GUIDE 25

General requirements for the competence of calibration and testing laboratories

Third edition 1990

Contents

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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 third edition of ISO/IEC Guide 25 was drawn up by the ISO Council Committee on conformity assessment (CASCO), in response to a request arising from ILAC '88, the International Laboratory Accreditation Conference held in Auckland (New Zealand) on 17-21 October 1988.

It was approved by the IEC Council in October 1990 and by the ISO Council in December 1990.

The documents produced by CASCO are issued as Guides and follow the general rules for development and promulgation of ISO and IEC standards except that they are the result of a consensus reached within a Council committee, endorsed by the ISO Council and the IEC Council.

The work of ISO/CASCO in preparing Guides, uses as a basis the principle that third party certification systems should, to the extent possible, be based on internationally agreed standards and procedures. While recognizing the major role of manufacturers' declaration of conformity through normal manufacturer/customer relationship, Council resolutions have emphasized the preparation of guidance documents on third party conformity assessment procedures in order that national systems may be compatible with one another so as to facilitate bilateral and multilateral agreements.

Whilst these documents are intended to provide guidance, it is hoped that any changes from the documents made in introducing systems nationally would be minimal. In recognizing 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.

General requirements for the competence of calibration and testing laboratories

Introduction

Since ISO/IEC Guide 25 was last revised in 1982 the use of quality systems in laboratories has greatly increased. Many countries have adopted ISO/IEC Guide 25 as the basis both for establishing quality systems in laboratories and for recognizing their competence, e.g. by accreditation. In recent years there have been many developments in the field of quality assurance which have led to new and improved guides and standards; it was recognized that there was a need to revise ISO/IEC Guide 25 to reflect these changes.

In this revision of the Guide attention is paid to the activities of both calibration and testing laboratories and account is taken of other requirements for laboratory competence such as those laid down in the OECD *Code of Good Laboratory Practice* (GLP) and the ISO 9000 series of quality assurance standards.

This Guide should provide a mechanism for promoting confidence in calibration and testing laboratories that can show that they operate in accordance with its requirements.

Acceptance of calibration and test results between countries will facilitate the removal of non-tariff barriers to trade.

The use of this Guide will facilitate cooperation between laboratories and other bodies to assist in the exchange of information and experience, and in the harmonization of standards and procedures.

This Guide is specific to calibration laboratories and testing laboratories.

Laboratories meeting the requirements of this Guide comply, for calibration and testing activities, with the relevant requirements of the ISO 9000 series of standards, including those of the model described in ISO 9002 when they are acting as suppliers producing calibration and test results.

For laboratories engaged in specific fields of testing such as the chemical field (see for example the OECD *Code of Good Laboratory Practice*) or the information technology field, the requirements of this Guide will need amplification and interpretation, as referred to in clause 4.2 of ISO/IEC Guide 55.

1 Scope

1.1 This Guide sets out the general requirements in accordance with which a laboratory has to demonstrate that it operates, if it is to be recognized as competent to carry out specific calibrations or tests.

1.2 Additional requirements and information which have to be disclosed for assessing competence or for determining compliance with other criteria may be specified by the organization or authority granting the recognition (or approval), depending upon the specific character of the task of the laboratory.

1.3 This Guide is for use by calibration and testing laboratories in the development and implementation of their quality systems. It may also be used by accreditation bodies, certification bodies and others concerned with the competence of laboratories.

2 References

ISO 8402 : 1986, *Quality — Vocabulary.*

ISO 9000 : 1987, *Quality management and quality assurance standards — Guidelines for selection and use.*

ISO 9001 : 1987, *Quality systems — Model for quality assurance in design/development, production, installation and servicing.*

ISO 9002 : 1987, *Quality systems — Model for quality assurance in production and installation.*

ISO 9003 : 1987, *Quality systems — Model for quality assurance in final inspection and test.*

ISO 9004 : 1987, *Quality management and quality system elements — Guidelines.*

ISO/IEC Guide 2 : 1986, *General terms and their definitions concerning standardization and related activities.*

International vocabulary of basic and general terms in metrology (VIM) : 1984, issued by BIPM, IEC, ISO and OIML.