5.2 Simple acceptance

With simple acceptance, as described earlier in this guide, the measurement uncertainty is not accounted in the result. For measurements recorded at the limits of the tolerance on the measurand, there is a 50% probability of conformity, and they are recorded as a pass.

Other decision rules may be requested by the client.

5 Application of measurement uncertainty principles (informative)

Refer to IEC Guide 98-4.

6 Guidance on making measurement uncertainty calculations including an example of how to perform the calculations (Procedure 1) (informative)

Refer to IEC Guide 98-4.

Annex A
(informative)

Information on the various probability distributions

Refer to ISO/IEC Guide 98-4.

Annex B
(informative)

Notes for IECEx assessors

It is not necessary for the IECEx assessment team to verify the ability of ExTLs in the IECEx to perform measurement uncertainty calculations that have acceptable national accreditation to ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories. ExTLs that do not have acceptable national accreditation shall be able to demonstrate, for the IECEx assessment team, their ability to evaluate measurement uncertainty.

NOTE When reviewing an ExTL against IEC 17025: 2017 note that the accuracy method that was included in Edition 1 of this guide has been removed from Edition 3.

Measurement uncertainty is only required to be applied to a measurement, where a tolerance limit on the measurand is included in the standard. For example:

– Gas mixture
– Drop height of impact weight

As an example, the explosion pressure determination test of IEC 60079-1 includes a tolerance on gas mixture but does not define a measurement uncertainty for the result. Whilst the uncertainty on the gas mixture can be determined, the explosion pressure result depends on numerous factors. These factors are compensated for in the subsequent overpressure test of the enclosure, which includes a safety factor. Naturally it is important to take an accurate measurement of the explosion pressure at the points selected by the ExTL. It is therefore sensible to use calibrated equipment to take that pressure measurement, but the uncertainty need not be calculated because no tolerance on that measurement is included in the standard.

The measurement uncertainty value is an indication of the level of *confidence* in the measurement of a result. It is not possible to prescribe limits to measurement uncertainty because the test equipment used may be different and the quantity of the measurand is also different. Proficiency testing gives a good indication of the accuracy of an ExTL to take measurements because their data is compared to other laboratories.

In general, the requirement of ISO/IEC 17025:2017 is met if the ExTL presents information according to the procedures stated. It is generally not necessary to challenge an ExTL on the information provided (see note). If an assessor is concerned that the accuracy of a particular item of equipment used for a test is poor, or a contribution to the calculated method is a large component of the combined uncertainty, then an observation only shall be raised to suggest that further research is undertaken to see if an improvement can be made.

NOTE ISO/IEC 17025: 2017 requires measurement uncertainty to be established but does not prescribe limits. Neither do the Ex standards prescribe limits to uncertainty, although limits to the measured amount are prescribed in some cases (for example, gas mixtures). It is not possible to apply an arbitrary maximum uncertainty because it would not be possible to compare that to the accuracy method.

Annex C
(normative)

Calibration guidance for measurement uncertainty

C.1 External calibration

Calibration shall be carried out by organisations that are accredited to ISO/IEC 17025 to carry out calibration by a nationally recognised accreditation body.

If a nationally accredited body is not available to carry out the calibration required, it is acceptable to use the original equipment manufacturer for as long as a calibration certificate is provided and the calibration is traceable to national standards. Measurement uncertainty shall be provided.

C.2 Internal calibration (by ExTL)

Internal calibration by an ExTL shall be carried out using externally calibrated equipment and shall produce an internal calibration certificate with measurement uncertainty detail.

C.3 Witness/offsite testing instrument calibration requirements

Manufacturers wishing to use their own equipment for offsite or witness tests shall arrange calibration of the equipment according to this Annex C.1 or C.2. For Annex C.2 the manufacturer may carry out their own internal calibration or use an ExTL.

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