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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

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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.

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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.

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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/

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3.1
organization
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives* (3.6)

Note 1 to entry: The concept of organization includes, but is not limited to, sole-trader, company, corporation, firm, enterprise, authority, partnership, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

Note 2 to entry: If the organization is part of a larger entity, the term "organization" refers only to the part of the larger entity that is within the scope of the *measurement management system* (3.19.4).

3.2
interested party (preferred term)
stakeholder (admitted term)
person or *organization* (3.1) that can affect, be affected by, or perceive itself to be affected by a decision or activity

EXAMPLE Customers, owners, people in an organization, *providers* (3.21), metrology institutions, regulators, unions, partners, society.

3.3
top management
person or group of people who directs and controls an *organization* (3.1) at the highest level

Note 1 to entry: Top management has the power to delegate authority and provide resources within the organization.

Note 2 to entry: If the scope of the *management system* (3.4) covers only part of an organization, then top management refers to those who direct and control that part of the organization.

3.4
management system
set of interrelated or interacting elements of an *organization* (3.1) to establish *policies* (3.5) and *objectives* (3.6), as well as *processes* (3.8) to achieve those objectives

Note 1 to entry: A management system can address a single discipline or several disciplines.

Note 2 to entry: The management system elements include the organization's structure, roles and responsibilities, planning and operation.

Note 3 to entry: The scope of a management system can include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.

3.5
policy
intentions and direction of an *organization* (3.1) as formally expressed by its *top management* (3.3)

3.6
objective
result to be achieved

Note 1 to entry: An objective can be strategic, tactical, or operational.

Note 2 to entry: Objectives can relate to different disciplines (such as finance, health and safety, and environment). They can be, for example, organization-wide or specific to a project, product, service or *process* (3.8).

Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended result, as a purpose, as an operational criterion, as a measurement management objective or by the use of other words with similar meaning (e.g. aim, goal, or target).

Note 4 to entry: In the context of *measurement management systems* (3.19.4), measurement management objectives are set by the *organization* (3.1), consistent with the measurement management *policy* (3.5), to achieve specific results.

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3.7
risk
effect of uncertainty

Note 1 to entry: An effect is a deviation from the expected — positive or negative.

Note 2 to entry: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.

Note 3 to entry: Risk is often characterized by reference to potential events and consequences, or a combination of these.

Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood of occurrence.

Note 5 to entry: In the context of *measurement management systems* (3.19.4), risk also refers to the impact of uncertainty in a measurement quantity as determined by the metrological methods used.

Note 6 to entry: Refer to ISO 31000 and IEC 31010 for additional guidance.

3.8
process
set of interrelated or interacting activities that uses or transforms inputs to deliver a result

Note 1 to entry: Whether the result of a process is called an output, a product or a service depends on the context of the reference.

3.9
competence
ability to apply knowledge and skills to achieve intended results

3.10
documented information
information required to be controlled and maintained by an *organization* (3.1) and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media and from any source.

Note 2 to entry: Documented information can refer to:

— the *management system* (3.4), including related *processes* (3.8);

— information created in order for the organization to operate (documentation);

— evidence of results achieved (records).

3.11
performance
measurable result

Note 1 to entry: Performance can relate either to quantitative or qualitative findings.

Note 2 to entry: Performance can relate to managing activities, *processes* (3.8), products, services, systems or *organizations* (3.1).

Note 3 to entry: In the metrological context, performance relates to the implementation of a process to obtain appropriate or measurable results.

3.12
continual improvement
recurring activity to enhance *performance* (3.11)

3.13
effectiveness
extent to which planned activities are realized and planned results are achieved

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3.14
requirement
need or expectation that is stated, generally implied or obligatory

Note 1 to entry: "Generally implied" means that it is custom or common practice for the *organization* (3.1) and *interested parties* (3.2) that the need or expectation under consideration is implied.

Note 2 to entry: A specified requirement is one that is stated, e.g. in *documented information* (3.10).

3.15
conformity
fulfilment of a *requirement* (3.14)

3.16
nonconformity
non-fulfilment of a *requirement* (3.14)

3.17
corrective action
action to eliminate the cause(s) of a *nonconformity* (3.16) and to prevent recurrence

3.18
audit
systematic and independent *process* (3.8) for obtaining evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

Note 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines).

Note 2 to entry: An internal audit is conducted by the *organization* (3.1) itself, or by an external party on its behalf.

Note 3 to entry: "Audit evidence" and "audit criteria" are defined in ISO 19011.

