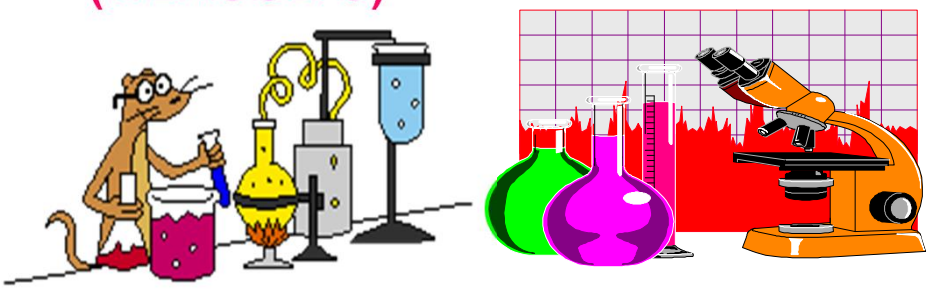
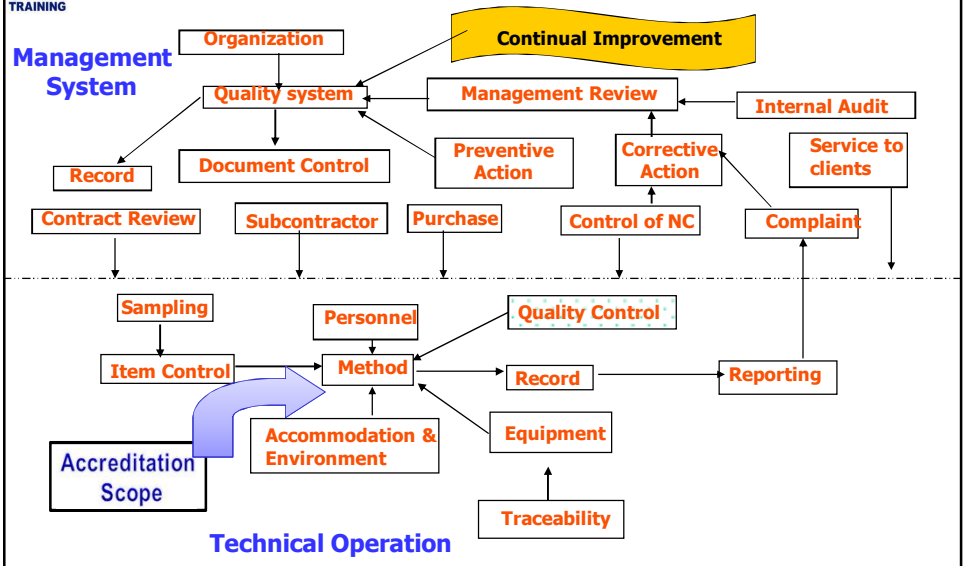
LECTURE 4

THE ELEMENTS OF ISO/IEC 17025 -

TECHNICAL REQUIREMENTS (CLAUSE 5)



ISO 17025 - RELATIONSHIP OF EACH REQUIREMENTS



5.1 - General

5.1.1 Factors contributing to correctness and reliability of test/calibrations :

- human factors (5.2)
- accommodation & environmental conditions (5.3)
- test/calibration methods & method validation (5.4)
- equipment (5.5)
- measurement traceability (5.6)
- sampling (5.7)
- handling of test and calibration items (5.8)

5.1.2 The extent the factors contribute to the total uncertainty of measurement differs considerably between tests/calibrations.
Lab shall take into account of these factors in developing tests / calibration procedures, training and qualification of personnel and in selection and calibration of equipment.

5.2 PERSONNEL

5.2.1 Competency of staff

- operates equipment, perform test/calibration, evaluate results, sign reports.
- shall be qualified by education, training, experience and/or demonstrated skills.

Supervision for staff undergoing training.

Note 1: Personnel certification requirements need to be fulfilled, if required.
Note 2: Opinions and interpretations – personnel have relevant knowledge.

5.2 PERSONNEL

5.2.2 Training needs

ÅManagement shall formulate goals for education, training and skills.

