# การปรับเปลี่ยนมาตรฐาน
# ISO/IEC 17025 : 2005

โดย
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# การปรับเปลี่ยนมาตรฐาน ISO/IEC 17025

- รับผิดชอบโดย ISO Committee on Conformity Assessment (ISO-CASCO)
- เวียนขอความเห็นจากประเทศสมาชิกที่เป็น national bodies of both ISO and IEC
- approved as ISO/IEC 17025
- ISO-CASCO – WG 44

# การปรับเปลี่ยนมาตรฐาน ISO/IEC 17025

- WD 1,2,3
- CD 1,2
- ***DIS***
- FDIS
- ISO /IEC 17025 : 2017 ?????

# ผล voting on CD

- agree to the circulation as DIS

| | CD1 | CD 2 |
|---|---|---|
| Yes | 22 | 35 |
| Yes with comments | 44 | 46 |
| No | 10 | 3 |
| Abstain | 10 | 5 |

- positive votes 86% 96%
- ***comments!!!*** ***2606 (598 pages)*** ***2356 (481 pages)***
- **An ISO/CASCO Record?**

# CD 2 to DIS

- ***2356 comments (481 pages)***
- ***20-23 Sep. 2016***
- **output** ***DIS***
- ballot period
  - ***2016-12-29 to 2017-03-22***

# Structure – Draft DIS

1 Scope

2 Normative references

3 Terms and definitions

4 General requirements

5 Structural requirements

6 Resource requirements

7 Process requirements

8 Management requirements

# Structure – Draft DIS

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

# Relationships with 9001

- **Introduction**

  **Laboratories that conform to this International Standard will also operate *generally* in accordance with the principles of ISO 9001.**

# Introduction

"**shall**" indicates a requirement;

"**should**" indicates a recommendation;

"**may**" indicates a permission;

"**can**" indicates a possibility or a capability.

# 1.Scope

1.1 This International Standard specifies the general requirements for the ***competence, impartiality and consistent operation*** of laboratories as defined in the standard.

# 1.Scope

**1.2 This International Standard is applicable to all organizations performing laboratory activities.**

*1, 2, 3rd party not mentioned further in the standard.*

# 1.Scope

**1.3 Laboratory customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others can also use this International Standard in confirming or recognizing the competence of laboratories.**

# *Question on ISO/IEC 17025 and sampling*

- Should the revised ISO/IEC 17025 be explicitly applicable to organizations that perform sampling without the subsequent testing or calibration?

- Result of survey
- 42 Members - YES
- 38 Members - NO

- **no clear consensus to the use of ISO/IEC 17025 for organizations that perform sampling without the subsequent testing or calibration.**

- **use the term *laboratory activities* *throughout the document instead of test and /or calibration activities***

- *define* ***laboratory activities*** **in the definition section.**

- **where sampling is defined as part of the laboratory activities**

## Definition :

**laboratory :** body that performs one or more of the following activities:

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

# 2. Normative references

- **Only VIM mentioned**
- ***All others put in Bibligraphy***

# 3 Terms and definitions

- **3.1 impartiality**
- **3.2 complaint**
  - **ISO 17000:2004,**
- **3.3 interlaboratory comparison**
  - **ISO/IEC 17043:2010, 3.4**

# 3 Terms and definitions

- **3.4 intra-laboratory comparison**
- **3.5 proficiency testing**
  - ISO/IEC 17043:2010, 3.7— modified: *the reference to the Annex and both notes deleted*.
  - **3.6 validation (VIM** 2.45 **) /ตัดทิ้ง**
- **3.7 verification (VIM** 2.44**) ) /ตัดทิ้ง**

# 3 Terms and definitions

- **3.8 working standard (new) ) /ตัดทิ้ง**
  - ISO/TR 16015:2003, 3.4.2
  - also called check standard,
- **3.9 (3.6) laboratory (new)**
  - body that performs one or more of the following activities:
    - Calibration
    - Testing
    - **sampling, associated with subsequent calibration and testing**

# 3 Terms and definitions

## 3.10 (3.7) decision rule (new)

- rule that describes how measurement uncertainty will be accounted for when stating conformity with a specified requirement

# 4 General requirements

- 4.1 Impartiality
- 4.2 Confidentiality

# 5 Structural requirements

- ส่วนใหญ่เหมือน ข้อ **4.1 in 2005 version**
- **Not mention "*technical management*"** and **"*quality manager*"**

  ให้ระบุว่าใครมีหน้าที่
- **Top management replaced by laboratory management**
- ***Delete —appoint deputies for key managerial personnel***

# 5 Structural requirements

**5.4 The laboratory shall define and document the range of laboratory activities for which it *conforms with this International Standard. 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. *(NEW)***

# 6 Resource requirements

6.1 General

6.2 Personnel

6.3 Laboratory facilities and environmental conditions

6.4 Equipment

6.5 Metrological traceability

6.6 Externally provided products and services

# 6.2 Personnel

Not mention:

- staff under training,
- job description

# 6.3 Laboratory facilities and environmental conditions

- **Delete** 5.3.5 good housekeeping (Version 2005)

# 6.4 Equipment

- **6.4.1.** Equipment includes measuring instruments, software, measurement standards, reference materials, reference data, reagents and consumables or auxiliary apparatus or combination thereof necessary for laboratory activities and which can influence the result. .

