SLOVENSKI STANDARD
oSIST prEN ISO 10012:2024

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Vodenje kakovosti - Zahteve za sisteme vodenja meritev (ISO/DIS 10012:2024)

Quality management - Requirements for measurement management systems (ISO/DIS 10012:2024)

Qualitätsmanagement - Anforderungen an Messmanagementsysteme (ISO/DIS 10012:2024)

Management de la qualité - Exigences pour les systèmes de management de la mesure (ISO/DIS 10012:2024)

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17.020	Meroslovje in merjenje na splošno	Metrology and measurement in general

oSIST prEN ISO 10012:2024 **en,fr,de**

DRAFT International Standard

ISO/DIS 10012

Quality management – Requirements for measurement management systems

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

ICS: 17.020; 03.100.70

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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 documents 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.

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

This is a major revision of the ISO 10012:2003, whose purpose is to establish the basis for an organization to develop a measurement management systems.

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.

ISO 10012 was prepared by a multi-national, multi-disciplinary working group (WG27) convened by ISO Technical Committee 176, Subcommittee SC3.

Introduction

The main objective of a measurement management system (MMS) is to have confidence in the validity and reliability of the measurement results. This includes managing the risk of measurement processes that could produce incorrect results affecting the quality of an organization's products and/or services. The purpose of ISO 10012 is to provide an organization with the appropriate framework for implementing measurement management system requirements.

ISO 10012 standard assists organizations who have or would like to establish a measurement management system. This standard provides the necessary framework for an organization in designing, maintaining and continually improving the measurement management system capability of supporting the measurement of the organization's delivered products and/or services at the required quality level.

This is a major revision of the ISO 10012:2003, whose purpose is to establish the basis for an organization to develop a measurement management system for end-to-end application of measurement processes in the organization (see Figure 1). ISO 10012 is implemented in process design and development, test, monitoring and delivering of valid measurement results. This revision also provides an organization the basis to demonstrate conformity to measurement management system requirements.

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

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 an organization's products and services.

The notes, examples and annexes are not mandatory requirements of the standard, but are provided to assist users in understanding concepts and terms presented in the standard.

Various informative documents are referenced in this standard. The references to these standards and industry documents are provided so that users of this standard can find further information on specific topics and industry best practices.

In this document the following verbal forms are used:

— 'shall' indicates a requirement;

— 'should' indicates a non-mandatory recommendation;

— 'may' indicates a permission for use;

— "can" indicates a possibility or a capability.

Information marked as "NOTE" is for guidance in understanding or clarifying the associated requirement.

Quality Management – Requirements for Measurement Management Systems

1 Scope

This International Standard specifies the requirements for a measurement management system (MMS) 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 International Standard are generic and intended to apply to any organization, whatever its type or size, or the products and services it provides.

This International Standard 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.

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 9000:2015, Quality management systems — Fundamentals and vocabulary

ISO 9001:2015, Quality management systems

ISO/IEC GUIDE 99: 2012, International vocabulary of metrology - Basic and general concepts and associated terms

ISO/ IEC guide, 98-4:2012 , uncertainty of measurement

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000: 2015 and 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/

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 (single person company), 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 *management system* (3.4).

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, suppliers, metrologists, regulators, unions, partners, or 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 of *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 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 financial, health and safety, and environment) and can apply at different levels (such as strategic, organization-wide, project, product and *process* (3.8)).

Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended result, a purpose, an operational criterion, as a measurement 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, measurement objectives are set by the *organization* (3.1) , consistent with the measurement *policy (3.5)*, to achieve specific results.

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 (as defined in ISO Guide 73) and "consequences" (as defined in ISO Guide 73), 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 (as defined in ISO Guide 73) of occurrence.

Note 5 to entry: In application with metrology, risk refers to the impact of uncertainty in a measurement quantity as determined by the metrological methods used.

3.8
process
set of interrelated or interacting activities which transforms inputs into 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* (3.23)).

Note 3 to entry: In many standards and quality documents, documented information is referred to as *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 application 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

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, independent and documented *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 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).

SOURCE: ISO GUIDE 99

3.20
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 metrological processes, this refers to experimentally obtain one or more quantity values that can reasonably be attributed to a quantity. For further details, refer to ISO GUIDE 99.

3.21
measurement process
set of operations to determine the value of a quantity

SOURCE: ISO 9000