DRAFT International Standard

ISO/DIS 10012

Quality management – Requirements for measurement management systems

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

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Foreword

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

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

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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

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

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

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

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

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

Introduction

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

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

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

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

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

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

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

In this document the following verbal forms are used:

— 'shall' indicates a requirement;

— 'should' indicates a non-mandatory recommendation;

— 'may' indicates a permission for use;

— "can" indicates a possibility or a capability.

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

Quality Management – Requirements for Measurement Management Systems

1 Scope

This International Standard specifies the requirements for a measurement management system (MMS) when an organization:

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

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

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

All the requirements of this International Standard are generic and intended to apply to any organization, whatever its type or size, or the products and services it provides.

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2015, Quality management systems — Fundamentals and vocabulary

ISO 9001:2015, Quality management systems

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

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000: 2015 and ISO/IEC GUIDE 99 and the following apply.

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

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

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

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

Note 2 to entry: If the organization is part of a larger entity, the term “organization” refers only to the part of the larger entity that is within the scope of the *management system* (3.4).

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

EXAMPLE Customers, owners, people in an organization, suppliers, metrologists, regulators, unions, partners, or society.

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

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

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

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

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

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

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

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

3.6
objective
result to be achieved

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

Note 2 to entry: Objectives can relate to different disciplines (such as financial, health and safety, and environment) and can apply at different levels (such as strategic, organization-wide, project, product and *process* (3.8)).

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

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

3.7
risk
effect of uncertainty

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

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

Note 3 to entry: Risk is often characterized by reference to potential events (as defined in ISO Guide 73) and "consequences" (as defined in ISO Guide 73), or a combination of these.

Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood (as defined in ISO Guide 73) of occurrence.

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

3.8
process
set of interrelated or interacting activities which transforms inputs into result

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

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

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

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

Note 2 to entry: Documented information can refer to:

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

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

— evidence of results achieved (*records* (3.23)).

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

3.11
performance
measurable result

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

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

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

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

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

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

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

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

3.15
conformity
fulfilment of a *requirement* (3.14)

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

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

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

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

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

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

3.19
measurement result
result of measurement
set of quantity values being attributed to a measurand together with any other available relevant information

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

SOURCE: ISO GUIDE 99

3.20
measurement
process (3.8) to determine a value

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

Note 2 to entry: In metrological processes, this refers to experimentally obtain one or more quantity values that can reasonably be attributed to a quantity. For further details, refer to ISO GUIDE 99.

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

SOURCE: ISO 9000

3.22
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.

3.23
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”.

3.25
measurement management system
part of a *management system* (3.4) with regard to *measurement* (3.20)

3.26
measuring equipment
measuring instrument, software, measurement standard, reference material or auxiliary apparatus, or a combination thereof, necessary to realize a *measurement process* (3.21)

SOURCE: ISO 9000:2015, 3.11.6.

3.27
metrological confirmation
set of operations required to ensure that measuring equipment 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 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.

Note 5 to entry: A diagram of the processes involving metrological confirmation is given in The intent of the measurement management standard is to achieve the intended results, including enhancing its measurement performance.

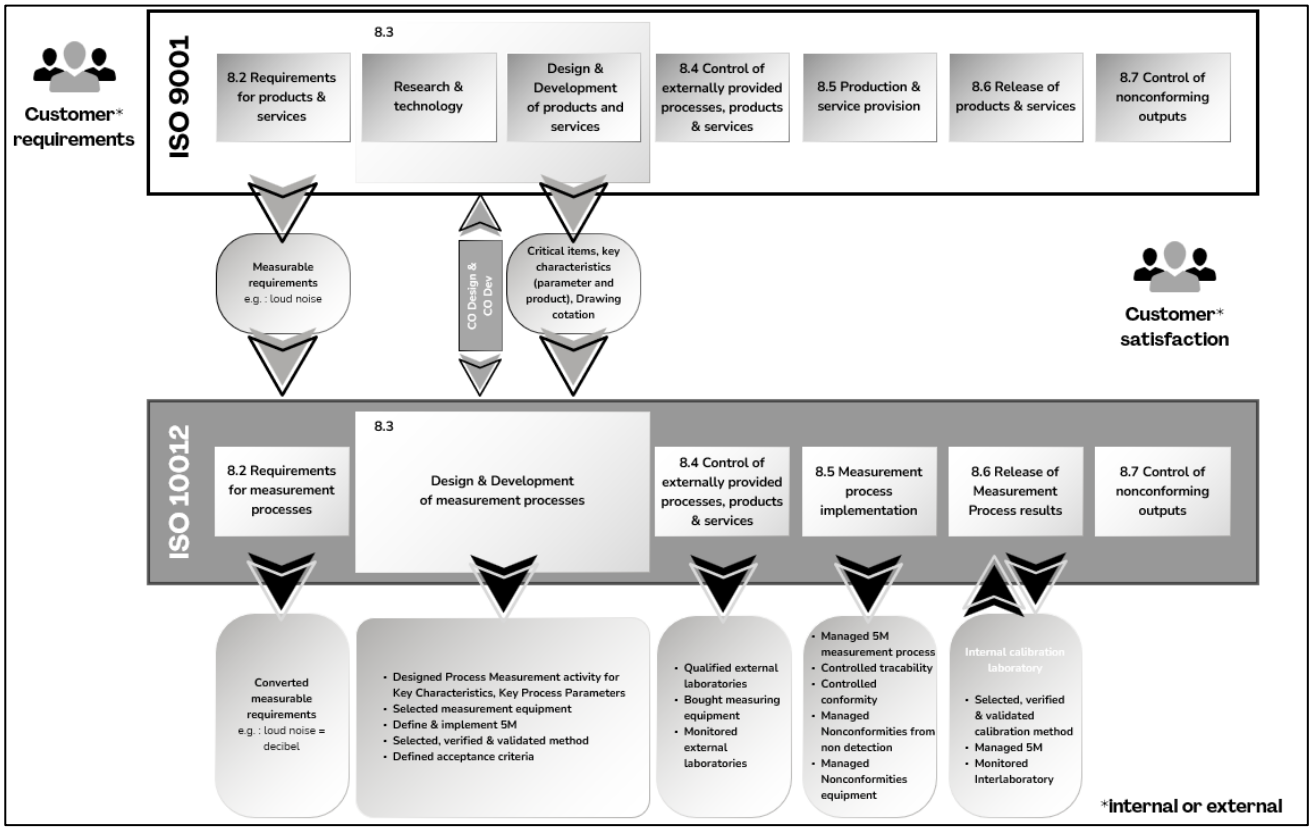

Figure 1.

3.28
metrological function
function with administrative and technical responsibility for defining and implementing the *measurement management system* (3.26)

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.

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

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

The Measurement management system shall apply metrological concepts to achieve the assurance of the reliability of the measurement and related risks.

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

All external and internal issues shall be reviewed.

NOTE 1 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 2 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge, and impartiality.

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;

d) the continuous monitoring of the needs and requirements of the interested parties and maintain those changes in the management process as appropriate.

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, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its measurement management system.

NOTE 1 This document only treats monitoring and measurements within the technical context (included metrological issues) and not the monitoring for financial or other performance strategy indices out of the context of this measurement management system.

NOTE 2 A large part of monitoring and measurements are related to quality assurance for product/services and their processes but equally applicable to include other disciplines such as the need of valid/reliable results from the measurement processes.

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 standard is to achieve the intended results, including enhancing its measurement performance.

