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BSI Standards Publication

Quality management — Requirements for measurement management systems

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National foreword

This British Standard is the UK implementation of EN ISO 10012:2026. It is identical to ISO 10012:2026. It supersedes BS EN ISO 10012:2003 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee QS/1/3, Quality Management - Supporting Standards.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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European foreword

This document (EN ISO 10012:2026) has been prepared by Technical Committee ISO/TC 176 "Quality management and quality assurance" in collaboration with CCMC.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2026, and conflicting national standards shall be withdrawn at the latest by August 2026.

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

This document supersedes EN ISO 10012:2003.

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Endorsement notice

The text of ISO 10012:2026 has been approved by CEN as EN ISO 10012:2026 without any modification.

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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.

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/

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.

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

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.

[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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1) Under preparation. Stage at the time of publication: ISO/FDIS 9000:2025.

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;

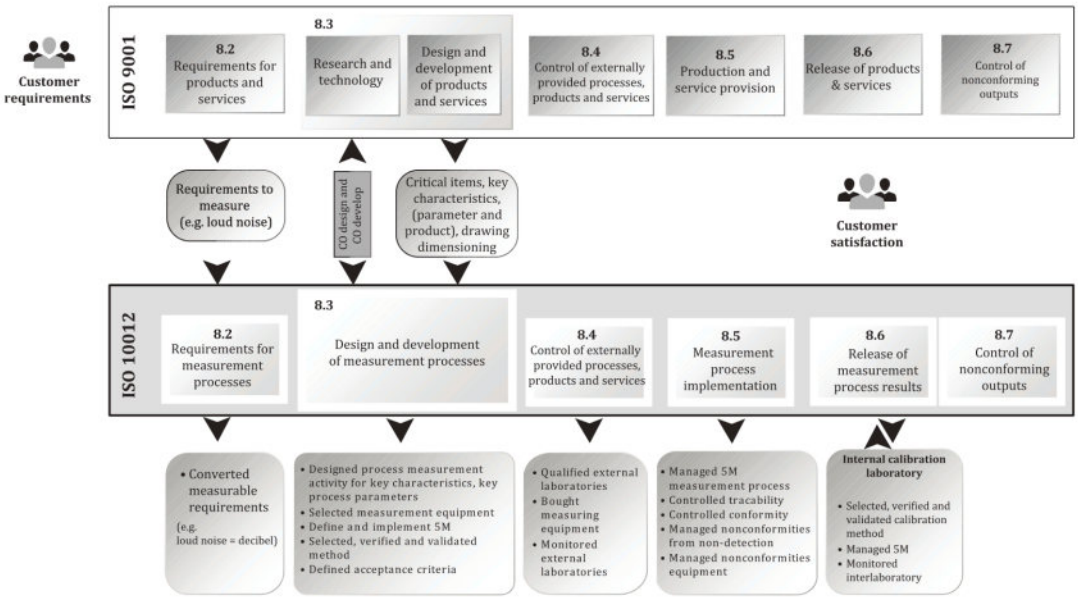
b) the requirements referred to in 4.2.

The scope shall be available as documented information.

The scope shall state the types of measurement activities related to product and services provided. It shall provide justification for any requirement of this document that the organization determines is not applicable to the scope of its measurement management system.

4.4 Measurement management system

The organization shall establish, implement, maintain, and continually improve a measurement management system, including the processes needed and their interactions, in accordance with the requirements of this document (see Figure 1). The intent of the measurement management system is to achieve the intended results, including enhancing the measurement management performance.



NOTE 1 Customer requirements and customer satisfaction refer to both external and internal customers

NOTE 2 5M refers to material, man (i.e. people), machine, measure, method (see Figure C.3).

Figure 1 — Relationship between measurement management system and quality management system with respect to the requirements of Clause 8 "Operation" in this document and ISO 9001

5 Leadership

5.1 Leadership and commitment

Top management shall demonstrate leadership and commitment with respect to the measurement management system by:

a) ensuring that the measurement management policy and measurement management objectives are established and are compatible with the strategic direction of the organization;

b) ensuring the integration of the measurement management system requirements into the organization's business processes;

c) ensuring that the resources needed for the measurement management system are available;

d) communicating the importance of effective measurement management and of conforming to the measurement management system requirements;

e) ensuring that the measurement management system achieves its intended result(s);

f) directing and supporting persons to contribute to the effectiveness of the measurement management system;

g) promoting continual improvement;

h) supporting other relevant roles to demonstrate their leadership as it applies to their areas of responsibility;

i) taking accountability for the effectiveness and relevance of the measurement management system;

j) promoting risk-based thinking.

NOTE Reference to "business" in this document can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence.

5.2 Measurement management policy

Top management shall establish a measurement management policy that:

a) is appropriate to the purpose of the organization;

b) provides a framework for setting measurement management objectives;

c) includes a commitment to meet applicable requirements;

d) includes a commitment to continual improvement of the measurement management system.

The measurement management policy shall:

— be available as documented information;

— be communicated within the organization;

— be available to interested parties, as appropriate;

— be understood and applied.

5.3 Roles, responsibilities and authorities

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned and communicated within the organization.

Top management shall assign the responsibility and authority for:

a) ensuring that the measurement management system conforms to the requirements of this document;

b) reporting on the performance of the measurement management system to top management;

c) ensuring that the measurement management system is delivering it's intended results;

d) ensuring that the integrity of the measurement management system is maintained when changes to the measurement management system are planned and implemented.

Top management shall appoint a specific member of the organization's management, who shall have the responsibility and authority for oversight of the above requirements and shall have access to top management to resolve measurement management issues.

5.4 Customer focus

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;

b) the risks and opportunities that can affect the validity and reliability of the processes measurement results and the ability to enhance customer satisfaction are determined and addressed;

c) the focus on enhancing customer satisfaction is maintained as described in 9.1.

6 Planning

6.1 Actions to address risks and opportunities

When planning for the measurement management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

— give assurance that the measurement management system can achieve its intended result(s);

— prevent, or reduce, undesired effects;

— achieve continual improvement;

— enhance desirable effects.

The organization shall plan:

a) actions to address these risks and opportunities;

b) how to:

1) integrate and implement the actions into its measurement management system processes;

2) evaluate the effectiveness of these actions;

3) document the processes used in the risks and opportunities analyses;

4) ensure new objectives do not compromise the existing measurement management system and validity and reliability of its results.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the measurement management system.

NOTE 1 The strategy for dealing with a risk includes these decision options: escalating, avoiding, transferring, mitigating, accepting.

NOTE 2 The strategy for dealing with an opportunity includes these decision options: escalating, exploiting, sharing, enhancing and accepting.

NOTE 3 The effectiveness of risk and opportunity responses shows whether the identified measures were appropriate and is an interface to the continuous improvement in the organization.

6.2 Measurement management objectives and planning to achieve them

The organization shall establish measurement management objectives at relevant functions and levels.

The measurement management objectives shall:

a) be consistent with the measurement management policy (see 5.2);

b) be measurable (if practicable);

c) take into account applicable requirements;

d) be monitored;

e) be communicated;

f) be updated as appropriate;

g) be available as documented information;

h) be relevant to the impact on the conformity of products and services and to enhancement of customer satisfaction.

When planning how to achieve its measurement management objectives, the organization shall determine:

— what will be done;

— what resources will be required;

— who will be responsible;

— when it will be completed;

— how the results will be evaluated;

— how the results will be documented.

NOTE Applicable requirements can include regulatory, legal, contractual, interested party or customer requirements, etc.

6.3 Planning of changes

When the organization determines the need for changes to the measurement management system, the changes shall be carried out in a planned manner.

The organization shall consider:

a) the purpose of the changes and their potential consequences;

b) the integrity of the measurement management system;

c) the availability of resources;

d) the allocation or reallocation of responsibilities and authorities;

e) notification of the changes to interested parties where applicable.

7 Support

7.1 Resources

7.1.1 General

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance, and continual improvement of the measurement management system.

The organization shall consider:

a) the capabilities of and constraints of existing internal resources;

b) what needs to be obtained from external providers.

7.1.2 People

The organization shall determine and provide the persons necessary for the effective implementation of its measurement management system and for the operation and control of its processes.

7.1.3 Facilities and environmental conditions

The requirements for facilities and environmental conditions necessary for the performance of the measurement activities shall be specified and monitored, and shall be available as documented information.

The facilities and environmental conditions shall be suitable for the measurement activities and shall not adversely affect the validity of measurement results.

When on-site work (i.e. outside of a controlled environment) is performed, the design of the measurement process shall consider conditions out of the control of the user. The measurement process shall be documented and monitored with due consideration regarding compensating environmental corrections, if required.

NOTE 1 Environmental conditions affecting measurement systems can include temperature, temperature gradient, humidity, hygiene, airflow, lighting, vibration, dust control, cleanliness, electromagnetic interference and other factors.

NOTE 2 Facilities can include buildings and associated utilities, transportation resources and communication systems. The documented information can include information regarding the facility's historical environmental performance and stability.

