

## **IEC GUIDE 115**

Edition 3.0 2023-04

# **GUIDE**

# GUIDE

Application of measurement uncertainty to conformity assessment activities in the electrotechnical sector

Application de l'incertitude de mesure aux activités d'évaluation de la conformité dans le secteur électrotechnique [023

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 17.020; 19.080

ISBN 978-2-8322-6712-7

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#### INTERNATIONAL ELECTROTECHNICAL COMMISSION

#### APPLICATION OF MEASUREMENT UNCERTAINTY TO CONFORMITY ASSESSMENT ACTIVITIES IN THE ELECTROTECHNICAL SECTOR

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This third edition of IEC Guide 115 has been prepared, in accordance with ISO/IEC Directives, Part 1, Annex A, by IECEE/CTL.

This third edition cancels and replaces the second edition published in 2021.

The main changes with respect to the previous edition are as follows:

- a) document was rewritten to align with ISO/IEC 17025:2017;
- b) content has been added to replace "accuracy method" with "simple acceptance" and added "decision rule";
- c) modified document title to state "measurement uncertainty";
- d) removed statement of document applicability to only IECEE CB Scheme;
- e) removed list of IEC technical committees to indicate document can be used by other committees and industries;
- f) added content for reporting statements of conformity.

The text of this Guide is based on the following documents:

Draft	Report on voting
SMBNC/30/DV	SMBNC/34/RV

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this Guide is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members\_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

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#### INTRODUCTION

This document has been prepared by the IECEE Committee of Testing Laboratories (CTL) to provide guidance on the practical application of the measurement uncertainty requirements of ISO/IEC 17025:2017 to the electrical safety testing conducted within the electrotechnical sector.

The aim of the CTL is, among other tasks, to define a common understanding of the test methodology with regard to the IEC standards as well as to ensure and continually improve the repeatability and reproducibility of test results among the member laboratories.

The practical approach to measurement uncertainty outlined in this document has been adopted for use in the IECEE Schemes, and is also extensively used around the world by testing laboratories engaged in testing electrical products to national safety standards.

ISO/IEC 17025 was written as a general use document, for all industries. Measurement uncertainty principles are applied to laboratory measurements and presentation of results to provide a degree of assurance that decisions made about conformance of the products tested, in accordance with the relevant requirements, are valid. Procedures and techniques for measurement uncertainty calculations are well established. This document is written to provide more specific guidance on the application of measurement uncertainty principles and applying the decision rule to conformance statements when reporting test results.

This document is of particular interest to IEC technical committees, which can decide to make use of it if necessary.

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#### APPLICATION OF MEASUREMENT UNCERTAINTY TO CONFORMITY ASSESSMENT ACTIVITIES IN THE ELECTROTECHNICAL SECTOR

#### 1 Scope

This document presents a practical approach to the application of measurement uncertainty to electrical safety testing conducted within the electrotechnical sector. It is specifically conceived for use in IECEE Schemes as well as by testing laboratories engaged in testing electrical products to national safety standards. It describes the application of measurement uncertainty principles.

This document provides guidance on making measurement uncertainty calculations and gives some examples relating to measurement uncertainty calculations for product conformity assessment testing.

NOTE The IEC Standardization Management Board (SMB) has decided that Guides such as this one can have mandatory requirements which shall be followed by all IEC committees developing technical work that falls within the scope of the Guide, as well as guidance which may or may not be followed. The mandatory requirements in this Guide are identified by the use of "shall". Statements that are only for guidance are identified by using the verb "should". (See ISO/IEC Directives, IEC Supplement:2021, A.1.1.)

#### 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories

#### 3 Terms, definitions and symbols

#### 3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at https://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp

### 3.1.1 measurand

quantity intended to be measured

[SOURCE: ISO/IEC Guide 99:2007, 2.3, modified - NOTES and EXAMPLES have been deleted.]

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#### 3.1.2

#### measurement uncertainty

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

[SOURCE: ISO/IEC Guide 99:2007, 2.26, modified – NOTES 1 to 4 have been deleted.]