ÅShall have policy and procedures for identifying training needs relevant to present and anticipated tasks of laboratory.

ÅThe effectiveness of training actions shall be evaluated.

5.2 PERSONNEL

5.2.3 Employees

Åshall use personnel employed or under contract.

Åcontract, additional staff - ensure competency and under supervision.

5.2.4 Job descriptions ï

- managerial, technical, key support personnel involved in tests/calibration.
- current.

Åmaintained.

5.2 PERSONNEL

Job Descriptions should define the following responsibilities (at least) :

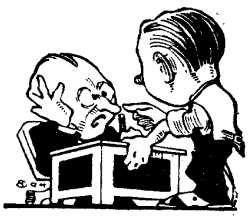
1.	With respect to performing test and/or calibrations *(e.g. performing sampling, conduct tests, operate equipment)*
2.	With respect to the planning of tests/cal and evaluation of results.
3.	For reporting opinions and interpretations
4.	With respect to method modification and development and validation of new methods
5.	Expertise and experience required
6.	Qualifications and training programme
7.	Managerial duties

5.2 – Personnel

5.2.5 Authorization and records

- specific personnel for specific activities.
- maintain records of authorization, competence, educational and professional qualifications, training, skills and experience.
- authorization and competency dated.

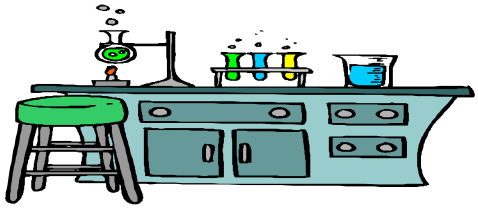
With authority there is responsibility and with responsibility there is accountability.



5.3 - Accommodation and environmental conditions

ÅA laboratory is any place, in a building or in the field where measurements, tests, calibrations or sampling is carried out.

Å The laboratory facilities shall not compromise the quality of tests/calibrations/examinations, QC procedures, safety of personnel, patient care or sample integrity.



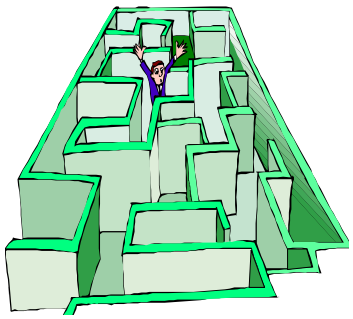
5.3 - Accommodation and environmental conditions

- The laboratory facilities shall facilitate correct performance of the tests / calibrations.
  - Environmental conditions do not invalidate results or adversely affect the required quality of any measurement.
  - Particular care shall be taken when work is carried out at sites.
  - The technical requirements for accommodation and environmental conditions that can effect results shall be **documented.**

5.3 - Accommodation and environmental conditions (cont…)

Accommodation considerations:

- Design and construction materials.
- Space including storage.
- Services and facilities.
- Access, security and safety.
- Area for administrative duties.



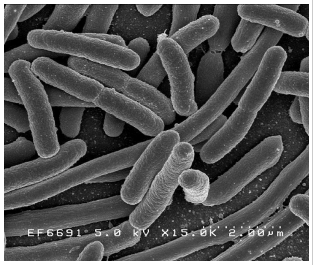
5.3 - Accommodation and environmental conditions (cont…)

Environment considerations:

The environment is the set of conditions that may influence the test and/or measurement results.

- temperature and humidity.
- dust, biological sterility, cleanliness.
- ventilation and fume extracts.
- vibration.
- cross contamination prevention.
- people access and security issues.

- **Good Housekeeping** important.



ACCOMMODATION or HOUSEKEEPING?

Reagents, cleaned glassware, testing activities in one space

Samples storage not appropriate

Waste and solvent stock storage not suitable

5.4 - Test and calibration methods and method validation

5.4.1 General

- Appropriate methods and procedures for all tests / calibrations within scope.
- Available and accessible instructions on the use and operation of all available equipment.
- Deviations from test / calibration methods are documented, technically justified, authorized and accepted by clients.

5.4.2 - Selection of methods

Need to consider:

- Customerûs 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.)

