Training Course

General Requirements for the competence of testing & calibration laboratories

ISO 17025:2017

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Course Introduction

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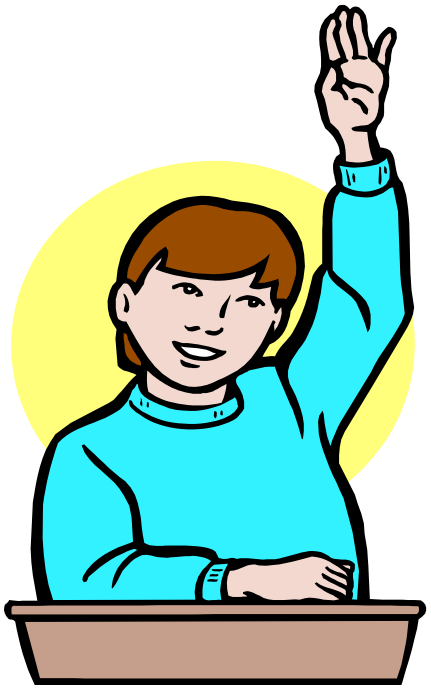
Course Introduction

التعريف بالمدرب

- المدير الفنى لوحدة الاختبارات الميكانيكية – مركز بحوث وتطوير الفلزات (CMRDI)
- كبير مقيمين – مقيم فنى بمجلس الامارات العالمى للاعتماد (DAC/EIAC)
- كبير مقيمين – مقيم فنى بجهاز الاعتماد العراقى (IQAS)
- عضو الهيئة الدولية البريطانية IRCA – برقم 6058912 – www.irca.org.
- كبير مقيمين لنظم إدارة الجودة والبيئة والسلامة المهنية - معتمد من IRCA.
- كبير مقيمين لنظم إدارة الجودة والبيئة والسلامة المهنية - معتمد من PECB - كندا.
- مدرب برامج كبير مقيمين أنظمة الجودة والبيئة والسلامة - معتمد من IQMS
- استشاري نظم إدارة الجودة من الهيئة الدولية الكندية PECB
- استشارى معتمد بمنظمة الأمم المتحدة للتنمية الصناعية (UNIDO)
- بكالوريوس هندسة الفلزات – دبلوم علوم المواد – كلية الهندسة – جامعة القاهرة
- محاضر دبلوم إدارة الجودة الشاملة - جامعة القاهرة (2011 - 2016 م)



Definitions

What is the meaning of "Quality" Word?

Definitions

Quality can be quantified : Q = P / E

Where

- **Q = quality**
- **P = performance (Organization determines)**
- **E = expectations (Customer determines)**

Definitions

Quality is :Fitness for purpose

What is Quality?

- **Meeting customers' needs or expectations?**
- **Value for money?**
- **Fitness for purpose?**
- **Customer satisfaction?**
- **Doing things right first time, every time**
- **Legislative compliance?**
- **All of the above?**

QA & QC - What's the difference?

Quality Control

- **Checking what you got is what you wanted**
  - **Activities include inspection, testing and measuring.**

Quality Assurance

- **Proactively building in quality & success**
  - **Activities include QMS design & management, training & training assessment, error-proofing, supplier approval processes.**

Quality Management

Complete QMS encompassing the above.

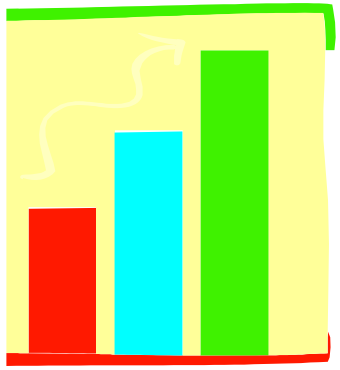
Accreditation Concepts

Definitions

- *Accreditation:* is a formal recognition that a laboratory, inspection body or a certification body (often known collectively as evaluation bodies or Conformity Assessment Bodies CABs) fulfils specified requirements and is competent to perform specific conformity assessment tasks
- *Accreditation Body (AB):* authoritative body which pe rforms accreditation.

Accreditation Concepts

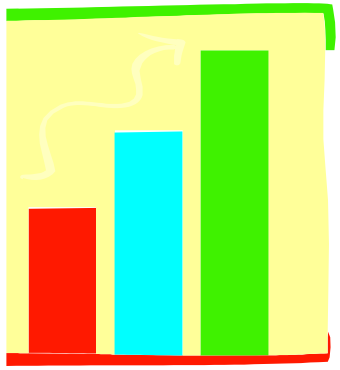
What is the Accreditation?



Accreditation means that an authoritative body formally recognizes that an organization or individual is competent to execute a specific service as described in the scope of accreditation

Accreditation Concepts

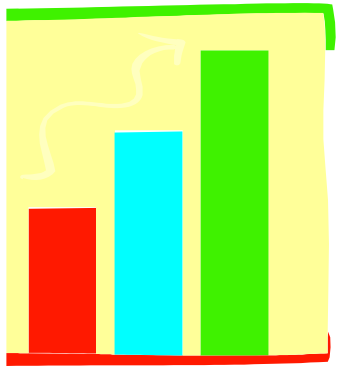
Why do Labs seek to be Accredited?



Laboratories can be checked and certified for their conformance to international quality management system standards using ISO-9001 or national regulations but it will not indicate anything about their technical competence or its ability to provide accurate and reliable test data.

Accreditation Concepts

Why do Labs seek to be Accredited?



