INTRODUCTION TO ISO/IEC 17025:2017 ~ transition

CLAUSE 4, 5, 6, 7

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SIRIM STS
Standard+Training+Consultancy

Module 3 – Clause Requirements

ISO/IEC 17025

SIRIM STS
Standard+Training+Consultancy

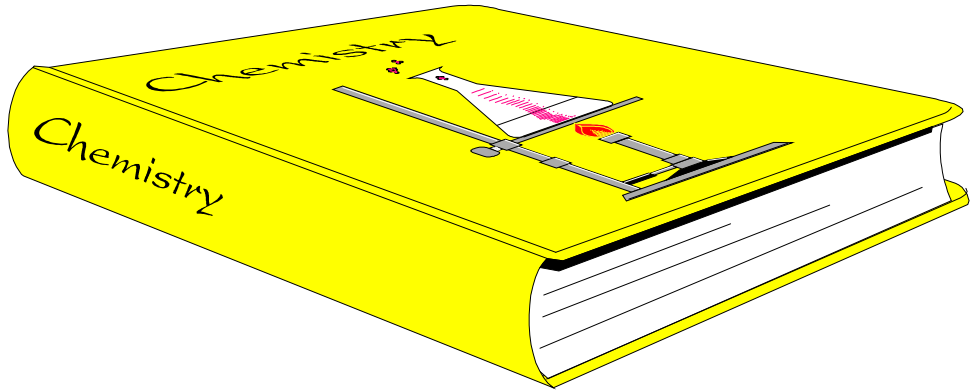
1 Scope

This International Standard

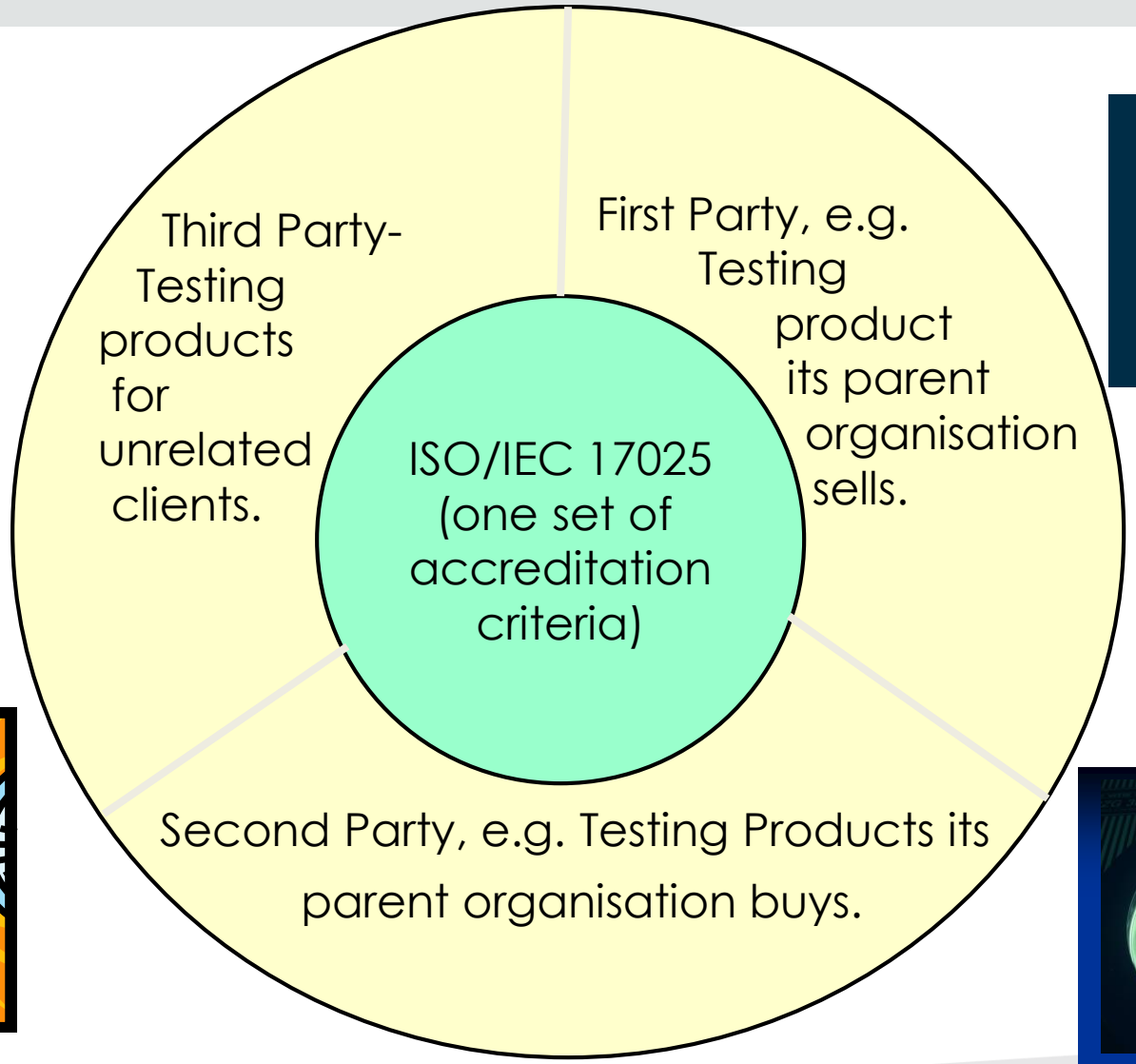
- specifies the general requirements for the competence impartiality and consistent operation of laboratories.
- applicable to all organization performing laboratory activities, regardless of number of personnel.

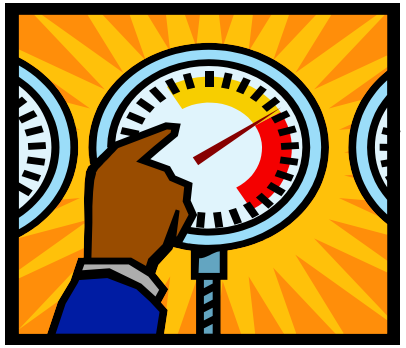
1 Scope

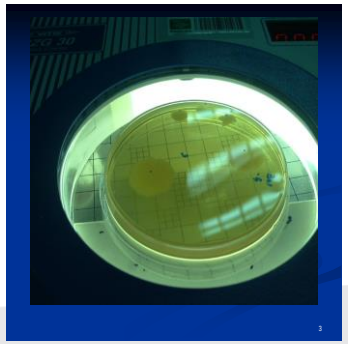
Laboratory customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others use this document in confirming or recognizing the competence of laboratories.