5.4.2 - Selection of methods

Need to consider:

- Preferably methods published in international, regional, or national standards and latest valid edition (unless not possible to do so).
- Laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations.
- Laboratory developed methods shall be validated.
- Customer shall be informed of the method chosen.

5.4.3 - Laboratory developed methods

- introduction of methods shall be a planned activity.
- assigned to qualified personnel equipped with adequate resources.
- methods must be validated.

5.4.4 - Non-standard methods

- to be agreed with customer.
- methods must be validated.

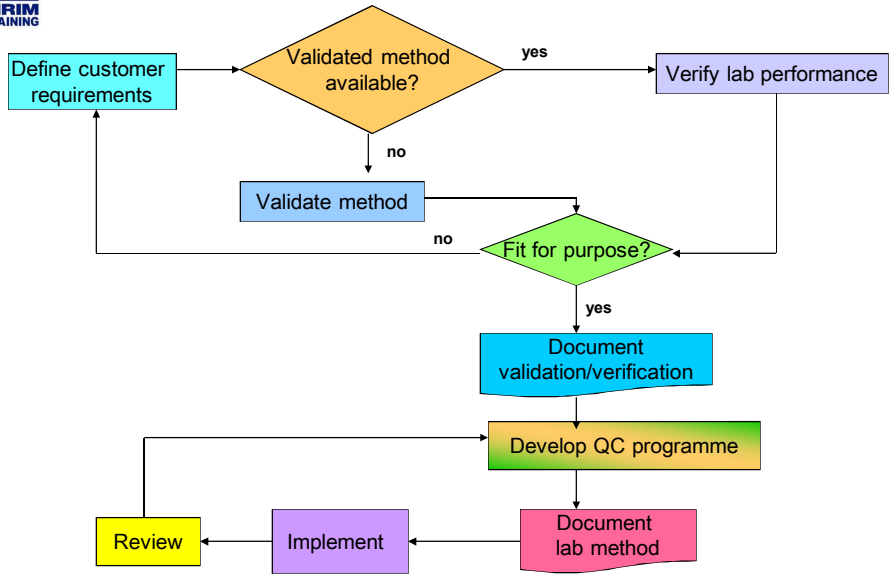
"The more we study this, the clearer it seems that what we have here is a fairly large chunk of concrete."

5.4.5 - Validation of methods

5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specified intended use are fulfilled.

The stated purpose of the validation is to confirm that the methods are fit for intended use.

General Approach To Method Validation



5.4.6 - Estimation of Uncertainty of Measurement

5.4.6.1 ***Calibration lab or testing lab performing own calibration*** traceable to SI units MUST formally estimate uncertainty for all calibrations.

5.4.6.2 ***Testing laboratories*** shall have and must apply procedures for estimating uncertainty of measurement. Where statistical rigor is not possible, laboratories shall at least attempt to identify components of uncertainty and make reasonable estimation.

5.4.6.3 All uncertainty components which are of importance shall be taken into account. Examples:

- reference standards
- reference materials
- methods
- equipment
- environmental conditions
- operator

What is measurement uncertainty?

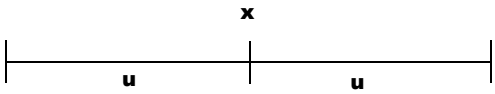
Whenever a measurement is made, the result obtained is only an estimate of the true value of the property being measured.

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

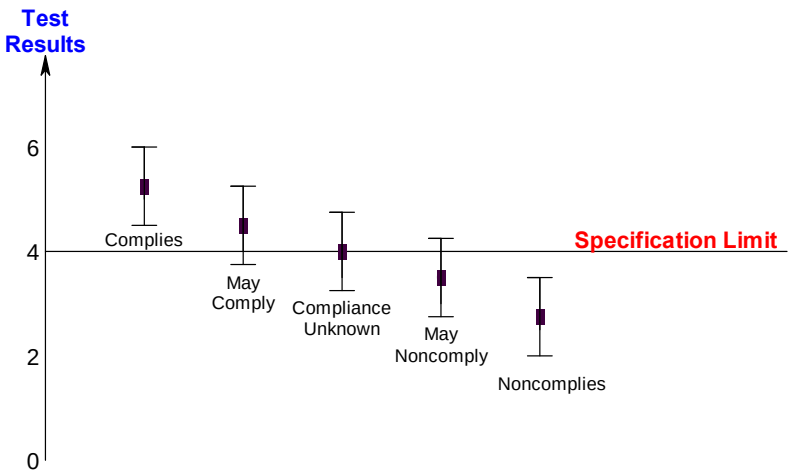
Å A parameter, associated with the result of a measurement, that characterizes the dispersion of the value that could reasonable be attributed to the measurand.