NOTE 3 A suitable environment can be a combination of human and physical factors.

7.1.4 Equipment

All equipment including hardware and software necessary to satisfy the specified metrological requirements shall be available and identified in the measurement management system, see 8.3.3.3 e).

7.1.5 Organizational knowledge

The organization shall determine the knowledge necessary for the operation of its measurement processes and to achieve continuity of measurement operations and services.

This knowledge shall be maintained and shall be made available to the extent necessary for the organization.

When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required technical and regulatory updates.

NOTE 1 Organizational knowledge includes best practice knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives.

NOTE 2 Organizational knowledge can be based on:

— internal sources (e.g. intellectual property, knowledge gained from experience, lessons learned from failures and successful projects, capturing and sharing undocumented knowledge and experience, the results of improvements in processes, products and services);

— external sources (e.g. standards, academia, conferences, gathering knowledge from customers or external providers).

7.2 Competence

The organization shall:

a) determine the necessary competence of person(s) doing work under its control that affects its measurement management performance;

b) ensure that these persons are competent on the basis of appropriate education, training or experience;

c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken.

Appropriate documented information shall be available as evidence of competence.

NOTE Applicable actions can include, for example: the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.

7.3 Awareness

Persons doing work under the organization's control shall be aware of:

a) the measurement management policy;

b) their contribution to the effectiveness of the measurement management system, including the benefits of improved measurement management performance;

c) the implications of not conforming with the measurement management system requirements;

d) any relevant measurement management system requirements;

e) their contribution that impacts on the validity of results;

f) the importance of ethical behaviour;

g) their contribution to product conformity.

7.4 Communication

The organization shall determine the internal and external communications relevant to the measurement management system including:

a) on what it will communicate;

b) when to communicate;

c) with whom to communicate;

d) how to communicate;

e) who communicates;

f) the importance of ethical behaviour.

In relation to communication, the originator of the communication shall ensure that the information is only provided to persons authorized to receive it. The confidentiality requirements of 7.5.3 shall be conformed to for both internal and external communications

In cases where it is necessary to notify a customer of a nonconforming process or documented information (see 10.2), the organization shall notify the customer in a timely manner so that the customer can properly analyse the effect of the nonconformity on the products and services provided by the organization.

The data shall be presented and communicated in a clear and concise manner which can be understood by all parties.

The organization shall implement ethical policies to protect data integrity and regarding the overall responsibility of the organization.

7.5 Documented information

7.5.1 General

The organization's measurement management system shall include:

a) documented information required by this document;

b) documented information determined by the organization as being necessary for the effectiveness of the measurement management system.

NOTE 1 The extent of documented information for a measurement management system can differ from one organization to another due to:

— the size of organization and its type of activities, processes, products and services;

— the complexity of processes and their interactions;

— the competence of persons.

NOTE 2 An example of documented information to be maintained is a record of analyses performed regarding the observed end of period of reliability (EOPR) versus the performance target for calibration activities.

NOTE 3 Documented information that affects the validity and reliability of results is, for example, uncertainty calculations or probability of false acceptance criteria (see ISO/IEC Guide 98-4 and ILAC-G8), or documented information which explains the proper use of measuring equipment required by the relevant measurement procedures.

7.5.2 Creating and updating documented information

When creating and updating documented information, the organization shall ensure appropriate:

— identification and description (e.g. a title, date, author, or reference number);

— format (e.g. language, software version, graphics) and media (e.g. paper, electronic);

— review and approval for suitability and adequacy.

NOTE Approval implies authorized persons and approval methods that are identified for the relevant types of documented information, as determined by the organization.

7.5.3 Control of documented information

Documented information required by the measurement management system and by this document shall be controlled to ensure:

a) it is available and suitable for use, where and when it is needed;

b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

For the control of documented information, the organization shall address the following activities, as applicable:

— distribution, access, retrieval and use;

— storage and preservation, including preservation of legibility;

— control of changes (e.g. version control);

— retention and disposition.

Documented information of external origin determined by the organization to be necessary for the planning and operation of the measurement management system shall be identified as appropriate, and controlled.

All persons performing functions within the measurement management system shall have access to documented information appropriate to their responsibilities.

NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

An organization has documented information available for a period consistent with its obligations, such as contractual, regulatory, etc. Access to this documented information should be consistent with the confidentiality commitments, and documented information should be readily available.

8 Operation

8.1 Operational planning and control

8.1.1 General

The organization shall plan, implement and control the processes needed to meet requirements, and to implement the actions determined in Clause 6, by:

— establishing criteria for the processes;

— implementing control of the processes in accordance with the criteria.

Documented information shall be available to the extent necessary to have confidence that the processes have been carried out as planned.

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization shall ensure that externally provided processes, products or services that are relevant to the measurement management system are controlled.

NOTE Determination of requirements for the measurement management system can include consideration of:

— personnel, process and product safety;

— reliability, availability and maintainability of measuring equipment;

— selection, development and deployment of embedded software;

— measuring equipment and software obsolescence.

8.1.2 Operational risk management

The organization shall plan, implement and control a process for managing operational risks to the achievement of applicable requirements. This includes, as appropriate to the organization, the measurement processes used to control the conformity of the products and services, such as:

a) collection of relevant data and information;

b) assignment of responsibilities for operational risk management;

c) determination of risk assessment criteria (e.g. likelihood, consequences, risk acceptance);

NOTE 1 This document does not specifically require the use of a risk register.

d) identification, assessment and communication of risks throughout operations;

e) determination, implementation and management of actions to mitigate risks that do not meet the specified risk acceptance criteria;

f) acceptance of risks remaining after implementation of mitigating actions.

NOTE 2 While 6.1 addresses the risks and opportunities when planning for the measurement management system of the organization, the scope of this subclause is limited to the risks associated with the operational processes stated in this clause, including those directly related to the measurement process.

When considering risk, organizations may include cybersecurity and counterfeit material issues in their analysis, such as considered in the aerospace and nuclear industries.

8.2 Requirements for measurement processes

8.2.1 General

Measurement processes, including measurement services, are performed to support determination conformity of product and services to mutually agreed requirements.

NOTE Measurement services include the performance of the measurements as well as the design and development of the measurement processes.

8.2.2 Customer communications

Communication with customers shall include, when appropriate:

a) conveying information relating to measurements required expressed as characteristics (criteria) to be determined and/or metrological requirements of the customer;

b) handling enquiries, contracts or orders, including changes;

c) handling and control of customer property;

d) establishing specific requirements for contingency actions, when appropriate;

e) obtaining customer feedback relating to measurement processes, results or performance, which also includes complaints.

NOTE Results include reports of measurement as well as considerations of the variability of the measurement methods as detailed in 8.6.2.

8.2.3 Determination of requirements related to the measurement processes

When determining the requirements for the measurement processes, the organization shall ensure that:

a) the requirements for the measurement processes are specified, including:

1) any applicable statutory and regulatory requirements;

2) the requirements considered necessary by the organization;

b) the organization can meet the claims for the measurement processes implemented;

c) operational risks (e.g. new technology, ability and capacity to perform appropriate measurements, human factor, measurement deviation, equipment wear) have been identified.

NOTE 1 Requirements for measurement processes are usually distinct from, and are not specified in, product requirements (they are usually given as an upper specification limit or a lower specification limit, or both).

NOTE 2 Requirements can include verification criteria and associated methods, maximum permissible measurement error and uncertainties.

Statements of measurement capability may only be made when the organization possesses the appropriate equipment, material and skills to perform the required operations.

8.2.4 Review of customer requirements for measurement processes

8.2.4.1 The organization shall ensure that it has the ability to meet customer requirements. The organization shall conduct a review before committing to provide a measurement service to the customer. This review shall be coordinated with applicable functions within the organization.

The metrological function shall ensure that customer requirements are converted into measurement criteria. These measurement process criteria shall be available as documented information.

The measurement processes shall be designed so that:

a) customer requirements for measurements are determined and converted into metrological requirements;

b) the results of measurements meet the metrological requirements of the customer;

c) conformity to customer requirements can be demonstrated.

The measurement process shall be realized under specified conditions designed to meet the metrological requirements of the customer.

NOTE Customer requirements for measurement refer to the product and service specifications requested by the customer.

8.2.4.2 The organization shall make available documented information, as applicable:

a) on the results of the review;

b) on any new customer requirements for the products and services.

8.2.5 Changes to requirements for measurement processes

The organization shall ensure that when the customer requirements for measurements have changed, the relevant documented information is amended and relevant parties are made aware of the change of requirements.

The organization shall retain previous versions of documented information. This procedure is referenced in 7.5.3.

8.3 Design and development of measurement processes

8.3.1 General

Measurement processes are part of the measurement management system and shall be designed and developed so that they can be planned, validated, implemented, documented and controlled. The measurement process shall meet the requirements of the customer and shall be considered in the measurement management system.

The responsibility of the design and development of a measurement process shall be integrated into the organization's process for the design and development of products and services. This is intended to ensure that the products and services of the organization can be measured, considering the specified acceptance criteria. It also ensures the validity and reliability of measurement results during verification and validation in the design and development process for products and services.