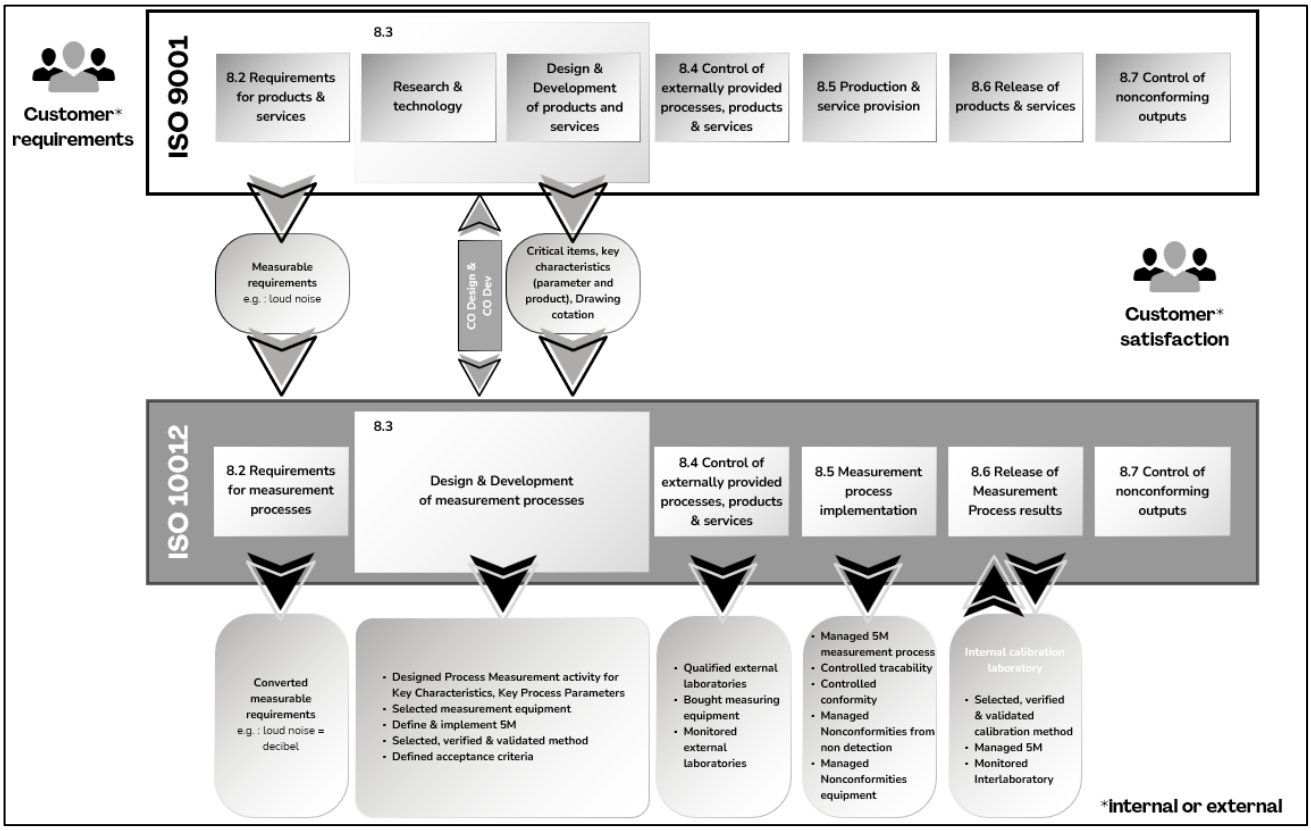

Figure 1The intent of the measurement management standard is to achieve the intended results, including enhancing its measurement performance.

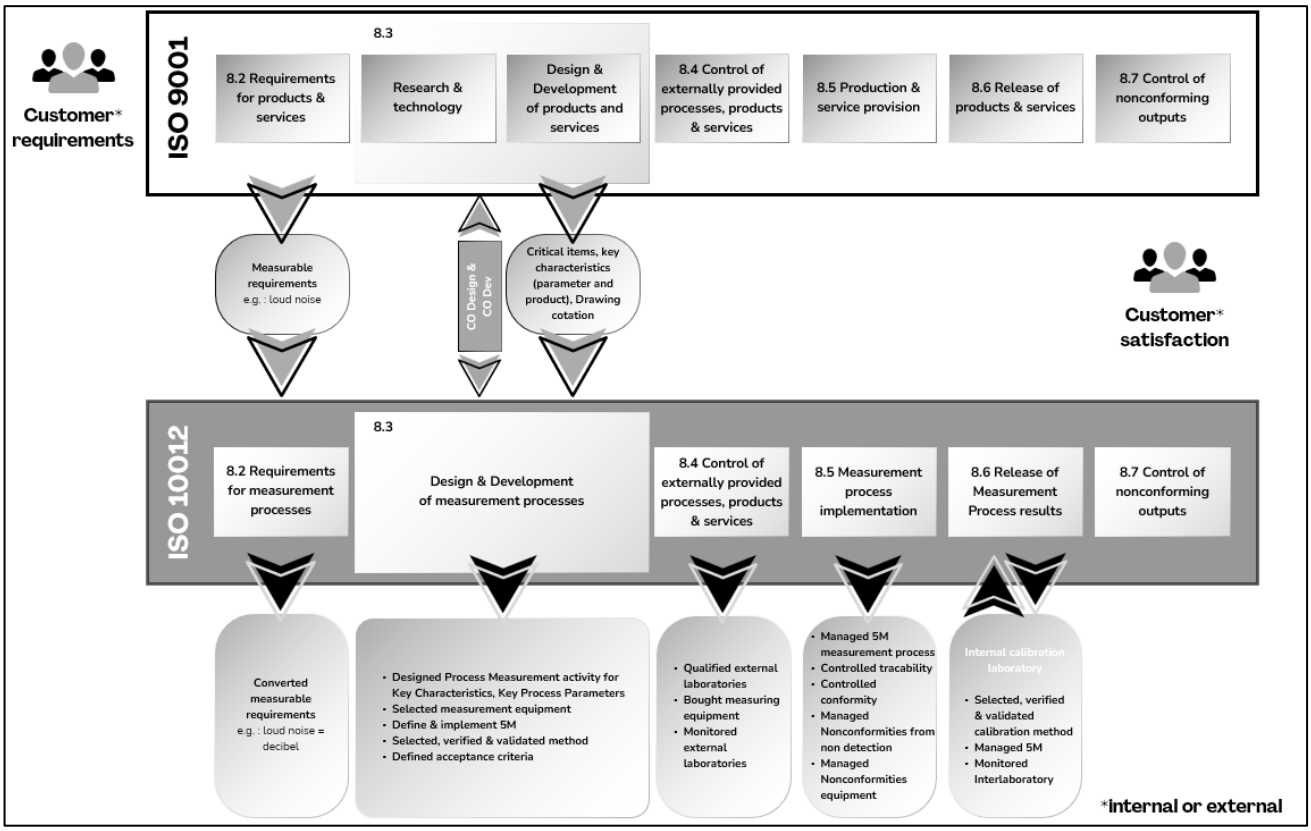

Figure 1 — Measurement management relationship to quality system management

5 Leadership

5.1 Leadership and commitment

5.1.1 General

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

a) ensuring that the measurement management system policy and measurement management system 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 results;

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.

5.1.2 Interested party focus

Top management shall demonstrate leadership and commitment with respect to interested partyfocus by ensuring that:

a) interested party measurement requirements are determined and converted into metrological requirements;

b) the measurement management system meets the interested party's metrological requirements;

c) conformity to interested party's specified requirements can be demonstrated;

d) the focus on enhancing interested party satisfaction is maintained.

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 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, understood and applied within the organization;

— be available to interested parties, as appropriate.

5.3 Roles, responsibilities and authorities

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated, and understood 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 processes are delivering their 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 have access to top management to resolve measurement management issues.

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 results(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:

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

— evaluate the effectiveness of these actions;

— document the processes used in the risks and opportunities analyses

— ensure new objectives do not compromise the existing measurement management system and results validity.

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

NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology, and other desirable and viable possibilities to address the organization's or its customers' needs.