-Increasing Reliability of Test Results

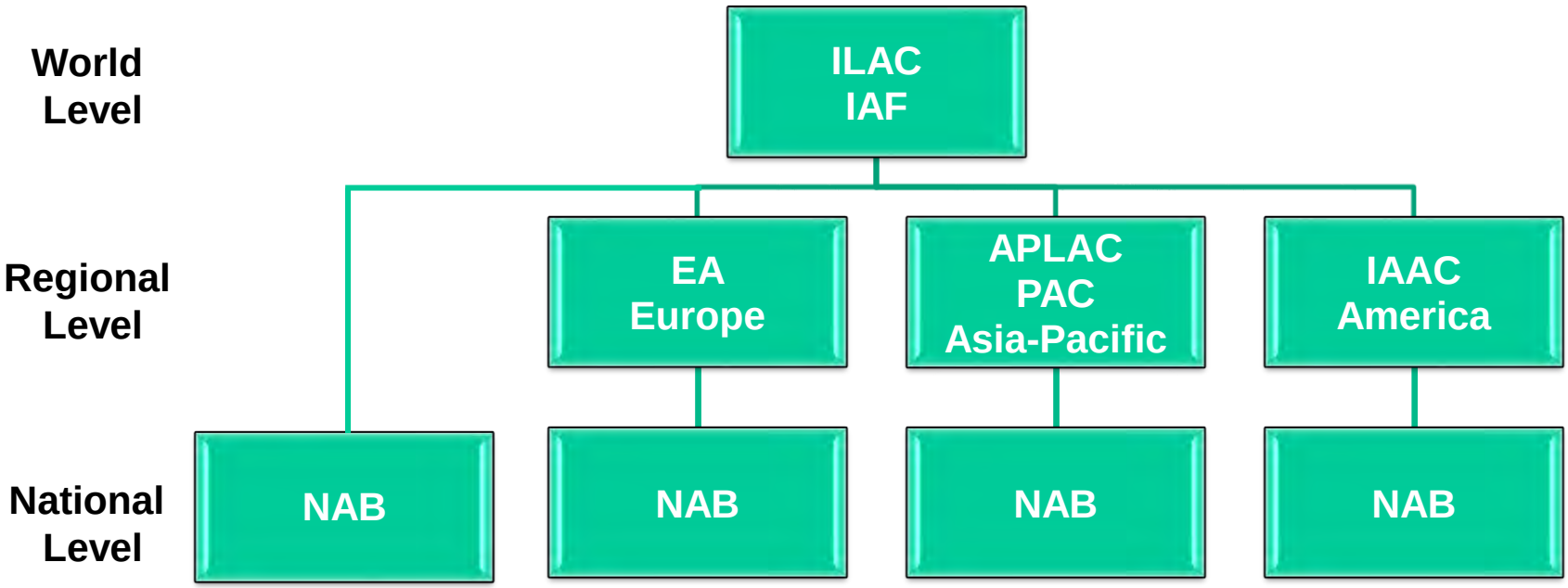
-Increasing Credibility of the Lab

-Increasing competitiveness of the lab

-Ensuring Lab Quality and Competency

Accreditation Concepts

Co-operation in Accreditation



ISO 17025:2017

Third Module

ISO/IEC 17025:2017

ISO/CASCO

Secretariat: ISO

Voting begins on:
2017-08-14

Voting terminates on:
2017-10-09

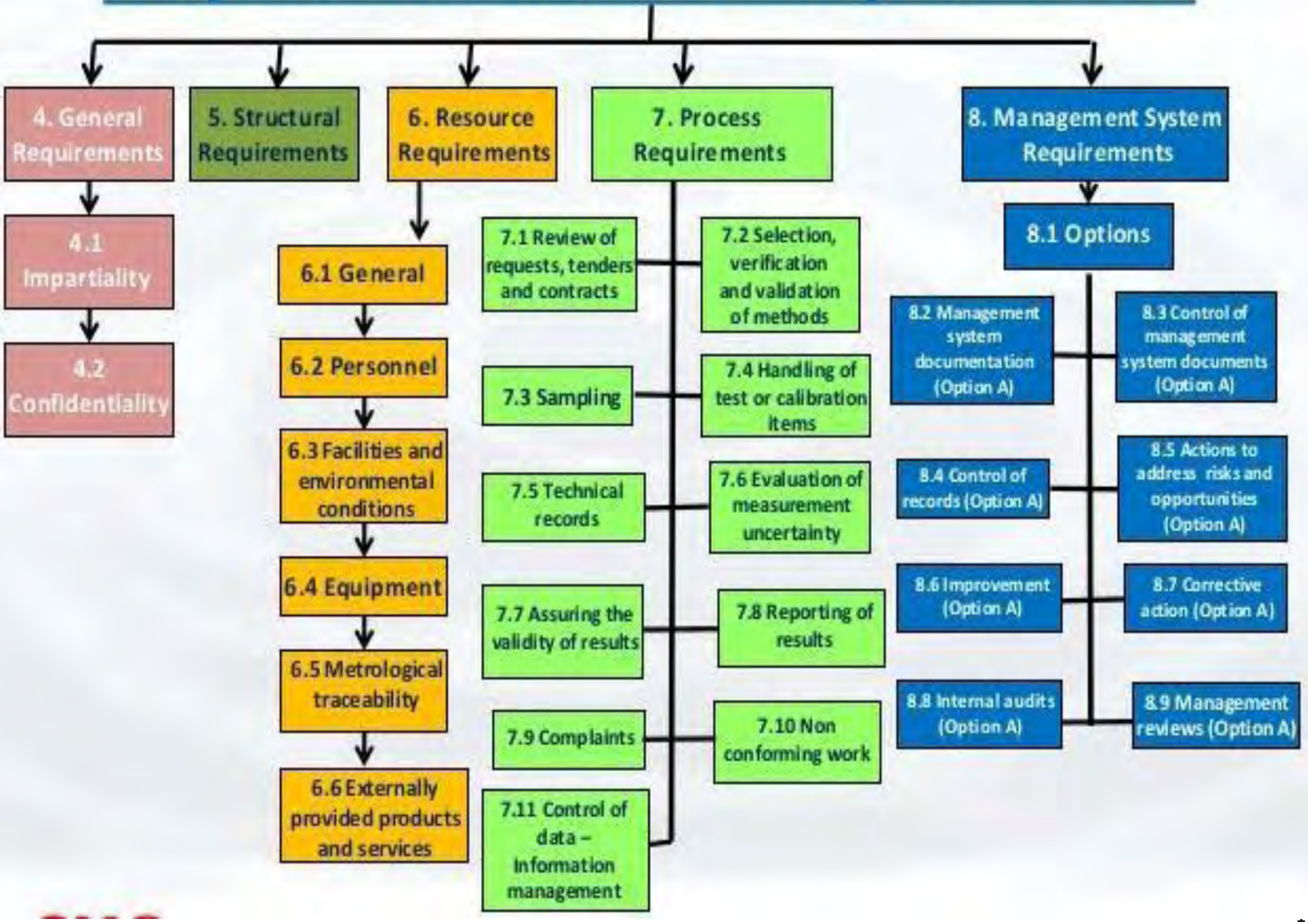
General requirements for the competence of testing and calibration laboratories

Exigences générales concernant la compétence des laboratoires d'étalonnages et d'essais

Previous versions

- **ISO/IEC Guide 25/1990 , EN 45001**
- **ISO/IEC 17025:1999**
- **ISO/IEC 17025:2005**

ISO/IEC 17025: 2017 Requirements



ISO/IEC 17025:2017

Scope

This document specifies the general requirements for the :

A- competence.

B- impartiality

C- consistent operation of laboratories

This document is applicable to all organizations performing laboratory activities, regardless of the number of personnel

ISO/IEC 17025:2017

Normative References

A- ISO/IEC Guide 99,

B- International vocabulary of metrology — Basic and general concepts and associated terms (VIM)

C- ISO/IEC 17000, Conformity assessment — Vocabulary and general principles

ISO/IEC 17025:2017

Terms&defenitions

- For the purposes of this document, the terms and definitions given in ISO/IEC Guide 99 and ISO/IEC 17000 and the following apply.

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

A- ISO Online browsing platform: available at

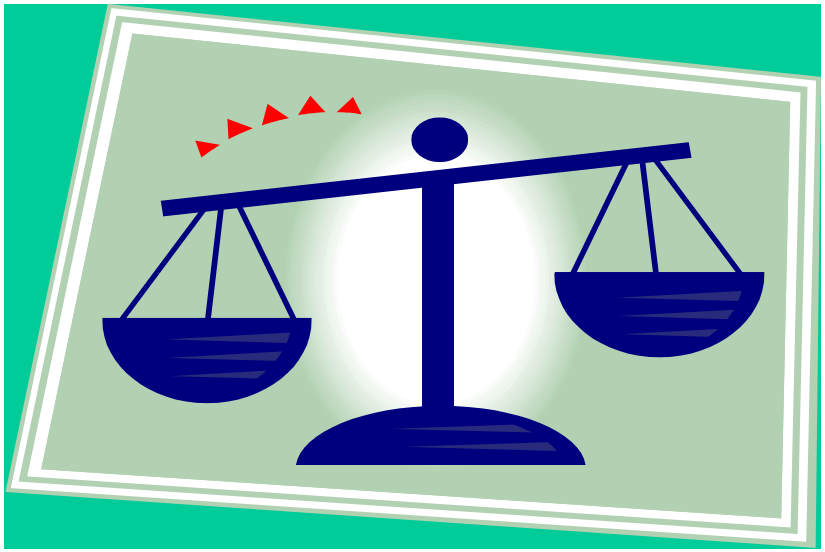
https://www.iso.org/obp.

