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IS/ISO 10012 : 2003

भारतीय मानक

मापन प्रबंध तंत्र – मापन प्रक्रम और मापन उपस्कर के लिए अपेक्षाएँ

(पहला पुनरीक्षण)

Indian Standard

MEASUREMENT MANAGEMENT SYSTEMS — REQUIREMENTS FOR MEASUREMENT PROCESSES AND MEASURING EQUIPMENT

(First Revision)

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NATIONAL FOREWORD

This Indian Standard (First Revision) which is identical with ISO 10012 : 2003 'Measurement management systems — Requirements for measurement processes and measuring equipment' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendations of the Quality Management Sectional Committee (MSD 2) and approval of the Management and Systems Division Council.

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

This is the first technical revision of IS/ISO 10012-1 : 1992 and ISO 10012-2 : 1997. In this revision, ISO 10012 : 2003 has been adopted so as to make Indian Standard identical with the International Standard. Therefore, this standard cancels and replaces IS/ISO 10012-1 : 1992 and ISO 10012-2 : 1997.

The text of the ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

In this adopted standard, normative reference appears to the following International Standard, for which Indian Standard also exists. The Indian Standard, which is to be substituted in its place, is listed below along with its degree of equivalence for the edition indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 9000 : 2000	IS/ISO 9000 : 2000 Quality management systems — Fundamentals and vocabulary	Identical

In this adopted standard, normative reference has also been made to VIM : 1993 'International vocabulary of basic and general terms used in metrology' for which no Indian Standard exists. The concerned Sectional Committee has reviewed the provisions of this International Standard and has decided that it is acceptable as such for use in conjunction with this standard.

Introduction

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

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

References to this International Standard can be made

— by a customer when specifying products required,

— by a supplier when specifying products offered,

— by legislative or regulatory bodies, and

— in assessment and audit of measurement management systems.

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

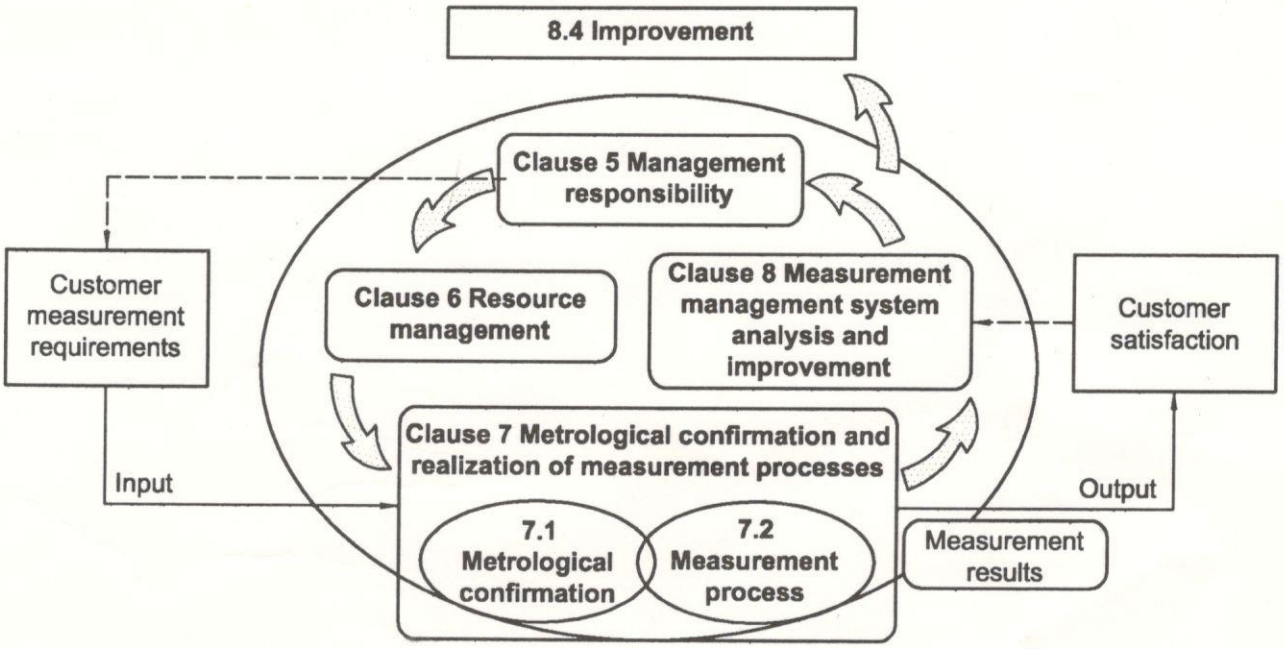


Figure 1 — Model of measurement management system

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

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

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

Indian Standard

MEASUREMENT MANAGEMENT SYSTEMS — REQUIREMENTS FOR MEASUREMENT PROCESSES AND MEASURING EQUIPMENT

(First Revision)

