
**Measurement management systems —
Requirements for measurement
processes and measuring equipment**

*Systèmes de management de la mesure — Exigences pour les
processus et les équipements de 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 10012 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 3, *Supporting technologies*.

This first edition of ISO 10012 cancels and replaces ISO 10012-1:1992 and ISO 10012-2:1997, of which it constitutes a technical revision.

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Introduction

An effective measurement management system ensures that measuring equipment and measurement processes are fit for their intended use and is important in achieving product quality objectives and managing the risk of incorrect measurement results. The objective of a measurement management system is to manage the risk that measuring equipment and measurement processes could produce incorrect results affecting the quality of an organization's product. The methods used for the measurement management system range from basic equipment verification to the application of statistical techniques in the measurement process control.

In this International Standard, the term "measurement process" applies to physical measurement activities (e.g. in design, test, production, inspection).

References to this International Standard can be made

- by a customer when specifying products required,
- by a supplier when specifying products offered,
- by legislative or regulatory bodies, and
- in assessment and audit of measurement management systems.

One of the stated management principles in ISO 9000 addresses the process-oriented approach. Measurement processes should be considered as specific processes aiming to support the quality of the products produced by the organization. Application of the measurement management system model applicable to this International Standard is shown in Figure 1.

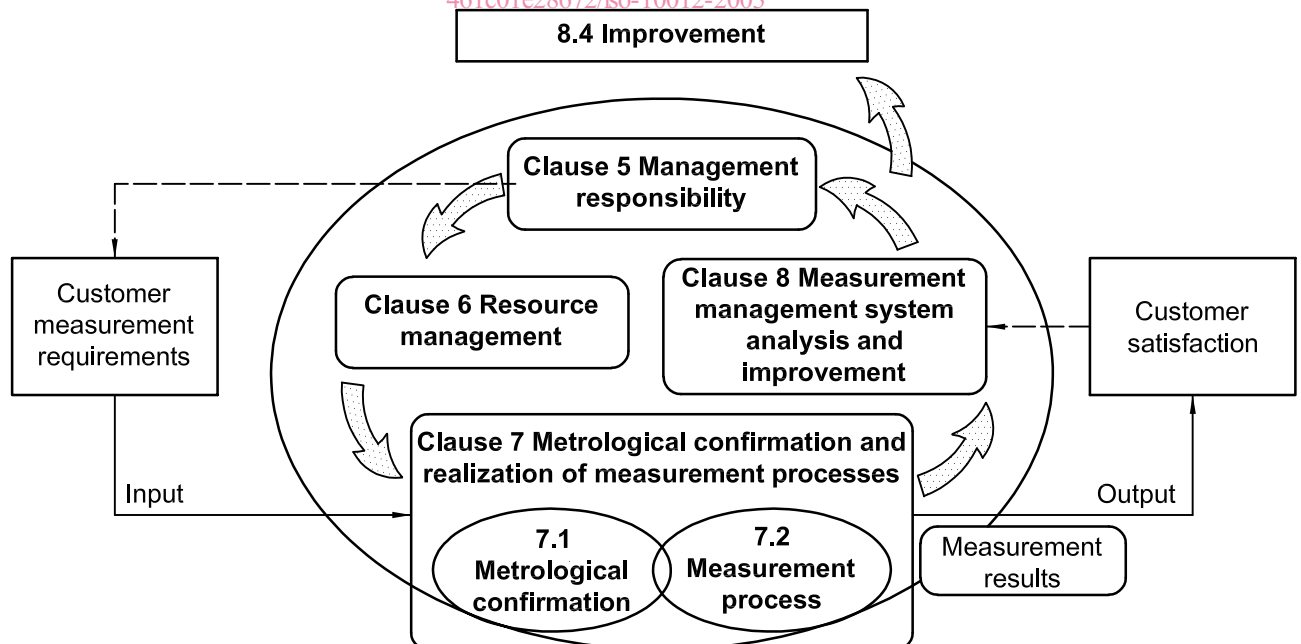


Figure 1 — Model of measurement management system

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This International Standard includes both requirements and guidance for implementation of measurement management systems, and can be useful in improving measurement activities and the quality of products. The requirements appear in normal typeface. Guidance appears in italic typeface within a box after the appropriate requirement paragraph. Guidance is for information only and is not to be construed as adding to, limiting, or modifying any requirement.

Organizations have the responsibility to determine the level of controls needed and to specify the measurement management system requirements to be applied as part of their overall management system. Except by agreement, this International Standard is not intended to add to, subtract from, or replace any requirements of other standards.