B- IEC Electropedia: available at http://www.electropedia.org

General requirements

4.1 Impartiality (5 Sub clauses)

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 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 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:

4.1 Impartiality

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 Sub clauses)

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.

4.2.1 The laboratory shall inform the customer in advance, of the information it intends to place in the public domain.

4.2 Confidentiality

4.2.1 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 Confidentiality

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.

4.2 Confidentiality

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, except as required by law.

5- Structural requirements

5.1 The laboratory or the organization of which it is part shall be an entity that can be held legally responsible for its laboratory activities (Non Governmental)

5- Structural requirements

5.2 The laboratory shall identify management that has overall responsibility for the laboratory.

5.3 The laboratory shall 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 It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of:

5- Structural requirements

A-This International Standard,

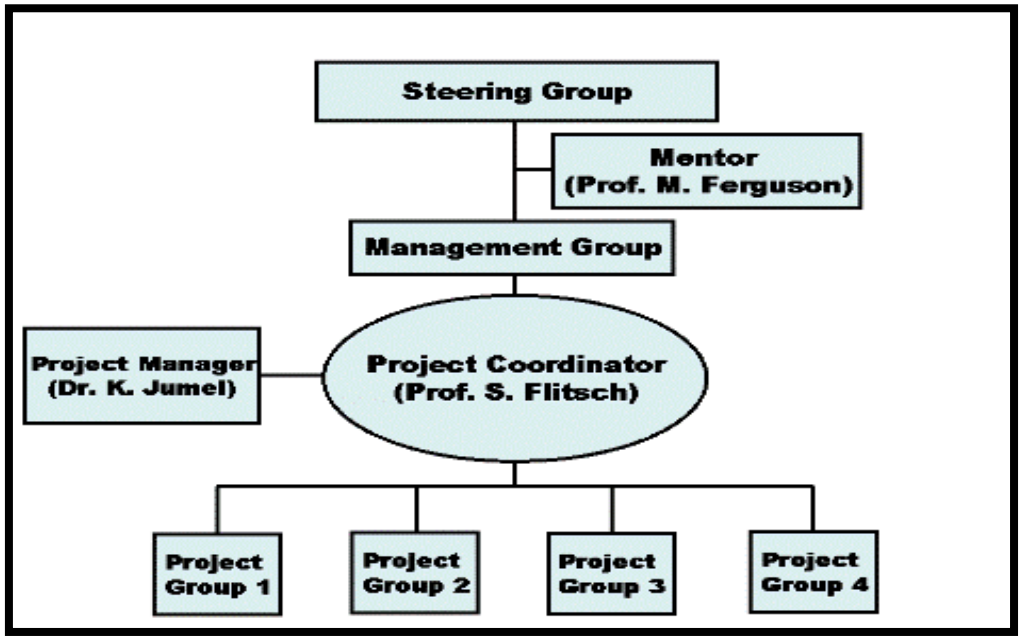
B- Regulatory authorities (NEW)

C- Needs of The Customer,

D- organizations providing recognition

5- Structural requirements

5.5 The laboratory shall



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

5- Structural requirements

5.5 The laboratory shall

b. specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the results of lab activities;

(JDC)

5- Structural requirements

5.7 a- Appropriate communication processes

b- the integrity of the management system is maintained when changes to the management

System are planned and implemented (NEW)

Resource requirements

6.1 General

The laboratory shall have available the :

A- personnel.

B- facilities

C- equipment

D- systems and support services necessary

Why ? **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:

A- act impartially, (NEW)

B- be competent .

C- work in accordance with the laboratory's management system

Resource requirements

6.2 Personnel

6.2.2 The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for :

A- education,

B- qualification

C- training

D- technical knowledge,

E- skills and experience.

Resource requirements

6.2 Personnel

6.2.3 The lab shall ensure the competence of its personnel who:

- **Operate Specific Equipment,**
- **Perform Tests/Calibrations,**
- **Evaluate Results,**
- **Sign Test/Calibration Certificates**
- **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

6.2.6 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(NEW)

B- analysis of results, including statements of conformity or opinions and interpretations (NEW)

C- report, review and authorization of results

6.3 Facilities & 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.

6.3 Facilities & Environmental conditions

Due attention shall be paid, for example,

- **Dust,**
- **Radiation,**
- **Electrical Supply,**
- **Temperature and Humidity,**
- **Electromagnetic disturbances,**
- **Sound And Vibration Levels.**
- **Microbial contamination**

6.3 Facilities & Environmental conditions

6.3.2 The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented.

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6.3 Facilities & Environmental conditions

6.3.3 The laboratory shall:

- **Monitor,**
- **Control,**
- **Record.**

environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results

6.3 Facilities & Environmental conditions

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

Resource requirements

6.4 Equipment

6.4.1 The laboratory shall have access to equipment that is required for the correct performance of laboratory activities and that can influence the results (NEW)

A- measuring instruments

B- software

C- measurement standards

D- reference materials (NEW ISO 17034)

E- reference data,

F- reagents , consumables or auxiliary apparatus

6.4 Equipment

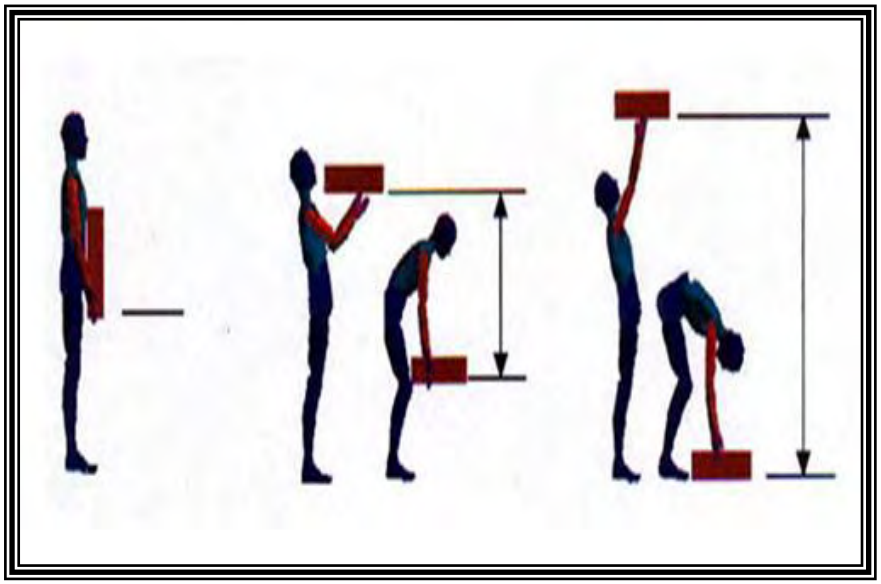
6.4.3 Procedures are required for:

A- Safe Handling,

B- Transport,

C- Storage,

D- Use & Maintenance.



of equipment in order to ensure proper functioning and to prevent contamination or deterioration.