1 Scope

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

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

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

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

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*

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

3 Terms and definitions

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

3.1
measurement management system
set of interrelated or interacting elements necessary to achieve metrological confirmation and continual control of measurement processes

3.2
measurement process
set of operations to determine the value of a quantity

3.3
measuring equipment
measuring instrument, software, measurement standard, reference material or auxiliary apparatus, or a combination thereof, necessary to realize a measurement process

3.4
metrological characteristic
distinguishing feature which can influence the results of measurement

NOTE 1 Measuring equipment usually has several metrological characteristics.

NOTE 2 Metrological characteristics can be the subject of calibration.

3.5
metrological confirmation
set of operations required to ensure that measuring equipment conforms to the requirements for its intended use

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

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

NOTE 3 The requirements for intended use include such considerations as range, resolution and maximum permissible errors.

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

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

3.6
metrological function
function with administrative and technical responsibility for defining and implementing the measurement management system

4 General requirements

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

Guidance

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

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

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

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

5 Management responsibility

5.1 Metrological function

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

Guidance

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

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

5.2 Customer focus

The management of the metrological function shall ensure that

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

b) the measurement management system meets the customers' metrological requirements, and

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

5.3 Quality objectives

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

Guidance

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

— *no nonconforming product is to be accepted nor conforming product rejected due to incorrect measurements;*

— *no measurement process is to be out of control for more than one day without detection;*

— *all metrological confirmations are to be completed by the agreed times;*

— *there are to be no illegible metrological confirmation records;*

— *all of the technical training programmes are to be completed per the established schedule;*

— *the amount of time measuring equipment is out of operation is to be reduced by a stated percentage.*

5.4 Management review

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

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

6 Resource management

6.1 Human resources

6.1.1 Responsibilities of personnel

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

Guidance

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

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

6.1.2 Competence and training

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

Guidance

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

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

6.2 Information resources

6.2.1 Procedures

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

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

Guidance

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

6.2.2 Software

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

Guidance

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

Off-the-shelf software might not require testing.

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

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

6.2.3 Records

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

Guidance

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

6.2.4 Identification

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

6.3 Material resources

6.3.1 Measuring equipment

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

Guidance

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

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

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

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

The management of the metrological function shall establish, maintain and use documented procedures for receiving, handling, transporting, storing and dispatching measuring equipment, in order to prevent abuse, misuse, damage and changes to its metrological characteristics. There shall be procedures for processing measuring equipment introduced into or removed from the measurement management system.

6.3.2 Environment

The environmental conditions required for the effective operation of the measurement processes covered by the measurement management system shall be documented.

Environmental conditions affecting measurements shall be monitored and recorded. Corrections based on the environmental conditions shall be recorded and applied to measurement results.

Guidance

Environmental conditions affecting measurement results can include temperature, rate of change of temperature, humidity, lighting, vibration, dust control, cleanliness, electromagnetic interference, and other factors. Equipment manufacturers usually provide specifications giving ranges and maximum loads, and limitations of environmental conditions, for correct use of the equipment.

6.4 Outside suppliers

The management of the metrological function shall define and document the requirements for products and services to be provided by outside suppliers for the measurement management system. Outside suppliers shall be evaluated and selected based on their ability to meet the documented requirements. Criteria for selection, monitoring and evaluation shall be defined and documented, and the results of the evaluation shall be recorded. Records shall be maintained of the products or services provided by outside suppliers.

Guidance

If an outside supplier is used for testing or calibration, the supplier should be able to demonstrate technical competence to a laboratory standard such as ISO/IEC 17025. Products and services provided by outside suppliers might require verification to the specified requirements.

7 Metrological confirmation and realization of measurement processes

7.1 Metrological confirmation

7.1.1 General

Metrological confirmation (see Figure 2 and Annex A) shall be designed and implemented to ensure that the metrological characteristics of the measuring equipment satisfy the metrological requirements for the measurement process. Metrological confirmation comprises measuring equipment calibration and measuring equipment verification.

Guidance

Recalibration of the measuring equipment is not necessary if the equipment is already in a valid calibration status. Metrological confirmation procedures should include methods to verify that measurement uncertainties and/or measuring equipment errors are within permissible limits specified in the metrological requirements.

Information relevant to the metrological confirmation status of measuring equipment shall be readily available to the operator, including any limitations or special requirements.

The metrological characteristics of measuring equipment shall be suitable for its intended use.