Types of Laboratory







2. Normative References

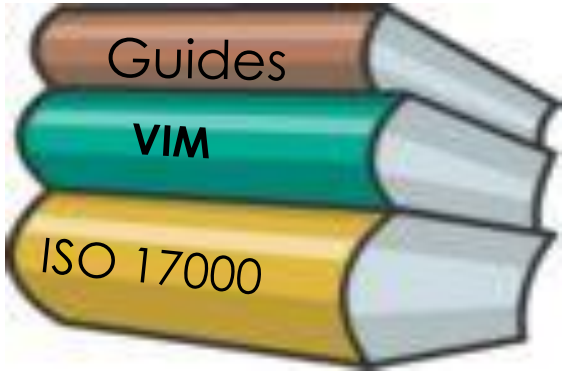
(Document that provides rules, guidelines, or characteristics for activities or their results).

ISO/IEC Guide 99, International Vocabulary of metrology- Basic and general concepts and associated term (VIM)

ISO/IEC 17000 Conformity Assessment – vocabulary and general principles.

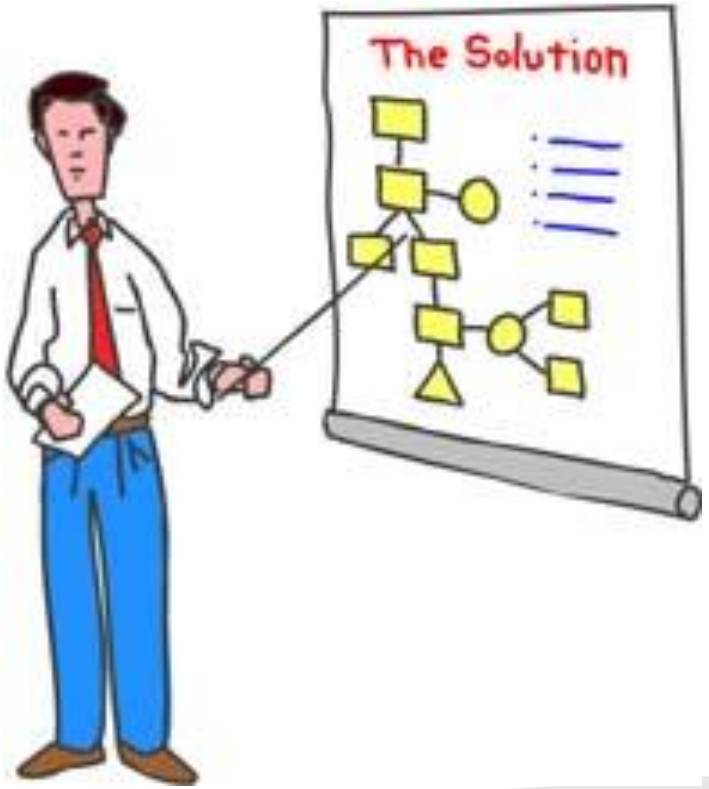
3. Terms and Definitions

ISO/IEC Guide 99 and ISO/IEC 17000.



CLAUSE 4

GENERAL REQUIREMENTS



4.1- IMPARTIALITY

4.1.1 Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.

4.1.2 The laboratory management shall be committed to impartiality.

4.1.3 The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.

4.1.4 The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.

NOTE: A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.

4.1.5 If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.

4.2 Confidentiality

4.2.1 The laboratory shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities.

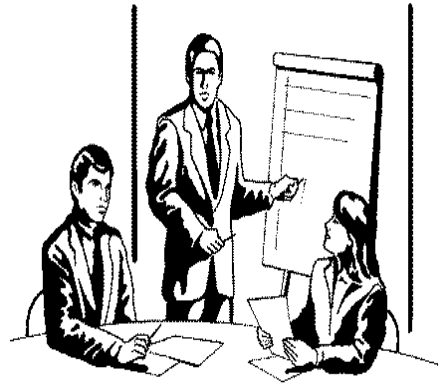
inform the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.

4.2.2 When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.

4.2 Confidentiality

4.2.3 Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) shall be confidential between the customer and the laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source.

4.2.4 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities.



Clause 5

Structural requirements

5. Structural requirements

5.1 The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities.

NOTE : For the purposes of this document, a governmental laboratory is deemed to be a legal entity on the basis of its governmental status.

The laboratory shall :

5.2 identify management that has overall responsibility for the laboratory.

5.3 define and document the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.

5. Structural requirements

5.4 Laboratory activities shall be meet :

- the requirements of this document,
- the laboratory's customers,
- regulatory authorities and organizations providing recognition.

This shall include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.

5. Structural requirements

5.5 The laboratory shall:

a) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services;

b) specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;

c) document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.

5. Structural requirements

5.6 The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

a) implementation, maintenance and improvement of the management system;
b) identification of deviations from the management system or from the procedures for performing laboratory activities;
c) initiation of actions to prevent or minimize such deviations;
d) reporting to laboratory management on the performance of the management system and any need for improvement;
e) ensuring the effectiveness of laboratory activities.

5. Structural requirements

5.7 Laboratory management shall ensure that:

a) communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements;

b) the integrity of the management system is maintained when changes to the management system are planned and implemented.

CLAUSE 6

RESOURCE REQUIREMENTS

6. Resource requirement

6.1 General

The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities

6.2 Personnel

6.2.1 All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system.

The laboratory shall :

6.2.2 document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience.

6.2.3 ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.

6.2.4 The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities.

6.2 Personnel

6.2.5 The laboratory shall have procedure(s) and retain records for:

a) determining the competence requirements;
b) selection of personnel;
c) training of personnel;
d) supervision of personnel;
e) authorization of personnel;
f) monitoring of competence of personnel.

6.2.6 The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:

a) development, modification, verification and validation of methods;
b) analysis of results, including statements of conformity or opinions and interpretations;
c) report, review and authorization of results.

6.3 Facilities and environmental conditions

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

NOTE : Influences that can adversely affect the validity of results can include, but are not limited to, microbial contamination, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound and vibration.

6.3.2 The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented.

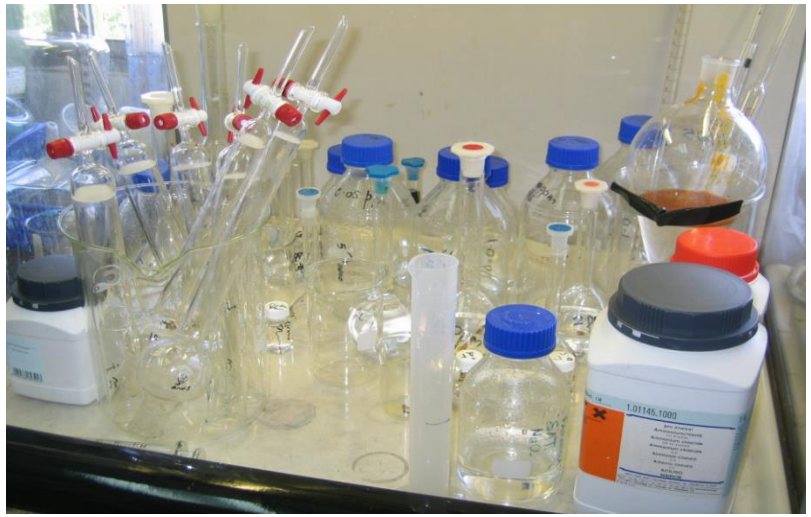
6.3.3 The laboratory shall monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results.