6.4 Equipment

6.4.4 The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service (New).

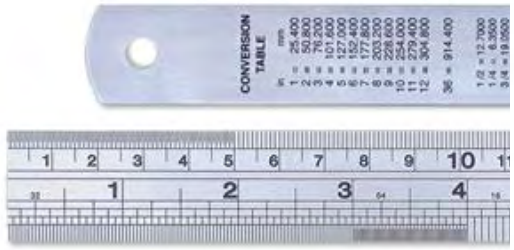
6.4.5 The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.

6.4 Equipment

6.4.6 Measuring equipment shall be calibrated when:

A- the measurement accuracy or measurement uncertainty affects the validity of the reported results.

B- calibration of the equipment is required to establish the metrological traceability of the reported results.



6.4 Equipment

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

A- those used for the direct measurement of the measurement, e.g. use of a balance to perform a mass measurement.

B- those used to make corrections to the measured value, e.g. temperature measurements.

C- those used to obtain a measurement result calculated from multiple quantities.

6.4 Equipment

6.4.7 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 Equipment

6.4.10 intermediate checks procedure

6.4.11 When 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 the following:

a) Equipment identification,

b) Manufacturer's name and serial number.

c) Equipment checks (complies, capability and calibration) – verification.

d) Current location, where appropriate;

6.4 Equipment

6.4.13 Records shall be retained for equipment the following:

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

6.4 Equipment

6.4.13 Records shall be retained for equipment the following:

g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment

h) details of any damage, malfunction, modification to, or repair of, the equipment

6.5 Metrological traceability

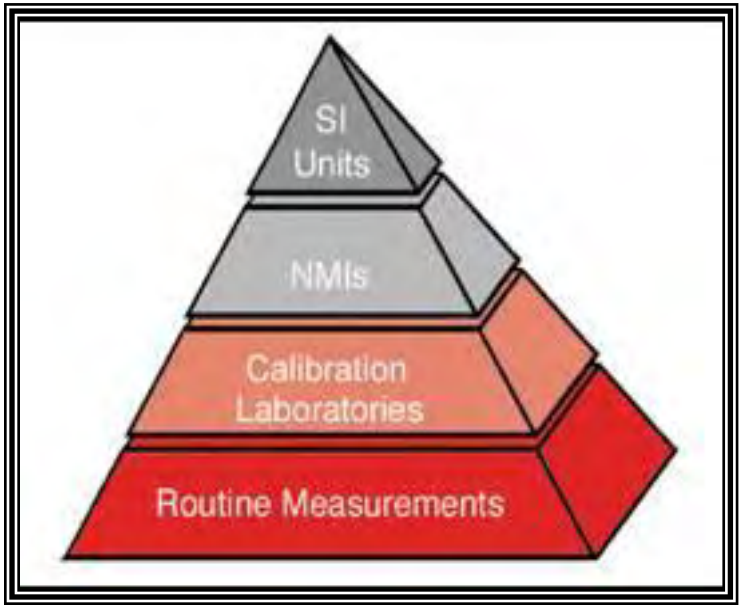
General

ALL equipment (even environmental conditions ones) shall be calibrated before being put into service.

The lab shall have procedures for the calibration of its 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.



6.5 Metrological traceability

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

A- calibration provided by a competent laboratory (ISO 17025).

B- certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI (ISO 17034).

C- direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards

6.5 Metrological traceability

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

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:

6.6 Externally provided 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

6.6 Externally provided products/services

6.6.1 Products can include, for example:

A- measurement standards and equipment,

B- auxiliary equipment.

C- consumable materials and reference materials

6.6.1 Services can include, for example:

D- calibration services, sampling services,

E- testing services,

F- facility and equipment maintenance services,

G- proficiency testing services

H- assessment and auditing services.

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.

6.6 Externally provided products and services

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

C- ensuring that externally provided products and services conform to the laboratory's established requirements,

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

6.6 Externally provided products and services

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

7.1 Review of requests, tenders and contracts

7.1.1 The laboratory shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that :

:

a) the Customer Requirements, the Methods to be Used are:

- **Defined,**
- **Documented,**
- **Understood.**

7.1 Review of requests, tenders and contracts

7.1.1 The procedures shall ensure that:

C- where external providers are used:

- **the requirements of 6.6 are applied ,**
- **the laboratory advises the customer of the specific laboratory activities to be performed by the external provider ,**
- **gains the customer's approval;.**

7.1 Review of requests, tenders and contracts

7.1.1 The procedures shall ensure that:

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

- 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

7.1.2 The laboratory shall inform the customer when the method requested by the customer is considered to be inappropriate or out of date

7.1.3 When 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 (NEW)

7.1 Review of requests, tenders and contracts

7.1.4 Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results (NEW)

7.1 Review of requests, tenders and contracts

7.1.5 The customer shall be informed of any deviation from the contract.

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

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1 The laboratory shall use appropriate methods and procedures for all laboratory activities which including:

- **Sampling,**
- **Handling and Transport,**
- **Storage and Preparation of UUT's,**
- **Statistical Techniques For Analysis,**
- **Estimation of The Measurement Uncertainty.**

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.2 instructions, standards, manuals and reference data shall be:

- **kept up to date ,**
- **Made readily available to personnel.**

7.2 Selection, verification and validation of methods

7.2.1.3 Selection and verification of methods

- **The laboratory shall use methods that meet Customer needs.**
- **International/national standards are preferable.**
- **Latest valid edition of a standard shall be insured.**

7.2 Selection, verification and validation of methods

7.2.1.4 When the customer does not specify the method, the lab shall use:

International/national standards,

or

Reputable technical organizations,

or

In relevant scientific texts or journals,

or

As specified by the manufacturer of the equipment.

7.2 Selection, verification and validation of methods

7.2.1.5 Selection and verification of methods (NEW)

- **The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance International/national standards are preferable.**
- **Records of the verification shall be retained.**
- **If the method is revised by the issuing body, verification shall be repeated**

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.6 When method development is required, this shall be :

- **a planned activity ,**
- **be assigned to competent personnel equipped with adequate resources,**
- **periodic review shall be carried out to confirm that the needs of the customer are still being fulfilled,**
- **Any modifications to the development plan shall be approved and authorized,……..(NEW)**

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.7 Deviation from test/calibration methods shall occur only if the deviation:

- **Has been documented,**
- **Technically justified,**
- **Authorized,**
- **Accepted by the customer (in advanced in contract)**

7.2 Selection, verification and validation of methods

7.2.2 Validation of methods

7.2.2 The laboratory shall validate:

- **Non-standard methods,**
- **Lab Developed method**
- **Standard methods used outside their intended scope.**

The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.

7.2 Selection, verification and validation of methods

Validation can include procedures for sampling, handling and transportation of test or calibration items

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 CRM.

B- systematic assessment of the factors influencing the result

C- testing method robustness through variation of controlled parameters

D- comparison of results achieved with other validated methods;

E- interlaboratory comparisons

F- evaluation of measurement uncertainty of the results

7.2 Selection, verification and validation of methods

7.2.2 Validation of methods

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 Non-standard methods,

7.2 Selection, verification and validation of methods

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

Performance characteristics can include, but are not limited to:

A- measurement range, accuracy.