Guidance

Examples of characteristics for measuring equipment include:

— *range,*

— *bias,*

— *repeatability,*

— *stability,*

— *hysteresis,*

— *drift,*

— *effects of influencing quantities,*

— *resolution,*

— *discrimination (threshold),*

— *error, and*

— *dead band.*

Metrological characteristics of measuring equipment are factors contributing to the measurement uncertainty (see 7.3.1) which allows direct comparison with the metrological requirements towards establishing metrological confirmation.

Qualitative statements of the metrological characteristics in terms of, for example, "required accuracy of measuring equipment" should be avoided.

7.1.2 Intervals between metrological confirmation

The methods used to determine or change the intervals between metrological confirmation shall be described in documented procedures. These intervals shall be reviewed and adjusted when necessary to ensure continuous compliance with the specified metrological requirements.

Guidance

Data obtained from calibration and metrological confirmation histories, and advancing knowledge and technology, may be used for determining intervals between metrological confirmation. Records obtained using statistical process control techniques for measurements can be useful in determining whether or not to modify metrological confirmation intervals.

The calibration interval may be equal to the metrological confirmation interval (see OIML D10).

Each time nonconforming measuring equipment is repaired, adjusted or modified, the interval for its metrological confirmation shall be reviewed.

7.1.3 Equipment adjustment control

Access to adjusting means and devices on confirmed measuring equipment, whose setting affects the performance, shall be sealed or otherwise safeguarded to prevent unauthorized changes. Seals or safeguards shall be designed and implemented such that tampering will be detected.

The metrological confirmation process procedures shall include actions to be taken when seals or safeguards are found damaged, broken, bypassed or missing.

Guidance

The requirement for sealing does not apply to adjustment means or devices that are intended to be set by the user without the need for external references; for example, zero adjusters.

Special attention should be paid to write-protection techniques to prevent unauthorized changes to software and firmware.

The decisions about what measuring equipment should be sealed, the controls or adjustments which will be sealed, and the sealing material such as labels, solder, wire, paint, are normally left to the metrological function. Implementation of a sealing programme by the metrological function should be documented. Not all measuring equipment lends itself to sealing.

7.1.4 Records of the metrological confirmation process

Records of the metrological confirmation process shall be dated and approved by an authorized person to attest to the correctness of the results, as appropriate.

These records shall be maintained and available.

Guidance

The minimum time for the retention of records depends on many factors including the customer's requirements, statutory or regulatory requirements, and manufacturer liability. Records concerned with measurement standards may need to be retained indefinitely.

Records of the metrological confirmation process shall demonstrate whether each item of measuring equipment satisfies the metrological requirements specified.

The records shall include the following, as necessary:

a) the description and unique identification of the equipment manufacturer, type, serial number, etc.;

b) the date on which the metrological confirmation was completed;

c) the result of the metrological confirmation;

d) the assigned interval for metrological confirmation;

e) identification of the metrological confirmation procedure (see 6.2.1);

f) the designated maximum permissible error(s);

g) the relevant environmental conditions and a statement about any corrections necessary;

h) the uncertainties involved in calibrating the equipment;

i) details of any maintenance, such as adjustment, repairs or modifications carried out;

j) any limitations of use;

k) identification of the person(s) performing the metrological confirmation;

l) identification of the person(s) responsible for the correctness of the recorded information;

m) unique identification (such as serial numbers) of any calibration certificates and reports, and other relevant documents;

n) evidence of the traceability of the calibration results;

o) the metrological requirements for the intended use;

p) the calibration results obtained after and, where required, before any adjustment, modification or repair.

Guidance

Calibration results should be recorded so that the traceability of all the measurements can be demonstrated and so that the calibration results can be reproduced under conditions close to the original conditions.

In some instances, a verification result is included in the calibration certificate or report where it is stated whether the equipment complies with (or fails to comply with) specified requirements.

The records may be in manuscript, typescript or microfilm, or in an electronic or a magnetic memory, or other data medium.

The maximum permissible error may be determined by the metrological function, or by reference to the measuring equipment manufacturer's published specification

The metrological function shall ensure only authorized persons are permitted to generate, amend, issue or delete records.

7.2 Measurement process

7.2.1 General

Measurement processes which are part of the measurement management system shall be planned, validated, implemented, documented and controlled. Influencing quantities affecting the measurement processes shall be identified and considered.

The complete specification of each measurement process shall include identification of all relevant equipment, measurement procedures, measurement software, conditions of use, operator abilities, and all other factors affecting the reliability of the measurement result. The control of measurement processes shall be carried out in accordance with documented procedures.

Guidance

A measurement process can be limited to the use of a single item of measuring equipment.

A measurement process may require data correction, for example, due to environmental conditions.

