INTERNATIONAL ACCREDITATION SERVICE®

New ISO/IEC 17025:2017 – Update Course

(based on DIS Version)

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ISO/CASCO WG 44 Member

INTERNATIONAL ACCREDITATION SERVICE®

About IAS

1975
IAS established

(5 accreditations)

March 2002

IAS becomes a nonprofit, public benefit corporation

(190 accreditations)

Jan 2003

IAS transition into ICC as wholly owned subsidiary

April 1999-Oct 2000

IAS becomes signatory to APLAC and ILAC for TL/CL/Inspection Agencies

May 2011

IAS achieves IAF/PAC MRA recognition for ISO 17065

(500+ accreditations)

Summer 2013

Continued growth at domestic and international levels

(700+ accreditations)

2015

IAS achieves IAF & PAC MRA recognition for ISO 17021 EMS & QMS

2017

1000+ accreditations worldwide

About IAS

IAS currently accredits over 1000 entities in 36 countries

INTERNATIONAL ACCREDITATION SERVICE®

About IAS - Accreditation Programs

- **Building Department Accreditation**
- **Building Department Service Providers**
- **Calibration Laboratories-ISO/IEC 17025**
- **Curriculum Development**
- **Fabricator Inspection**
- **Field Evaluation Bodies**
- **Fire Prevention and Life Safety Departments**
- **Inspection Agencies-ISO 17020**
- **Management Systems-ISO 17021**
- **Metal Building Systems**
- **Personnel Certification Bodies-ISO 17024**
- **Product Certification Agencies-ISO 17065**
- **Special Inspection Agency**
- **Testing Laboratories –ISO 17025**
- **Training Agencies**

About ISO

International Organization for Standardization

It's all in the name
Because 'International Organization for Standardization' would have different acronyms in different languages (IOS in English, OIN in French for *Organisation internationale de normalisation*), its founders decided to give it the short form ISO.
ISO is derived from the Greek isos (ΙΣΟΣ), meaning equal.
Whatever the country, whatever the language, we are always ISO.

The ISO story began in **1946** when delegates from 25 countries met at the Institute of Civil Engineers in London and decided to create a new international organization 'to facilitate the international coordination and unification of industrial standards'.

On 23 February 1947 the new organization, ISO, officially began operations.

http://www.iso.org/iso/home/about.htm#2012_aboutiso_iso_name-text-Anchor

ISO/CASCO

CASCO is the ISO committee that works on issues relating to conformity assessment. CASCO develops policy and publishes standards related to conformity assessment, it does not perform conformity assessment activities.
Membership to CASCO is open to full and correspondent members.

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ISO/CASCO/WG44

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International Harmonized Stage Codes

STAGE	SUBSTAGE						
				90 Decision Substages			
	00 Registration	20 Start of main action	60 Completion of main action	92 Repeat an earlier phase	93 Repeat current phase	98 Abandon	99 Proceed
00 Preliminary stage	**00.00** Proposal for new project received	**00.20** Proposal for new project under review	**00.60** Close of review			**00.98** Proposal for new project abandoned	**00.99** Approval to ballot proposal for new project
10 Proposal stage	**10.00** Proposal for new project registered	**10.20** New project ballot initiated	**10.60** Close of voting	**10.92** Proposal returned to submitter for further definition		**10.98** New project rejected	**10.99** New project approved
20 Preparatory stage	**20.00** New project registered in TC/SC work programme	**20.20** Working draft (WD) study initiated	**20.60** Close of comment period			**20.98** Project deleted	**20.99** WD approved for registration as CD
30 Committee stage	**30.00** Committee draft (CD) registered	**30.20** CD study/ballot initiated	**30.60** Close of voting/ comment period	**30.92** CD referred back to Working Group		**30.98** Project deleted	**30.99** CD approved for registration as DIS
40 Enquiry stage	**40.00** DIS registered	**40.20** DIS ballot initiated: *5 months*	**40.60** Close of voting	**40.92** Full report circulated: DIS referred back to TC or SC	**40.93** Full report circulated: decision for new DIS ballot	**40.98** Project deleted	**40.99** Full report circulated: DIS approved for registration as FDIS