NOTE 3 The effectiveness of the actions can be evaluated by technical methods such as analysis of end of period reliability or similar parameters.

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 (5.2);

b) be measurable (if practicable);

c) take into account applicable requirements (e.g., regulatory, legal, contractual);

d) be monitored;

e) be communicated and available to appropriate personnel;

f) be updated as appropriate;

g) be available as documented information.

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 documented, and evaluated.

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 appropriate.

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 Personnel

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 measurement processes.

7.1.3 Environment and facilities

The requirements for facilities and environmental conditions necessary for the performance of the measurement activities shall be defined, monitored, and made 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.

NOTE 1 When on-site work (i.e. outside of a controlled environment) is performed, the design of the process must consider conditions out of the control of the user. The process must be documented and monitored with due consideration regarding compensating environmental corrections, if required.

NOTE 2 Environmental conditions affecting measurement systems may include temperature, temperature gradient, humidity, hygiene, airflow, lighting, vibration, dust control, cleanliness, electromagnetic interference, and other factors.

NOTE 3 Facilities can include buildings and associated utilities, transportation resources, and communication technology. This may include information regarding the facility's historical performance and stability.

NOTE 4 As noted in the NOTE A of the clause 7.1.4 in the ISO 9001, 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 Clause 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 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 it's 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;

d) when a regulatory requirement exists, the personnel performing those functions shall be qualified in accordance with these regulatory requirements.

Appropriate documented information shall be available as evidence of competence.

A periodic review shall be performed for the competence requirements

NOTE 1 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.

NOTE 2 The organization should have procedure(s) and retain documented information regarding assignment of supervision of personnel and monitoring of their competence.

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 performance;

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

d) any relevant measurement management system requirements including latest revisions;

e) their contribution that impacts of the validity of results (See NOTE);

f) the importance of ethical behaviour;

g) their contribution to product conformity.

NOTE The validity of results applies to all portions of the final service or process (e.g., safety, measurement data, etc.).

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 (e.g., target audience);

d) how to communicate;

e) who communicates;

f) the importance of ethical behaviour.

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

In cases where it is necessary to notify a customer of a non-conforming process or document (as defined in Clause 10.2) the originator shall notify their customer in a timely manner so that the customer may properly analyze the effect of the non-conformance on their process or products.

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

The format of transmitting data shall be mutually agreed to by all parties.

The organization shall implement ethical policies which will protect data integrity and the overall responsibility of the organization.

NOTE 1 The timing of the document information supply may be defined in contractual negotiation between the parties under contract.

NOTE 2 This covers transferability of data and security of the data.

NOTE 3 Communication should include internal and external feedback relevant to the measurement management system.

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

Determination of the effectiveness of document information should include items such as results of audits, responses to audit finding as described in Clause 9 of this standard, also processes that measure effectiveness of the measurement management system in fulfilling its requirements.

Documented information that affect the validity of results shall include information of all appropriate processes in calculations involved in their verification of adequacy.

NOTE 1 Examples of documented information that affects the validity of results can be uncertainty calculation, or probability of false acceptance criteria (ISO/IEC Guide 98-4 and ILAC G8), or document which explain the proper use of laboratory equipment required by the procedures.

NOTE 2 An example would be documented information of analyses, end of period of reliability (EOPR) versus performance target for calibration activities should be maintained.

NOTE 3 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

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 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).

All persons using the measurement management system shall have access to the parts of the measurement management system appropriate to their responsibilities.

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);

— archiving 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.

The organization shall establish a documented process that reviews are conducted of documents of external origin to confirm that those documents in use are still current and applicable.

NOTE 1 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.

NOTE 2 The organization may retain documented information 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, contractual documents, products or services that are relevant to the measurement management system are controlled.

NOTE Determination of requirements for the measurement management systems may include consideration of:

— personnel, process, and product safety;

— reliability, availability and maintainability;

— selection and development of embedded software;

— measurement device and software obsolescence.

8.1.2 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 organisation, the measurement processes used to control the conformity of the products and services, such as:

a) relevant data and information

b) assignment of responsibilities for operational risk management;

c) definition of risk assessment criteria (e.g., likelihood, consequences, risk acceptance). See NOTE 3;

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

e) identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria;

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

NOTE 1 While Clause 6.1 addresses the risks and opportunities when planning for the measurement management system of the organization, the scope of this Clause (8.1.2) is limited to the risks associated to the operational processes related to the measurement process (Clause 8).

NOTE 2 The risks need to be evaluated, and updated when necessary, across design and operational activities.

NOTE 3 This standard does not specifically require the use of a risk register.

NOTE 4 This clause does not require an additional risk policy when the organization has an existing risk policy in place.

8.2 Requirements for measurement processes

8.2.1 General

Measurement processes, including measurement services, are performed to support determination of conformance of product and services within the organization.

NOTE 1 Measurement service includes not only the performance of the measurements, but also the design and definition of the measurement processes.

NOTE 2 The term service includes tasks such as repair of equipment where measurements are used in the repair process.

8.2.2 Customer communications

Communication with customers shall include:

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

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

c) obtaining customer feedback relating to measurement processes, results, or performance. Customer feedback also includes complaints;

d) handling and control of customer property;

e) establishing specific requirements for contingency actions, when appropriate.

NOTE Results include not only reports of measurement but also considerations of the variability of the measurement methods.

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 defined, including:

— any applicable statutory and regulatory requirements;

— those considered necessary by the organization;

b) the organization can meet the claims for the measurement processes it offers;

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

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

NOTE 2 Requirements may include verification criteria and associated method, maximum permissible measurement error and allowable uncertainties.

NOTE 3 Statements of measurement capability should 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 the 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 to measurement criteria. These measurement process criteria shall be documented.

The measurement processes shall ensure that:

a) customer measurement requirements are determined and converted into metrological requirements;

b) the results of measurements meet the customers' metrological requirements;

c) conformity to customer-specified requirements can be demonstrated.

The measurement process shall be realized under defined conditions designed to meet the metrological requirements.

8.2.4.2 The organization shall retain documented information, as applicable:

a) on the results of the review;

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

8.2.5 Changes to requirements for measurement processes

The organization shall ensure that when the customer's measurement requirements are changed, relevant documented information is amended and that relevant parties are made aware of the changed requirements.

The organization shall retain previous version of the documented information. This procedure is referenced in the Clauses 7.5.3.2.c and 7.5.3.2.d.

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

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, 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, and also assuring the validity and reliability of measurement results during the 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, clause 3.3), critical items, safety and environmental requirements, etc.

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 measurement process is necessary (see NOTE 1);

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) that the practicality of the measurement of the characteristics of the products is taken into account by the designing and development teams and users prior to completion of design;

g) where the organization is making measurements on items it designs, 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 (NOTE 2);

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

j) the level of involvement expected for the design and development process by customers and other relevant interested parties (e.g., regulators), 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. For each phase, define the tasks, necessary resources, responsibilities, design content, and inputs and outputs.

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

n) the impact of the environment and sustainability of the measurement process (NOTE 3).

NOTE 1 Validation is only necessary when processes or tools are introduced or changed, which impact the final output.

NOTE 2 Consideration should be given to ergonomics in the design of the measurement process.

NOTE 3 An example would be the use of a strain gauge inclinometer instead of a mercury inclinometer.

NOTE 4 The design and the development process should consider measurement process optimization.

NOTE 5 The organization responsible for the measurement management system needs to make sure that the characteristics are realistic.

8.3.3 Design and development inputs

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

a) determination of the performance of the measurement process (NOTE 1, 2 and 3);

b) identification of risk elements in the measurement process (see Clause 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) design of process to use information derived from previous similar design and development activities;

e) the need for maintenance and frequency of calibration (periodicity) while designing measurement process including the capabilities of the calibration and maintenance facilities (NOTE 4);

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 organization shall determine the level of performance (such as acceptance criteria) and a suitable sampling plan.