6.3.4 Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include, but not be limited to:

a) access to and use of areas affecting laboratory activities;
b) prevention of contamination, interference or adverse influences on laboratory activities;
c) effective separation between areas with incompatible laboratory activities.

6.3.5 When the laboratory performs laboratory activities at sites or facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this document are met.

ACCOMMODATION or HOUSEKEEPING?



Reagents, cleaned glassware, testing activities in one space

Samples storage not appropriate

Waste and solvent stock storage not suitable

6.4 Equipment

6.4.1 The laboratory shall have access to equipment including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus which is required for the correct performance of laboratory activities and which can influence the result.

NOTE 1 A multitude of names exist for reference materials and certified reference materials, including reference standards, calibration standards, standard reference materials and quality control materials. Reference materials from producers meeting the requirements of ISO 17034 come with a product information sheet/certificate that specifies, amongst other characteristics, homogeneity and stability for specified properties and, for certified reference materials, specified properties with certified values, their associated measurement uncertainty and metrological traceability.

Reference materials should be used from producers that meet ISO 17034.

NOTE 2 ISO Guide 33 provides guidance on the selection and use of reference materials. ISO Guide 80 provides guidance to produce in house quality control materials.

6.4 Equipment

The laboratory shall ..

6.4.2 shall ensure that the requirements for equipment of this document are met if uses equipment outside its permanent control.

6.4.3 have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration.

6.4.4 verify that equipment conforms to specified requirements before being placed or returned into service.

6.4.5 The equipment used for measurement shall be capable of achieving the measurement accuracy or measurement uncertainty required to provide a valid result.

6.4.6 Measuring equipment shall be calibrated when:

- the measurement accuracy or measurement uncertainty affects the validity of the reported results, or
- calibration of the equipment is required to establish the metrological traceability of the reported result.

NOTE: Types of equipment having an effect on the validity of the reported results can include:

- those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement;
- those used to make corrections to the measured value, e.g. temperature measurements;
- those used to obtain a measurement result calculated from multiple quantities.

6.4 Equipment

6.47 The laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.

6.4.8 All equipment requiring calibration or which has a defined period of validity shall be labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity.

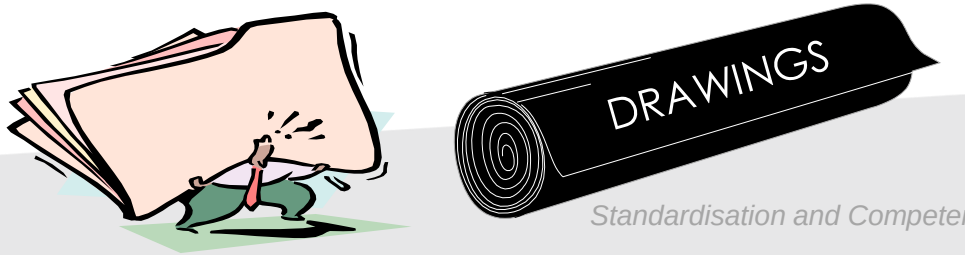
6.49 Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, shall be taken out of service. It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly. The laboratory shall examine the effect of the defect or deviation from specified requirements and shall initiate the management of nonconforming work procedure (see 7.10).

When

6.4.10 intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure.

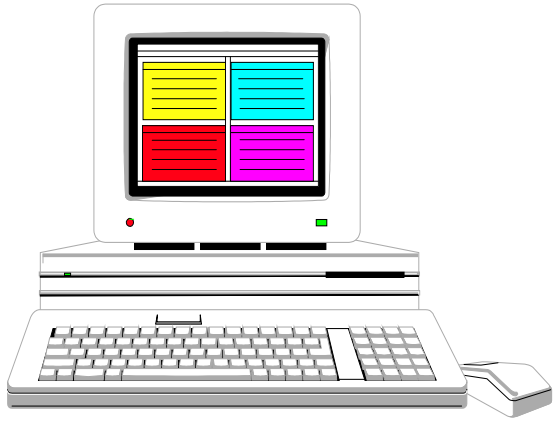
6.4.11 calibration and reference material data include reference values or correction factors, the laboratory shall ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.

6.4.12 The laboratory shall take practicable measures to prevent unintended adjustments of equipment from invalidating results.



6.4 Equipment

6.4.13 Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable:



a) the identity of equipment, including software and firmware version;
b) the manufacturer's name, type identification, and serial number or other unique identification;
c) evidence of verification that equipment conforms with specified requirements;
d) the current location;
e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;
f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;
g) the maintenance plan and maintenance carried out to date, where relevant to the performance of
h) the equipment details of any damage, malfunction, modification to, or repair of, the equipment.

6.5 Metrological traceability

6.5.1 The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.

NOTE 1 : In ISO/IEC Guide 99, metrological traceability is defined as the “property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty”.
NOTE 2 : See Annex A for additional information on metrological traceability.

6.5.2 The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through one of the following:

a) calibration provided by a competent laboratory;

NOTE 1 Laboratories fulfilling the requirements of this document are considered to be competent.

b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI;

NOTE 2 Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.

c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.