7.2.2 Measurement process design

The metrological requirements shall be determined based on customer, organization, and statutory and regulatory requirements. The measurement processes designed to meet these specified requirements shall be documented, validated as appropriate and, if necessary, agreed to with the customer.

For each measurement process, the relevant process elements and controls shall be identified. The choice of elements and control limits shall be commensurate with the risk of failure to comply with specified requirements. These process elements and controls shall include the effects of operators, equipment, ambient conditions, influence quantities and application methods.

Guidance

In specifying the measurement processes, it may be necessary to determine

— *what measurements are necessary to ensure the quality of the product,*

— *the methods of measurement,*

— *the equipment required to execute the measurement and to define it, and*

— *the required skills and qualifications of the personnel performing the measurements.*

Measurement processes may be validated by comparisons to results of other validated processes, by comparisons of results by other measurement methods, or by continuous analysis of measurement process characteristics.

The measurement process shall be designed to prevent erroneous measurement results, and shall ensure the prompt detection of deficiencies, and timely corrective actions.

Guidance

The effort devoted to measurement process control should be commensurate with the importance of the measurements to the quality of the final product of the organization. Examples of where a high degree of measurement process control is appropriate include critical or complex measurement systems, measurements ensuring product safety, or measurements resulting in subsequent high cost if incorrect. Minimal process control may be adequate for simple measurements of non-critical parts. Procedures for process control may be in generic form for similar types of measuring equipment and applications, such as the use of hand tools for measuring machined parts.

The impact of influencing quantities on the measurement process should be quantified. It may be necessary to design and carry out specific experiments or investigations to do this. When this is not possible, the data, specifications and warnings provided by an equipment manufacturer should be used.

The performance characteristics required for the intended use of the measurement process shall be identified and quantified.

Guidance

Examples of characteristics include

— *measurement uncertainty,*

— *stability,*

— *maximum permissible error,*

— *repeatability,*

— *reproducibility, and*

— *the skill level of the operator.*

Other characteristics may be important for some measurement processes.

7.2.3 Realization of the measurement process

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

Conditions to be controlled shall include

a) the use of confirmed equipment,

b) application of validated measurement procedures,

c) the availability of required information resources,

d) maintainance of the required environmental conditions,

e) the use of competent personnel,

f) the proper reporting of results, and

g) the implementation of monitoring as specified.

7.2.4 Records of measurement processes

The metrological function shall maintain records to demonstrate compliance with the requirements of the measurement process, including the following:

a) a full description of the measurement processes implemented, including all elements (e.g. operators, any measuring equipment or check standards) used and the relevant operating conditions;

b) the relevant data obtained from measurement process controls, including any information relevant to the measurement uncertainty;

c) any actions taken as a result of data from the measurement process control;

d) the date(s) on which each measurement process control activity was carried out;

e) the identification of any relevant verification documents;

f) identification of the person responsible for providing the information for the records;

g) the abilities (required and achieved) of the personnel.

Guidance

For recording purposes, batch identification can be adequate for consumable items used in measurement process control.

The metrological function shall ensure only authorized persons are permitted to generate, amend, issue or delete records.

7.3 Measurement uncertainty and traceability

7.3.1 Measurement uncertainty

The measurement uncertainty shall be estimated for each measurement process covered by the measurement management system (see 5.1).

Uncertainty estimations shall be recorded. The analysis of measurement uncertainties shall be completed before the metrological confirmation of the measuring equipment, and the validation of the measurement process. All known sources of measurement variability shall be documented.

Guidance

The concepts involved and the methods that can be used in combining the uncertainty components and presenting the results are given in the "Guide to the expression of uncertainty in measurement" (GUM). Other documented and accepted methods may be used.

It is possible that some components of uncertainty will be small compared to other components and this could make their detailed determination unjustifiable on technical or economic grounds. If so, the decision and justification should be recorded. In all cases, the effort devoted to determining and recording uncertainties of measurements should be commensurate with the importance of the measurement results to the quality of the product of the organization. The recording of uncertainty determinations may take the form of "generic statements" for similar types of measuring equipment, with contributions being added for individual measurement processes.

The uncertainty of the measurement result should take into account, among other contributions, the uncertainty of the calibration of the measuring equipment.

The appropriate use of statistical techniques for analysing the results of preceding calibrations, and for assessing the results of calibrations of several similar items of measuring equipment, can assist in the estimation of uncertainties.

7.3.2 Traceability

The management of the metrological function shall ensure that all measurement results are traceable to SI unit standards.

Traceability to SI units of measurement shall be achieved by reference to an appropriate primary standard or by reference to a natural constant, the value of which in terms of the relevant SI units is known and recommended by the General Conference on Weights and Measures and the International Committee for Weights and Measures.