NOTE 1 The criteria that can be considered when developing the 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

— Metrologically traceable measurement results (e.g., to SI units)

NOTE 2 The accuracy and uncertainty of the process and equipment used should be commensurate with the consumer's and producer's risks (false-acceptance and false-rejection risks) to comply with specified requirements.

NOTE 3 The measurement decision risk and decision rules related to particular equipment and processes are often defined statistically in terms of Probability of False Acceptance (PFA) risk (also referred to as consumer risk) and End Of Period Reliability (EOPR). See Annex D.

NOTE 4 Information on the methods for establishing calibration intervals (periodicity) can be found in ILAC G24/OIML D10 (2022) or NCSLI RP-1 Calibration Intervals (see Annex B).

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 retain documented information 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 specifying the measurement processes, the input required shall include:

a) appropriate methods of measurement;

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

f) the minimum required skills to operate the measurement 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.

NOTE The person developing the measurement method should be able to obtain adequate information for proper development of the measurement process. The source of any externally obtained information used should 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 defined;

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 shall exist of the authorizations related to each design and development phase.

The effective implementation of these controls will assist in facilitating timely corrective actions.

NOTE 1 The measurement process should result in limiting erroneous measurement results and deficiencies as covered in Clause 8.1.2.

NOTE 2 The measurement process should be designed to limit the risk of false acceptance or rejection if needed (see Annex D for further information).

The measurement process may be validated by comparisons to results of other established processes, or by comparisons of results obtained by other measurement techniques.

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

NOTE 3 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 4 The application and control of monitoring and measuring equipment includes consideration of those items described in Clauses 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, these 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, define test objectives and conditions, parameters 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, or prior to use. When no SI traceable standards exist, the basis used for calibration or verification shall be retained as documented information;

b) identified in order to determine their status;

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

NOTE Calibration or verification may be conducted using a variety of methodologies. The determination of the validity of the calibration and associated intervals or methods required is further explained for instance in ILAC G24.

8.3.4.4 During the design of the measurement process, the needs for measurement process monitoring as described in the Clause 8.5.5.2 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 define the data needed so that the measurement process and the measured value can be traced along with the characteristics to verify the conformity of the measurement results for the products and services.

The organization shall retain documented information 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) influencing 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 calipers), an exhaustive review each time the process is used may not be necessary.

8.3.5.3 Measurement uncertainty

The measurement uncertainty for each measurement process shall be evaluated using an appropriate methodology covered by the measurement management system.

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

NOTE 1 The concepts and methods of evaluating the measurement uncertainty components are defined in and may include but not limited to

— the “Guide to the expression of uncertainty in measurement” (GUM) in the ISO/IEC Guide 98-3 series of documents;

— VDA5 measurement and inspection process: capabilities, planning, management;

— ISO 22514-7:2021 : Statistical methods in process management — Capability and performance — Part 7: Capability of measurement processes;

— UKAS M3003 the expression of uncertainty and confidence in measurement;

— other documented and accepted methods may be used (e.g., measurement process capability).

NOTE 2 It is possible that some components of measurement uncertainty will be negligible compared to other components and this could make their inclusion inappropriate on technical or economic grounds. If so, the decision and justification for exclusion should be documented. In all cases, the effort devoted to evaluating uncertainties of measurements should be commensurate with the decision risk target.

NOTE 3 The recording of uncertainty determinations may take the form of “generic statements” for similar types of measuring equipment (e.g., calipers), 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 a SI unit exists, it shall be used for measurement traceability. In cases where such a unit does not exist, the use of a consensus standard, natural constant or appropriate standard reference material produced in conformity with ISO 17034:2016, is permissible.

Consideration of traceability issues resulting in nonconformities are discussed in Clause 8.7.

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

NOTE 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 Clause 8.1.2).

NOTE Calibration certificates or test reports shall be traceable 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, 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 need to be changes made prior to the release of the final revised process.

NOTE It is recommended that there should be a change management process within the organization.

Final release for use should only be authorized after a technical review to ensure that the revised process meets the technical requirements of the measurement management system.

The organization shall retain documented information 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 customer, prior to implementation, about changes that affect customer requirements.

8.4 Control of externally provided processes, products and services

8.4.1 General

The organization shall ensure that externally provided processes, products and services conform to contractual and regulatory requirements.

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

The organization shall identify and manage the risks associated with the external provision of 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 (see NOTE).

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

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

b) products and services 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 processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions.

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

NOTE 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 reflect the risk represented by the use of the provider's processes, products or services.

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

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

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

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

a) review of required documented information and objective evidence of the conformity of the measurement processes, products and services from the external provider (e.g., accompanying documented information, certificate of conformity, test documented information, statistical documented information, process control documented information, results of production process verification and assessment of changes to the production process thereafter);

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

c) review of production part approval process data;

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

e) review of delegations of measurement processes used for the verification of the product when it is externalized.

NOTE 1 Where a provider does not have either a quality system or working measurement management system, the controls above should be applied in a rigorous manner in order to mitigate risk and assure a proper level of control is in place to ensure the conformity of product and services.

NOTE 2 Data from external providers and the reported characteristics of the material or equipment supplied are often a critical component of determining uncertainty of measurement for the whole 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.

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, method, work instructions);

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 D);

h) appropriate documented information 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 that certified reference material shall be in conformity with ISO 17034:2016, or approved by the organization prior to use;

j) the requirement to notify the organization of non-conforming measurement processes, equipment or services and obtain approval for appropriate corrective actions.

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, as appropriate:

a) the availability of documented information defining (NOTE 1):

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

— the results to be obtained;

b) the availability and use of appropriate resources for monitoring and measurement, consistent with the requirements stated in the Clause 8.3.4.3.

c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs and acceptance criteria for measurement process, have been met. Ensuring that documented information for monitoring and measurement activity for measurement processes include:

— acceptance and rejection criteria;

— where in the process, verification operations are to be performed;

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

— any specific monitoring and measurement equipment required and instructions associated with their use;

— the verification of the equipment used in the measurement processes;

— 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;
   - data provided in a usable format. Refer to NOTES 2, 3 and 4 for discussion of desirable methodology.
   - the documented information of the measurement process in electronic form shall have back-ups. Whereby if the system ceases to function through component failures, power loss etc. There will still be documented information . existing and retrievable of the current calibration instrument's, 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 5);

j) the implementation of release, delivery, and post-delivery activities affecting measurement results;

k) the establishment of criteria for workmanship (e. g., written instructions, representative samples, illustrations);

l) evidence that all measurement processes have been carried out 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 Clause 7.1.3);

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

NOTE 1 Documented information defining measurement process characteristics may include numerical data defining measurement processes, capabilities, repeatability and reproducibility criteria, specified conditions. See Clause 7.5.

NOTE 2 It is desirable that calibration and process uncertainty data are 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 should be in an easily transportable format.

NOTE 3 When implementing a measurement system consideration of the data variability and the volume of data can be considered. For example in a large room the need to take environmental data may be performed on a sampling rather than continuous basis.

NOTE 4 The concept of transportability of data is considered in methodologies such as FAIR data (Findability, Accessibility, Interoperability, and Reuse of digital assets).

NOTE 5 In some cases, seals are used to prevent unauthorised adjustment affecting measurement performance of an instrument. A broken seal may indicate if an adjustment has taken place that may affect metrological integrity.

8.5.1.2 Control of embedded measurement 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 must be subject to verification or calibration.

The storage requirements must be defined for the embedded measurement 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 is sometimes employed.

8.5.1.3 Verification of measurement processes

The organization shall implement measurement process verification activities to ensure that they meet the requirements and ensure confidence in the results. See NOTE 1.

The organization shall use a measurement representative 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 invalidate the original results occur (e.g., design changes, changes to an influencing parameter). See NOTE 2.