B- measurement uncertainty of the results

C- limit of detection, limit of quantification, selectivity of the method

D- linearity,

E- repeatability or reproducibility, robustness

7.2 Selection, verification and validation of methods

7.2.2 Validation of methods

7.2.2.4 laboratory shall 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

Process requirements

7.3 Sampling

7.3.1 The lab shall have a sampling plan and method for

Substances

Materials

Products

- Plans and method shall be available at sampling locations.
- Sampling plans shall be based on appropriate statistical methods.
- The sampling method shall address the factors to be controlled to ensure the validity of subsequent testing or calibration results.

7.3 Sampling

7.3.3 The Lab shall retain records of sampling data that forms part of the testing or calibration, These records shall include:

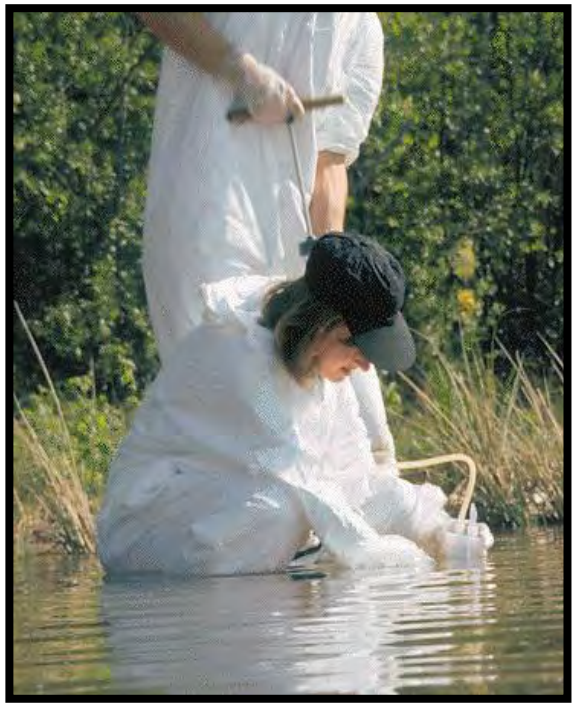
a) reference to the sampling method

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;



7.3 Sampling

7.3.3 The Lab shall retain records of sampling data that forms part of the testing or calibration, These records shall include:

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.

7.4 Handling of test items

7.4.1 The lab shall have procedures for:

A-Transportation,

B-Receipt,

C- Handling,

D-Protection,

E-Storage,

F-Retention/disposal.

7.4 Handling of test items

7.4.1 Precautions shall be taken to :

A- avoid deterioration,

B- contamination,

C- loss or damage to the item during handling, transporting, storing/waiting

D- preparation for testing or calibration,

E- Handling instructions provided with the item shall be followed

Handling instructions provided with the item shall be followed.

7.4 Handling of test items

7.4.3 Departures from normal or specified conditions as described in the test/calibration method, shall be recorded.

When:

A- There is doubt as to the suitability of the sample,

B- sample does not conform to the description provided,

C- No sufficient details for the test/calibration required,

The lab shall consult the customer for further instructions before proceeding and shall record the discussion.

7.5 Technical Records

7.5.1 The laboratory shall ensure that technical records for each laboratory activity contain :

$$\sigma = \sqrt{\frac{1}{N}\sum_{i=1}^{N}(x_i - \overline{x})^2}$$

A- the results (raw data),

B- report and sufficient information to facilitate,

C- factors affecting the measurement of uncertainty

D- enable the repetition of the laboratory activity under conditions as close as possible to the original

7.5 Technical Records

7.5.1 Observations, Data and Calculations shall be recorded at the time they are made.

7.5 Technical Records

7.5.2 The laboratory shall ensure that amendments to technical records:

A- can be tracked to previous versions or to original observations.

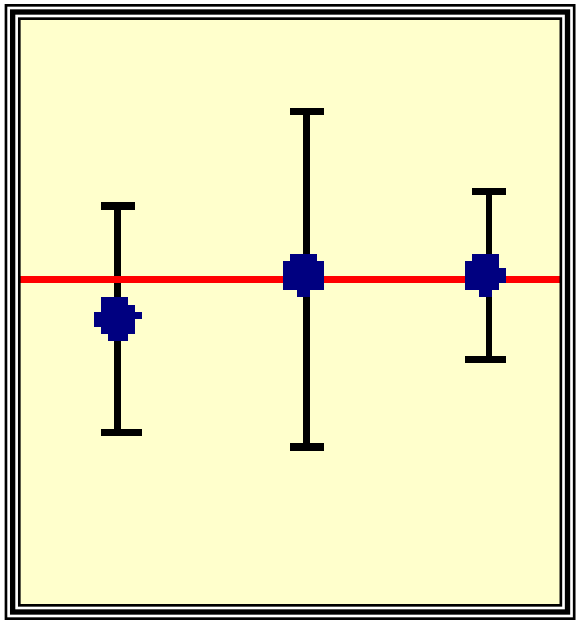
B- Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.,

7.6 Evaluation of measurement uncertainty

7.6.2 A laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations.

7.7 Ensuring the validity of results

7.7.1 (In lab) The laboratory shall have a 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



7.7 Ensuring the validity of results

7.7.2 (Out of lab) The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed.

7.7 Ensuring the validity of results

7.7.2 shall include, but not be limited to, either or both of the following:

a) participation in proficiency testing;

b) Participation in interlaboratory comparisons other than proficiency testing

Clause 7:
Process Requirements

7.8 Reporting of results

(8 sub clauses)

5.10 Reporting of results

(old version)

7.8 Reporting of results

7.8.1 General:

7.8.1.1 The results shall be reviewed and authorized prior to release,

7.8.1.2 The results shall be provided accurately, clearly, unambiguously and objectively, and report can be classifies to:

A- test report calibration certificate

B- calibration certificate ,

C- report of sampling

7.8 Reporting of results

7.8.1 General:

7.8.1.2 and shall include:

A- all the information agreed with the customer and necessary for the interpretation of the results.

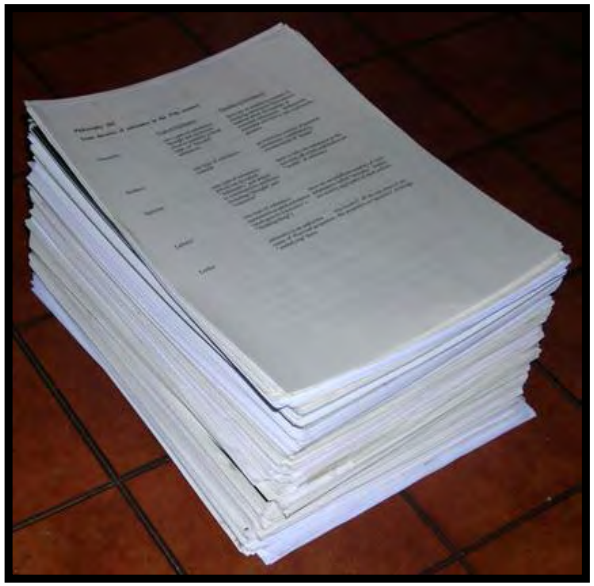
B- all information required by the method used,

- **All issued reports shall be retained as technical records**
- **Reports can be issued as hard copies or by electronic means**

7.8 Reporting of results

7.8.1 General:

7.8.1.3 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 Reporting of results

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

7.8.2.1 Each report shall include at least the following information:

A- a title (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, including when performed at a customer facility or at sites away from the laboratory’s permanent facilities, or in associated temporary or mobile facilities;

D- unique identification and a clear identification of the end;

7.8 Reporting of results

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

7.8.2.1 Each report shall include at least the following information

E- the name and contact information of the customer.