Where agreed to, consensus standards used in contractual situations shall only be used when SI unit standards or recognized natural constants do not exist.

Guidance

Traceability is usually achieved through reliable calibration laboratories having their own traceability to national measurement standards. For example, a laboratory complying with the requirements of ISO/IEC 17025 could be considered reliable.

National metrology institutes are responsible for national measurement standards and their traceability, including those instances where the national measurement standard is held by facilities other than the national metrology institute. Measurement results may be traceable through a national metrology institute external to the country where the measurement is made.

Certified reference materials may be considered as reference standards.

Records of traceability of measurement results shall be maintained for as long as required by the measurement management system, the customer, or by statutory and regulatory requirements.

8 Measurement management system analysis and improvement

8.1 General

The metrological function shall plan and implement the monitoring, analysis and improvements needed

a) to ensure conformity of the measurement management system with this International Standard, and

b) to continually improve the measurement management system.

8.2 Auditing and monitoring

8.2.1 General

The metrological function shall use auditing, monitoring and other techniques, as appropriate, to determine the suitability and effectiveness of the measurement management system.

8.2.2 Customer satisfaction

The metrological function shall monitor information relating to customer satisfaction as to whether the customer's metrological needs have been met. The methods for obtaining and using this information shall be specified.

8.2.3 Measurement management system audit

The metrological function shall plan and conduct audits of the measurement management system to ensure its continuing effective implementation and compliance with the specified requirements. Audit results shall be reported to affected parties within the organization's management.

The results of all audits of the measurement management system, and all changes to the system, shall be recorded. The organization shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes.

Guidance

Measurement management system audits may be carried out as a part of the audits of the organization's management system.

ISO 19011 provides guidance on auditing systems.

Audits of the measurement management system may be carried out by the organization's metrological function, or by contracted or third-party personnel. Auditors should not audit their own areas of responsibility.

8.2.4 Monitoring of the measurement management system

Within the processes comprising the measurement management system, the metrological confirmation and measurement processes shall be monitored. Monitoring shall be in accordance with documented procedures and at established intervals.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

Monitoring of the measurement management system shall provide for the prevention of deviations from requirements by ensuring the prompt detection of deficiencies and timely actions for their correction. This monitoring shall be commensurate to the risk of failure to comply with the specified requirements.

The results of monitoring of the measurement and confirmation processes and any resulting corrective actions shall be documented to demonstrate that the measurement and confirmation processes have continuously complied with the documented requirements.

8.3 Control of nonconformities

8.3.1 Nonconforming measurement management systems

The metrological function shall ensure the detection of any nonconformities, and shall take immediate action.

Guidance

Nonconforming elements should be identified to prevent inadvertent use.

Interim actions (e.g. workaround plans) may be used until the corrective actions have been implemented.

8.3.2 Nonconforming measurement processes

Any measurement process known to give, or suspected of producing, incorrect measurement results shall be suitably identified and shall not be used until appropriate actions have been taken.

If a nonconforming measurement process is identified, the process user shall determine the potential consequences, make the necessary correction, and take the necessary corrective action.

A measurement process modified due to a nonconformity shall be validated before use.

Guidance

Failure of a measurement process due, for example, to deterioration of a check standard or change of operator competence, may be revealed by post-process indicators such as

— *analysis of control charts,*

— *analysis of trend charts,*

— *subsequent inspections,*

— *interlaboratory comparisons,*

— *internal audit, and*

— *customer feedback.*

8.3.3 Nonconforming measuring equipment

Any confirmed measuring equipment that is suspected or known

a) to have been damaged,

b) to have been overloaded,

c) to malfunction in such a way that may invalidate its intended use,

d) to produce incorrect measurement results,

e) to be beyond its designated metrological confirmation interval,

f) to have been mishandled,

g) to have a damaged or broken seal or safeguard,

h) to have been exposed to influencing quantities that can adversely affect its intended use (e.g. electromagnetic field, dust),

shall be removed from service by segregation, or identified by prominent labelling or marking. The nonconformity shall be verified and a nonconformity report prepared. Such equipment shall not be returned to service until the reasons for its nonconformity have been eliminated and it is again confirmed.

Nonconforming measuring equipment which is not returned to its intended metrological characteristics shall be clearly marked or otherwise identified. Metrological confirmation of such equipment for other uses shall ensure that the altered status is clearly apparent and includes identification of any limitations of use.

Guidance

If it is impractical to adjust, repair or overhaul equipment found not to be fit for its intended use, an option is downgrading and/or a change in its intended use. Reclassification should only be used with great care as it can cause confusion between the allowable uses of apparently identical pieces of equipment. This includes limited metrological confirmation of only some of the ranges or functions of multiranged equipment.