NOTE Specified acceptance criteria consider such items as key characteristics (see EN 9100:2018, 3.3), critical items, and safety and environmental requirements.

The organization shall establish, implement and maintain a measurement design and development process that is appropriate to ensure the valid and reliable measurement results in subsequent provision of products and services.

8.3.2 Design and development planning

In determining the stages and controls for design and development of measurement processes, the organization shall consider:

a) the nature, duration and complexity of the design and development activities;

b) the required process stages, including applicable design and development reviews;

c) the required design and development verification and where validation of the measurement process is necessary;

NOTE Validation is considered necessary when new measurement processes and measuring equipment are introduced or the existing ones changed, which impact the final output of measurement results.

d) the responsibilities and authorities of the persons involved in the design and development process;

e) the internal and external resource needs for the design and development of measurement processes;

f) the practicality of the measurement of the product characteristics and ensuring this is taken into account by product design and development teams and users prior to completion of the measurement process design;

g) where the organization is performing measurements on items it designs and develops, that all affected parts of the organization shall communicate regarding the design of the measurement management process;

h) the need for involvement of customers and users in the design and development process; consideration should be given to ergonomics in the design of the measurement process;

i) the requirements for procurement of externally provided products and services;

j) the level of control expected for the design and development process by customers and other relevant interested parties (e.g. regulatory authorities), where applicable;

k) the documented information needed to demonstrate that design and development requirements have been met;

l) when appropriate, dividing the design and development effort into distinct phases, specifying the tasks, necessary resources, responsibilities, design content, inputs and outputs of each phase;

m) the ability to provide, review, verify, test and maintain measurement processes;

n) the impact on the environment and sustainability of the measurement process.

EXAMPLE The use of a strain gauge inclinometer instead of a mercury inclinometer.

The design and the development process should consider measurement process optimization.

8.3.3 Design and development inputs

8.3.3.1 In developing methodology for the design and development of the measurement process, the organization shall consider the aim of the measurement process to consistently provide valid and reliable results. The organization shall consider the following:

a) determination of the performance of the measurement process; the accuracy and uncertainty of the measurement process and measuring equipment used should be verified against the consumer's and producer's risks (false-acceptance and false-rejection risks) to comply with specified requirements (see Annex C for guidance);

NOTE 1 Criteria that can be considered when designing and developing the measurement process include accuracy, measurement process uncertainty, repeatability, reproducibility, false acceptance risks (consumer risk) or false rejection risk (producer risk), end of period reliability, measurement capability index, maintainability, stability, and metrologically traceable measurement results.

b) identification of risk elements in the measurement process (see 8.1.2), and potential consequences of failure due to the nature of the measurement process;

c) identification of standards or codes of practice that the organization has committed to implement;

d) the previous similar design of measurement processes to use information for design and development activities, when applicable;

e) the need for maintenance and frequency of calibration (periodicity) while designing measurement process including the capabilities of the calibration and maintenance facilities;

NOTE 2 Information on the methods for establishing calibration intervals (periodicity) can be found in ILAC-G24:2022/OIML D 10:2022[19] or NCSLI RP-1[20] (see Annex C).

f) the potential consequences of obsolescence (e.g. materials, processes, components, equipment), when applicable;

g) when the use of sampling is appropriate in the measurement process, the level of performance (such as acceptance criteria) and a suitable sampling plan.

8.3.3.2 Inputs shall be adequate for design and development purposes, complete and unambiguous. Conflicting design and development inputs shall be resolved.

The organization shall have documented information available on design and development inputs.

NOTE The organization can also consider as design and development inputs other information such as benchmarking, external provider feedback, internally generated data and in-service data.

8.3.3.3 In the design and development of measurement processes, the inputs required shall include:

a) appropriate methods of measurement;

b) the functional and performance requirements of the resulting measurement process;

c) the processes necessary to ensure the quality of the measurement results;

d) methods to be used in evaluating measurement uncertainties;

e) the equipment required to perform the measurement;

f) the minimum required skills of persons operating the measuring equipment;

g) the minimum qualifications and training of the personnel performing the measurements, as required;

h) statutory and regulatory requirements;

i) standards or codes of practice that the organization has committed to implement;

j) potential consequences of failure due to the nature of the products and services being measured;

k) when applicable, the potential consequences of obsolescence (e.g. materials, processes, components, equipment, products);

l) additional relevant factors influencing the measurement results (e.g. temperature, humidity, lighting, noise, magnetic interference).

The source of any externally obtained information used shall be recorded.

8.3.4 Design and development controls

8.3.4.1 The organization shall apply controls to the design and development of the measurement process to ensure that:

a) the measurement results to be achieved are specified;

b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;

c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;

d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;

e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;

f) documented information of these activities is retained;

g) the appropriate application and control of monitoring and measuring equipment has been specified;

h) documented information of the authorizations related to each design and development phase exists;

i) the measurement process is designed to limit the risk of false acceptance or rejection and deficiencies (see 8.1.2 and Annex C for further information).

The effort devoted to control of the measurement process shall be commensurate with the importance of the measurements to the safety and quality of the product or service being measured and provided.

NOTE 1 Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.

NOTE 2 The application and control of monitoring and measuring equipment includes consideration of those items described in 8.3.5.4, 8.5.1.2 and 8.5.2, especially, but not limited to, those that relate to validity and traceability of resulting measurement.

8.3.4.2 When tests are necessary for verification and validation, those tests shall be planned, controlled, reviewed and documented to ensure the following:

a) test plans or specifications identify the test item being tested and the resources being used, and specify test objectives and conditions, factors to be recorded and relevant acceptance criteria;

b) test procedures describe the test methods to be used, proper performance of the test and how to record the results;

c) the test item submitted shall be of the correct configuration;

d) the requirements of the test plan and the test procedures are observed;

e) the acceptance criteria are met.

8.3.4.3 Monitoring and measuring devices shall be:

a) calibrated or verified, or both, prior to use; when no SI traceable standards exist (see 8.3.5.4), the basis used for calibration or verification shall be available as documented information;

b) identified in order to determine their metrological confirmation status;

c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

NOTE Calibration or verification can be conducted using a variety of methodologies. The determination of the validity of the calibration and associated intervals or methods required is further explained in Annex A.

8.3.4.4 During the design and development of the measurement process, the needs for measurement process monitoring as described in the 8.5.1.1 shall be considered.

8.3.5 Design and development outputs

8.3.5.1 General

The organization shall ensure that design and development outputs:

a) meet any documented input requirements;

b) meet the acceptance criteria;

c) specify the characteristics of the measurement process that are essential for the intended purpose and conformity of results;

d) specify, as applicable, the controls required for critical items, including any key characteristics and specific actions to be taken for use of these items;

e) are approved by authorized person(s) prior to release;

f) specify the characteristics and criteria of appropriate devices to be used during the given measurement process and prevent any unauthorized additions and deviations from this list.

The organization shall specify the data needed so that the measurement process and the measured value can be associated with the characteristics to verify the conformity of the measurement results for the products and services.

The organization shall make documented information available on design and development outputs.

NOTE Data can include:

— the unique identifier of the device which is used to measure the characteristic, as defined in the drawings, part lists, and specifications necessary to define the configuration and the design features of the product;

— the technical data and repair schemes for operating and maintaining the device.

8.3.5.2 Measurement process description

The description of each measurement process shall include, where appropriate:

a) identification of all types of relevant equipment;

b) measurement procedures;

c) measurement process uncertainties;

d) influence quantities;

e) measurement software;

f) conditions of use;

g) reference materials;

h) required operator capabilities;

i) any other factors affecting the reliability of the measurement result and including their analysis.

NOTE Where an organization employs simple measurements (e.g. manual measurement using callipers), an exhaustive review each time the process is used is not always necessary.

8.3.5.3 Measurement uncertainty

The organization shall identify the contributions to measurement uncertainty for the measurement processes. When evaluating measurement uncertainty, all contributions, including those arising from sampling, shall be taken into account using appropriate methods of analysis.

The analysis of measurement uncertainties shall be documented before the metrological confirmation of the measuring equipment, and validation of the measurement process.

In the case of measuring equipment or a significant parameter of the measurement process being changed, the measurement uncertainty shall be reviewed.

The concepts and methods of evaluating the measurement uncertainty components are specified in and may include, but are not limited to:

— ISO/IEC Guide 98-3;

— VDA 5[22];

— ISO 22514-7;

— UKAS M3003[21].

Other documented and accepted methods may be used (e.g. measurement process capability).

It is possible that some components of measurement uncertainty will be negligible compared to other components and this can make their inclusion inappropriate on technical or economic grounds. If so, the decision and justification for exclusion shall be documented. In all cases, the effort devoted to evaluating uncertainties of measurements shall be commensurate with the decision risk target.

The recording of measurement uncertainty evaluations may take the form of "generic statements" for similar types of measuring equipment (e.g. callipers), with contributions being used for individual measurement processes.