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International Harmonized Stage Codes

40 Enquiry stage	**40.00** DIS registered	**40.20** DIS ballot initiated: *5 months*	**40.60** Close of voting	**40.92** Full report circulated: DIS referred back to TC or SC	**40.93** Full report circulated: decision for new DIS ballot	**40.98** Project deleted	**40.99** Full report circulated: DIS approved for registration as FDIS
50 Approval stage	**50.00** FDIS registered for formal approval	**50.20** FDIS ballot initiated: *2 months*. Proof sent to secretariat	**50.60** Close of voting. Proof returned by secretariat	**50.92** FDIS referred back to TC or SC		**50.98** Project deleted	**50.99** FDIS approved for publication
60 Publication stage	**60.00** International Standard under publication		**60.60** International Standard published				
90 Review stage		**90.20** International Standard under periodical review	**90.60** Close of review	**90.92** International Standard to be revised	**90.93** International Standard confirmed		**90.99** Withdrawal of International Standard proposed by TC or SC
95 Withdrawal stage		**95.20** Withdrawal ballot initiated	**95.60** Close of voting	**95.92** Decision not to withdraw International Standard			**95.99** Withdrawal of International Standard

International Harmonized Stage Codes

Enquiry stage
The Draft International Standard (DIS) is submitted to ISO Central Secretariat by the committee secretary. It is then circulated to all ISO members who get 3-5 months to vote and comment on it. (The *submission interface* should be used to submit the draft).
The DIS is approved if a two-thirds of the P-members of the TC/SC are in favor and not more than one-quarter of the total number of votes cast are negative
If the DIS is approved the project goes straight to publication. However, the committee leadership can decide to include the FDIS stage if needed.

ISO/IEC 17025:2017

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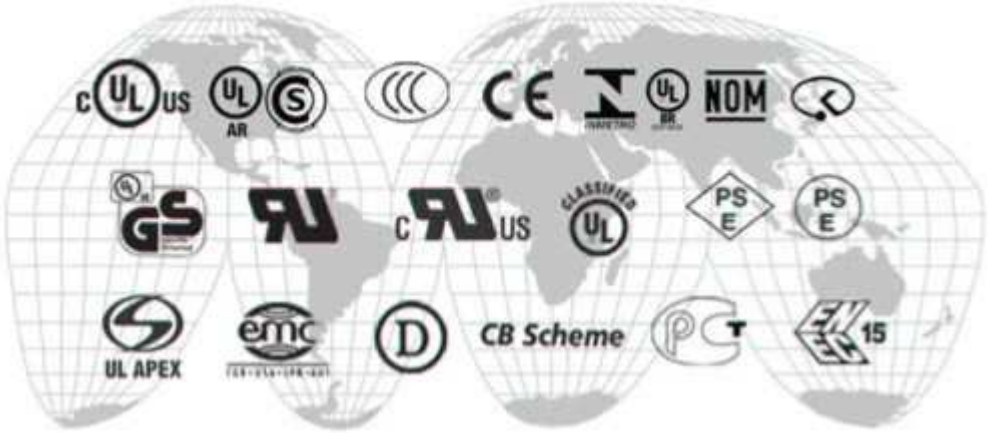
Conformity Assessment

Conformity assessment, is any activity to determine, directly or indirectly, that a process, product, or service meets relevant technical standards and fulfills relevant requirements.



Conformity assessment activities may include:

- **Testing.**
- **Surveillance.**
- **Inspection.**

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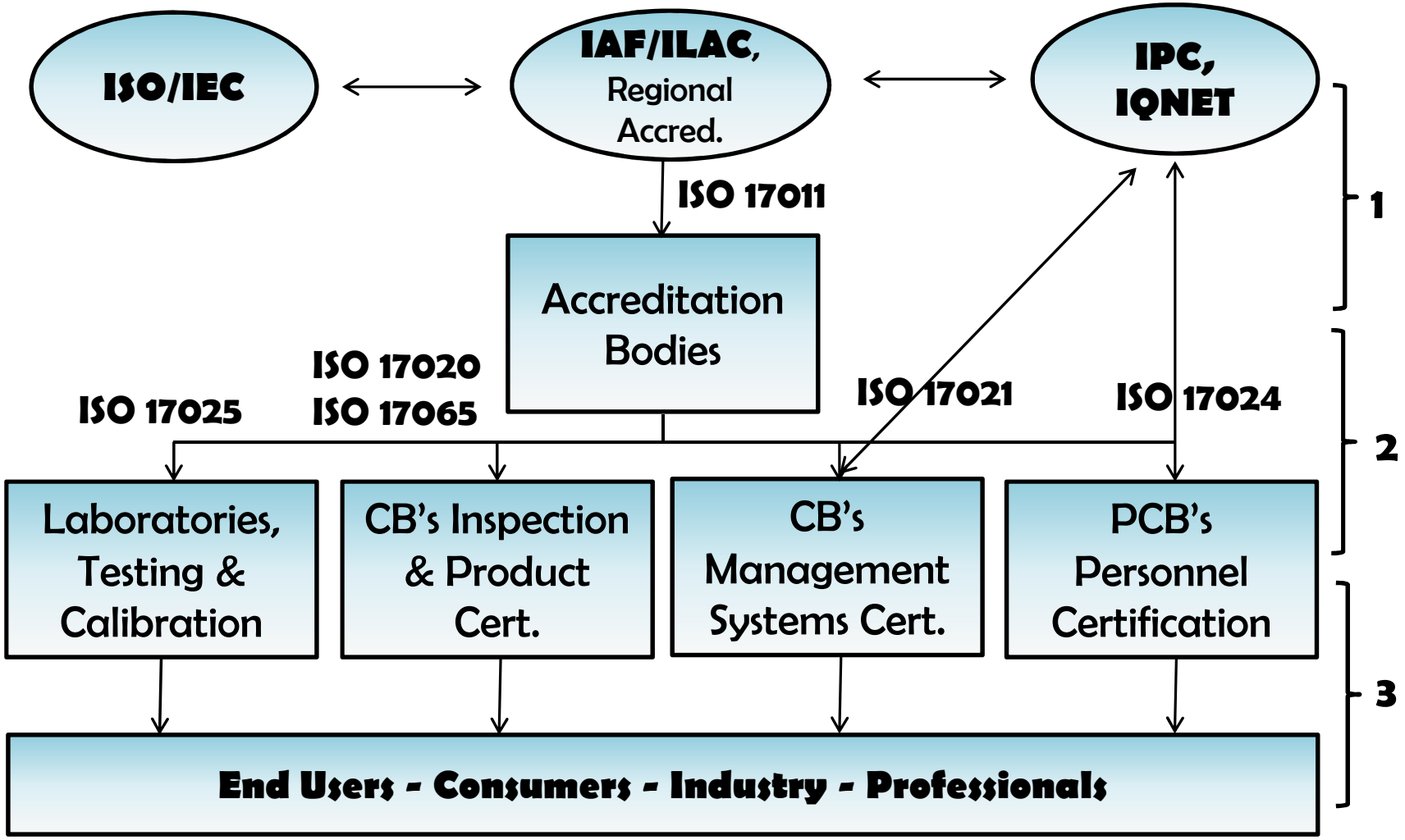
Conformity Assessment Structure



Quality management principles

2008	2015
Customer focus	Customer focus
Leadership	Leadership
Involvement of people	Engagement of people
Process approach	Process approach
System approach to management	
Continual improvement	Improvement
Factual approach to decision making	Evidence-based decision making
Mutually beneficial supplier relationship	Relationship management

