



GUIDE 58

Calibration and testing laboratory accreditation systems — General requirements for operation and recognition

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) together form a system for worldwide standardization as a whole. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

This Guide replaces ISO/IEC Guide 54:1988, *Testing laboratory accreditation systems — General recommendations for the acceptance of accreditation bodies*, and ISO/IEC Guide 55:1988, *Testing laboratory accreditation systems — General recommendations for operation*. It was drawn up by the ISO Council Committee on conformity assessment, ISO/CASCO, on the basis of a draft transmitted by the International Laboratory Accreditation Conference (ILAC '90) and in collaboration with laboratory experts.

Its object is to provide guidance for the setting up and operation of a laboratory accreditation body and to facilitate agreements between such bodies on mutual recognition of accreditation of testing laboratories.

Whilst ISO/IEC Guides such as this are intended to provide guidance, it is hoped that any changes from the documents made in introducing systems nationally would be minimal. In recognition of the fact that some countries may choose to adopt the Guides directly, they are written to enable this to be done by including words such as "shall" to indicate those aspects which desirably would be mandatory. The overriding basis that the document is intended to provide guidance holds good.

It is only in recent years that national accreditation bodies have developed on a large scale because of the necessity to make available testing services of an assessed level of quality to all sectors of the economy and also to facilitate mutual acceptance of calibration and test results.

This Guide was approved by the ISO Council Committee on conformity assessment (ISO/CASCO) in September 1992 and by the IEC Council in October 1992.

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Calibration and testing laboratory accreditation systems — General requirements for operation and recognition

1 Scope

This document sets out the general requirements for the operation of a system for accreditation of calibration and/or testing laboratories so that the accreditations granted and the services covered by the accreditations may be recognized at a national or an international level and the body operating the accreditation system may be recognized at national or international level as competent and reliable.

Users of the services of an accreditation body, other than the laboratories accredited by that accreditation body, may require compliance with requirements additional to those specified in this document.

The object of this document is to provide guidance for the setting up and operation of an accreditation body and to facilitate agreements on mutual recognition of accreditation of laboratories between such bodies.

NOTE – It is recognized that agreements on mutual recognition of accreditations aiming at the removal of barriers to across-border trade may have to cover other aspects not explicitly specified in these general requirements, such as proficiency testing or other interlaboratory comparisons, exchange of staff or training programmes. In particular, with a view to creating confidence and harmonizing the interpretation and implementation of standards, each accreditation body should encourage technical cooperation and exchange of experience among laboratories accredited by it, and it should be prepared to exchange information on accreditation procedures and practices with other accreditation bodies.

2 References

ISO/IEC Guide 2:1991, *General terms and their definitions concerning standardization and related activities*.

ISO/IEC Guide 25:1990, *General requirements for the competence of calibration and testing laboratories*.

ISO/IEC Guide 43:1984, *Development and operation of laboratory proficiency testing*.

ISO 8402, *Quality management and quality assurance — Vocabulary*.

ISO 10011-1:1990, *Guidelines for auditing quality systems — Part 1: Auditing*.

ISO 10011-2:1991, *Guidelines for auditing quality systems — Part 2: Qualification criteria for quality systems auditors*.

3 Definitions

The relevant definitions contained in ISO/IEC Guide 2 are applicable.

In addition, the following definitions apply for the purposes of this document:

3.1 laboratory: Body that calibrates and/or tests.

[3.1 of ISO/IEC Guide 25:1990]

3.2 accreditation: Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.

NOTE – Accreditation does not of itself qualify the laboratory to approve any particular product. However, accreditation may be relevant to approval and certification authorities when they decide whether or not to accept data produced by a given laboratory in connection with their own activities.

[13.7 of ISO/IEC Guide 2:1991, with the addition of a note]

For the purposes of this document the term “client” refers to any organization or person that engages the services of a calibration or testing laboratory.

4 Accreditation body

4.1 General provisions

4.1.1 The procedures under which the accreditation body operates shall be administered in a non-discriminatory manner.

Access to an accreditation system operated by an accreditation body shall not be conditional upon the size of the laboratory or membership of any association or group, nor shall there be undue financial conditions to restrict participation.

4.1.2 The competence of an applicant laboratory shall be assessed by the accreditation body against all of the requirements of ISO/IEC Guide 25.

4.1.3 The requirements of ISO/IEC Guide 25 may have to be interpreted for a specific calibration, test, or type of calibration or test by the accreditation body. These interpretations shall be formulated by relevant and impartial committees or persons possessing the necessary technical competence. They shall be published by the accreditation body.

4.1.4 The accreditation body shall require accredited laboratories to maintain impartiality and integrity.