#### 3.1.3

#### decision rule

documented rule that describes how measurement uncertainty will be accounted for with regard to accepting or rejecting an item, given a specified requirement and the result of a measurement

[SOURCE: ISO/IEC Guide 98-4:2012, 3.3.12]

#### 3.1.4

#### simple acceptance

decision rule in which the producer and user of the measurement result agree, implicitly or explicitly, to accept as conforming (and reject otherwise) an item whose property has a measured value in the tolerance interval

Note 1 to entry: The definition is based on ISO/IEC Guide 98-4:2012, 8.2.1.

Note 2 to entry: Within the IECEE CB Scheme, the producer is the laboratory and the user is the Certification Body.

#### 3.1.5

#### coverage factor

number larger than one by which a combined standard measurement uncertainty is multiplied to obtain an expanded measurement uncertainty

Note 1 to entry: A coverage factor is usually symbolized k (see also ISO/IEC Guide 98-3:2008, 2.3.6).

[SOURCE: ISO/IEC Guide 99:2007, 2.38]/sist/1ed94bed-7b07-4c13-af7e-77ca80e6c158/iec-

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#### 3.1.6

#### combined standard uncertainty

standard measurement uncertainty that is obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model

[SOURCE: ISO/IEC Guide 99:2007, 2.31, modified – The NOTE has been deleted.]

#### 3.1.7

#### measurement error

measured quantity value minus a reference quantity value

[SOURCE: ISO/IEC Guide 99:2007, 2.16, modified - NOTES 1 and 2 have been deleted.)

#### 3.1.8

#### expanded measurement uncertainty

product of a combined standard measurement uncertainty and a factor larger than the number one

Note 1 to entry: The factor depends upon the type of probability distribution of the output quantity in a measurement model and on the selected coverage probability.

Note 2 to entry: The term "factor" in this definition refers to a coverage factor.

[SOURCE: ISO/IEC Guide 99:2007, 2.35, modified – NOTE 3 has been deleted.]

#### 3.1.9

#### level of confidence

probability that the value of the measurand lies within the quoted range of measurement uncertainty

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#### 3.1.10

#### standard deviation

positive square root of the variance

### 3.1.11

#### standard uncertainty

uncertainty of the result of a measurement expressed as a standard deviation

[SOURCE: ISO/IEC Guide 98-3:2008, 2.3.1]

#### 3.1.12

#### Type A evaluation method

method of evaluation of measurement uncertainty by the statistical analysis of a series of observations

#### 3.1.13

#### Type B evaluation method

method of evaluation of measurement uncertainty by means other than the statistical analysis of a series of observations (e.g. rectangular, triangular, distribution)

#### 3.2 Symbols

 $X_i$  quantity input

 $x_i$  uncertainty contributor

Application of measurement uncertainty principles 4

#### General 4.1

Qualification and acceptance of CB test laboratories (CBTL) - for example, in the 4.1.1 IECEE - is performed in accordance with ISO/IEC 17025.

ISO/IEC 17025:2017 states:

#### 7.6 Evaluation of measurement uncertainty

**7.6.1** Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.

**7.6.2** A laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations.

**7.6.3** 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 method.

NOTE 1 In those cases where a well-recognized 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.

**4.1.2** ISO/IEC 17025:2017, 7.8.3.1 states that the test report shall, where necessary for the interpretation of the test results, include the following:

- c) where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:
  - it is relevant to the validity or application of the test results;
  - hters a customer's instruction so requires, or d94bed-7b07-4c13-af7e-77ca80e6c158/iec-
    - the measurement uncertainty affects conformity to a specification limit;

Guidance on evaluation of measurement uncertainty is given in Annex A.

#### 4.2 Background

**4.2.1** A challenge to applying measurement uncertainty principles to conformity assessment activities is managing the cost, time and practical aspects of determining the various sources of uncertainty. Some possible contributions are either unknown or would take considerable effort, time and cost to establish. There are a number of proven techniques available to address this challenge. These techniques include selecting those contributors which significantly influence measurement uncertainty.