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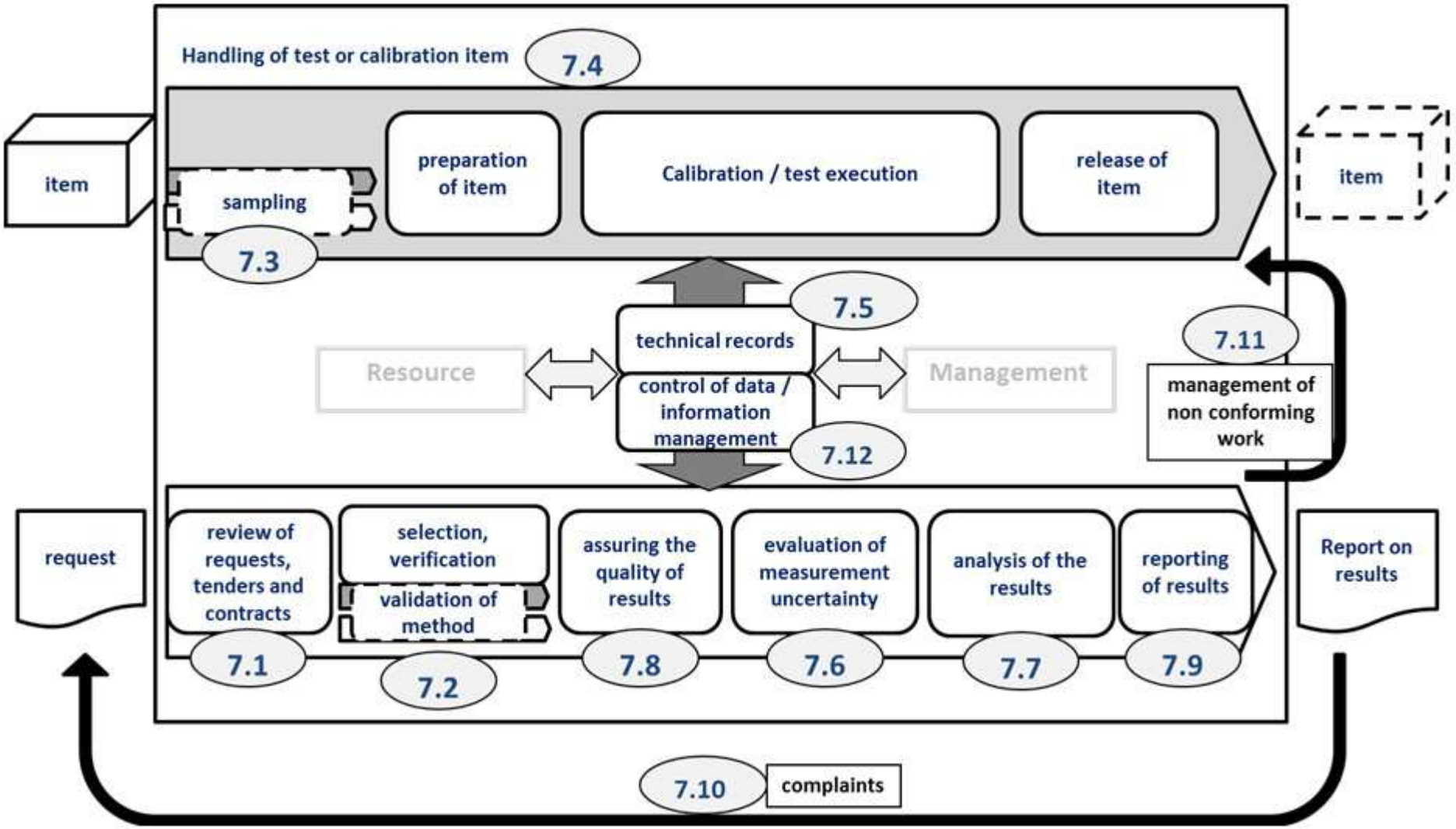
New ISO/IEC 17025 Process Approach



New ISO/IEC 17025 Structure

Version 2005

1. Scope
2. Normative references
3. Terms and definitions
4. **Management requirements**
5. **Technical requirements**

Annex A (informative) Nominal cross-references to ISO 9001:2000
Annex B (informative) Guidelines for establishing applications for specific fields
Bibliography

Version 2017

1. Scope
2. Normative references
3. Terms and definitions
4. **General requirements**
5. **Structural requirements**
6. **Resource requirements**
7. **Process requirements**
8. **Management requirements**

Annex A (informative) Metrological traceability
Annex B (informative) Management system
Bibliography

Changes in the requirements of ISO/IEC 17025

- Usage of term “Laboratory Activities” instead of test/cal
- Should 17025 be explicitly applicable to organizations that perform sampling without testing/cal?