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

NOTE 1 These activities may include risk assessments, studies, capability, repeatability and reproducibility, and inter comparisons.

NOTE 2 This activity is similar to the activity referred to as “First Article Inpection” in many manufacturing organizations.

8.5.2 Identification and traceability

Traceability, in this context, refers to documented information and similar items related to the measurement process (refer to 3.6.13 in ISO 9000).

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

Measuring equipment and technical procedures used in the measurement management systemshall be clearly identified, individually or collectively. The metrological confirmation status of the equipment shall be identified. 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. The measurement process shall identify the specific piece of equipment. The equipment of the measurement management system shall be able to be distinguished from other equipment.

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

The organization shall control the unique identification of the outputs when traceability is a requirement and shall retain the documented information necessary to enable traceability. The documented information regarding traceability may include items such as:

a) sequential recordings of controls and verification;

b) equipment used in the measurement process;

c) equipment used to monitor and record the influencing factors (e.g., temperature and humidity).

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.

The organization shall identify, verify, protect, and safeguard customers’ or external providers’ property provided for use 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 retain documented information 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.

NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

8.5.5 Measurement process post-delivery activities

8.5.5.1 General

The organization shall meet requirements for post-delivery measurement activities associated with the measurement result. The items below shall be considered in post-delivery activities:

a) in carrying out 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, obsolescence).

NOTE : Refer to clause 8.7 regarding handling of non-conforming material and reports.

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8.5.5.2 Support in the interpretation of the measurements results

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

a) all results shall be given with their uncertainties when possible and relevant;

b) consideration of the effect of uncertainty in the reporting of the results.

NOTE The impact of uncertainty should be considered relative to measurement management system aspects related to the process as shown in figure D.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 retain documented information describing the results of the review of 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, production 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. These results include, where appropriate, and not limited to :

a) test reports;

b) calibration certificates;

c) calibrated / verified devices or equipment.

8.6.2 Documented information relating to release of results

The organization shall retain documented information on the release of measurement processes.

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

a) evidence of conformity with the acceptance criteria;

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

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

d) any special handling instructions related to the measurement process (e.g: temperature stabilization of gage blocks) ;

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

When required to demonstrate validation or revalidation of the measurement process (see clause 8.5.1.1 G) , the organization shall ensure that retained documented information provides evidence that the measurement process met the defined requirements.

8.7 Control of non-conforming outputs

8.7.1 Handling nonconforming outputs

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

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 o n the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

The organization's process for control of non-conformance shall be kept up to date as documented information including arrangements for :

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

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

c) timely reporting of non-conformities 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 non-conforming measures that allowed the release of products and services which ultimately become non-conforming after delivery, as appropriate to their impacts (see Clause 10.2).

The organization shall handle non-conforming outputs in one or more of the following ways:

a) correction ;

b) suspension of the measurement process ;

c) informing the customer ;

d) using without modification or adjustment with approval by relevant authority and when required by contract, with the customer of the measurement process. This is sometimes referred to as use-as-is.

NOTE : In the context of item d) :

- approval from an authorized representative of the organization responsible for the design of the measurement process or of persons delegated to the entity designing the measurement process;
- authorization from the customer, if the nonconformance of results in a deviation from the requirements of the contract.

In the event of suspension of the measurement process, the measurement system shall be visibly identified or isolated in a safe area so that it cannot be reintroduced into the measurement process until it is corrected.

If the measuring equipment is a cause in the deviation of the measuring process, the equipment shall be repaired or adjusted. If the equipment cannot be repaired or properly adjusted shall be conspicuously and permanently marked, until properly dispositioned. This does not preclude the retention of equipment in a downgraded status with appropriate controls and usage definition.

Conformity to measurement requirements shall be verified for previous non-conforming outputs when the process is corrected.

8.7.2 Documented information

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

The organization shall determine:

a) what needs to be monitored and measured;

b) the criteria against which the organization will evaluate its measurement processes' performance, and appropriate indicators;

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

d) when the monitoring and measuring shall be performed;

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

Documented information regarding these items shall be available as evidence of the results.

The organization shall ensure that calibrated or verified monitoring and measurement 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) conformity of the value determined by the measurement processes used to attest to the conformity of the products and services;

b) the degree of customer satisfaction;

c) the performance and effectiveness of the measurement management system

d) wether 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 the organization's own requirement
for its management system, including the measurement processes and related activities .

These should include but not limited to :

— uncertainty calculations and validations of uncertainty;

— documented information of traceability of the process steps used to declare product conformity;

— contractual requirements imposed on external providers.

b) conforms to the requirements of this document;

c) is effectively implemented and maintained.

NOTE 1 See ISO 19011 for guidance in performing audits.

NOTE 2 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 (period of performance), methods and processes, 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 NOTE);

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

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 should be based on their level of competence and understanding of measurement processes, including application of measurement uncertainties, 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:

— relevant communication(s) from interested parties, including complaints;

— the extent to which performances objectives have been met;

— measurement process performance;

— nonconformities and corrective actions;

— monitoring and measurement results;

— audit results including those specified in Clauses 8.4.2 and 9.2;

— the performance of external providers;

— data on the error and/or uncertainty of the measurements.

e) the adequacy of resources;

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

g) opportunities for continual improvement.

9.3.3 Management review results

The outputs of the management review shall include decisions and actions related to:

a) opportunities for improvement;

b) any need for changes to the measurement management system;

c) resource needs;

d) risks identified;

e) actions, if needed, when measurement management system objectives have not been achieved.

The organization shall retain documented information as evidence of the results of management reviews.

10 Improvement

10.1 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 of 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 optimization of the measurement processes.

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

10.2 Nonconformity and corrective action

When a nonconformity occurs, the organization shall:

a) react to the non-conformity, and as applicable:
   — take action to control and correct it;
   — deal with consequences;

b) evaluate the need for action to eliminate the cause(s) of the non-conformity, in order that it does not recur or occur elsewhere, by:
   — reviewing the nonconformity ;
   — determining the causes of the nonconformity;
   — 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 non-conformity;

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

Corrective actions shall be appropriate to the effects of the non-conformities encountered.

Nonconformities shall include any complaints from customers.

Documented information shall be available as evidence of:

- the nature of the non-conformities and any subsequent actions taken;
- the results of any corrective action.

Annex A
(informative)

Calibration intervals optimization

A.1 General

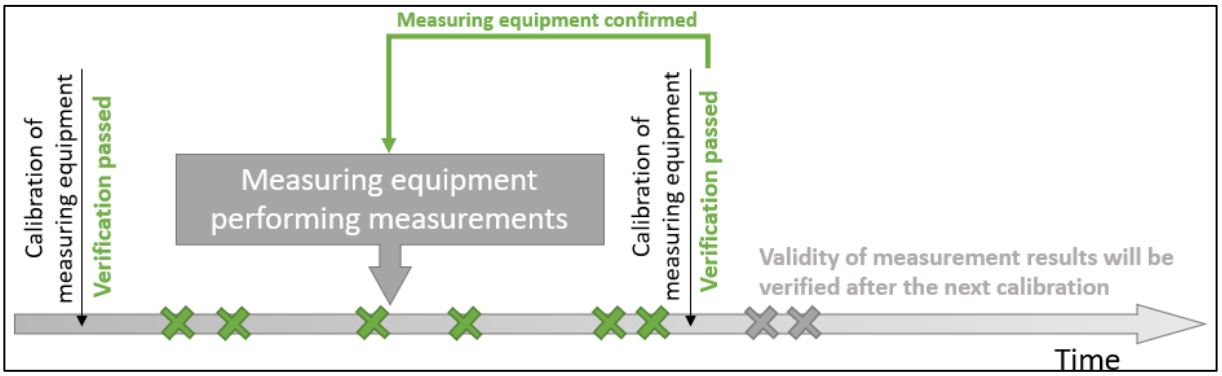
This annex only covers instruments, and not the measurement process.