Following the requirements laid down in this International Standard will facilitate compliance with requirements for measurements and measurement process control specified in other standards, for example, ISO 9001:2000, Subclause 7.6, and ISO 14001:1996, Subclause 4.5.1.

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Measurement management systems — Requirements for measurement processes and measuring equipment

1 Scope

This International Standard specifies generic requirements and provides guidance for the management of measurement processes and metrological confirmation of measuring equipment used to support and demonstrate compliance with metrological requirements. It specifies the quality management requirements of a measurement management system that can be used by an organization performing measurements as part of the overall management system, and to ensure metrological requirements are met.

This International Standard is not intended to be used as a requisite for demonstrating conformance with ISO 9001, ISO 14001 or any other standard. Interested parties can agree to use this International Standard as an input for satisfying measurement management system requirements in certification activities.

This International Standard is not intended as a substitute for, or as an addition to, the requirements of ISO/IEC 17025.

NOTE Other standards and guides exist for particular elements affecting measurement results, for example, details of measurement methods, competence of personnel, and interlaboratory comparisons.

2 Normative references

The following referenced documents are indispensable for the application 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 9000:2000, *Quality management systems — Fundamentals and vocabulary*

VIM:1993, *International vocabulary of basic and general terms used in metrology*. Published jointly by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 and VIM and the following apply:

3.1

measurement management system

set of interrelated or interacting elements necessary to achieve metrological confirmation and continual control of measurement processes

3.2

measurement process

set of operations to determine the value of a quantity

**3.3
measuring equipment**

measuring instrument, software, measurement standard, reference material or auxiliary apparatus, or a combination thereof, necessary to realize a measurement process

**3.4
metrological characteristic**

distinguishing feature which can influence the results of measurement

NOTE 1 Measuring equipment usually has several metrological characteristics.

NOTE 2 Metrological characteristics can be the subject of calibration.

**3.5
metrological confirmation**

set of operations required to ensure that measuring equipment conforms to the requirements for its intended use

NOTE 1 Metrological confirmation generally includes calibration and verification, any necessary adjustment or repair, and subsequent recalibration, comparison with the metrological requirements for the intended use of the equipment, as well as any required sealing and labelling.

NOTE 2 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 The requirements for intended use include such considerations as range, resolution and maximum permissible errors.

NOTE 4 Metrological requirements are usually distinct from, and are not specified in, product requirements.

NOTE 5 A diagram of the processes involved in metrological confirmation is given in Figure 2.

**3.6
metrological function**

function with administrative and technical responsibility for defining and implementing the measurement management system

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4 General requirements

The measurement management system shall ensure that specified metrological requirements are satisfied.

Guidance
Specified metrological requirements are derived from requirements for the product. These requirements are needed for both measuring equipment and measurement processes. Requirements may be expressed as maximum permissible error, permissible uncertainty, range, stability, resolution, environmental conditions or operator skills.

The organization shall specify the measurement processes and the measuring equipment that are subject to the provisions of this International Standard. When deciding the scope and extent of the measurement management system, the risks and consequences of failure to comply with metrological requirements shall be taken into account.

The measurement management system consists of the control of designated measurement processes and metrological confirmation of measuring equipment (see Figure 2), and the necessary supporting processes. The measurement processes within the measurement management system shall be controlled (see 7.2). All measuring equipment within the measurement management system shall be confirmed (see 7.1).

Changes to the measurement management system shall be in accordance with the procedures of the organization.

5 Management responsibility

5.1 Metrological function

The metrological function shall be defined by the organization. Top management of the organization shall ensure the availability of necessary resources to establish and maintain the metrological function.

Guidance

The metrological function may be a single department or distributed throughout the organization.

The management of the metrological function shall establish, document and maintain the measurement management system and continually improve its effectiveness.

5.2 Customer focus

The management of the metrological function shall ensure that

- a) customer measurement requirements are determined and converted into metrological requirements,
- b) the measurement management system meets the customers' metrological requirements, and
- c) compliance to customer-specified requirements can be demonstrated.

5.3 Quality objectives

The management of the metrological function shall define and establish measurable quality objectives for the measurement management system. Objective performance criteria and procedures for the measurement processes, and their control, shall be defined.