F- identification of the method used

G- a description, unambiguous identification, and, when necessary, the condition of the item;

H- the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results

7.8 Reporting of results

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

7.8.2.1 Each report shall include at least the following information

I- the date(s) of performance of the laboratory activity.

J- the date of issue of the report.

K- reference to the sampling plan.

L- a statement to the effect that the results relate only to the items tested, calibrated or sampled.

7.8 Reporting of results

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

7.8.2.1 Each report shall include at least the following information

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

- Including a statement specifying that the report shall not be reproduced except in full without approval of the laboratory can provide assurance that parts of a report are not taken out of context

7.8 Reporting of results

7.8.2.2 The laboratory shall be responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer shall be clearly identified. In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received.

7.8 Reporting of results

7.8.3 Specific requirements for test reports

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

A- information on specific test conditions, such as environmental conditions

B- where relevant, a statement of conformity with requirements or specifications

7.8 Reporting of results

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

C-where applicable, the measurement uncertainty presented in the same unit as that of the measured or in a term relative to the measured (e.g. percent) 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**

7.8 Reporting of results

7.8.3 Specific requirements for test reports

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

D- where appropriate, opinions and interpretations

E- additional information that 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

7.8 Reporting of results

7.8.4 Specific requirements for Calibration reports

7.8.4.1 In addition to the requirements listed in 7.8.2, test reports shall, include the following:

A- the measurement uncertainty of the measurement result.

B- the conditions (e.g. environmental).

C- a statement identifying how the measurements are metrological traceable.

D- the results before and after any adjustment or repair, if available.

E- a statement of conformity with requirements or specifications.

F- where appropriate, opinions and interpretations.

7.8 Reporting of results

7.8.4.2 Where the laboratory is responsible for the sampling activity, calibration certificates shall meet the requirements listed in 7.8.5.

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 Reporting of results

7.8.5 Reporting sampling – specific requirements

in 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;

7.8 Reporting of results

7.8.5 Reporting sampling – specific requirements

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

d) a reference to the sampling plan and sampling method;

e) details of any environmental conditions during sampling that affect the interpretation of the results

f) information required to evaluate measurement uncertainty for subsequent testing or calibration

7.8 Reporting of results

7.8.6 Reporting statements of conformity

7.8.6.1 When a statement of conformity to a specification or standard is provided, the laboratory shall 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.

7.8 Reporting of results

7.8.6 Reporting statements of conformity

The laboratory shall report on the statement of conformity, such that the statement clearly identifies:

a) to which results the statement of conformity applies;

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

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

7.8 Reporting of results

7.8.7 Reporting opinions and interpretations

7.8.7.1 When opinions and interpretations are expressed, the laboratory shall ensure that only personnel authorized for the expression of opinions and interpretations release the respective statement. The laboratory shall document the basis upon which the opinions and interpretations have been made.

7.8 Reporting of results

7.8.7 Reporting opinions and interpretations

7.8.7.2 The opinions and interpretations expressed in reports shall be based 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 Reporting of results

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 Reporting of results

7.8.8 Amendments to reports

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.

- Such amendments shall meet all the requirements of this document.

7.8 Reporting of results

7.8.8 Amendments to reports

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 The laboratory shall have a documented process to receive, evaluate and make decisions on Complaints.

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

7.9 Complaints

7.9.2 Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that it is responsible for.

7.9.2 The laboratory shall be responsible for all decisions at all levels of the handling process for complaints.

7.9 Complaints

7.9.3 The process for handling complaints shall include :

a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;

b) tracking and recording complaints, including actions undertaken to resolve them.

c) ensuring that any appropriate action is taken.

7.9 Complaints

7.9.4 The laboratory receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.

7.9.5 Whenever possible, the laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.

7.9 Complaints

7.9.6 The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.

7.9.7 Whenever possible, the laboratory shall give formal notice of the end of the complaint handling to the complainant.

7.10 Control of nonconforming work

7.10.1 The laboratory shall have a procedure that shall be implemented when any aspect of its laboratory activities or results of this work do not conform to :

- its own procedures ;

- 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 Control of nonconforming work

7.10.1 The procedure shall ensure that:

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

b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory.

7.10 Control of nonconforming work

7.10.1 The procedure shall ensure that:

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.

7.10 Control of nonconforming work

7.10.1 The procedure shall ensure that:

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

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

7.10 Control of nonconforming work

7.10.2 The laboratory shall retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f).

7.10.3 Where the evaluation indicates that 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

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

Sample Size = n	A_2	A_3	d_2	D_3	D_4	B_3	B_4
2	1.880	2.659	1.128	--	3.267	--	3.267
3	1.023	1.954	1.693	--	2.574	--	2.568
4	0.729	1.628	2.059	--	2.282	--	2.266
5	0.577	1.427	2.326	--	2.114	--	2.089
6	0.483	1.287	2.534	--	2.004	0.030	1.970
7	0.419	1.182	2.704	0.076	1.924	0.118	1.882
8	0.373	1.099	2.847	0.136	1.864	0.185	1.815
9	0.337	1.032	2.970	0.184	1.816	0.239	1.761
10	0.308	0.975	3.078	0.223	1.777	0.284	1.716
11	0.285	0.927	3.173	0.256	1.744	0.321	1.679
12	0.266	0.886	3.258	0.283	1.717	0.354	1.646
13	0.249	0.850	3.336	0.307	1.693	0.382	1.618
14	0.235	0.817	3.407	0.328	1.672	0.406	1.594
15	0.223	0.789	3.472	0.347	1.653	0.428	1.572
16	0.212	0.763	3.532	0.363	1.637	0.448	1.552
17	0.203	0.739	3.588	0.378	1.622	0.466	1.534
18	0.194	0.718	3.640	0.391	1.608	0.482	1.518
19	0.187	0.698	3.689	0.403	1.597	0.497	1.503
20	0.180	0.680	3.735	0.415	1.585	0.510	1.490
21	0.173	0.663	3.778	0.425	1.575	0.523	1.477
22	0.167	0.647	3.819	0.434	1.566	0.534	1.466
23	0.162	0.633	3.858	0.443	1.557	0.545	1.455
24	0.157	0.619	3.895	0.451	1.548	0.555	1.445
25	0.153	0.606	3.931	0.459	1.541	0.565	1.435

7.11 Control of data and information management

7.11.2 The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction.

7.11 Control of data and information management

7.11.2 Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be :

a) **authorized;**

b) **documented**

c) **validated before implementation**

7.11 Control of data and information management

Note (1) **“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 The laboratory information management system(s) shall:

a) be protected from unauthorized access;

b) be safeguarded against tampering and loss;

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

7.11 Control of data and information management

7.11.3 The laboratory information management system(s) shall:

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

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

7.11 Control of data and information management

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

7.11 Control of data and information management

7.11.5 The laboratory shall ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel.

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

8.1 Options

8.1.1 General:

- The laboratory shall establish, document, implement and maintain a management system
- Lab shall meet the requirements of Clauses 4 to 7
- the laboratory shall implement a management system in accordance with Option A or Option B