The methods shown 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 measurement instrument.

Before optimizing the calibration intervals, it is important to understand the role of calibration. The purpose of establishing calibration intervals is to ensure that results obtained with an instrument between two calibrations continues to fulfil specified requirements. If the conformity of an instrument issued from a verification certification at the end of a calibration interval is found to pass verification that means that all measurements provided by the instrument results since the last calibration are reliable (Figure B.1).



Note to figure: The 'X' represents measurements being performed.

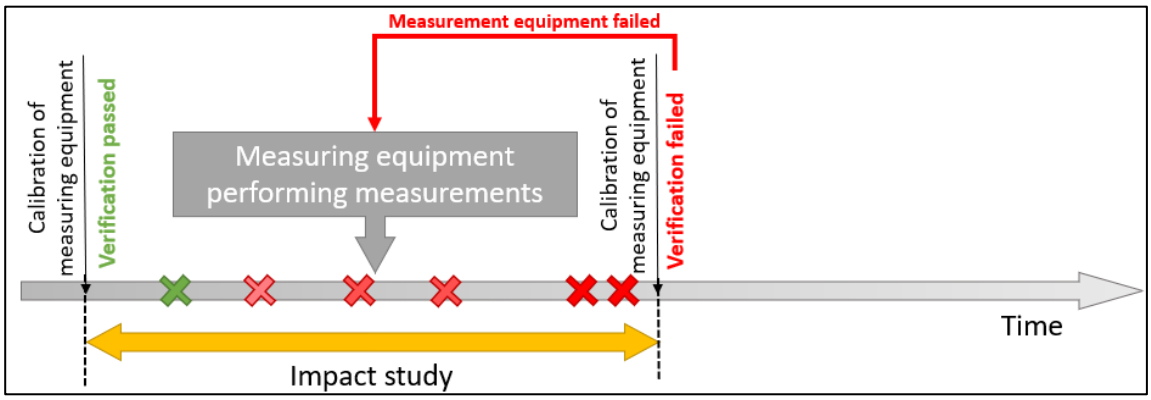
Figure A.1 — Relationship between calibration and measurement results.

Figure:

- change 'instrument not validated yet' to 'validity of measurement results will be verified after the next calibration'
- Replace 'Measurements' by 'Measuring equipment'
- Replace 'Pass verification' by ' Verification passed'
- Replaced 'Instrument conforms' by 'Measuring equipment confirmed'

NOTE The International Vocabulary of Metrology, ISO/IEC Guide 99:2007 (also known as the VIM) distinguishes between calibration [ISO/IEC Guide 99:2007, Clause 2.39] and verification [ISO/IEC Guide 99:2007, Clause 2.44]. In this annex we assume that the process is carried out so that both calibration and verification are performed in unison. Conformity is the responsibility of the user of the equipment. One must choose maximum permissible measurement errors compatible with one's own needs and declaration of conformity strategies according to one's acceptable risk. These 2 points cannot be implicitly known to the calibration laboratory and must therefore be validated if the laboratory declares the conformity of the equipment.

The ISO 9001 requires that each instrument for which it is essential to provide confidence in the validity of measurement results, "shall be calibrated or verified, or both, at specified intervals". Defining calibration intervals is part of metrology. Too short calibration intervals lead to a high cost in money and time, and it is not justified for reliable instruments. Calibration intervals that are too long may lead to non-conformity and related impact to previously performed measurements using that instrument (Figure B.2).



Note to figure: The 'X' represents measurements being performed.

Figure A.2 — Failure situation leading to impact study.

It is important to understand the following:

— short calibration intervals do not prevent the instrument from failure, this is not preventive maintenance;

— there is always a possible risk of non-conform measurements, even with a conforming instrument due to uncertainty of measurement (see Annex D).

A.3 Calibration interval optimization

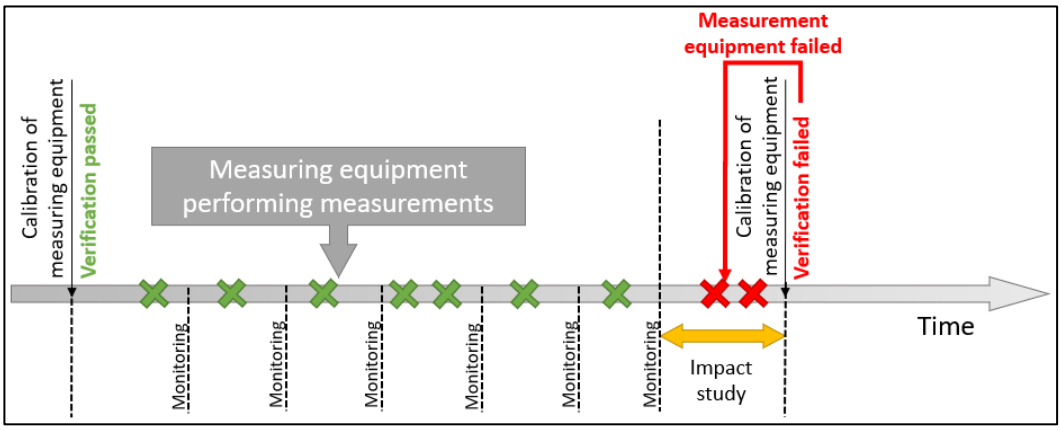
Calibration interval optimization means that the interval between two calibrations is the largest interval allowed without any impact (or minimal affordable impact) on the measurements.

Calibration interval optimization is one of many aspects of modern metrology. It implies that instruments and their processes are known, as well as the different parameters impacting the measurements (environment, use of the instruments, operators, etc.).

A.4 Strategies

A.4.1 Monitoring

Monitoring the instrument on a regular basis is an approach to increase calibration interval, while assuring the reliability of the measurement results. Figure B.3expresses the reduction in the period of time impact study might be needed when using monitoring.



Note to figure: The 'X' represents measurements being performed.

Figure A.3 — Effect of monitoring on impact study.

Example of monitoring can be:

— regular measurements on a stable item

— measurement duplication

— interlaboratory comparison

— control charts

NOTE Implicit in this method is that if monitoring is used, organizations need to formalize those monitoring processes.

A.4.2 Conditional calibration

Conditional calibration means that the instrument is calibrated when collected information indicates that the instrument may no longer be reliable. This may 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 suspension of calibration interval, is used with measurement and test 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 calibration date, reducing the amount of calibration activities. Examples of such items are:

— gauge blocks

— ring and plug gauges

— inside/outside verniers

— dial test indicators

— calipers

— length gauge

— vee block

— straight edge

— square

NOTE This method needs to be used with care so no equipment which degrades with time such as electronic indicators are subject to abeyance.

An example of this is a pin gauge or similar device where once measured and validated, it is not affected by time since calibration. The calibration may be defined as having a valid usage period of one year within the five years since it was last calibrated. The longer period basically is to verify no oxidation (rust) or other situation has occurred in the five years since the previous calibration. 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:

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

— the device itself has a chemical compound (like a wax) applied over a measurement surface that is peeled off before use to indicate the item is now in service;

— the device 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 must have appropriate entries and/or labels to detail the date the item 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 5 years). So, the gauge could be used for one month and then be put into abeyance for 18 months and reuse started again as long as the valid usage period nor the recalibration period is not exceeded. To properly employ this method requires care and understanding of the users. It might also require the use of additional documented information keeping and controls (personnel or process).

A.4.4 Existing approaches

A.4.4.1 Drift method

The purpose of the Drift method is to statistically study past calibration results of instruments which are 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 instrument. This method is documented in AFNOR FD X07-014:2006.