3.19
measurement
process (3.8) to determine a value

Note 1 to entry: According to ISO 3534-2, the value determined is generally the value of a quantity.

Note 2 to entry: In the context of *measurement management systems* (3.19.4), this refers to experimentally obtaining one or more quantity values that can reasonably be attributed to a quantity. For further details, refer to ISO/IEC Guide 99.

3.19.1
measurement result
result of measurement
set of quantity values being attributed to a measurand together with any other available relevant information

Note 1 to entry: A measurement result generally contains "relevant information" about the set of quantity values, such that some may be more representative of the measurand than others. This may be expressed in the form of a probability density function (PDF).

Note 2 to entry: No measurement result is valid without an associated statement of measurement uncertainty (see ISO/IEC Guide 98-1:2024).

[SOURCE: ISO/IEC Guide 99:2007, 2.9, modified — Notes 2 and 3 to entry deleted. New Note 2 to entry added.]

3.19.2
measurement process
set of operations to determine the value of a quantity

Note 1 to entry: See Figure C.3 for an illustration of the measurement process.

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[SOURCE: ISO 9000:—,[1)] 3.11.8, modified — Note 1 to entry added.]

3.19.3
measuring equipment
measuring instrument, software, measurement standard, reference material or auxiliary apparatus, or a combination thereof, necessary to realize a *measurement process* (3.19.2)

[SOURCE: ISO 9000:—, 3.11.9]

3.19.4
measurement management system
part of a *management system* (3.4) with regard to *measurement* (3.19)

3.20
monitoring
determining the status of a system, a *process* (3.8) or an activity

Note 1 to entry: To determine the status, there can be a need to check, supervise or critically observe.

3.21
provider
organization (3.1) that provides a product or a service

EXAMPLE Producer, distributor, retailer or vendor of a product or a service.

Note 1 to entry: A provider can be internal or external to the organization.

Note 2 to entry: In a contractual situation, a provider is sometimes called “contractor”.

3.22
metrological confirmation
set of operations required to ensure that *measuring equipment* (3.19.3) conforms to the *requirements* (3.14) for its intended use

Note 1 to entry: Metrological confirmation generally includes calibration or verification, any necessary adjustment or repair, and subsequent recalibration, comparison with the *metrological requirements* (3.24) for the intended use of the equipment, as well as any required sealing and labelling.

Note 2 to entry: Metrological confirmation is not achieved until and unless the fitness of the measuring equipment for the intended use has been demonstrated and documented.

Note 3 to entry: The requirements for intended use include such considerations as range, resolution and maximum permissible errors.

Note 4 to entry: Metrological requirements are usually distinct from, and are not specified in, product requirements.

3.23
metrological function
function with administrative and technical responsibility for defining and implementing the *measurement management system* (3.19.4)

3.24
metrological requirements
set of *requirements* (3.14) for *measurement processes* (3.19.2) that include criteria and practices necessary to ensure that *measurements* (3.19) are reliable and comply with applicable requirements and regulations

Note 1 to entry: This may include, among other things, the accuracy and precision of the measurement process, metrological traceability, calibration frequency, personnel training levels and necessary maintenance operations.

Note 2 to entry: Metrological requirements for measurement processes are generally separate from product requirements and are not specified in the latter (usually given as an upper or lower specification limit, or both).

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3.25
measurement service
task(s) and associated processes performed to implement a measurement or to document a measurement

EXAMPLE Repair of equipment where measurements are used in the repair process.

4 Context of the organization

4.1 Understanding the organization and its context

The organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended result(s) of its measurement management system.

The organization shall determine whether climate change is a relevant issue.

It is important to understand and specify the structure of the organization and how it impacts on measurements and their intended results.

The measurement management system enables the transfer of information within the entire organization, so that each part of the organization is working with the same information.

The organization shall monitor and review information about all the determined external and internal issues.

NOTE 1 Issues can include positive and negative factors or conditions for consideration.

NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.

NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

4.2 Understanding the needs and expectations of interested parties

The organization shall determine:

a) the interested parties that are relevant to the measurement management system;

b) the relevant requirements of these interested parties;

c) which of these requirements will be addressed through the measurement management system.

The organization shall monitor and review information about these interested parties and their relevant requirements.

NOTE Relevant interested parties can have requirements related to climate change.

4.3 Determining the scope of the measurement management system

The organization shall determine the boundaries and applicability of the measurement management system to establish its scope.

When determining this scope, the organization shall consider:

a) the external and internal issues referred to in 4.1;

b) the requirements referred to in 4.2.

The scope shall be available as documented information.

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