Managerial Requirements ISO 17025

8.1.1 Options A

8.1.2 As a minimum, the management system of the laboratory shall address the following :

- **management system documentation (see 8.2);**
- **control of management system documents (see 8.3);**
- **control of records (see 8.4);**
- **actions to address risks and opportunities (see 8.5) (NEW)**
- **improvement (see 8.6);**
- **corrective actions (see 8.7);**
- **internal audits (see 8.8);**
- **management reviews (see 8.9).**

8.1 Options

8.1.3 Option B:

- laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001

8.1 Options

8.1.3 Option B:

- **Meet the requirements of Clauses 4 to 7 (As in option A)**

- **fulfils at least the intent of the management system requirements specified in 8.2 to 8.9.**

References : ISO/IES 17025:2017 – Annex B

8.2 Management System Documentation

8.2.1 Laboratory management shall establish, document, and maintain policies and objectives for the fulfilment of the purposes of this document

8.2 Management System Documentation

8.2.1 Laboratory shall ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization

8.2 Management System Documentation

The quality policy statement may include the following:

a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers.

b) the management's statement of the laboratory's standard of service.

c) the purpose of the management system related to quality (e.g. Equipment, Methods, Staff, Scope off work … etc).

8.2 Management System Documentation

The quality policy statement may include the following:

d) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work;

8.2 Management System Documentation

The quality policy statement mat include the following:

e) the laboratory management's commitment:

- **To comply with this International Standard.**
- **To continually improve the effectiveness of the management system.**

8.2 Management System Documentation

8.2.2 The policies and objectives shall address the competence, impartiality and consistent operation of the laboratory (NEW)

8.2.3 Laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

8.2 Management System Documentation

8.2.4 All documentation, processes, systems, records, related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system.

8.2.5 All personnel involved in Lab activities shall have access to the parts of the MS documentation and related information that are applicable to their responsibilities.

8.3 Control of Management System Documentation

8.3.1 The laboratory shall control the documents that relate to the fulfilment of this document (ISO/IEC 17025:2017)

- **Internally Generated**
- **From External Sources**

8-3 Control of Management System Documentation

8.3.2 The laboratory shall ensure that:

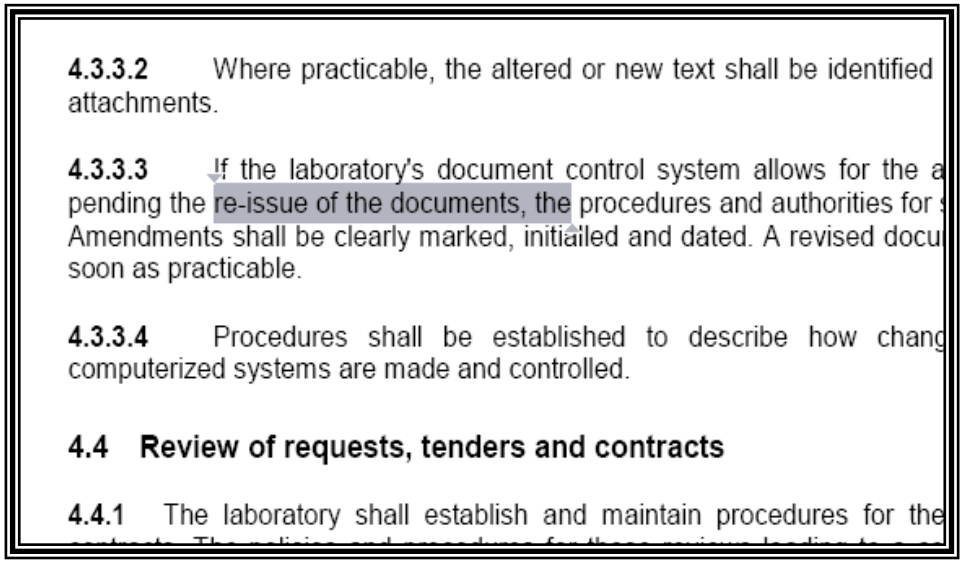
b) documents are periodically reviewed and, where necessary, revised to ensure:

- **Continuing Suitability**
- **Compliance with applicable requirements;**

8-3 Control of Management System Documentation

8.3.2 The laboratory shall ensure that:

C- changes and the current revision status of documents are identified



4.3.3.2 Where practicable, the altered or new text shall be identified attachments.

4.3.3.3 If the laboratory's document control system allows for the a pending the re-issue of the documents, the procedures and authorities for Amendments shall be clearly marked, initialled and dated. A revised docu soon as practicable.

4.3.3.4 Procedures shall be established to describe how chang computerized systems are made and controlled.

4.4 Review of requests, tenders and contracts

4.4.1 The laboratory shall establish and maintain procedures for the

8-3 Control of Management System Documentation

8.3.2 The laboratory shall ensure that:

e- Internal Documents shall be uniquely identified. Such identification shall include:

- **the date of issue**
- **revision identification,**
- **page numbering,**
- **the total number of pages**
- **the issuing authority(ies).**

8-3 Control of Management System Documentation

8.3.2 The laboratory shall ensure that:

f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose

8.4 Control of Records

8.4.1 The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document (ISO/IEC 17025:2017)

8.4 Control of Records

8.4.2 The laboratory shall implement the controls needed for :

1. **Identification,**
2. **Storage,**
3. **Protection,**
4. **Back up,**
5. **Archive,**
6. **Retrieval,**
7. **Retention time,**
8. **Disposal.**

8.4 Control of Records

8.4.2 All records shall be stored and retained in such a way that :

- **They are readily retrievable**
- **Provide a suitable environment to prevent damage and loss.**

Retention times shall be established.

8 Managerial System Requirements

8.5.1 The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:

a) give assurance that the management system achieves its intended results;

b) enhance opportunities to achieve the purpose and objectives of the lab

c) prevent, or reduce, undesired impacts and potential failures in the lab activities;

d) achieve improvement.

Managerial System Requirements

8.5.2 The laboratory shall plan:

a) actions to address these risks and opportunities;

b) how to:

— integrate and implement these actions into its management system;

— evaluate the effectiveness of these actions.

8.5.3 Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.