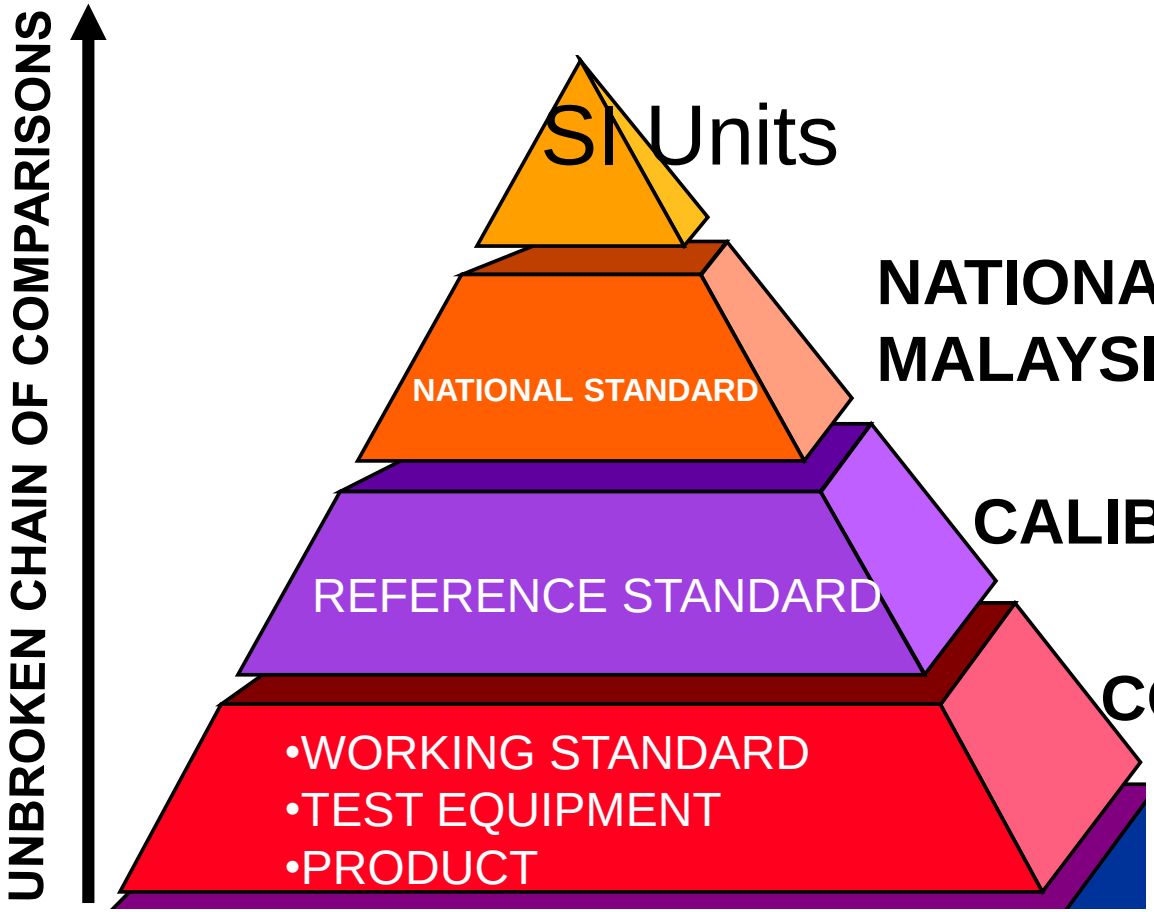
NOTE 3 Details of practical realization of the definitions of some important units are given in the SI brochure.

6.5.3 When metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metrological traceability to an appropriate reference, e.g.

a) certified values of certified reference materials provided by a competent producer;

b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

TRACEABILITY TO NATIONAL STANDARDS



NATIONAL METROLOGY INSTITUTE of MALAYSIA **NMIM**

CALIBRATION SERVICES

COMPANIES/LABS

The SI units

length	metre : m
mass	kilogram: kg
time	second: s
electric current	ampere: A
thermodynamic temperature	kelvin: K
amount of substance	mole: mol
luminous intensity	candela: cd
plane angle	radian: rad
solid angle	steradian:Sr

Equipment Calibration

ISO / VIM: Calibration is a set of operations that are establish under specified conditions, the relationship between the values of quantities indicated by an item of test equipment, or values represented by a material measure or a reference material, and the corresponding values realized by standards. **Uncertainty of each calibration point should be estimated.**

It may involve:

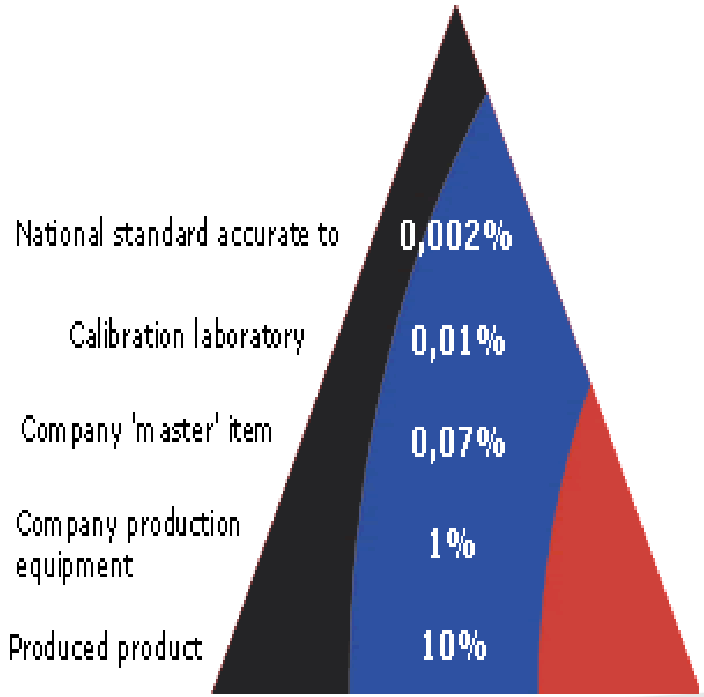
• Assigning corrections to indications in the test equipment, or

• Assigning values to the scale on an instrument.

Calibration involves comparison between a

reference item or reference material and

the test equipment being calibrated.



Frequency of Calibration

- A calibration is valid only for the moment it was completed.
- In reality, however, calibration frequency will be based on risk versus cost.
- Where measurements are critical or are near equipment limits, a rigorous calibration programme is needed based on:
  - Type of instrument (robust or delicate)
  - Use and abuse
  - Environmental conditions
  - Permanent or temporary location
  - Maintenance programme
  - History of stable performance
  - Measurement uncertainty required
  - Criticality of test results

6.6 Externally provided products and services

6.6.1 The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:

a) are intended for incorporation into the laboratory's own activities;

b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider;

c) are used to support the operation of the laboratory.

NOTE: Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services.

Requirement for Purchase Product

Supplier Records

6.6 Externally provided products and services

6.6.2 The laboratory shall have a procedure and retain records for:

a) defining, reviewing and approving the laboratory's requirements for externally provided products and services;

b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;

c) ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer;

d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

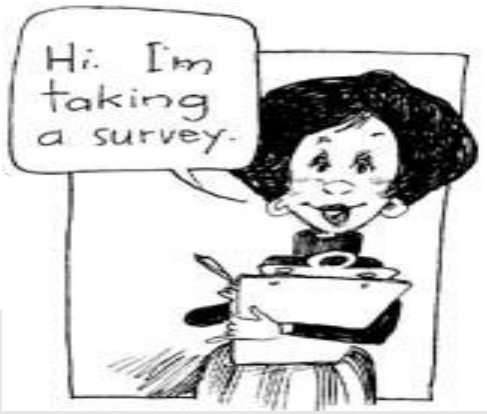
6.6.3 The laboratory shall communicate its requirements to external providers for:

a) the products and services to be provided;

b) the acceptance criteria;

c) competence, including any required qualification of personnel;

d) activities that the laboratory, or its customer, intends to perform at the external provider's premises.