8.3.5.4 Metrological traceability

The organization shall ensure metrological traceability of measurement results to provide confidence in the measurement process. This establishes and maintains metrological traceability through a documented unbroken chain of calibrations.

Where an International System of Units (SI) exists, it shall be used for metrological traceability. In cases where such a unit does not exist, the use of a consensus standard, natural constant or appropriate certified reference material produced in conformity with ISO 17034 may be used.

Documented information of traceability of measurement results shall be maintained for the period required by the measurement management system or by the customer (whichever has the longest period).

A consensus standard is a "standard" established by agreement between two or more parties as a common measurement reference.

Parties involved in establishing a consensus standard should consider and document additional risk elements introduced by the use of such standard (see 8.1.2).

Calibration certificates or test reports shall indicate traceability to, and identify equipment used in, the process that affects the measurement uncertainty. Identification includes definition of the specific equipment used in the measurement process.

8.3.6 Design and development changes

The organization shall identify, review and control changes made during, or subsequent to, the design and development of the measurement process, and include a change management process to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

During the development of the measurement process, there may be changes made prior to the release of the final revised process.

The organization shall authorize a final release after a review and have documented information available on:

a) design and development changes;

b) the results of reviews;

c) the authorization of the changes;

d) the actions taken to prevent adverse impacts.

The organization shall implement a process with criteria for notifying its customers, prior to implementation, about changes that affect customer requirements.

8.4 Control of externally provided measurement processes, products and services

8.4.1 General

The organization shall be responsible for the conformity of all externally provided measurement processes and services including those from sources specified by the customer.

The organization shall identify and manage the risks associated with the external provision of measurement processes, products and services, as well as the selection and use of external providers.

The organization shall require that external providers of measurement services apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.

This shall include the right of access to the external provider, including the applicable areas of external provider's facilities and to applicable documented information to ensure that the appropriate activities are being carried out.

NOTE 1 External providers can require a contractual non-disclosure agreement be in effect to provide access to their facilities and data.

The organization shall determine the controls to be applied to externally provided measurement processes, products and services when:

a) they are intended for incorporation into the organization's own products and services;

b) they are provided directly to the customer(s) by external providers on behalf of the organization;

c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.

The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers, based on their ability to provide measurement processes or products and services in accordance with requirements. The organization shall have documented information available of these activities and any necessary actions taken.

NOTE 2 Organizations implementing ISO/IEC 17025 can demonstrate conformity to the testing and calibration requirements through documented information produced for ISO/IEC 17025.

8.4.2 Type and extent of control

The process for control of external providers shall consider the risk represented by the use of the provider's processes, products or services.

Verification activities of externally provided measurement processes, products and services shall be performed according to the risks identified by the organization.

The organization shall ensure that externally provided processes remain within the scope of its measurement management system.

The organization shall determine the verification, or other activities, necessary to ensure that the externally provided measurement processes, products and services meet the specified requirements.

In order to evaluate the external providers conformity, the following verification activities may include:

a) a review of required documented information and objective evidence of the conformity of the measurement processes, products and services from the external provider;

NOTE Accompanying documented information can be, for example, certificate of conformity, test reports, statistical information, process control information, results of production process verification and assessment of changes to the production process thereafter.

b) an inspection and audit at the external provider's premises;

c) a review of production part approval process data;

d) an inspection of products or verification of services upon receipt;

e) a review of the delegation of measurement processes used for the verification of the product.

Data from external providers and the reported characteristics of the material or equipment supplied are often a critical component of determining measurement uncertainty for the whole measurement process. Therefore, the data provided to the organization by the external provider should be retained for at least the period that the organization would retain its own documented information and reports relevant to the measurements performed. For recording purposes, batch identification can be adequate for consumable items used in measurement process control (see also the requirements in 7.5.3).

8.4.3 Information for external providers

The organization shall ensure the adequacy of requirements prior to their communication to the external provider.

The organization shall communicate to external providers its requirements, which may include:

a) the measurement processes including the identification of relevant technical data (e.g. specifications, methods, work instructions, equipment, equipment configurations);

b) the approval of methods, measurement processes and equipment;

c) competence, including any required qualification of persons;

d) the external providers' interactions with the organization;

e) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises;

f) the implementation of a measurement management system including measurement processes design control;

g) the use of statistical techniques for product acceptance and related instructions for acceptance by the organization (see Annex C);

h) appropriate documented information that is available both prior to and after acquisition of such equipment or material; this may include, but is not limited to, specification sheets, operating manuals, calibration reports and other relevant metrological information;

i) where an external provider provides a standard reference material used in the measurement process, the reference material shall be in conformity with ISO 17034, or approved by the organization prior to use (e.g. such as a certified reference material);

j) the requirement to notify the organization of nonconforming measurement processes, equipment or services and obtain approval for appropriate corrective actions;

k) specific requirements and expectations for handling proprietary/sensitive information (including hardware, software and intellectual property) and the required agreements needed to ensure the protection of such information.

8.5 Measurement process implementation

8.5.1 Control of measurement processes

8.5.1.1 General

The organization shall implement measurement processes under controlled conditions.

The controlled conditions shall include the following information, as appropriate:

a) The availability of documented information defining:

   1) the characteristics of the measurement processes to be provided or activities to be performed;

   2) the results to be obtained.

   NOTE 1 Documented information describing measurement process characteristics can include numerical data defining measurement processes, capabilities, repeatability and reproducibility criteria, and specified conditions.

b) The availability and use of suitable monitoring and measuring resources.

c) The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for the control of processes or outputs and acceptance criteria for the measurement process have been met. The organization shall ensure that the documented information includes:

   1) acceptance and rejection criteria;

   2) where in the process verification operations are to be performed;

   3) measurement results to be retained (at a minimum, an indication of acceptance or rejection);

   4) any specific monitoring and measuring equipment required and instructions for their use;

   5) the verification of the equipment used in the measurement processes;

   6) the use of statistical sampling in a measurement process for product or service acceptance.

d) Monitoring to ensure that measurement processes are under control and conforming to requirements, including the following:

   1) Data shall be provided in a usable format. Calibration and process uncertainty data shall be available in an easily accessible commonly used digital format to enable analysis, and to support continual improvement. Unless the data being provided are proprietary, the data shall be in an easily transportable format.

   NOTE 2 The concept of transportability of data is considered in methodologies such as FAIR (findability, accessibility, interoperability and reuse of digital assets) data.

2) The documented information of the measurement process in electronic form shall have back-ups. This means that if the electronic documentation system ceases to function through component failures, power loss, etc., there will still be existing and retrievable documented information of the current calibration measuring equipment, tools, etc.

e) The use of suitable infrastructure and environment for the operation of the measurement processes.

f) The appointment of competent persons, including any required qualification.

g) Validation, and periodic revalidations, of the ability of the measurement processes to obtain the intended results, when the outputs cannot be verified by monitoring or measurement carried out at a later stage.

h) The implementation of actions to prevent inadvertent human error.

i) The implementation of actions to maintain metrological integrity.

NOTE 3 In some cases, seals are used to prevent unauthorized adjustment affecting the measurement performance of measuring equipment. A broken seal can indicate that an adjustment has taken place that can affect metrological integrity.

j) The implementation of release, delivery and post-delivery activities affecting measurement results.

k) The establishment of criteria for workmanship with regards to proper implementation of the measurement process (e.g. in written procedures, instructions, representative samples and illustrations).

l) Evidence that all measurement processes have been implemented as planned, or if not, that the changes have been documented and authorized.

m) The control and monitoring of utilities and supplies affecting the measurement processes (e.g. water, compressed air, electricity, chemical products, see 7.1.3).

n) The methods used to determine or modify the metrological confirmation intervals described in documented information (discussed in Annexes A and B).

8.5.1.2 Control of embedded measuring equipment in tooling, facilities and test programs

The measurement equipment embedded in the tools, the tools themselves and the installations, as well as the computer programs used to control, monitor or measure the production processes, shall be validated and confirmed metrologically before their final availability for production.

When using a reference standard to validate embedded sensors, the reference standard shall be subject to verification or calibration.

The storage requirements shall be specified for the embedded measuring equipment, used in production and their storage conditions. This includes any necessary periodic verifications of the preservation conditions.

NOTE In some cases, it is not practical to individually control and validate measurement devices in facility installations. The use of a reference standard to validate the system of embedded sensors can be employed.

8.5.1.3 Verification of measurement processes

The organization shall implement verification activities to ensure that measurement processes meet requirements and ensure confidence in the measurement results.

The organization shall use the initial measurement of the first implementation of the measurement process to verify that the measurement process produces results that meet the requirements. This process should be repeated when changes that can invalidate the original results occur, which can include design changes and changes to an influencing parameter.

NOTE This verification activity is similar to the activity referred to as “first article inspection” in many manufacturing organizations.

The organization shall have documented information relating to the results of the measurement process verification.

8.5.2 Identification and traceability

Traceability, in this clause, refers to retained documented information and similar items related to the measurement process (refer to ISO 9000:—, 3.5.11).