Definitions: laboratory

body that performs one or more of the following activities:

- **calibration**
- **testing**
- **sampling, associated with subsequent calibration and testing**

Changes in the requirements of ISO/IEC 17025

- Dependence vs *Independence* vs Impartiality to be clarified

Definitions impartiality

presence of objectivity

Note 1: Objectivity is understood to mean that conflicts of interest do not exist, or are resolved so as not to adversely influence the activities of the laboratory.

Note 2: Other terms that are useful in conveying the element of impartiality are freedom from conflicts of interest, freedom from bias, freedom from prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment and balance.
[SOURCE: ISO/IEC 17021-1:2015, 3.2]

Changes in the requirements of ISO/IEC 17025

(Obligatory wording, adapted to laboratories)

- The laboratory shall not allow commercial, financial or other pressures to compromise impartiality
- Laboratory activities shall be structured and managed so as to safeguard impartiality
- all personnel of the laboratory, either internal or external, that could influence the conformity assessment activities, shall act impartially

Changes in the requirements of ISO/IEC 17025

Resource Requirements - Externally Provided Products and Services

- Procurement and subcontracting are considered as externally provided services, in conformity with ISO 9001:2015
- No explicit reference to "subcontracting" anymore
- External testing and calibration services are basically treated like external services - summarized in one section.

Therefore:

- **Requirements also for control of the external provider and communication to the customer (acceptance criteria are to be communicated to the customer)**
- **Definition of criteria for reviewing external products and services is needed**

Changes in the requirements of ISO/IEC 17025

Subcontracted and Off-site work

"**The laboratory shall only claim conformity with this International Standard for the range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis**"

"The laboratory shall carry out its activities in such a way as to meet the requirements of this International Standard, its customers, regulatory authorities and organizations providing recognition. The laboratory shall be responsible for 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**."

Conditions

"When the laboratory performs activities at **facilities outside its permanent control**, it shall ensure that the requirements related to facilities and environmental conditions of this International Standard are met."

Changes in the requirements of ISO/IEC 17025

Risk based approach
(I) Actions to address risks and opportunities

Objectives:

- give assurance that the management system can achieve its intended results
- enhance opportunities to achieve purpose and objectives
- prevent, or reduce, undesired impacts and potential failures
- achieve improvement

Actions:

- shall be planned and evaluated
- shall be proportionate to the potential impact
- shall be updated when a nonconformity occurs

Changes in the requirements of ISO/IEC 17025

Risk based approach (II)

Options to Address:

- identifying and avoiding threats,
- taking risk in order to pursue an opportunity,
- eliminating the risk source,
- changing the likelihood or consequences,
- sharing the risk or retaining risk by informed decision

Consequences:

- “preventive measures“ no longer explicitly stated, because prevention is a core task of quality management and risk based approach
- No formalized risk management required
- Expression of measurement uncertainty as conceptual basis for dealing with the risk of a measurement result
- Accreditation: difficult to assess

Changes in the requirements of ISO/IEC 17025

- Risk management requirements

Introduction: This International Standard requires the laboratory to plan and implement actions to address risks and opportunities.

The laboratory shall identify risks to its impartiality

- …risk associated with the decision rule employed (such as false accept and false reject when a statement of conformity is requested)
- actions to address risks (related to MS)

Actions to address risks and opportunities

- Risks and opportunities associated with the laboratory activities
- The laboratory shall plan actions to address these risks and opportunities;

Risk of recurrence of the non-conformities encountered (Corrective Actions)

The inputs to management review shall include: results of risk identification

Changes in the requirements of ISO/IEC 17025

- Not required deputies for lab mgmt. (not possible in one man labs)
- Traceability issues

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

Metrological traceability of measurement results shall be assured through calibrations by laboratories that can demonstrate competence, measurement capability and traceability.

NOTE: Calibration laboratories fulfilling the requirements of this International Standard are considered to be competent.