If the result of a metrological verification prior to any adjustment or repair indicates that the measuring equipment did not meet the metrological requirements such that the correctness of the measurement results may have been compromised, the equipment user shall determine the potential consequences and take any necessary action. This can involve re-examination of product produced using measurements taken with the nonconforming measuring equipment.

8.4 Improvement

8.4.1 General

The metrological function shall plan and manage the continual improvement of the measurement management system based on the results of the audits, management reviews and of other relevant factors, such as feedback from customers. The metrological function shall review and identify potential opportunities to improve the measurement management system, and modify it as necessary.

8.4.2 Corrective action

When a relevant measurement management system element does not meet the specified requirements, or when relevant data show an unacceptable pattern, action shall be taken to identify the cause and eliminate the discrepancy.

Correction and corrective action solutions shall be verified before returning the measurement process to use.

The criteria for taking corrective action shall be documented.

8.4.3 Preventive action

The metrological function shall determine action(s) to eliminate the causes of potential measurement or confirmation nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. A documented procedure shall be established to define requirements for

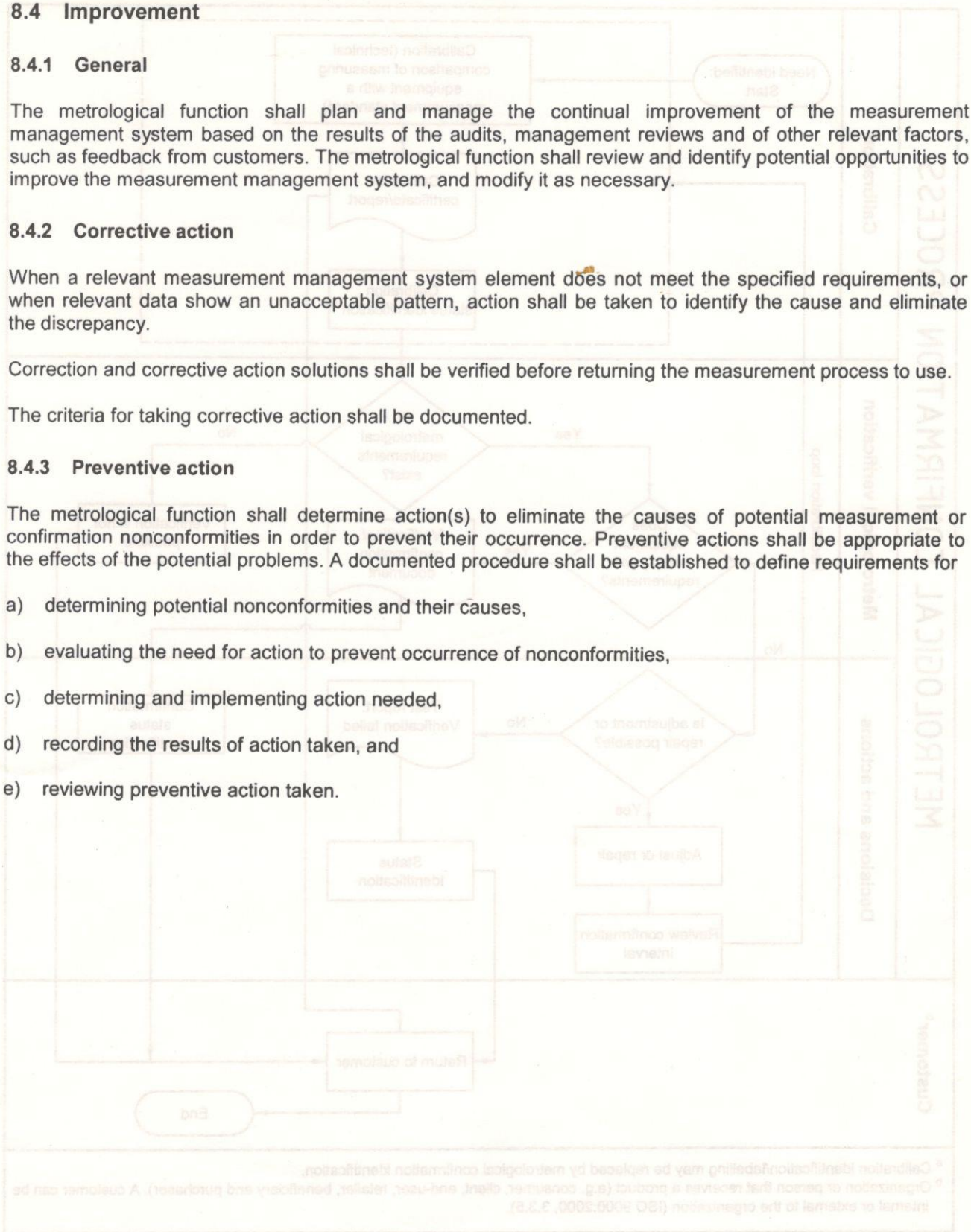
a) determining potential nonconformities and their causes,