The organization shall use suitable means to identify outputs of measurement processes when it is necessary to ensure the conformity of products and services.

Measuring equipment and technical procedures used in the measurement process shall be clearly identified, individually or collectively.

When acceptance authority media are used (e.g. stamps, electronic signatures, passwords), the organization shall establish controls for the media (e.g. paper, electronic).

The organization shall ensure full traceability of the measurement process, and retain all elements involved in measuring a characteristic and demonstrating the conformity of the related product or service. This traceability shall include, at a minimum:

— identification of the product or service concerned;

— the measured characteristic;

— the measuring equipment used, and its associated metrological confirmation status;

— the measurement conditions;

— the operator or system that performed the measurement.

It shall be possible to clearly identify, for each result, the elements that enabled its production. Only qualified and compliant equipment shall be used.

Equipment designed for specific use that is confirmed only for use in particular measurement processes, shall be:

— clearly identified or controlled to prevent unauthorized use;

— identified within the measurement process;

— distinguishable from other measuring equipment.

When environmental factors, such as temperature, can influence a critical characteristic being measured, they shall be recorded to demonstrate the validity of the results and the conformity of the measured characteristics.

8.5.3 Property belonging to customers or external providers

The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization. This includes personally owned and customer-supplied equipment used to provide evidence of measurement method outputs and/or conformity.

The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use with, or incorporation into, the organization's measurement process.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and have documented information available as evidence on what has occurred.

NOTE A customer's or external provider's property can include materials, components, tools, equipment, software, premises, intellectual property and personal data.

8.5.4 Preservation

The organization shall preserve the measurement process outputs, to the extent necessary to ensure conformity to requirements.

8.5.5 Measurement process post-delivery activities

The organization shall meet requirements for post-delivery measurement activities performed after implementation of measurement processes associated with the measurement result. The following items shall be considered in post-delivery activities:

a) during the implementation of the measurement process, the operator shall consider any time-related limitations on equipment or other matters affecting the measurement results;

b) collection and analysis of measurement process implementation data (e.g. performance, reliability, lessons learned);

c) control, updating and provision of technical documented information relating to measuring equipment use, maintenance, repair and overhaul;

d) customer support of measurement processes (e.g. queries, warranties, maintenance, replacement equipment, resources).

Support in the interpretation of the measurements results.

The organization shall ensure that measurement results are correctly interpreted in regard to metrological knowledge. This specifically concerns the treatment of the uncertainty of the measurement data and its use, including the following:

— all results shall be given with their measurement uncertainties when possible and relevant;

— the effect of uncertainty shall be considered when reporting the results.

The impact of uncertainty should be considered relative to measurement management system aspects related to the process (e.g. see in Figure C.3).

8.5.6 Control of changes

The organization shall review and control changes to the measurement process, to the extent necessary to ensure continuing conformity with requirements.

Persons authorized to approve measurement process changes shall be identified.

The organization shall have documented information describing the results of the review of measurement process changes, the person(s) authorizing the change and any necessary actions arising from the review.

NOTE Measurement process changes can include the changes affecting processes, measuring equipment, tools or software programs.

8.6 Release of measurement process results

8.6.1 Planned arrangements for release of results

The organization shall implement planned arrangements, at appropriate stages, to verify that the requirements relative to the measurement processes have been met.

The release of measurement process results to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

NOTE These results may include, where appropriate, and are not limited to:

— test reports, calibration certificates and calibrated/verified devices or equipment;

— reports of life test results;

— declaration of product conformity.

8.6.2 Documented information relating to release of results

The organization shall have documented information on the release of measurement process results.

The documented information shall include documents that provide evidence of validity of test reports and calibration certificates such as, but not limited to:

a) evidence of conformity to the acceptance criteria;

b) the measurement uncertainty analysis methodology used in the measurement process;

c) data from internal and external sources for evidence of calibration of measuring equipment used in the measurement process;

d) any special handling instructions related to the measurement process (e.g. environmental stabilization of measuring equipment or tested articles);

e) documented information of the person(s) authorizing the release.

When required to demonstrate validation, revalidation or reliability of the measurement process, see 8.5.1.1 g), the organization shall ensure that documented information provides evidence that the measurement process results meet the specified requirements.

8.7 Control of nonconforming outputs

8.7.1 Handling of nonconforming outputs

The organization shall ensure that outputs that do not conform to the agreed requirements are promptly handled so that nonconforming outputs arising from the implemented measurement process cannot compromise the conformity of products and services.

NOTE In this clause, the term "nonconforming outputs" relates to the failure of the measurement process results that bring into question the confidence of any declaration of conformity of products or services.

The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after the delivery of products, and during or after the provision of services.

The organization's process for control of nonconformities shall be available as documented information, including arrangements for:

a) defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;

b) taking actions necessary to contain the effect of the nonconformity on other processes, products or services;

c) timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties; when applicable, the customer is notified, and the product or output of the measurement process is reviewed;

d) defining corrective actions for nonconforming measurement processes that allowed the release of products and services which ultimately become nonconforming after delivery, as appropriate to their impacts (see 10.2).

The organization shall handle nonconforming outputs in one or more of the following ways:

— correction;

— suspension of the measurement process;

— informing the customer;

— using without modification or adjustment with the approval of the relevant authority (this is sometimes referred to as "use-as-is").

In the event of suspicion that measuring equipment is yielding inappropriate results, the measuring equipment shall be visibly identified or isolated in a restricted area so that it cannot be reintroduced into the measurement process until it is corrected. If the measuring equipment is found to be the cause in the deviation of the measurement process, the equipment shall be repaired or adjusted, or the deviation accepted and the uncertainty budget adjusted appropriately. If the equipment cannot be repaired or properly adjusted, it shall be conspicuously and permanently marked, until properly disposed of. This does not preclude the retention of equipment in a downgraded status with appropriate controls and usage definition.

Conformity to measurement process requirements shall be verified for previous nonconforming outputs after the measuring equipment has been corrected.

8.7.2 Documented information

The organization shall have documented information available that:

a) describes the nonconformity;

b) describes the actions taken;

c) describes any concessions obtained;

d) identifies the authority approving the action in respect of the nonconformity.

9 Performance evaluation

9.1 Monitoring, measurement, analysis, and evaluation

9.1.1 General

The organization shall determine:

a) what needs to be monitored and measured;

b) the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results;

c) when the monitoring and measuring shall be performed;

d) when the results from monitoring and measurement shall be analysed and evaluated.

Documented information shall be available as evidence of the results.

The organization shall evaluate the performance and the effectiveness of the measurement management system.

The organization shall also determine the criteria against which the organization will evaluate its measurement processes' performance, and appropriate performance indicators.

The organization shall ensure that calibrated or verified monitoring and measuring equipment is used and maintained, as appropriate.

9.1.2 Customer satisfaction

The organization shall monitor customers' satisfaction and determine if their needs and expectations have been fulfilled.

The organization shall determine the methods for obtaining, monitoring and reviewing this information.

9.1.3 Analysis and evaluation

The organization shall analyse and evaluate appropriate data and information arising from the performance of the measurement management system.

The results of analysis shall be used to evaluate:

a) suitability and adequacy of the measurement results obtained from the measurement processes attesting to the conformity of the products and services to the specified requirements;

b) the degree of customer satisfaction;

c) the performance and effectiveness of the measurement management system;

d) whether the measurement management system planning has been implemented effectively;

e) the effectiveness of actions taken to address risks and opportunities;

f) the performance of external providers.

9.2 Internal audit

9.2.1 General

The organization shall conduct internal audits at planned intervals to provide information on whether the measurement management system:

a) conforms to:

   1) the organization's own requirements for its measurement management system;

   2) the requirements of this document;

b) is effectively implemented and maintained.

NOTE 1 The audit of the measurement management system, includes, but is not limited to:

— uncertainty calculations and validations of uncertainty;

— documented information of traceability of the measurement process outputs used to declare product or service conformity;

— contractual requirements imposed on external providers.

NOTE 2 See ISO 19011 for guidelines for auditing management systems.

NOTE 3 When conducting internal audits, performance indicators can be evaluated to determine whether the measurement management system is effectively implemented and maintained.

9.2.2 Internal audit programme

The organization shall plan, establish, implement and maintain (an) audit programme(s), including the frequency, methods, responsibilities, planning requirements and reporting.

When establishing the internal audit programme(s), the organization shall consider the importance of the processes concerned and the results of previous audits.

The organization shall:

a) define the audit objectives, criteria and scope for each audit;

b) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process (see the note);

c) ensure that the results of audits are reported to relevant managers;

d) take appropriate correction and corrective actions without undue delay.

Documented information shall be available as evidence of the implementation of the audit programme(s) and the audit results.

NOTE The selection of auditors is based on their level of competence and understanding of measurement processes, including evaluation of measurement uncertainty, use of test equipment and relevant experience.

9.3 Management review

9.3.1 General

Top management shall review the organization's measurement management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.