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Guidance

Examples of such quality objectives at different organizational levels are as follows:

- *no nonconforming product is to be accepted nor conforming product rejected due to incorrect measurements;*
- *no measurement process is to be out of control for more than one day without detection;*
- *all metrological confirmations are to be completed by the agreed times;*
- *there are to be no illegible metrological confirmation records;*
- *all of the technical training programmes are to be completed per the established schedule;*
- *the amount of time measuring equipment is out of operation is to be reduced by a stated percentage.*

5.4 Management review

Top management of the organization shall ensure the systematic review of the measurement management system at planned intervals to ensure its continual adequacy, effectiveness and suitability. The top management shall ensure that the necessary resources are available to review the measurement management system.

The results of the management review shall be used by the management of the metrological function to modify the system as necessary, including improving measurement processes (see Clause 8) and reviewing quality objectives. The results of all reviews and all actions taken shall be recorded.

6 Resource management

6.1 Human resources

6.1.1 Responsibilities of personnel

The management of the metrological function shall define and document the responsibilities of all personnel assigned to the measurement management system.

Guidance

These responsibilities may be defined in organization charts, job descriptions, and work instructions or procedures.

This International Standard does not exclude the use of specialist personnel external to the metrological function.

6.1.2 Competence and training

The management of the metrological function shall ensure that personnel involved in the measurement management system have demonstrated their ability to perform their assigned tasks. Any specialized skills required shall be specified. The management of the metrological function shall ensure that training is provided to address identified needs, records of training activities are maintained, and that the effectiveness of the training is evaluated and recorded. Personnel shall be made aware of the extent of their responsibilities and accountabilities, and the impact of their activities on the effectiveness of the measurement management system and product quality.

Guidance

Competence may be achieved through education, training and experience, and demonstrated by testing or observed performance.

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When using staff who are undergoing training, adequate supervision shall be provided.

6.2 Information resources

6.2.1 Procedures

Measurement management system procedures shall be documented to the extent necessary and validated to ensure the proper implementation, their consistency of application, and the validity of measurement results.

New procedures or changes to documented procedures shall be authorized and controlled. Procedures shall be current, available and provided when required.

Guidance

Technical procedures may be based on published standard measurement practices, or on customers' or equipment manufacturers' written instructions.

6.2.2 Software

Software used in the measurement processes and calculations of results shall be documented, identified and controlled to ensure suitability for continued use. Software, and any revisions to it, shall be tested and/or validated prior to initial use, approved for use, and archived. Testing shall be to the extent necessary to ensure valid measurement results.

Guidance

Software may be in several forms, such as embedded, programmable, or off-the-shelf packages.

Off-the-shelf software might not require testing.

Testing may include virus checking, checking of user-programmed algorithms, or a combination thereof as necessary to achieve the required measurement result.

Software configuration control can help maintain the integrity and validity of measurement processes using software. Archiving may be accomplished by creating back-up copies, off-site storage, or any other means to safeguard programming, ensure accessibility, and to provide the level of traceability necessary.

6.2.3 Records

Records containing information required for the operation of the measurement management system shall be maintained. Documented procedures shall ensure the identification, storage, protection, retrieval, retention time and disposition of records.

Guidance

Examples of records are confirmation results, results of measurement, purchasing, operational data, nonconformance data, customer complaints, training, qualification, or any other historical data supporting the measurement processes.

6.2.4 Identification

Measuring equipment and technical procedures used in the measurement management system shall be clearly identified, individually or collectively. There shall be an identification of the status of the metrological confirmation of equipment. Equipment confirmed for use only in a particular measurement process or processes shall be clearly identified or otherwise controlled to prevent unauthorized use. Equipment used in the measurement management system shall be distinguishable from other equipment.

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6.3 Material resources**6.3.1 Measuring equipment**

All measuring equipment necessary to satisfy the specified metrological requirements shall be available and identified in the measurement management system. Measuring equipment shall have a valid calibration status prior to being confirmed. Measuring equipment shall be used in an environment that is controlled or known to the extent necessary to ensure valid measurement results. Measuring equipment used to monitor and record the influencing quantities shall be included in the measurement management system.

Guidance

Measuring equipment can be confirmed for use for particular measurement processes, and not confirmed for use for other measurement processes because of differing metrological requirements. Metrological requirements for the measuring equipment are derived from specified requirements for the product or the equipment to be calibrated, verified and confirmed.

The maximum permissible error may be designated by reference to the published specification of the measuring equipment manufacturer, or by the metrological function.

Measuring equipment may be calibrated by an organization other than the metrological function performing the metrological confirmation.

The characterization of reference materials might meet the requirement for calibration.