International Standard

ISO 10012

Quality management — Requirements for measurement management systems

Management de la qualité — Exigences pour les systèmes de management de la mesure

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 3, *Supporting technologies*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/SS F20, *Quality assurance*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 10012:2003), which has been technically revised.

The main changes are as follows:

— the document has been restructured to follow the harmonized structure for management system standards;

— the clauses have been extensively revised in response to the needs of interested parties.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document assists organizations who have or intend to implement a measurement management system, by providing the necessary framework for an organization in designing, maintaining and continually improving a measurement management system.

This is a major revision of ISO 10012:2003, whose purpose is to establish the basis for an organization to implement and improve a measurement management system for end-to-end application of measurement processes in the organization (see Figure 1).

The main objective of a measurement management system is to provide confidence in the validity and reliability of the measurement results and ensure capability to support the measurement of the organization's delivered products and/or services at the required quality level. This includes managing the risk associated with measurement processes that can produce incorrect measurement results affecting the quality of an organization's products and/or services.

A measurement management system can be implemented in the design and development, test, monitoring and delivering of valid measurement results. It also provides an organization with the basis to demonstrate conformity to measurement management system requirements.

This document can be used by any industrial sectors requiring a measurement management system, and is complementary to the requirements of ISO 9001, ISO 14001 or other management system standards.

The implementation of a management system for confirmation of validity of measurements is an important decision for an organization to establish a robust measurement management system that will provide a consistent level of measurement quality for its products and services.

Quality management — Requirements for measurement management systems

1 Scope

This document specifies the requirements for a measurement management system when an organization:

a) needs to demonstrate its ability to consistently ensure confidence in validity and reliability of measurement results and thereby to provide a consistent level of measurement quality for an organization's products and services;

b) aims to rely on reliable and valid measurement results useful to enhance customer satisfaction and effectively apply its measurement management system processes;

c) implements processes for a measurement management system that enhance conformity with customer, statutory and regulatory requirements.

All the requirements of this document are generic. This document is applicable to any organization, regardless of its type or size, or the products and services it provides. This includes organizations manufacturing products and providing engineering services (except for calibration and test services included within the scope of ISO/IEC 17025).

This document is not intended to substitute requirements for, or to add requirements to, the general requirements for the competence of testing and calibration laboratories specified in ISO/IEC 17025.

NOTE For organizations that operate internal testing and calibration laboratories, the competence of those functions can be evaluated in accordance with ISO/IEC 17025.

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.

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

ISO 17034, *General requirements for the competence of reference material producers*

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000, ISO/IEC Guide 99 and the following apply.

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/