9.3.2 Management review inputs

The management review shall include:

a) the status of actions from previous management reviews;

b) changes in external and internal issues that are relevant to the measurement management system;

c) changes in needs and expectations of interested parties that are relevant to the measurement management system;

d) information on the measurement management system performance, including trends in:

   1) nonconformities and corrective actions;

   2) monitoring and measurement results;

   3) audit results;

e) opportunities for continual improvement;

f) the adequacy of resources;

g) the effectiveness of actions taken to address risks and opportunities (see 6.1);

h) relevant communication(s) with interested parties, including complaints;

i) the extent to which performance objectives have been met;

j) measurement process performance;

k) the performance of external providers.

9.3.3 Management review results

The results of the management review shall include decisions related to continual improvement opportunities and any need for changes to the measurement management system.

The management review results shall also include:

a) resource needs;

b) risks and opportunities identified;

c) opportunities of the integration of the measurement management system with other business processes;

d) actions to be taken, if needed, when measurement management system objectives have not been achieved.

Documented information shall be available as evidence of the results of management reviews.

10 Improvement

10.1 Continual improvement

10.1.1 Measurement management system improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the measurement management system.

These shall include:

a) addressing future needs and expectations, relevant to the measurement management system;

b) correcting, preventing or reducing undesired effects;

c) improving the performance and effectiveness of the measurement management system.

The organization shall consider the results of analysis and evaluation and the results from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

10.1.2 Measurement process improvement

The organization shall establish post-implementation activities to continue the improvement of the measurement processes.

These activities shall include, as appropriate, and are not limited to, the elements described in 8.3 along with lessons learned.

10.2 Nonconformity and corrective action

When a nonconformity occurs, the organization shall:

a) react to the nonconformity, and as applicable:

   1) take action to control and correct it;

   2) deal with the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

   1) reviewing the nonconformity;

   2) determining the causes of the nonconformity;

3) determining if similar nonconformities exist, or can potentially occur;

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) make changes to the measurement management system, if necessary;

f) forward the corrective action requests to an external provider if it is determined that the external provider is responsible for the nonconformity;

g) take specific actions when timely and effective corrective actions are not achieved.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

Nonconformities shall include any complaints from customers.

Documented information shall be available as evidence of:

— the nature of the nonconformities and any subsequent actions taken;

— the results of any corrective action.

Annex A
(informative)

Calibration intervals optimization

A.1 General

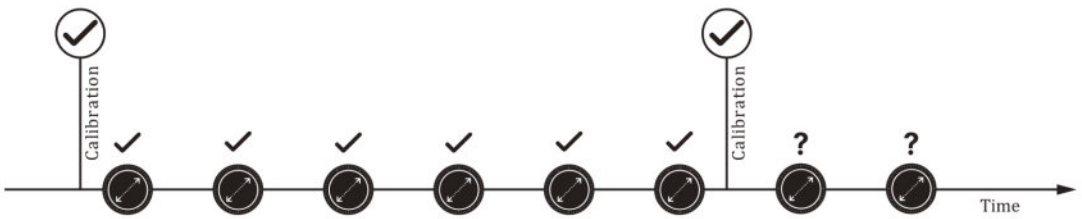
This annex only covers measuring equipment and not the measurement process.

The methods stated in this annex are for information only. Other methods may be equally applicable.

A.2 Calibration interval

Calibration interval refers to the time (or the number of uses) between calibrations of a measuring equipment.

Before optimizing the calibration intervals, it is important to understand the role of calibration. The purpose of establishing calibration intervals is to ensure that measurement results obtained with measuring equipment between two calibrations fulfils specified requirements. If the conformity of a measuring equipment issued from a verification certification at the end of a calibration interval is found to pass verification, this indicates that all measurement results provided by the measuring equipment since the last calibration may be assumed that most measurements provided by the measuring equipment in this interval are valid and reliable (see Figure A.1).



Key

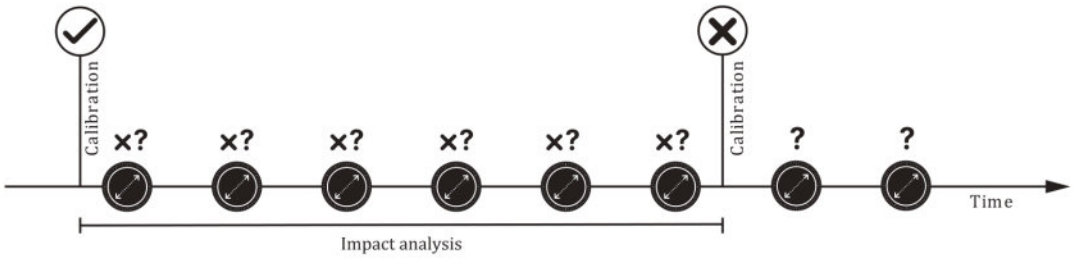
- verification passed
- verification failed
- ×? potential nonconforming measurements
- ✓ conforming measurements[a]
- ? measurements will be confirmed after the next calibration
- measurements being performed

[a] The measurement results are considered valid and reliable, when all factors influencing the measurement process results have been confirmed conform to specified requirements (see Figure C.3).

Figure A.1 — Relationship of measurement results obtained between two calibrations

The International Vocabulary of Metrology, ISO/IEC Guide 99:2007 (also known as the "VIM"), distinguishes between calibration and verification (see ISO/IEC Guide 99:2007, 2.39 and 2.44, respectively). In this annex, it is assumed that both calibration and verification are performed in unison. Ensuring conformity to the specified requirements is the responsibility of the user of the equipment. The user shall choose maximum permissible measurement errors compatible with their own needs, and declaration of conformity strategies according to their acceptable risk. These two points cannot be implicitly known by the calibration laboratory and shall therefore be validated if the laboratory declares the conformity of the equipment.

ISO 9001 requires that each measuring equipment for which it is essential to provide confidence in the validity and reliability of measurement results "shall be calibrated or verified, or both, at specified intervals" (see ISO 9001:—, 7.1.5.2). Defining calibration intervals is part of metrology. Too short calibration intervals lead to a high cost in money and time, and are not justified for reliable measuring equipment. Calibration intervals that are too long can lead to nonconformity and related impacts to previously performed measurements using that measuring equipment (see Figure A.2).



Key

✓	verification passed
✗	verification failed
×?	potential nonconforming measurements
✓	conforming measurements[a]
?	measurements will be confirmed after the next calibration
◐	measurements being performed

[a] The measurement results are considered valid and reliable, when all factors influencing the measurement process results have been confirmed conform to specified requirements (see Figure C.3).

Figure A.2 — Failed verification resulting in impact analysis

It is important to understand that:

— short calibration intervals do not prevent the measuring equipment yielding incorrect measurement results (calibration or verification is not preventive maintenance);

— there is always a probability of nonconforming measurements, even with a conforming measuring equipment, due to uncertainty of measurement (see Annex C).

A.3 Calibration interval optimization

Calibration interval optimization refers to the interval between two calibrations is the largest interval allowed without any impact (or minimal acceptable impact) on the measurements.

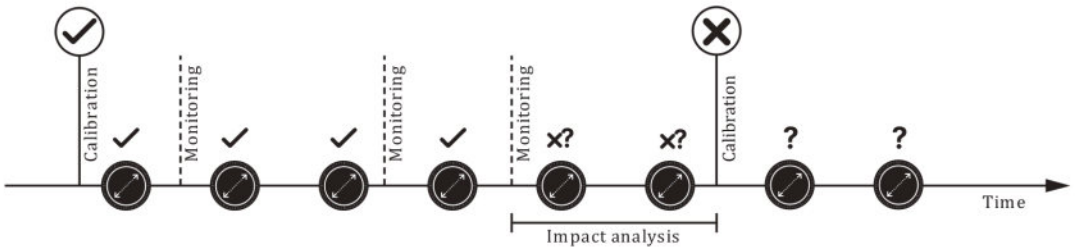
Calibration interval optimization is one of many aspects of modern metrology. It implies that measuring equipment and their processes are known, as well as the different factors impacting the measurement results (environment, use of the measuring equipment, operators, etc.).

A.4 Strategies

A.4.1 Monitoring

Monitoring the measuring equipment on a regular basis is an approach to adjust the calibration interval, while assuring the validity and reliability of the measurement results.

Figure A.3 expresses the effect on the period of impact analysis when monitoring is used.



Key

- verification passed
- verification failed
- potential nonconforming measurements
- conforming measurements[a]
- measurements will be confirmed after the next calibration
- measurements being performed

[a] The measurement results are considered valid and reliable, when all factors influencing the measurement process results have been confirmed conform to specified requirements (see Figure C.3).

Figure A.3 — Effect of the monitoring of measuring equipment on reducing the time period of impact analysis

Examples of monitoring are:

— regular measurements on a stable item;

— interlaboratory comparison;

— control charts.

This method implies that if monitoring is used, organizations should formalize those monitoring processes in accordance with 8.5 and 8.6.

A.4.2 Conditional calibration

Conditional calibration means that the measuring equipment is calibrated when collected information indicates that perhaps the measuring equipment is no longer reliable. This can occur after a fault detected in monitoring, concern related to damage resulting from mishandling, etc.