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 ñThe 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).

Compliance With Specification



5.4.7 - Control of Data

5.4.7.1 Calculations and data transfers subject to appropriate checks in a systematic manner.

5.4.7.2 Electronic data:

- Computer software validated
- Procedures for protecting of data
- Computer and automated equipment are maintained to ensure proper functioning

5.5 – Equipment

5.5.1 Laboratory shall be furnished with all equipment required for correct performance of test / calibration. Equipment outside permanent control must meet requirements of standard.

5.5.2 Equipment comply to specification of tests / calibration.
Have calibration program for key values of instruments where these properties have a significant effect on results.

Shall be checked and or calibrated before used.

5.5 – Equipment

5.5.3 Operated by authorised personnel. Up to date instructions readily available for use.

5.5.4 Uniquely identified, when practicable.

5.5.5 Records maintained. (see next slide clause 5.5.5)

5.5.6 Procedures for safe handling, transport, storage, use and planned maintenance to ensure proper functioning and to prevent contamination.

5.5.7 Defective equipment; isolated or labeled out of service. Effect of defect on tests/ calibration examined and ñcontrol of non-conforming workò instituted if necessary.

Clause 5.5.5

5.5.5 Records shall be maintained of each item of equipment and its software significant to the tests. Records shall include at least the following:

(a) identity of the item of equipment and its software.
(b) manufacturerôs name, type identification, serial number or other unique identification.
(c) checks that equipment complies with specification.
(d) current location, where appropriate.
(e) manufacturerôs instructions, if available and reference to their location.
(f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria and due date of next calibration.
(g) maintenance plan, where appropriate, and maintenance carried out to date.
(h) any damage, malfunction, modification or repair of the equipment.

5.5 – Equipment

5.5.8 Calibration status of equipment identified including date when last calibrated and date or expiration criteria when recalibration is due.

5.5.9 Equipment goes outside control of laboratory must be checked before returned to service.

5.5.10 Intermediate checks to maintain confidence in the calibration status shall be carried out according to defined procedure.

5.5.11 Where calibrations give rise to correction factors, laboratory shall have procedures to ensure that copies are correctly updated.

5.5.12 Equipment safeguarded from adjustments that would invalidate results.

5.6 - Measurement traceability

5.6.1 General

All equipment used for tests and /or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of result of test, calibration or sampling shall be **calibrated** before use.

5.6.2 Specific Requirements

5.6.2.1 Calibration and 5.6.2.2 Testing

- established program and procedure for the calibration
- traceable to SI units
- when calibrations that cannot be made traceable to SI units:

- use certified reference materials
- use specified methods agreed by all parties concerned
- participate in Proficiency Testing (where possible)