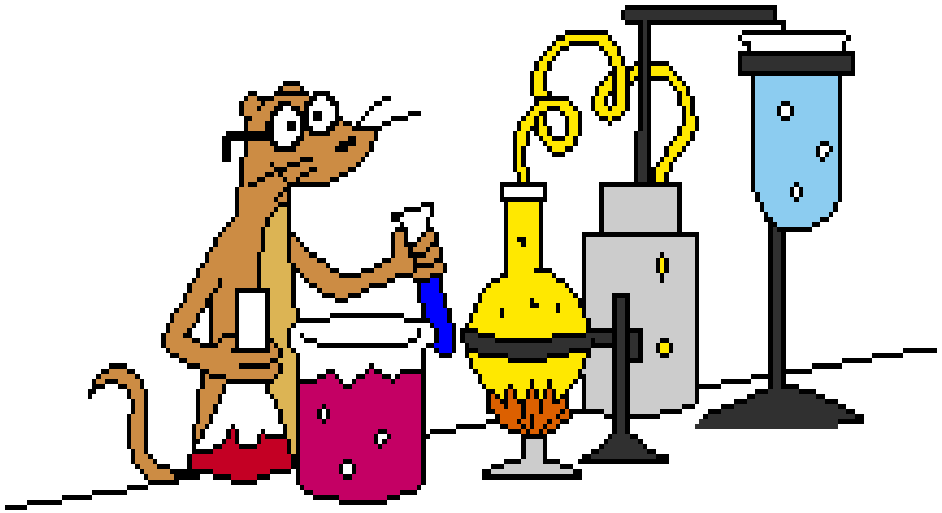
Exercise 3

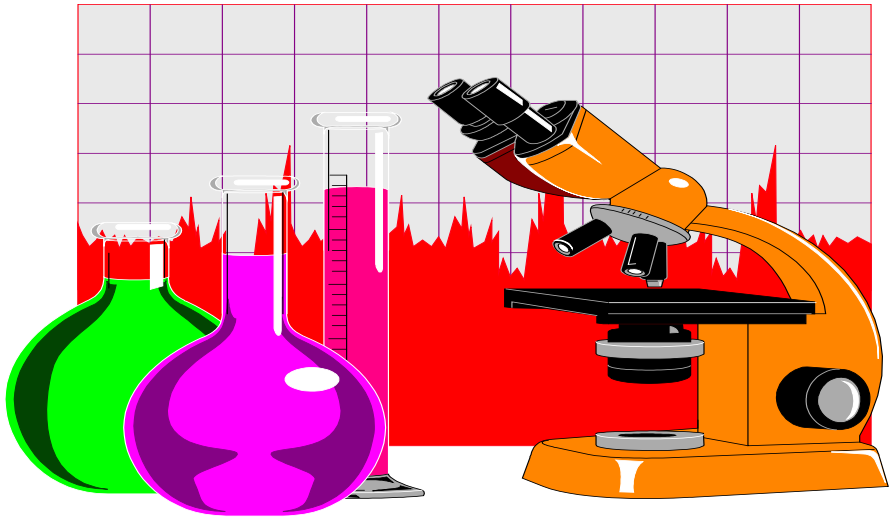
Refer to the standard, please find the answer and write the appropriate clause.

Duration: 30 minutes

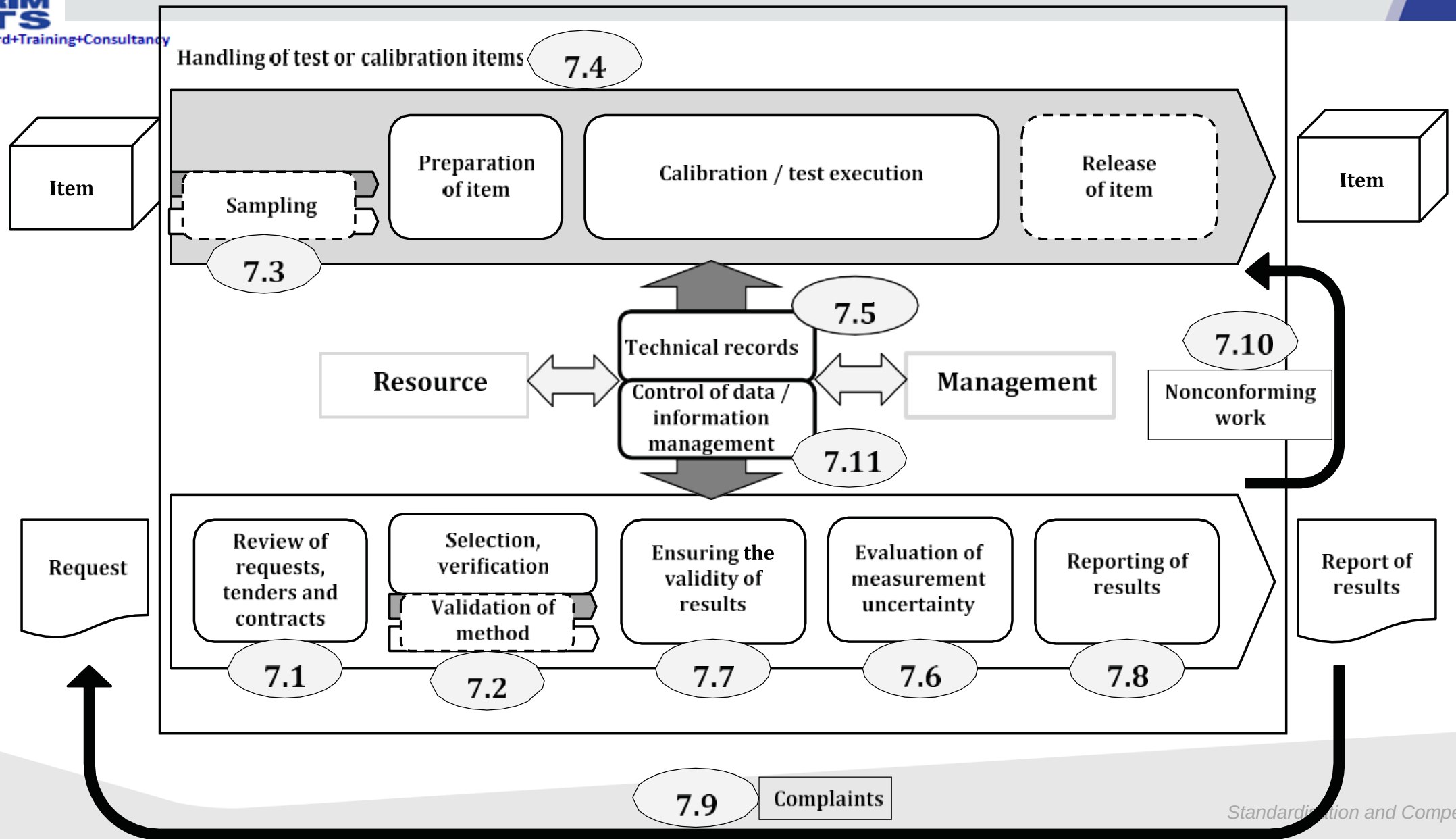
CLAUSE 7

PROCESS REQUIREMENTS





Operational processes of a laboratory



7.1 Review of requests, tenders and contracts

7.1.1 The procedure shall ensure that:

a) the requirements are adequately defined, documented and understood;

b) the laboratory has the capability and resources to meet the requirements;

c) where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval;

NOTE 1: It is recognized that externally provided laboratory activities can occur when:
- the laboratory has the resources and competence to perform the activities, however, for unforeseen reasons is unable to undertake these in part or full;
- the laboratory does not have the resources or competence to perform the activities.

d) the appropriate methods or procedures are selected and are capable of meeting the customers' requirements.