A.4.3 Abeyance

The abeyance process, which is the temporary deferment of calibration interval, is used with measurement and test measuring equipment whose measured quantity value is not related to time but rather to usage. It defines the calibration interval starting from the date of first use rather than the actual calibration date, reducing the amount of calibration activities. Examples of items where the abeyance process may be used include:

— gauge blocks;

— ring and plug gauges;

— inside/outside Vernier callipers;

— dial test indicators;

— callipers;

— length gauge;

— vee block;

— straight edge;

— square.

This method should be used with care so that equipment that degrades with time, such as electronic indicators, is not subject to abeyance.

An example of this is a pin gauge or similar measuring equipment where, once measured and validated, it is not affected by time since calibration. The calibration periodicity can be set at one year of use while the last calibration date is five years ago. For long periods of non-use, it is still necessary to check the condition of the equipment (e.g. the absence of oxidation). In order to use this process, a method should be employed that identifies gauges not yet used (put into service). Some typical methods of implementing this are:

— using sealed bags or containers with appropriate seals, to indicate usage;

— the measuring equipment itself has a material (e.g. a wax) applied over a measurement surface that is peeled off before use to indicate the item is now in service;

— the measuring equipment is in a controlled storage location (such as a tool crib) that maintains documented information of issuance and return.

In these cases, the calibration control system used by the organization shall have appropriate entries and/or labels to indicate the date the measuring equipment was put in service and the calibration due date based on the calibration interval (periodicity) assigned to that item or class of items.

Variations of this method use start-stop periods to accumulate the usage time within the specified longer calibration interval (in the case of the example, five years). So, the gauge can be used for one month and then be put into abeyance for 18 months and reuse started again as long as neither the valid usage period nor the recalibration period is exceeded. To properly employ this method requires care and understanding of the users. It can also require the use of additional documented information keeping and controls (personnel or process).

A.4.4 Existing methods and approaches

A.4.4.1 Drift method

The purpose of the drift method is to statistically study past calibration results of measuring equipment which is subject to wear (such as go-no go), to plan appropriate future metrological confirmations. This approach yields to specific calibration intervals based on the state and the use of each measuring equipment. This method is documented in AFNOR FD X07-014:2006.

A.4.4.2 Periodicity ratio approach

The periodicity ratio approach is an approach based on the ratio of the equipment uncertainty to the overall uncertainty of the measurement process. This provides an idea of the impact of the measuring equipment in the measurement process. If the ratio is low, the measuring equipment has little impact and the periodicity is high. On the contrary, if the ratio is close to 1, the impact of the measuring equipment is high and the periodicity is low. This method is documented in AFNOR FD X07-014:2006.

A.4.4.3 OPPERET approach

The OPPERET (optimization periodicity calibration) approach is a methodology to assess measuring equipment according to a set of qualitative or/and quantitative criteria that are weighted by their impact to the measurement process. This assessment is then converted into a set of calibration intervals based on Gaussian distributions. This method is documented in AFNOR FD X07-014:2006.

A.4.4.4 Risk-based approach

Methods used to determine the intervals between calibrations are reviewed and adjusted when necessary to ensure continuous conformity with the specified metrological requirements within the specified period of validity. These metrological requirements often include acceptable risk. ILAC-G24/OIML D 10[19] and NCSLI RP-1[20] describe various methods of determining intervals of calibration based on historical performance bounded by risk. Another approach to risk management of calibration intervals is FMECA (failure modes, effects and criticality analysis) systems whereby a matrix is constructed of criticality of measurement versus surveillance requirements.

Annex B
(informative)

Measurement uncertainty

B.1 General

This annex is provided to increase awareness of the users of this document about the notion of measurement uncertainty. Measurement uncertainty evaluation is not the purpose of this annex. For more information, see ISO/IEC Guide 98-1, ISO/IEC Guide 98-3, ISO/IEC Guide 98-4, ISO/IEC 17025 and Reference [18]).

In this context, measurement uncertainty is inherent to systematic or statistical fluctuations that impact a measurement. Physically, measurement uncertainty is represented by a confidence interval, which manifests as a range of possible values, with various probability. Measurement uncertainty is an essential concept as it quantifies the reliability of measurements, helping organizations to make informed decisions.

B.2 Concepts

Organizations perform measurements for different purposes, such as conformity assessment of products and services (testing and inspection), material characterization, comparison, etc. All measurements contain errors. When using a statistical approach, the measurement process error, e_m, is an outcome of a probability distribution, describing the uncertainty of the measurement process. The measured value observed is equal to the true value (which cannot be known) plus the measurement process error, as shown by Formula (B.1):

$$Y_{\text{measured}} = Y_0 + e_m \tag{B.1}$$

where

Y_{measured} is the observed value, which is an approximation of the true value;
Y_0 is the true value of the measurand; this value cannot be known;
e_m is the measurement process error.

The measurement process error, e_m, is different every time the measurement is done. To evaluate an uncertainty, a set of possible errors is examined rather than a single error.

Whatever the use of the measurement, it is necessary to quantify the measurement uncertainty to evaluate the risk of producing an erroneous measurement (see Annex C).

When a quantity is measured, the outcome depends on the measuring system (see ISO/IEC Guide 99:2007, 3.2), the measurement procedure, the skill of the operator, drift of the measuring equipment, the environment, and other effects (see ISO/IEC Guide 98-1:2024).

Measurement uncertainty can arise from (see ISO/IEC Guide 98-3:2008, 3.3.1, and ISO/IEC Guide 99:2007, 2.26):

— systematic effects (e.g. equipment stability);

— random effects (e.g. repeatability, noise, reproducibility);

— customers-specified contractual requirements (some contracts can specify particular procedures for evaluation of measurement uncertainty with specified uncertainty budgets).

NOTE 1 Uncertainty budget is an itemized table of components that contribute to the uncertainty of measurement results.

NOTE 2 Measurement uncertainties concern all measurement processes in organizations and are not restricted to calibration and testing laboratories.

NOTE 3 Measurement uncertainty of measurement results is evaluated considering all contributions within the whole measurement process. It is not restricted to the measurement uncertainty of calibration of the measuring equipment.

B.3 Quantification of the measurement uncertainty

There are numerous methods for evaluating measurement uncertainties. This document does not constrain the user in how to analyse and evaluate measurement uncertainty. However, this document does mandate that the organization should have a method of evaluation, using a recognized approach. A measurement performed without appropriate evaluation of measurement uncertainty should be considered incomplete.

As it states in ISO/IEC Guide 98-1:2024, 5.1.4:

> "To support the use of JCGM 100:2008[16], JCGM 101:2008[17] (see also Clause 5.4) provides a procedure for validating it in any particular case. The procedure is based on a numerical comparison of the results provided by the two approaches, that of JCGM 101:2008 being regarded as a gold standard for the purpose. If these results agree to within the desired numerical accuracy, the application of JCGM 100:2008 can be regarded as acceptable. Otherwise, an alternative approach, such as the propagation of distributions (JCGM 101:2008) itself, should be considered for the uncertainty evaluation [8, Clauses 5.7-5.11]."

Annex C
(informative)

Measurement decision risk and rules

C.1 General

This annex is an introduction to pass/fail decision rules and associated measurement decision risk. Techniques are readily available to estimate percentage of false acceptance risk and corresponding false rejection risk for a sample decision rule.

It is important to know that the rationale for the application of decision rules in manufacturing is to clearly specify risk with the purpose of improving yields, eliminating waste and reduction of the use of environmental resources needed to produce products while meeting the expectations of an organization's customers. While process capability measures (i.e. Cpk, process capability index) guard banding against process variations and simple product tolerance analysis perform this function, the use of decision rules, rigorously applied from the design stage, result in an improvement in the critical factors with less iterations of the process. Proper decision rule(s) reduce(s) the probability of creating errors or having to run several trials or configurations.

Significant details of decision rules and associated decision risks and their application are provided in ISO 14253-1:2017, ISO/TR 14253-6:2012, ISO/IEC Guide 98-4, ILAC-G8:09/2019[18], UKAS M3003[21], VDA 5[22] and References [23] and [24] provide.

C.2 Measurement decision risk

When performing a measurement and subsequently comparing the result to a specification, making a statement of conformity (e.g. in or out of specification, pass/fail), the following two outcomes are possible:

a) The organization makes a correct pass/fail decision regarding conformity to specifications.

b) The organization makes an incorrect pass/fail decision regarding conformity to specifications.

Measurements are associated with errors, which are typically quantified by using statistical methodology. Annex B provides an explanation of measurement uncertainty.

Figure C.1 shows two identical measurement results but with different measurement uncertainties. The expanded uncertainty in the lower result (case A) lies entirely within the specification limit. The upper result (case B) has significantly larger measurement uncertainty. The risk of falsely accepting a result in case B is higher because of the larger measurement uncertainty corresponding to the portion of the interval in Figure C.1 labelled "What is the level of risk?".