A.4.4.2 Periodicity ratio approach

The Periodicity ratio approach is a mathematical approach (inverse exponential) based on the quadratic ratio of the measurement process uncertainty and the instrument uncertainty. This approach yields to a calibration interval based on the weighted analysis of the instrument uncertainty over the measurement process uncertainty. 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 each instrument according to a set of qualitative or/and quantitative criteria that are weighted by impact to the measurement. 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 defined period of validity. These metrological requirements often include acceptable risk. OIML D10/ILAC-G24 and NCSLI RP-1 describe various methods of determining intervals of calibration based on historical performance bounded by risk. Another approach to risk management of calibration intervals is the FMECA (Failure Modes, Effects and Criticality Analysis) systems whereby a matrix is constructed of criticality of measurement versus surveillance requirements.

Annex B
(informative)

Uncertainty of measurements

B.1 General

This annex is provided to increase reader awareness about the notion of measurement uncertainty. Measurement uncertainty evaluation is not the purpose of this annex. However, relevant references are listed in the bibliography.

In this context, measurement uncertainty is inherent to the margin of doubt or variability that surrounds 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 a purpose, such as conformity assessment, material characterization, comparison, etc. All measurements contain errors. 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 error:

$$\boldsymbol{Y_{measured} = Y_0 + e_m} \quad (1)$$

where

$\boldsymbol{Y_{measured}}$ is the observed value, which is an evaluation of the true value.

$\boldsymbol{Y_0}$ is the true value of the measurand. This value cannot be known.

$\boldsymbol{e_m}$ is the measurement process error. This error, $\boldsymbol{e_m}$, is different every time the measurement is done. To evaluate an uncertainty, we are interested in a set of possible errors, and not in a single error. See EXAMPLE 2.

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 D).

When a quantity is measured, the outcome depends on the measuring system [ISO/IEC Guide 99:2007, clause 3.2], the measurement procedure, the skill of the operator, the environment, and other effects (ISO/IEC Guide 98-1: 2009).

Measurement uncertainty may arise from (ISO/IEC Guide 98-3: 2009, Clause 3.3.1, and ISO/IEC Guide 99:2007, Clause 2.26):

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

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

— customers-specified contractual requirements (some contracts may specify particular procedures for evaluation of measurement uncertainty with defined 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 uncertainties. This standard does not constrain the user in how to analyze 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 stated in, ISO GUIDE 98-1 Clause 5.1.4 :

‘5.1.4 To support the use of JCGM 100:2008 [7], JCGM 101:2008 [8] (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

[11][12]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 define 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), 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 parameters with less iterations of the process. Proper decision rule(s) reduce the probability of creating errors or having to run several trials or configurations.

References [3b], [5], [9], [10], [11], [12], [13] and [14] provided significant details of measurement decision risk and its application.

C.2 Measurement decision risk

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

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

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

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

Figure D.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 D.1labelled "What is the level of risk?".

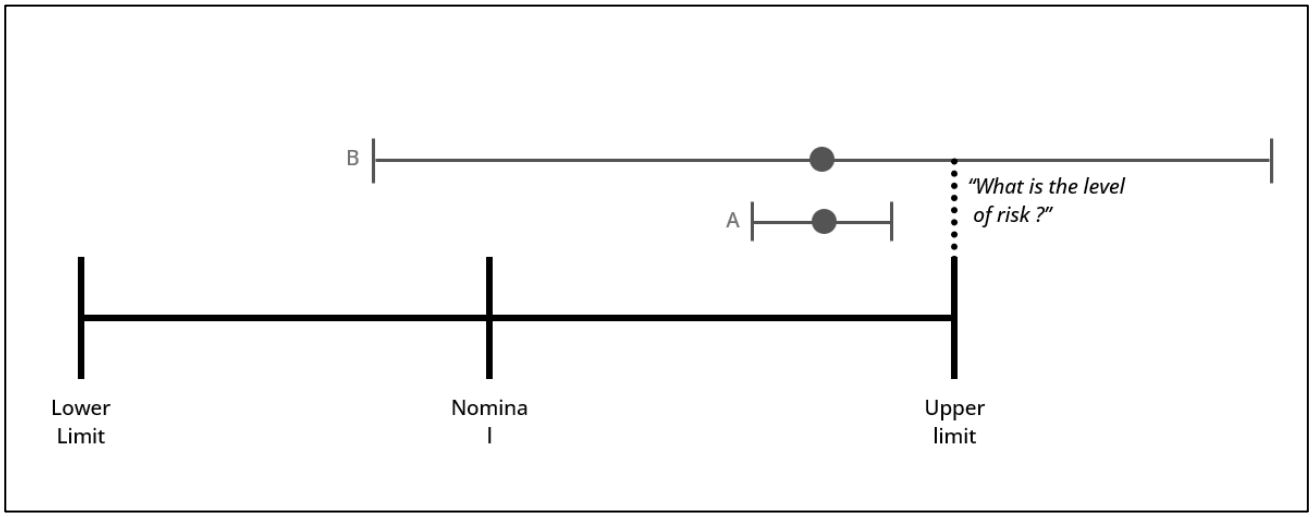
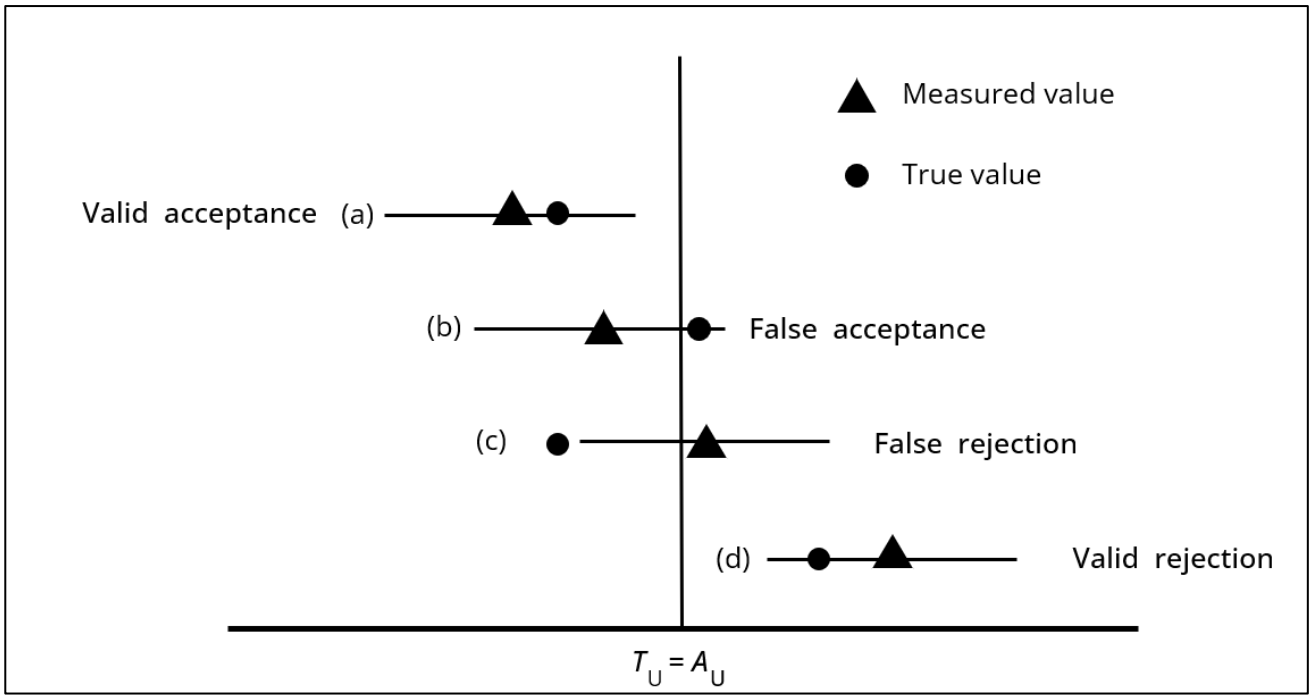


Figure C.1 — Illustration of measurement decision risk.