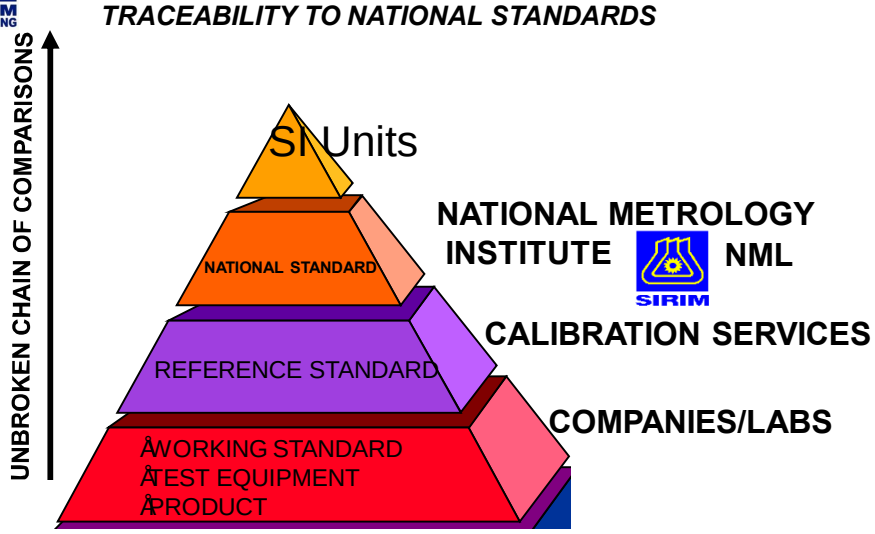
Measurement traceability

TRACEABILITY:

PROPERTY OF THE RESULT OF A MEASUREMENT OR THE VALUE OF A STANDARD WHEREBY IT CAN BE RELATED TO STATED REFERENCES, USUALLY NATIONAL OR INTERNATIONAL STANDARDS, THROUGH AN UNBROKEN CHAIN OF COMPARISONS ALL HAVING STATED UNCERTAINTIES.

VIM 1993-Ref B6

TRACEABILITY TO NATIONAL STANDARDS



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

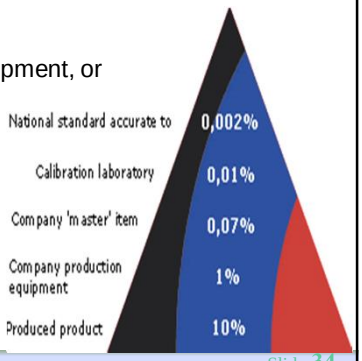
ISO / VIM: Calibration is a set of operations that are establish under specified conditions, the relationship between the values of quantities indicated by an item of test equipment, or values represented by a material measure or a reference material, and the corresponding values realized by standards.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

It may involve:

ÅAssigning corrections to indications in the test equipment, or

ÅAssigning 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

5.6.3 - Reference Standards and Reference Materials

5.6.3.1 Reference Standards

- Program and procedure for calibration of its reference standards. Shall be calibrated by a body that can provide traceability.
- Reference standard only used for calibration only and for no other purpose UNLESS evidence there is assurance of no invalidation.

5.6.3 - Reference Standards and Reference Materials

5.6.3.2 Reference Materials

(A reference material is a material or substance, one or more of whose property values is sufficiently homogenous and well established to be used for the calibration of test equipment, the assessment of a test method or for assigning values to materials.)

Åtraceable to SI units or to certified reference materials.

5.6.3.3 Intermediate checks

ÅIntermediate checks needed to maintain calibration status of reference standards and materials.

5.6.3.4 Transport and storage

ÅProcedure of safe handling transport, storage and use of reference standards and materials to prevent contamination and to protect their integrity.

5.7 - Sampling

5.7.1 Sampling plan and procedures for sampling. Plan and procedures available at location where sampling is undertaken. Sampling plans based on statistical methods (whenever reasonable).

5.7.2 Deviations requested by customer require detailed records.

5.7.3 Procedures for recording relevant data and operations related to sampling. These records shall include:

- # sampling procedure
- # identification of sampler
- # environmental conditions (if relevant)
- # identification of sample location
- # the statistics sampling procedures are based upon (if appropriate)

5.8 - Handling of test and calibration items

5.8.1 Procedures for transport, receipt, handling, protection, storage retention, disposal.

5.8.2 System for uniquely identifying item through out life in the laboratory.

5.8.3 Any deviation recorded; consultation with client.

5.8.4 Procedures and facilities to avoid damage to item (protect integrity / security while in custody).

Record of environmental conditions.

5.9 - Assuring the Quality of Test and Calibration Results

5.9.1 Must have quality control procedures for monitoring of tests and calibration results. Monitoring shall be planned, reviewed and may include, but not limited to the following:

- regular use of certified reference materials and/or internal quality control using secondary reference materials;
- participation in interlaboratory comparison or proficiency testing programmes;
- replicate testing using same or different method;
- retesting or recalibration of retained items;
- correlation of results for different characteristics of an item.