NOTE 2: For internal or routine customers, reviews of requests, tenders and contracts can be performed in a simplified way.

7.1 Review of requests, tenders and contracts

7.1.2Inform the customer when the method requested by the customer is considered to be inappropriate or out of date.

7.1.3When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance) the specification or standard, and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer.

NOTE: For further guidance on statements of conformity, see ISO/IEC Guide 98-4.

7.1.4Any differences between the request or tender and the contract shall be resolved before laboratory activities commence. Each contract shall be acceptable both to the laboratory and the customer. Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results.

7.1.5 Inform customer on any deviation from the contract.

7.1.6 If a contract is amended after work has commenced, the contract review shall be repeated and any amendments shall be communicated to all affected personnel.

7.1.7 The laboratory shall cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed.

NOTE: Such cooperation can include:

a) providing reasonable access to relevant areas of the laboratory to witness customer-specific laboratory activities;
b) preparation, packaging, and dispatch of items needed by the customer for verification purposes.

7.1.8 Records of reviews, including any significant changes, shall be retained. Records shall also be retained of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities.

7.2 Selection, verification and validation method

7.2.1Selection and verification method

(7.2.1.1) Appropriate methods and procedures for all lab activities ie procedure measurement uncertainty and data analysis

(7.2.1.2) Method available and accessible

(7.2.1.3) Use the latest valid method

(7.2.1.4) - If customer does not specified method, inform the method chosen
- Recommend to use published method in international, regional, or national standards and latest valid edition (unless not possible to do so).

(7.2.1.5) -verify method to ensure its achieve performance .
- record retained
- Repeated verification if method modified

(7.2.1.6) method development shall be a planned activity and assigned to competent personnel equipped with adequate resources.
- Review periodically to confirm the need of customer .
- Modification to development plan shall be approved and authorized

(7.2.1.7) Deviations from methods are documented, technically justified, authorized and accepted by clients.

Selection of methods

Need to consider:

- Customer's wants and needs / requirements
  - Screening or confirmatory test.
  - For export certification.
  - For routine or non-routine testing.
  - To comply with regulatory requirements.
  - For checking product lots / consignment testing.
  - For product certification.
  - For research purposes.
  - Forensic purposes.
  - For trade (customs tariffs, importing regulations, goods evaluation, etc.)

7.2 Selection, verification and validation method

7.2.2 Validation method

7.2.2.1 Shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified

NOTE 2 : The techniques used for method validation can be one of, or a combination of, the following:

a) *calibration or evaluation of bias and precision using reference standards or reference materials;*

b) *systematic assessment of the factors influencing the result;*

c) *testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;*

d) *comparison of results achieved with other validated methods;*

e) *interlaboratory comparisons;*

f) *evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method*

7.2 Selection, verification and validation method

7.2.2 Validation method

7.2.2.2 When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed.

7.2.2.3 The performance characteristics of validated methods as assessed for the intended use, shall be relevant to the customers' needs and consistent with specified requirements.

NOTE Performance characteristics can include, but are not limited to:

a) the measurement range,
b) accuracy,
c) the measurement uncertainty of the results,
d) limit of detection,
e) limit of quantification,
f) selectivity of the method,
g) linearity,
h) repeatability or reproducibility,
i) robustness against external influences or cross- sensitivity against interference from the matrix of the sample or test object, and bias.

7.2 Selection, verification and validation method

7.2.2 Validation method

7.2.2.4 Retain the following records of validation:

a) the validation procedure used;

b) specification of the requirements;

c) determination of the performance characteristics of the method;

d) results obtained;

e) a statement on the validity of the method, detailing its fitness for the intended use.

7.3 Sampling

7.3.3 Retain records of sampling data that forms part of the testing or calibration that is undertaken. These records shall include, where relevant:

a) reference to the sampling method used;
b) date and time of sampling;
c) data to identify and describe the sample (e.g. number, amount, name);
d) identification of the personnel performing sampling;
e) identification of the equipment used;
f) environmental or transport conditions;
g) diagrams or other equivalent means to identify the sampling location when appropriate;
h) deviations, additions to or exclusions from the sampling method and sampling plan.

7.3 Sampling

Clause 7.3.1

- Have a sampling plan and method .
- sampling method shall address the factors to be controlled
- The sampling plan and method available at the site and based on statistical methods.

7.3.2 The sampling method shall describe:

a) the selection of samples or sites;

b) the sampling plan;

c) preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration.

NOTE When received into the laboratory, further handling can be required as specified in 7.4.

7.4 Handling of test or calibration items

Clause7.4.1

Have procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items,

Protect the integrity of the test or calibration item and the interests of the laboratory and the customer.

Avoid damage to item (deterioration, contamination and loss) while in custody.

Handling instructions provided shall be followed.

7.4.2 uniquely identifying item through out life in the laboratory, include sub division, group and transfer of items

7.4.3 Any deviation during receipt recorded;

consult with client before proceeding

7.4.4 stored under specified environmental condition and record the environmental conditions.

7.5 Technical record

Record Control Procedure

7.5.1 Ensure technical records contain results, report and sufficient information (if possible) to facilitate :

- Identification of factors affecting measurement result and its uncertainty.
- Enable the test or calibration to be repeated using original conditions.

- include the date and the identity of personnel responsible for each laboratory activity and for checking data and results.
- Recording - observations, data and calculations shall be
  - recorded at the time they are made
  - identifiable to the specific task.

7.5.2 amendments to technical records can be tracked to previous versions or to original observations.

- Both the original and amended data and files kept, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

7.6 Evaluation of measurement uncertainty

7.6.1 identify the factors contribute to measurement uncertainty including sampling, shall be taken into account using appropriate methods of analysis

7.6.1 calibration labs, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations.

7.6.3 testing lab shall evaluate measurement uncertainty.