8.6 Improvement

8.6.1 The laboratory shall identify and select opportunities for improvement and implement any necessary actions

Opportunities for improvement can be identified through :

A- review of the operational procedures

B- the use of the policies

C- overall objectives

D- audit results, corrective actions, management review

E- suggestions from personnel

F- risk assessment (NEW)

G- analysis of data, and proficiency testing results

8.6 Improvement

8.6.2 The lab shall seek (+/-) feedback

The feedback shall be analyzed to improve:

- **The Management System,**
- **Lab Activities,**
- **Customer Service.**

8.7 Corrective Actions

8.7.1 When a nonconformity occurs, the laboratory shall:

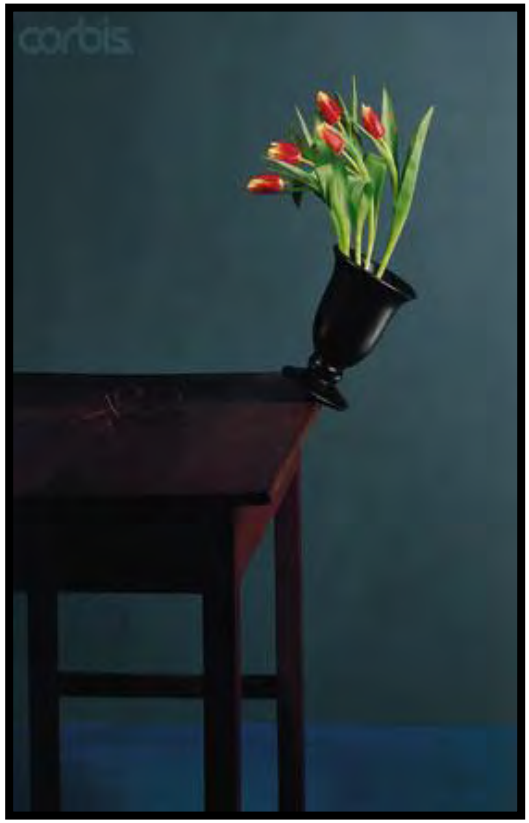
a- react to the nonconformity and, as applicable:

- **take action to control and correct it (NEW)**
- **address the consequences (NEW)**

Managerial Requirements ISO 17025

7.10 Control of nonconforming work

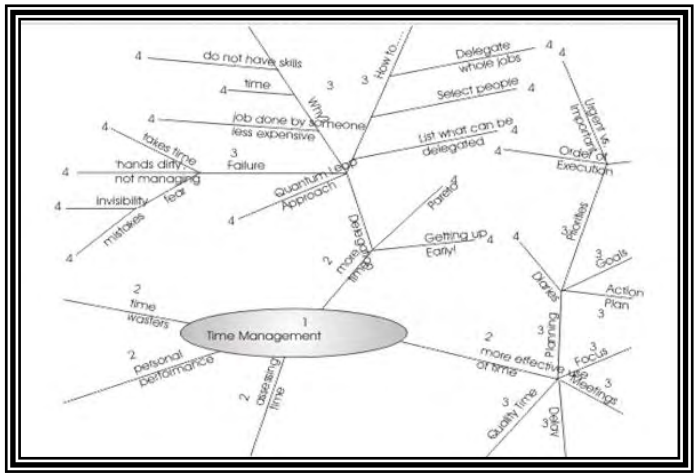
- Correction
- Corrective
- Preventive

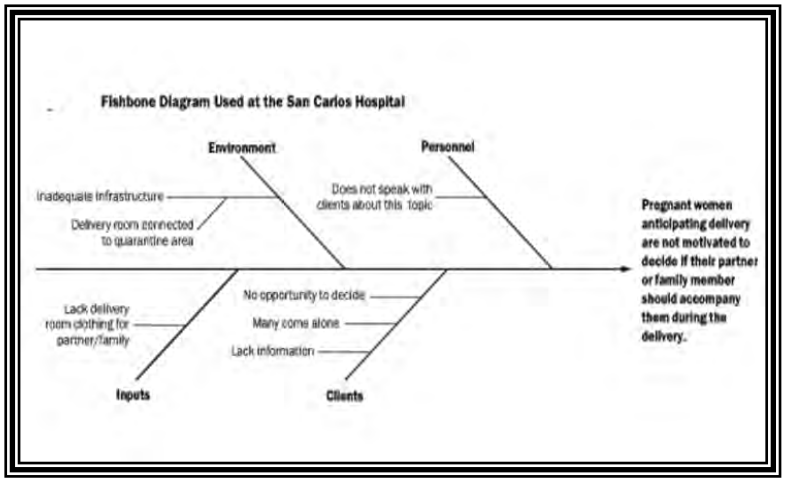


Actions

8.7 Corrective Actions

8.7.1 When a nonconformity occurs, the laboratory shall





b- evaluate the need for action to eliminate the cause(s) of the nonconformity:

- **reviewing and analyzing the nonconformity**
- **determining the causes of the nonconformity**
- **determining if similar nonconformities exist**

8.7 Corrective Actions

8.7.1 When a nonconformity occurs, the laboratory shall

e- update risks and opportunities determined during planning

(NEW)

f- make changes to the management system, if necessary

8.8 Internal Audits

8.8.1 The laboratory shall conduct internal audits at planned intervals to provide information on whether the management system

a- confirms to :

- the laboratory's own requirements for its management system, including the laboratory activities.

- the requirements of this document

b- is effectively implemented and maintained

8.8 Internal Audits

8.8.2 The laboratory shall:

a- plan, establish, implement and maintain an audit programme including :

- **the frequency**
- **methods,**
- **responsibilities,**
- **planning requirements and,**
- **reporting**

8.8 Internal Audits

8.8.2 The laboratory shall:

a- take into consideration (NEW):

- **importance of the laboratory activities concerned**
- **changes affecting the laboratory**
- **the results of previous audits**

8.8 Internal Audits

8.8.2 The laboratory shall:

b- define the audit criteria and scope for each audit (NEW):

8.8 Internal Audits

8.8.2 The laboratory shall:

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

d- implement appropriate correction and corrective actions without undue delay

e- retain records as evidence of the implementation of the audit programme

8.9 Management Reviews

8.9.1 The laboratory management shall review its management system at planned intervals.

- **in order to ensure its:**
- **continuing suitability**
- **adequacy and effectiveness**
- **including the stated policies and objectives related to the fulfilment of this document.**

8.9 Management Reviews

Management review input :

A- changes in internal, external issues that are relevant to the lab (NEW)

b- fulfilment of objectives

c- suitability of policies and procedures

d- status of actions from previous management reviews (NEW)

e- outcome of recent internal audits

f- corrective actions

g- assessments by external bodies

h-changes in the volume and type of the work

i- customer and personnel (NEW) feedback

j- Complaints

k- effectiveness of any implemented improvements

8.9 Management Reviews

Management review input :

l- adequacy of resources

m- results of risk identification (NEW)

n- outcomes of the assurance of the validity of results

o- other relevant factors, such as monitoring activities and training

8.9 Management Reviews

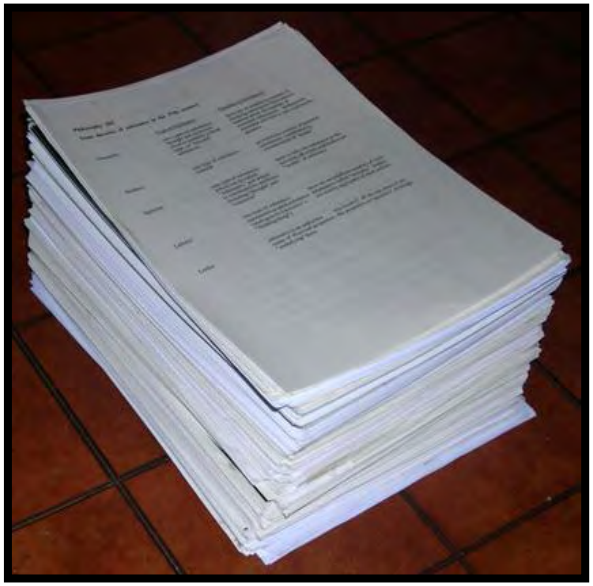
Management review output :

a- the effectiveness of the management system and its processes

b- improvement of the laboratory activities

c- provision of required resources

d- any need for change



9 Final