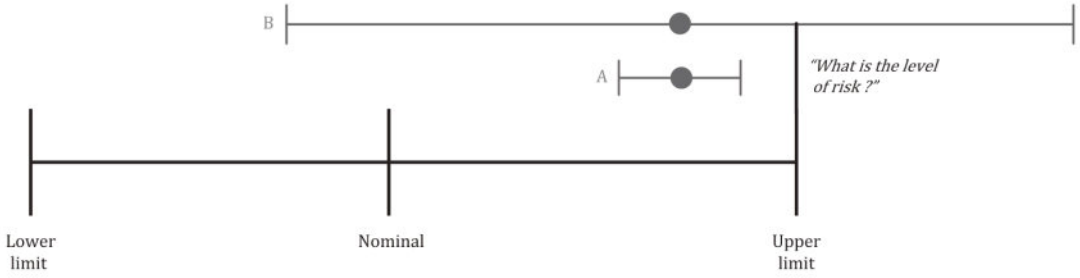
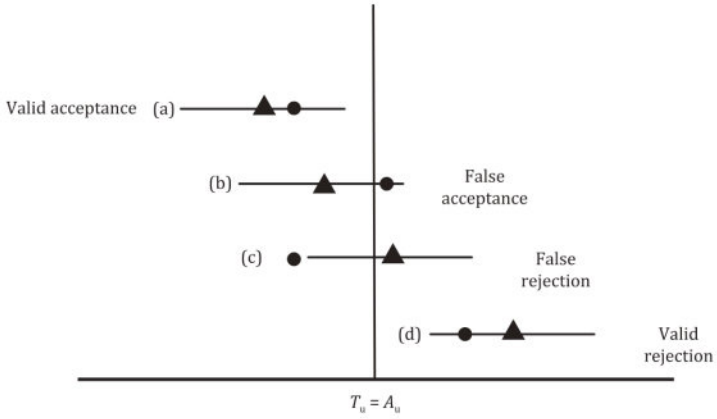


Figure C.1 — Illustration of measurement decision risk

Annex B highlights the relationship of a measured value, measurement error and the true value. Figure C.2 illustrates the four outcomes of a simple decision rule for a given measurement uncertainty. The "true" value of measurand can occur anywhere in the measurement uncertainty statistical coverage interval, as Figure C.2 illustrates. In fact, with small probability, the true value can also be outside the coverage interval as per use case (c).



Key

▲ measured value

● true value

NOTE 1 The upper acceptance limit, A_U, coincides with the upper limit of tolerance, T_U.

NOTE 2 Source: ISO/IEC Guide 98-4:2012, 8.3.

Figure C.2 — Four outcomes of a simple acceptance decision rule close to the upper limit of tolerance, T_U

C.3 Decision rule

A decision rule is a "documented rule that describes how measurement uncertainty will be accounted for with regard to accepting or rejecting an item, given a specified requirement and the result of a measurement" (see ISO/IEC Guide 98-4:2012, 3.3.12).

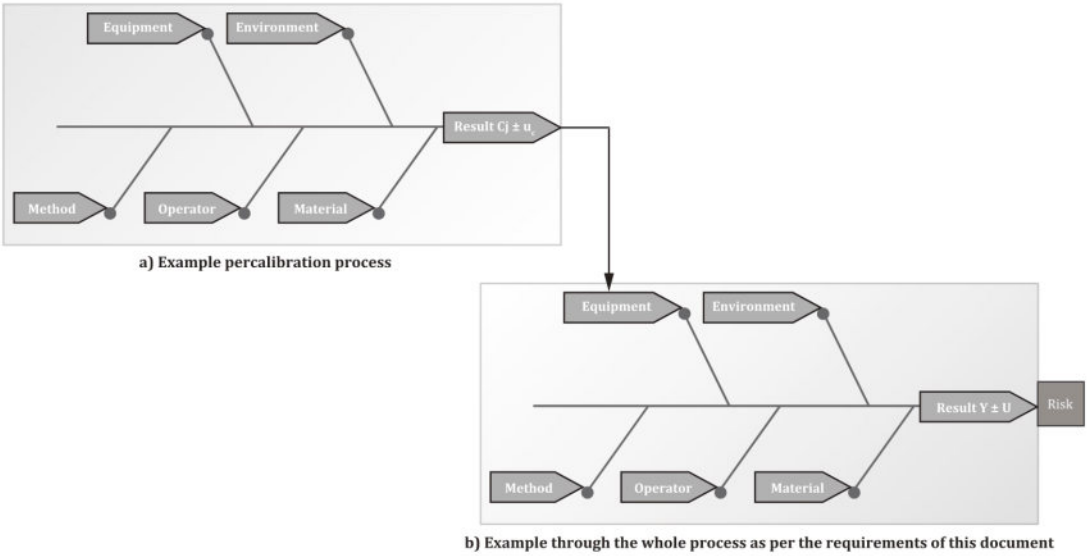
NOTE 1 Different decision rules result in different levels of false-acceptance or false-rejection risk.

Measurement decision risk quantifies the statistical probability associated with a given decision rule, e.g. that due to uncertainty in measurements, the organization will incorrectly report the conformity or nonconformity of the measuring equipment under test to the specification.

False acceptance risk (also known as "consumer risk" or "beta risk") is associated with incorrect pass decisions.

False rejection risk (also known as "producer risk" or "alpha risk") is associated with incorrect fail decisions.

NOTE 2 Measurement decision risk is applied to the whole measurement process implemented within the measurement management system, considering product tolerances and performance requirements. See Figure C.3 for a graphical representation of typical contributors to the measurement decision risk. It includes the measurement uncertainty in the calibration process for the measuring equipment used in accordance with 8.4.1 and also the measurement uncertainty contributors of the measurement process itself. The propagation of these errors and their combination through the resulting process can then be quantified as risk.



a) Example percalibration process

b) Example through the whole process as per the requirements of this document

Subfigure a) shows some typical contributors to uncertainty and should not be considered comprehensive or applicable to all situations.

For subfigure b), when the calibration processes shown in subfigure a) are outsourced, the requirements of 8.4 apply.

Key

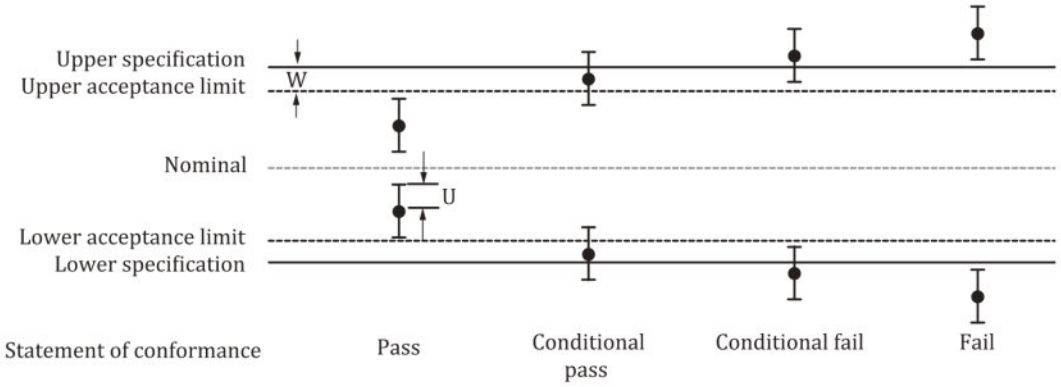
Cj	trueness correction
Y	measurand
u_C	calibration uncertainty
U	uncertainty including u_C

Figure C.3 — Examples of sources of measurement uncertainty and process contributors to risk

C.4 Decision rule example

The selection of decision rules in measurement methods is particular to the application and should take into account consideration of the proper application of measurement methods. In cases where large sample sizes are used, ISO/IEC Guide 98-4 provides a well-understood basis for decision rules. In cases where measurement sample sizes are small (e.g. calibration activities, safety risk for the final user), the application of ILAC-G8:09/2019[18] may be more appropriate.

ILAC-G8:09/2019[18] provides an overview of common pass/fail decision rules. Tools exist for estimating the percentage level of false acceptance risk.



U = 95 % expanded measurement uncertainty

NOTE For an explanation of this figure, refer to ISO/IEC Guide 98-3 and ISO/IEC Guide 98-4.

Figure C.4 — Non-binary statement of conformity with guard band

The decision rule illustrated in Figure C.4 is a non-binary decision rule that employs a guard band, *w*, which takes into account a value of the measurement uncertainty extended to 95 % (w = U), to report the results. This results in the following four possible statements of conformity:

— Pass: Measurement results have low false acceptance risk.

— Conditional pass: Measurement results are observed as being in specification/acceptance limits. However, there is increased risk of false acceptance compared with "pass". It is possible that organizations shipping products with final test results as "conditional pass" will see their process margin eroding, leading to risk of increased warranty costs.

— Conditional fail: Measurement results are observed out of specification. There is increased risk of false rejection compared to "fail". It is possible that organizations are falsely rejecting their products in final tests, resulting in lower yields and unnecessary rework.

— Fail: Measurement results have low false rejection risk.

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