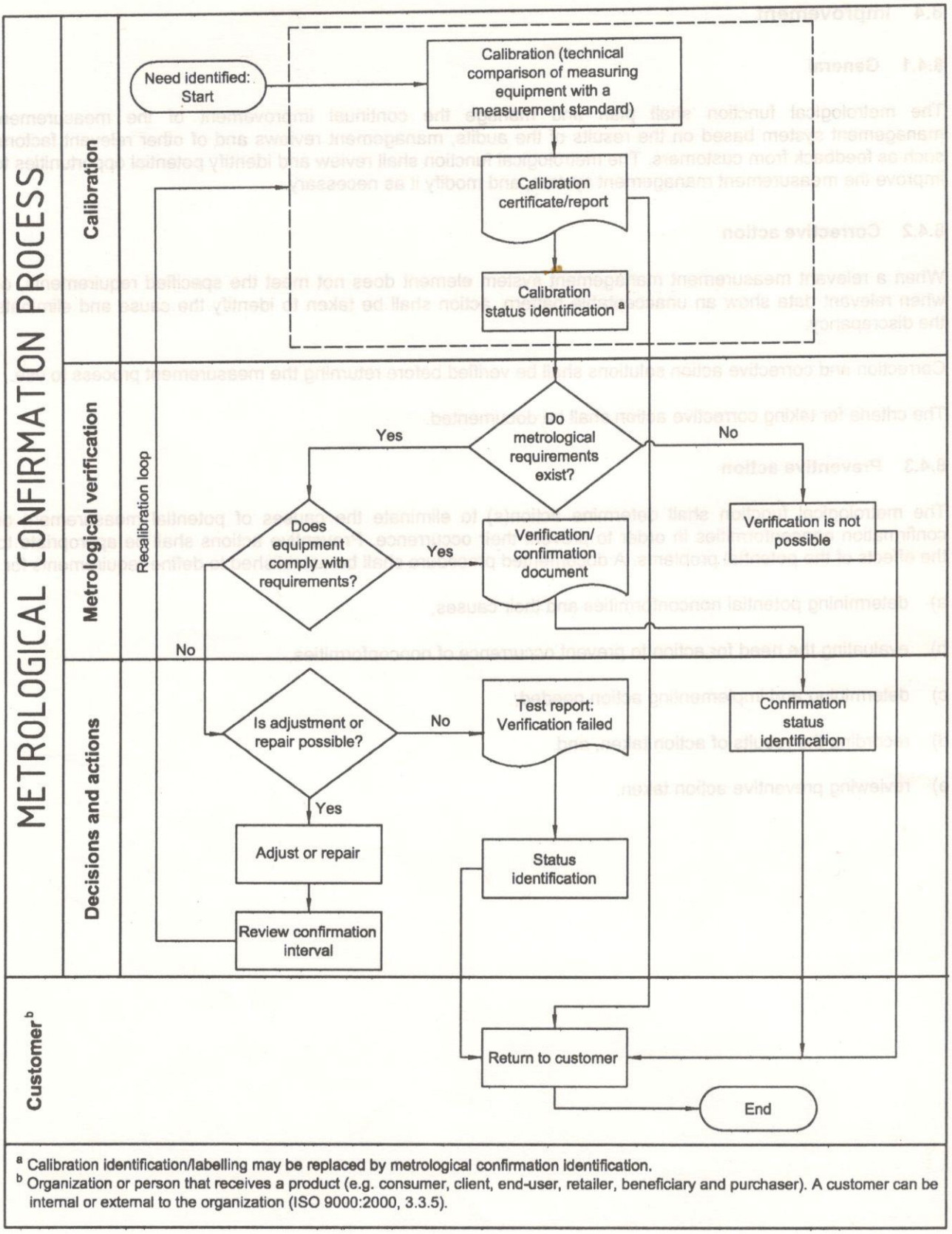
b) evaluating the need for action to prevent occurrence of nonconformities,

c) determining and implementing action needed,

d) recording the results of action taken, and

e) reviewing preventive action taken.





[a] Calibration identification/labelling may be replaced by metrological confirmation identification.
[b] Organization or person that receives a product (e.g. consumer, client, end-user, retailer, beneficiary and purchaser). A customer can be internal or external to the organization (ISO 9000:2000, 3.3.5).