**4.2.2** Test methods used under the IECEE Certification Body (CB) Scheme are in essence consensus standards. Criteria used to determine conformance with requirements are most often based on a consensus of judgment of the limits that are applicable to the test result. Exceeding the limit by a small amount does not result in an imminent hazard. Test methods used can have a statement expressing the maximum permissible measurement uncertainty expected to be achieved when the method is used. Historically, and still today, test laboratories have used state-of-the-art equipment and have not considered measurement uncertainty when comparing test results to specification limits: the observed results were compared directly to the limits stated in the standard. Safety standards have been developed in this environment and the specification limits in the standards reflect this practice. This practice provides the basis for use of the simple acceptance decision rule under the IECEE CB Scheme (see 4.3.3).

#### 4.3 Measurement uncertainty principles – Application of procedures

**4.3.1** When a test results in measurement of a variable, there is uncertainty associated with the measured result obtained.

**4.3.2** Measurement uncertainty is used for statements of conformity within the IECEE CB Scheme in accordance with ISO/IEC 17025:2017, 7.6.1 and 7.6.3. The reporting of the measurement uncertainty for measurements is not necessary unless the test standard or customer requires it in accordance with ISO/IEC 17025:2017, 7.8.3.1 c).

NOTE Within the IECEE CB Scheme, the customer is understood to be the Certification Body.

**4.3.3** When comparing the obtained measurement results with the applicable limits in accordance with the specification in the IEC standards, the conformance decision is made without applying the measurement uncertainty. Refer to Figure 1. This is often called "simple acceptance" (see ISO/IEC Guide 98-4:2012, 8.3.1.2).

**4.3.4** Simple acceptance anticipates the agreement of an acceptable level of measurement uncertainty when applying the decision rule. For this purpose, the contributors to measurement uncertainty can be limited to those related to the measuring equipment as noted below. Other contributors can be considered by the laboratory.

- a) Equipment accuracy: Meets the requirements of the test standard or, where not stated in the test standard, the default values given in IECEE OD-5014.
- b) Control of environment: Ambient temperature, humidity, power quality, etc. for use of the measurement equipment are controlled. These are not considered as significant contributors if they are within the equipment manufacturer's specifications for the stated accuracy specification.
- c) Resolution: It is not considered to be a significant contributor for conformance decision purposes if it is the same, or better, than the least significant digit of the test method specification or the conformance criteria provided by the test standard.

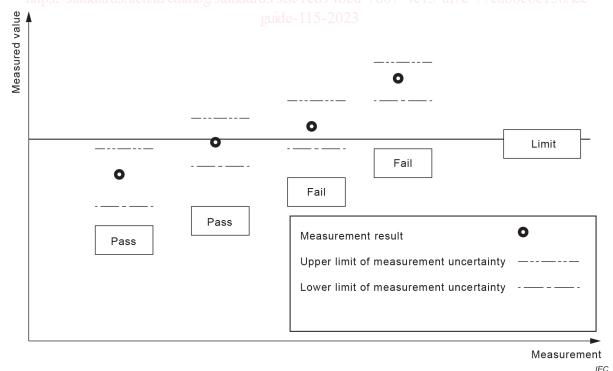


Figure 1 – Application of simple acceptance

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#### 4.4 Reporting statements of conformity

In order to fulfil the requirement of ISO/IEC 17025:2017, 7.8.6.1, the test report should contain a general statement such as: "Measurement uncertainty is not applied when providing statements of conformity in accordance with IEC Guide 115:2023, 4.3.3."

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#### Annex A

(informative)

#### Measurement uncertainty calculations for product conformity assessment testing

#### A.1 Overview

This Annex A is meant to be a short and simplified summary of the steps to be taken by a CB test laboratory (CBTL) when the need to estimate measurement uncertainties arises. It also includes examples of how to perform the calculations. It is by no means a comprehensive document about measurement uncertainty, the sources and estimation of measurement uncertainty in general, but is intended to offer a practical approach for most applicable circumstances in the IECEE CB Scheme.