5.9.2 Quality control data shall be analysed and where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported.

5.10 - Reporting the Results

Test reports and calibration certificates are the PRODUCTS of accredited laboratories - regardless of the customer. These products has basic requirements.

5.10.1 Å accurately, clearly, unambiguously, objectively and with any specific instructions in test or calibration methods.

Å results reporting may be simplified for internal customer or written agreement with the customer .

5.10 Reporting the Results

5.10.2 - Test Reports and Calibration Certificates

Information required:

a) Title e.g. Test Report or Calibration Certificate.
b) Name and Address of Laboratory or location of test if different from address.
c) Unique identification of report on each page and a clear end of report.
d) Name and address of customer.
e) Identification of method used.
f) Description of test/calibration items.
g) Date of receipt of test/calibration items and if critical to validity and application of results, date of performance of measurement.
h) Reference to the sampling plan used.
i) Results of measurement.
j) Name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test/calibration report.
k) Where relevant, a statement to the effect that results relate to the test items tested/calibrated.

5.10.3 - Test Reports

5.10.3.1 Additional information required where necessary for interpretation :

a) deviations from, additions to, or exclusions from test method, and information on specific test conditions such as environmental.

b) where relevant, a statement of compliance/non-compliance with requirements.

c) where applicable, a statement on the estimated uncertainty of measurement.

d) where appropriate and needed, opinions and interpretations.

e) additional information require by specific methods and customers.

5.10.3.2 In addition sampling details shall be reported where necessary for interpretation of results.

Sampling date, sample identification, location of sampling, sampling plan, environmental conditions, any deviations from sampling specification.

5.10.4 - Calibration Certificates

5.10.4.1 Additional information required where necessary for interpretation:

a) conditions under which the calibrations are made.
b) uncertainty of measurement and/or statement on compliance with an identified metrological specification or clauses thereof.
c) evidence that measurements are traceable.

5.10.4.2 Certificate shall only relate to quantities and the results of functional tests. A compliance statement shall identify the clause of specification. If compliance statement omits measurement results, the lab must keep record of results. Compliance statement shall take into account of the uncertainty of measurement.

5.10.4.3 Calibration results before and after adjustment or repair, if available, shall be reported.

5.10.4.4 Certificate shall not contain any recommendation on calibration interval, except agreed by customer or superseded by regulations.

5.10.5 OPINIONS AND INTERPRETATIONS

When opinions and interpretations are included, the lab shall document upon which the opinions and interpretations are made.

Opinions and interpretations shall be clearly marked.

5.10.6 Testing and Calibration Results obtained from Subcontractors

Test report - results by subcontractor be clearly identified.
(The subcontractor shall report the results in writing or electronically).

Calibration certificate - the laboratory performing the work shall issue the calibration certificate to the contracting laboratory.

5.10.7 Electronic transmission of results

In the case of transmission of results by telephone, telex, fax or other electronic or electromagnetic means, the requirements of this International Standard shall be met (see 5.4.7 Control of data).

5.10.8 Format of Reports and Certificates

Design shall accommodate each test and minimize possibility of misunderstanding or misuse.

5.10.9 Amendments to Test Reports and Calibration Certificates

Material amendments to a test report or calibration certificate shall be made only in the form of a further document or data transfer, which includes the statement:
ñSupplement to Test Report (or Calibration Certificate), serial number é (or otherwise identified)ò or an equivalent wording. If issue a complete new report, new document shall be uniquely identified and contain reference to the original it replaces.

Ensuring Good Laboratory Process

- Good laboratory process is followed ï suitable system
- Security
- Audit trail
- Document Management
- The shift from manual to automated process will minimize threat to data integrity:
  - ï Backing up data regularly.
  - ï Controlling access to data via security mechanism.
  - ï Designing user interfaces that prevent the input of valid data.
  - ï Using error detection and correction software when transmitting data.


Thank you
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TRAINING
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