Changes in the requirements of ISO/IEC 17025

- Internal QC compulsory, PT/ILC optional

Regularly monitor the validity of activities undertaken and the quality of the laboratory output.

a) regular use of reference materials or quality control materials;
b) regular use of alternative metrologically traceable instrumentation;
c) functional check of measuring and testing equipment;
d) use of check or working standards with control charts, where applicable;
e) periodic 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 data by competent laboratory personnel;
j) intralaboratory comparisons;
k) blind test.

Changes in the requirements of ISO/IEC 17025

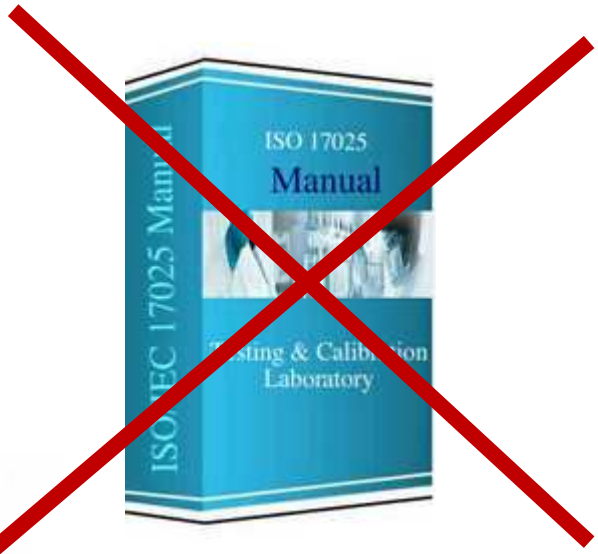
Reporting of results

- Content given by the customer shall be identified
- No "signature" required anymore (but an "identification" of a person authorizing the report)
- Texts on "statement of conformity" now in this section together with "opinions and interpretations"

Changes in the requirements of ISO/IEC 17025

Documentation Requirements

Quality Manual is NOT here anymore



Changes in the requirements of ISO/IEC 17025

Minimum **management system requirements** of the laboratory (Option A):

- management system documentation
- control of management system documents
- control of records
- actions to address risks and opportunities
- improvement
- corrective action
- internal audits
- management review

Changes in the requirements of ISO/IEC 17025

- MS Options (removing Option B is not approved by CPC-Chairman's Policy and Coordination Group)
- Reduce procedures to technical requirements (process approach)
- Reduce records requirements in MS with a more flexible approach
- Need for records and which ones. Uniform terminology policy vs process vs procedure vs documented information

Changes in the requirements of ISO/IEC 17025

Procedures

Personnel (documented process)

The facility and environmental requirements necessary for the performance of the laboratory activities shall be documented.

The laboratory shall have documented processes for appropriate handling, transport, storage, use and planned maintenance of equipment

“Management of nonconforming work” procedure

When intermediate checks are needed to maintain confidence in the performance of the equipment, these checks shall be carried out according to a defined procedure

Changes in the requirements of ISO/IEC 17025

Procedures

When calibration and reference material data include reference values or correction factors, the laboratory shall have procedures to ensure the correction factors and reference values are updated and implemented to meet specified requirements.

The laboratory shall have a procedure for evaluating external providers

The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts.

The laboratory shall use appropriate methods and procedures for all tests and/or calibrations.

Changes in the requirements of ISO/IEC 17025

Procedures

Procedure used for the validation of methods

The laboratory shall have procedures for sampling

Sampling procedure

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

A laboratory performing calibrations, including of its own equipment, shall apply procedures to evaluate the uncertainty of measurement for all calibrations

Changes in the requirements of ISO/IEC 17025

Procedures

A laboratory performing testing activities shall apply procedures for evaluating uncertainty of measurement.

Regularly monitoring the validity of activities undertaken and the quality of the laboratory output.