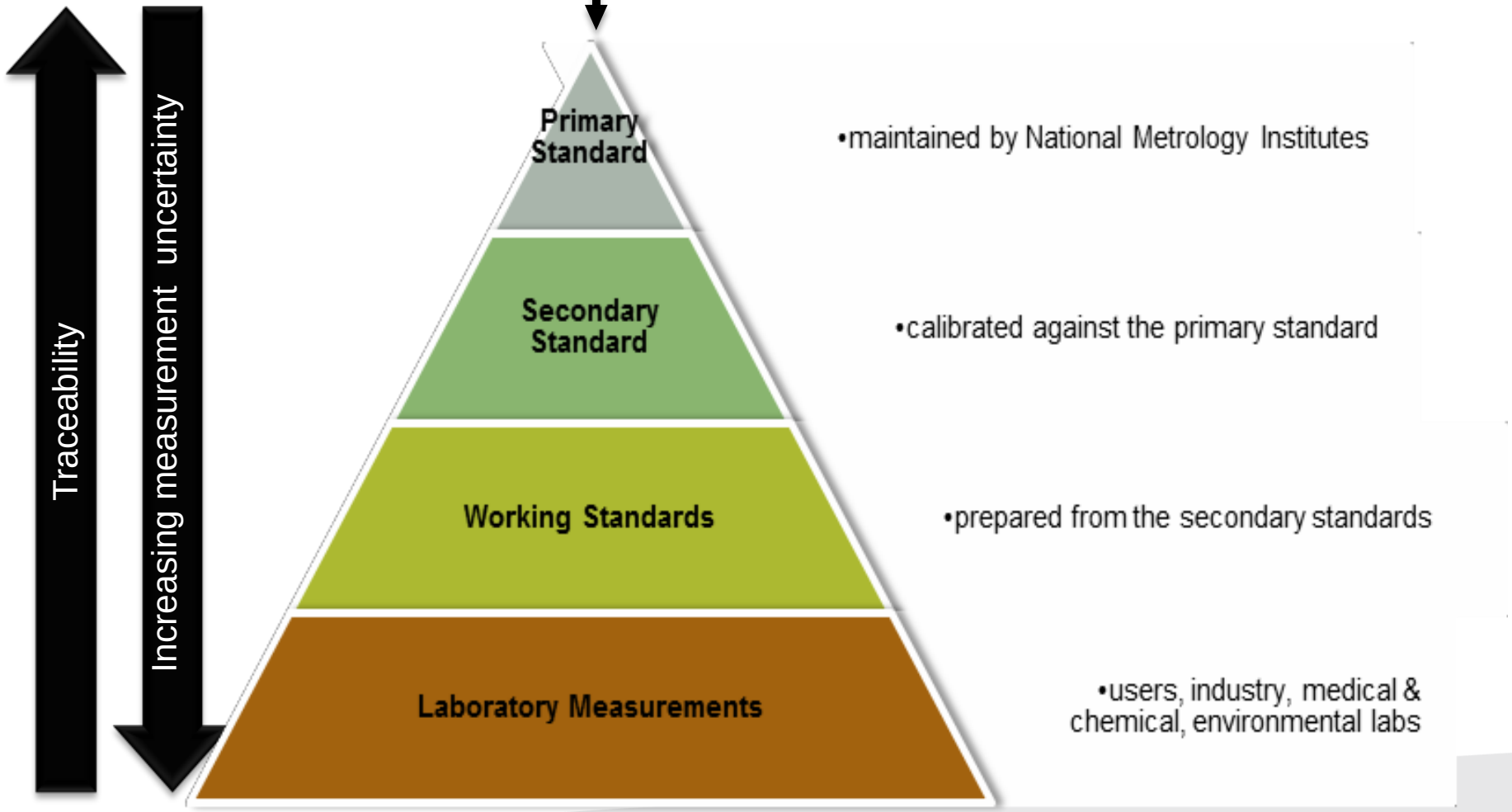
Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.

NOTE 1 In those cases where a well-recognized test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, the laboratory is considered to have satisfied 7.6.3 by following the test method and reporting instructions.

NOTE 2 For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result if the laboratory can demonstrate that the identified critical influencing factors are under control.

NOTE 3 For further information, see ISO/IEC Guide 983, ISO 5725 and ISO 21748.

Reference unit Definition → **e.g. SI**



What is measurement uncertainty?

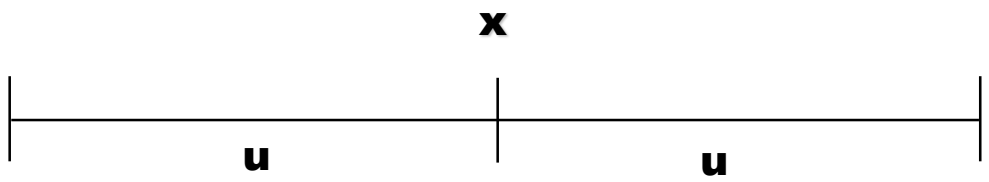
Whenever a measurement is made, the result obtained is only an estimate of the true value of the property being measured.

Many factors will cause measurement results to vary from the true value.

- uncontrollable random variations in the measurement process.
- limitations in the measuring equipment used
- the presence of bias (i.e. results being consistently higher or lower than they should be).

ISO definition of measurement uncertainty

- A parameter, associated with the result of a measurement, that characterizes the dispersion of the value that could reasonable be attributed to the measurand.



A range containing the true value

Concentration of lead in a sample of soil is reported as 85 ± 10 mg kg^{-1} should be interpreted as "The true value of the amount of lead present in the soil sample is somewhere between 75 mg kg^{-1} and 95 mg kg^{-1} (at a given level of confidence).

7.7 Ensuring the validity of results

7.7.1 Required procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:

a) use of reference materials or quality control materials;
b) use of alternative instrumentation that has been calibrated to provide traceable results;
c) functional check(s) of measuring and testing equipment;
d) use of check or working standards with control charts, where applicable;
e) intermediate checks on measuring equipment;
f) replicate tests or calibrations using the same or different methods;
g) retesting or recalibration of retained items;
h) correlation of results for different characteristics of an item;
i) review of reported results;
j) Intra-laboratory comparisons;
k) testing of blind sample(s).

7.7 Ensuring the validity of results

7.7.2 Monitor performance by comparison with results of other laboratories.

This monitoring shall be planned and reviewed

a) participation in proficiency testing;

NOTE ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 are considered to be competent.

b) participation in interlaboratory comparisons other than proficiency testing.

7.7.3 Data from monitoring activities shall be analysed, used to control and, if applicable, improve the laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported.

7.8 Reporting the results
7.8.1 General

Clause 7.8.1.1

The results shall be reviewed and authorized prior to release.

- accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling)
- include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used.
- reports retained as technical records.

NOTE 1 For the purposes of this document, test reports and calibration certificates are sometimes referred to as test certificates and calibration reports, respectively.

NOTE 2 Reports can be issued as hard copies or by electronic means, provided that the requirements of this document are met.

7.8.1.2 When agreed with the customer, the results may be reported in a simplified way. Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer shall be readily available.