#### A.2 Guidance on making measurement uncertainty calculations

#### A.2.1 General principles

No measurement is perfect and the imperfections give rise to measurement error in the result. Consequently, the result of a measurement is only an approximation to the measured value (measurand) and is only complete when accompanied by a statement of the uncertainty of that approximation. Indeed, because of measurement uncertainty, a true value can never be known.

### A.2.2 Uncertainty estimation approach CS.IICI. 21

The total uncertainty of a measurement is a combination of a number of component uncertainties. Even a single instrument reading can be influenced by several factors. Careful consideration is required to identify and list the factors that contribute to uncertainty. This is a very important step and requires a good understanding of the measuring equipment, the principles and practice of the test and the influence of environment on the measurement.

ISO/IEC Guide 98-3:2008 has adopted the approach of grouping uncertainty components into two categories based on their method of evaluation: Type A and Type B. This categorization of the methods of evaluation, rather than of the components themselves, avoids certain ambiguities.

#### A.2.3 Type A evaluation

Type A evaluation is carried out by calculation from a series of repeated observations, using statistical methods.

#### A.2.4 Type B evaluation

Type B evaluation is carried out by means other than that used for Type A. For example, by judgment based on the following information in Table A.1.

Data in calibration certificates	This enables corrections to be made and Type B uncertainties to be assigned
Previous measurement data	For example, history graphs can be constructed and yield useful information about changes with time
Experience with or general knowledge	Behaviour and properties of similar materials and equipment
Accepted values of constants	Associated with materials and quantities
Manufacturers' specifications	
All other relevant information	

#### Table A.1 – Type B uncertainties

#### A.2.5 Individual uncertainties

Individual uncertainties are evaluated by the appropriate method and each is expressed as a standard deviation and is referred to as a standard uncertainty.

#### A.2.6 Summary of steps when estimating uncertainty

**A.2.6.1** Identify the factors that can significantly influence the measured values and review their applicability. There are many possible sources in practice, mainly including the following.

- a) Contribution from calibration of the measuring instruments, including contribution from reference or working standards.
- b) Temperature error at the beginning and end of a test (e.g. winding resistance method).
- c) Uncertainty related to the loading applied and the measurement of it.
- d) Velocity of air flow over the test sample and uncertainty in measuring it.
- e) For digital instruments, there are the number of displayed digits and the stability of the display at the time the reading is taken. In addition, the reported uncertainty of an instrument does not necessarily include the display.
- f) Instrument resolution, limits in graduation of a scale.
- g) Approximations and assumptions incorporated in the measurement method.
- h) Uncertainty due to the procedures used to prepare the sample for test and actually testing it.
- i) If a computer is used to acquire the readings from the instrument, there is uncertainty associated with the processing of the data due to calculations or other manipulations within the computer such as analogue-to-digital conversions, and conversions between floating point and integer numbers.
- j) Rounded values of constants and other parameters used for calculations.
- k) Effects of environmental conditions (e.g. variation in ambient temperature) on the measurement.

NOTE 1 Negligible where environmental conditions are within the acceptable accuracy limits for the equipment (assumed and expected from a CBTL).

I) Personal bias in reading analogue instruments (e.g. parallax error or the number of significant figures that can be interpolated).

NOTE 2 Negligible in case of digital displays or in case of appropriate training (assumed and expected from a CBTL).

NOTE 3 This list does not state all of the items that can contribute to measurement uncertainty. It is possible that other factors will need to be identified and considered by each individual laboratory.

**A.2.6.2** Transform influencing factors  $x_i$  to the unit of the measured value (quantify), for which an uncertainty estimate will be made, if not already given in that unit. For example, if the unit of the measured value is the volt (V) and a resistor's tolerance in ohms ( $\Omega$ ) is one of the influencing factors, transform the change of resistance to the resulting contribution in volts.