Complaints (documented process)

Changes in the requirements of ISO/IEC 17025

Records

Records of competence

Records of the ongoing monitoring and periodic review with respect to the facility and environmental requirements

The laboratory … shall establish a documented calibration program

Equipment maintenance

Records of the verification processes to ensure products and service conform to the laboratory established requirements (when subcontracting)

Records of reviews (Contacts/tenders)

Changes in the requirements of ISO/IEC 17025

Records

Records of method(s) verification

Records of the communications with customer (when the method proposed by the customer is considered to be inappropriate or out of date)

Method validation records

Sampling records

Upon receipt of the test or calibration item, abnormalities or deviations from specified conditions shall be recorded.

Changes in the requirements of ISO/IEC 17025

Records

When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.

Technical records - The laboratory shall ensure that records for each laboratory activity contain the report or certificate and sufficient information…

The laboratory shall document the basis upon which the opinions and interpretations have been made.

Records from monitoring the validity of activities undertaken and the quality of the laboratory output

Changes in the requirements of ISO/IEC 17025

Records

All issued test reports or calibration certificates shall be maintained as technical records.

Complaint records

Nonconforming work and actions required records

Internal audit records

Management review records

INTERNATIONAL ACCREDITATION SERVICE®

Common Issues

Usage of logos in Lab Certs

Can we do it?

[redacted] ENGINEERING & MANUFACTURING CO.
(An ISO 9001 : 2008 Company)
All Types of Heavy Industrial Fabrication & Erection
S.No.63,Near Dehu-Alandi,Road,Jyotibanagar, Talawade, Pune-412114
E-mail -[redacted].com , Website-ww[redacted]om

MACHINES CALIBRATION REPORT

CATE	DATE OF CALIBARATIO N	CALIBARATIO N DUE DATE	CALIBRATIO N AGENCY	REMARK
/3772-0	04-09-2011	03-09-2012	UNIVERSAL INSTRUMENT	Satisfactory
/3772-0	04-09-2011	03-09-2012	UNIVERSAL INSTRUMENT	Satisfactory
/3928-0	11-09-2011	10-09-2012	UNIVERSAL INSTRUMENT	Satisfactory
/3928-0			UNIVERSAL	

[redacted] LABORATORIES
(A Govt. Approved Test House)
181, Padmavati Colony (B), New Sanganer Road,
Post-Shyam Nagar, Jaipur - 302 019 Tel. : 0141-2390604
E-mail : jagdamba_lab@yahoo.com
Web. : www.jagdambalab.com

An ISO 9001 : 2000 Certified Lab.

License No. Raj. : 2124, Date : 26.06.2002
(Form 38, Rule 150-E (f) Report of Test of Analysis By Approved Institution

CERTIFICATE OF ANALYSIS

Sample : MANDANA STONE Report No. R-310/2008
Manufactured by M/s. : MANDANA STONE COMPANY ,DHANI KASAR , MANDANA ,KOTA (RAJ.) Recd. Dt. 07/08/2008
Supplied by M/s. : MANDANA STONE COMPANY ,DHANI KASAR , MANDANA ,KOTA (RAJ.) Ref. No. N.S.
Batch No. N.S. D/M N.S. D/E N.S. Batch Size N.S. Sample Qty. 2kg app.
Mfg. Lic. No.

RESULT OF ANALYSIS :

	Description	: Red Coloured masses stone
(A)	Calcium(as Cao)	: 4.27%w/w
	Magnesium (as mgo)	: 1.51%w/w
	Sodium (as Na_2O)	: 0.45%w/w
	Potassium(as K_2O)	: 1.32%w/w

Usage of ISO 9001 logos in Lab Certs

- Can we do it?

ISO/IEC 17021:11 Clause 8.4.2
A certification body shall not permit its marks to be applied to laboratory test, calibration or inspection reports, as such reports are deemed to be products in this context.

ISO/IEC 17021-1:15 clause 8.3.2
A certification body shall not permit its marks to be applied to laboratory test, calibration or inspection reports or certificates.

INTERNATIONAL ACCREDITATION SERVICE®

New ISO 17025

- **Approx. 50,000 accredited labs globally**
- **Next ISO-CASCO-WG44 meeting July 10-14, 2017**
- **New ISO 17025 expected end of 2017**

THANK YOU

Dr. George Anastasopoulos

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