Annex C, Uncertainty of Measurements, of this standard highlights the relationship of a measured value, measurement error, and the true value. The figure below illustrates the four outcomes of a simple decision rule for a given measurement uncertainty. The true value can occur anywhere in the measurement uncertainty statistical coverage interval as Figure D.2 illustrates. In fact, with small probability, the true value can also be outside the coverage interval as per use case c.



Note to the Figure: The upper acceptance limit A_U coincides with the upper limit of tolerance T_U.

Figure C.2 — Four outcomes of a simple acceptance decision rule close to the upper limit of tolerance T_U. (see ISO/IEC Guide 98-4:2012, Clause 8.3).

C.3 Decision rule

A decision rule is a "rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement" (see Clause 3.3.12 ISO/IEC Guide 98-4).

NOTE 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, that due to uncertainty in measurements the organization will incorrectly report the conformance or non-conformance of the device under test to the specification.

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

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

NOTE Measurement decision risk is applied to the whole process used in the measurement management system, considering product tolerances, and performance requirements. See Figure D.3 for graphical representation of typical contributors to the measurement decision risk. It includes the uncertainty in the calibration process for the instruments used per clause 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.

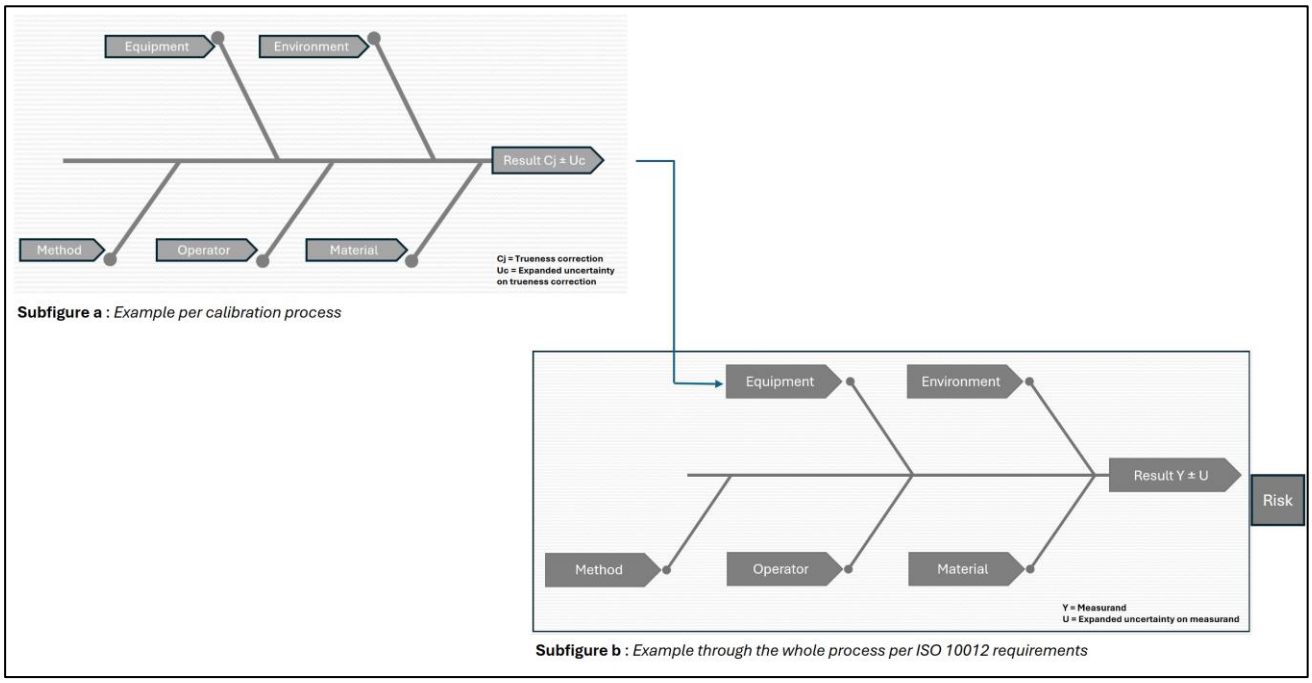


Figure C.3 — Examples of sources of measurement uncertainty and process contributors to risk

NOTE For the subfigure a : This figure is intended to show some typical contributors to uncertainty and should not be considered comprehensive or applicable to all situations.

In this figure Uc represents calibration uncertainty and U represents the uncertainty of the process including Uc.

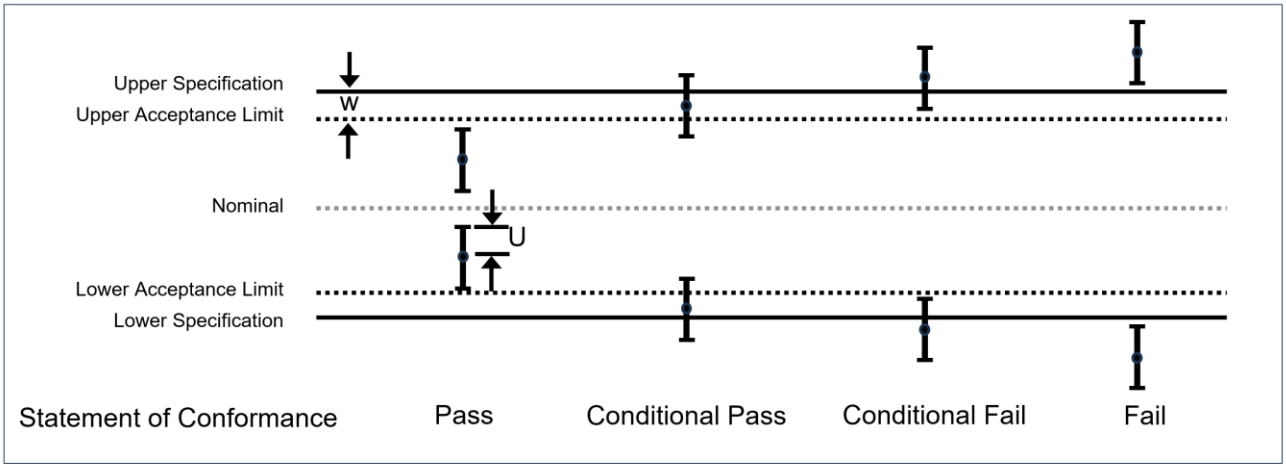
For the subfigure b : When calibration process (figure A) are outsourced, the reference clause 8.4 need to apply.

C.4 Decision Rule Example

The selection of decision rules in methods is particular to the application and needs to take into account consideration the proper application of methods. In cases where large sample sizes are used, the ISO Guide 98-4 document provides a well understood basis for decision rules. In cases where measurement

sample sizes may be small (such as calibration activities, or safety risk for the final user) the application of ILAC G8:09/2019 may be more appropriate.

ILAC-G8:09/2019 “Guidelines on Decision Rules and Statements of Conformity” 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

Figure C.4 — Non-binary Statement with Guard Band.

NOTE For explanation of the above refer to ISO/IEC Guide 98-3 and ISO/IEC Guide 98-4.

This decision rule uses a nonbinary decision rule that employs a guard band, *w*, in the amount of the 95% expanded measurement uncertainty ($w = U$), for reporting results. This results in four possible statements of conformity, as illustrated.

— **Pass** : results have low false acceptance risk

— **Conditional Pass** : results are observed in specification. However, there is increased risk of false acceptance compared with “Pass”. Organizations shipping product with final test results as “Conditional Pass” may see their process margin eroding leading to risk of increased warranty costs.

— **Conditional Fail** : results are observed out of specification. There is increased risk of false rejection compared to “Fail”. Organizations may be falsely rejecting their products in final test resulting in lower yields and unnecessary rework.

— **Fail** : results have low false rejection risk

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