Figure 2 — Metrological confirmation process for measuring equipment

Annex A
(informative)

Overview of the metrological confirmation process

A.1 Introduction

The metrological confirmation process has two inputs, the customer metrological requirements and the measuring equipment metrological characteristics, and one output, the metrological confirmation status of measuring equipment.

A.2 Customer metrological requirements (CMR)

The customer metrological requirements are those measurement requirements specified by the customer as relevant for the customer's production processes.They therefore depend on the specifications for the variables to be measured. The CMR include those involved in verifying the compliance of product with customer specifications, in addition to those arising from the control of the production process and its inputs. The determination and specification of these requirements is the responsibility of the customer, although this process may be performed on behalf of the customer by some suitably qualified person. This often requires a deep knowledge of the production processes as well as metrology. The CMR should also take into account the risk of bad measurements, and the effects of these on the organization and the business. The CMR may be expressed in terms of maximum permissible error, operational limits, etc. There should be enough detail to allow the operators of metrological confirmation processes to decide unequivocally whether or not a particular measuring equipment is capable of control, measuring or monitoring the specified variable or quantity according to its intended use.

EXAMPLE It is required that the pressure be controlled to between 200 kPa and 250 kPa in a process reactor for a critical operation. This requirement is to be interpreted and expressed as a CMR for the pressure-measuring equipment. This could result in a CMR that the equipment be capable of measuring a pressure range of 150 kPa to 300 kPa, with 2 kPa of maximum permissible error, an uncertainty of measurement of 0,3 kPa (not including the time-related effects), and with a drift not larger than 0,1 kPa per specified time period. The customer compares the CMR with the characteristics (either explicit or implicit) specified by the equipment manufacturer and selects measuring equipment and procedures that best match the CMR. The customer may specify a particular supplier's manometer with an accuracy class of 0,5 % and a range of 0 kPa to 400 kPa.

A.3 Measuring equipment metrological characteristics (MEMC)

Since the MEMC are often determined by calibration (or several calibrations) and/or tests, the metrological function within the metrological confirmation system specifies and controls all such necessary activities. The inputs for the calibration process are the measuring equipment, a measurement standard, and a procedure stating the environmental conditions. The calibration results should include a statement of the measurement uncertainty. This is an important characteristic as an input when evaluating the measurement uncertainty for the measurement process when the equipment is used. The calibration results may be documented within the metrological confirmation system by any appropriate method, for example as calibration certificates or calibration reports (when calibrations are outsourced), or by records of calibration results (when performed entirely within the metrological function of the organization).

Important characteristics for measurements, for example, measurement uncertainty, are not only dependent on the equipment but also on the environment, the specific measurement procedure, and sometimes the skills and experience of the operator. For this reason, it is very important that the whole measurement process be considered when selecting measuring equipment to satisfy requirements. This consideration is the responsibility of the metrological function for the organization, although specific activities may be performed either by the organization or by an appropriately qualified person, such as an independent metrologist.

A.4 Verification and metrological confirmation

After the calibration, the MEMC are compared to the CMR before confirming the equipment for its intended use. For example, the reported error of indication of the measuring equipment would be compared to the maximum permissible error specified as a CMR. If the error is smaller than the maximum permissible error, then the equipment complies with that requirement, and may be confirmed for use. If the error is greater, action should be taken to remove the nonconformity or the customer should be informed that the equipment cannot be confirmed.

Such direct comparison of MEMC and CMR is often termed verification (see ISO 9000). The metrological confirmation system is firmly based on such verifications, but should also include detailed consideration and review of the complete measurement process in order to give assurance of the quality of the measurements made with the equipment, in support of determining the compliance of a product with the customer requirements.

EXAMPLE Following the example in A.2, it is assumed that the error found by calibration is 3 kPa at 200 kPa, with a calibration measurement uncertainty of 0,3 kPa. Therefore, the instrument does not meet the requirement of maximum permissible error. After adjustment, the error found by calibration is 0,6 kPa and the uncertainty in the calibration process is 0,3 kPa. The instrument now complies with the maximum permissible error requirement and it may be confirmed for use, assuming that evidence demonstrating compliance with the drift requirement has been obtained. However, if the instrument was submitted for reconfirmation, the user of the instrument should be informed of the results of the first calibration since corrective actions may be required concerning product realization for a period before the instrument was taken out of use pending reconfirmation.

Whether performed by the user or by the metrological function, the results of the verification process may be compiled into a verification document, in addition to any calibration or test certificates or reports, as part of an audit trail within the metrological confirmation system. The final stage in the metrological confirmation system is the proper identification of the status of the measuring equipment, for example by labelling, marking, etc. After this, the measuring equipment may be used for the purpose it has been confirmed for.

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