7.8.2 Common requirements for reports(test, calibration or sampling)

7.8.2.1 Report include at least the following information :

a) a title (e.g. "Test Report", "Calibration Certificate" or "Report of Sampling");
b) the name and address of the laboratory;
c) the location of performance of the laboratory activities if difference from address;
d) unique identification;
e) the name and contact information of the customer;
f) identification of the method used;
g) a description and condition of the item ;
h) the date of receipt of the test or calibration item(s), and the date of sampling,
i) the date(s) of performance of the laboratory activity;
j) the date of issue of the report;
k) reference to the sampling plan and sampling method used
l) a statement to the effect that the results relate only to the items tested, calibrated or sampled;
m) the results with, where appropriate, the units of measurement;
n) additions to, deviations, or exclusions from the method;
o) identification of the person(s) authorizing the report;
p) clear identification when results are from external providers.

Report include a statement specifying that the report shall not be reproduced except in full, without approval of the laboratory.

7.8.2 Common requirements for reports(test, calibration or sampling

Clause 7.8.2.2

- Data provided by a customer shall be clearly identified.
- a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results.
- state in the report that the results apply to the sample as received.

7.8.3 Specific requirement for test report

7.8.3.1 In addition to the requirements listed in 7.8.2, include the following:

a) information on specific test conditions, such as environmental conditions;

b) where relevant, a statement of conformity with requirements or specifications (see 7.8.6);

c) where applicable, the measurement uncertainty ,when:

–it is relevant to the validity or application of the test results;

–a customer's instruction so requires, or

–the measurement uncertainty affects conformity to a specification limit;

d) opinions and interpretations (see 7.8.7);

e) additional information which may be required by specific methods, authorities, customers or groups of customers.

7.8.3.2 Where the laboratory is responsible for the sampling activity, test reports shall meet the requirements listed in 7.8.5 where necessary for the interpretation of test results.

7.8.4 Specific requirement for calibration certificates

7.8.4.1 Addition to the requirements 7.8.2, calibration certificates shall include the following:

a) the measurement uncertainty

NOTE *According to JCGM 200:2012, a measurement result is generally expressed as a single measured quantity value including unit of measurement and a measurement uncertainty.*

b) the conditions (e.g. environmental) under which the calibrations were made;

c) metrological traceability (see Annex A);

d) before and after any adjustment or repair, if available;

e) where relevant, a statement of conformity with requirements or specifications (see 7.8.6);

f) where appropriate, opinions and interpretations (see 7.8.7).

7.8.4.2 Where the laboratory is responsible for the sampling activity, calibration certificates shall meet the requirements listed in 7.8.5 where necessary for the interpretation of test results.

7.8.4.3 A calibration certificate or calibration label shall not contain any recommendation on the calibration interval except where this has been agreed with the customer.

7.8.5 Reporting sampling

Addition to the requirements listed in 7.8.2, reports shall include the following:

a) the date of sampling;
b) unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate);
c) the location of sampling, including any diagrams, sketches or photographs;
d) a reference to the sampling plan and sampling method;
e) details of any environmental conditions
f) information required to evaluate measurement uncertainty for subsequent testing or calibration.

7.8.6 Reporting statements of conformity

7.8.6.1 When a statement of conformity to a specification or standard is provided, document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and apply the decision rule.

NOTE Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.

7.8.6.2 Report on the statement of conformity, clearly identifies:

a) to which results the statement of conformity applies;

b) which specifications, standards or parts there of are met or not met;

c) the decision rule applied (unless it is inherent in the requested specification or standard).

NOTE : For further information, see ISO/IEC Guide 984.

7.8.7 Reporting opinions and interpretations

Clause 7.8.7.1

Ensure that only personnel authorized for the expression of opinions and interpretations releases the respective statement.

Document the basis upon which the opinions and interpretations have been made.

NOTE It is important to distinguish opinions and interpretations from statements of inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC 17065, and from statements of conformity as referred to in 7.8.6.

7.8.7.2 Base on the results obtained from the tested or calibrated item and shall be clearly identified as such.

7.8.7.3 When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained

7.8.8 Amendments to reports

7.8.8.1 When an issued report needs to be changed, amended or re-issued, any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report.

7.8.8.2 Amendments to a report after issue shall be made only in the form of a further document, or data transfer, which includes the statement "Amendment to Report, serial number... [or as otherwise identified]", or an equivalent form of wording.

Such amendments shall meet all the requirements of this document.

7.8.8.3 When it is necessary to issue a complete new report, this shall be uniquely identified and shall contain a reference to the original that it replaces.

7.9 Complaints

7.9.1 Have a documented process to receive, evaluate and make decisions on complaints.

7.9.2 A description of the complaints handling process available to any interested party on request.

Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, shall deal with it. The laboratory shall be responsible for all decisions at all levels of the handling process for complaints.

7.9.3 The process for handling complaints shall include at least the following elements and methods:

a) description of the process for receiving, validating, investigating the complaint, and deciding what
b) actions are to be taken in response to it;
c) tracking and recording complaints, including actions undertaken to resolve them;
d) ensuring that any appropriate action is taken.

7.9 Complaints

7.9.4 Validate the complaint.

7.9.5 Acknowledge receipt of the complaint, and provide with progress reports and the outcome.

7.9.6 Reviewed and approved the outcomes to be communicated to the complainant by, individual(s) not involved in the original laboratory activities in question.

NOTE: This can be performed by external personnel.

7.9.7 Provide formal notice of the end of the complaint handling to the complainant.

7.10 Non conforming work

Nonconforming work is any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria).

7.10.1 Have procedure :

a) Define the responsibilities and authorities for the management of nonconforming work;

b) Take actions based upon the risk levels (including halting or repeating of work and withholding of reports, as necessary)

c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;

d) a decision is taken on the acceptability of the nonconforming work;

e) where necessary, the customer is notified and work is recalled;

f) the responsibility for authorizing the resumption of work is defined

7.10.2 retain records of non conforming work and actions as specified in 7.10.1, bullets b) to f).

7.10.3 if the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory shall implement corrective action.

7.11 Control of data and information management

Clause 7.11.1

have access to the data and information needed to perform laboratory activities.

Clause 7.11.2

- validated for functionality the laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data.

- If there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation.

NOTE 1: In this document “laboratory information management system(s)” includes the management of data and information contained in both computerized and non-computerized systems. Some of the requirements can be more applicable to computerized systems than to non-computerized systems.

NOTE 2 : Commercial off the shelf software in general use within its designed application range can be considered to be sufficiently validated.

7.11 Control of data and information management

7.11.3 Lab information management systems shall:

a) be protected from unauthorized access;

b) be safeguarded against tampering and loss;

c) be operated in an environment that complies with supplier or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;

d) be maintained in a manner that ensures the integrity of the data and information;

e) include recording system failures and the appropriate immediate and corrective actions.

7.11.4 Ensure that the provider or operator of the system complies with all applicable requirements of this document, If a laboratory information management system is managed and maintained off-site or through an external provider,

7.11.5 Instructions, manuals and reference data relevant to the laboratory information management system(s) are available to personnel.

7.11.6 Calculations and data transfers checked in an appropriate and systematic manner.

Exercise 4

Refer to the standard, please find the answer and write the appropriate clause.

Duration: 30 minutes