# 6.4 Equipment

- 6.4.2 In those cases where the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this International Standard are met. (5.5.1 of 2005 version)

- ◦5.5.9 in 2005 version: When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service. ( Delete)

# 6.4 Equipment

- 6.4.3The laboratory shall have a procedure for handling, transport, storage, use and planned maintenance of equipment

# 6.4 Equipment

- 6.4.4 The laboratory shall verify that equipment complies with specified requirements before being placed into service.
- 5.5.2 of 2005 version :◦Calibrated or checked to establish it meets the requirements of specification

# 6.4 Equipment

- 6.4.5 **shall be capable of achieving the measurement accuracy and measurement uncertainty required to provide a valid result.**

# 6.4 Equipment

- 6.4.6 When the measurement accuracy and measurement uncertainty affect the validity of the reported result, or metrological traceability is a requirement, measuring equipment shall be calibrated.
- 5.6.1 in 2005 version : ◦All equipment used for tests and/or calibrations, including equipment for subsidiary measurements having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service.

# 6.4 Equipment

- **6.4.7. …The calibration program shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration. (new)**

# 6.4 Equipment

- 6.4.8 All equipment requiring calibration or which has a defined period of validity shall **be labelled, coded or otherwise identified** to allow the user of the equipment to readily identify the status of calibration or period of validity.
- ◦ ***Delete: including the date when last calibrated and the date or expiration criteria when recalibration is due***

# 6.4 Equipment

- 6.4.9 Records of equipment

**New** 6.4.9 f) dates, results and copies of documentation and certificates of **reference materials**, acceptance criteria, and the period of validity;

# 6.4 Equipment

- 6.4.10 Equipment that has been subjected to **overloading or mishandling** shall be taken out of service
- 6.4.11 **When intermediate checks are necessary** these checks shall be carried out according to a procedure

# 6.4 Equipment

6.4.12 shall ensure the correction factors and reference values are updated and implemented, as appropriate,

6.4.13 shall ensure practicable measures are taken to prevent unintended adjustments of equipment which would invalidate results.

# 6.4 Equipment

**New** **6.4.14 The laboratory shall select and use reference materials that are fit for the specific purpose in the measurement process.**

# 6.5 Metrological traceability

- **6.5.1 shall establish and maintain metrological traceability by means of a documented unbroken chain of calibrations**
- **6.5.2 shall ensure traceable to the International System of Units (SI) through: calibration; certified values of certified reference materials direct realization of the SI units and ensured by comparison, directly or indirectly, with national or international standards**
- **6.5.3 metrological traceability to the SI units is not technically possible**

# 6.6 Externally provided products and services

- 6.6.1 General
- 6.6.2 have a procedure and records for control of externally provided products and services
- 6.6.3 Communication of information to external providers

# 7 Process requirements

7.1 Review  of requests, tenders and contracts
7.2 Selection, verification and validation of methods
7.3 Sampling
7.4 Handling of test or calibration items
7.5 Technical records
7.6 Evaluation of measurement uncertainty
7.7 **Analysis of results NEW** ตัดทิ้ง
7.7 Assuring the quality of results
7.8 Reporting of results
7.9 Complaints
7.10 Management of nonconforming work
7.11 Control of data – Information management

# 7.1 Review of requests, tenders and contracts

- 7.1.1 General
- 7.1.2 Externally provided laboratory activities

# 7.1 Review of requests, tenders and contracts

- **NEW** 7.1.1.3 the decision rule
- **7.1.1.3 customer requests a statement of conformity to a specificatio (e.g. pass/fail, in-tolerance/out-of-tolerance) the decision rule shall be clearly defined. communicated to the customer. (new)**

# 7.2-7.5 No significant change

**7.6 evaluation of measurement uncertainty**

**7.6.1 laboratory performing calibrations, including of its own equipment,**

**7.6.2 laboratory performing sampling or testing activities**

**7.6.3 all components which are of significance shall be identified and taken into account using appropriate methods**

# 7.7 Assuring the quality of results

- **Minor change**

**7.7.1**

- **a) use of reference materials or quality control materials;**
- **b) use of alternative instrumentation that has been calibrated to provide traceable results**
- **c) functional check of measuring and testing equipment;**
- **d) use of check or working standards with control charts, where applicable;**
- **e) periodic intermediate checks on measuring equipment;**

# 7.7 Assuring the quality of results

- f) replicate tests or calibrations using the same or different methods
- g) retesting or recalibration of retained items;
- h) retesting or recalibration of retained items;
- i) review of reported data by competent laboratory personnel;
- j) intralaboratory comparisons;
- k) blind test.

7.7.2 PT/ Interlab

7.7.3 monitoring activities shall be analysed and appropriate action shall be taken

# 7.8 Reporting of results

- **7.8.1 General**
- **7.8.2 Test reports and calibration certificates – common requirements**
  - NEW h) the date(s) of performance of the test or calibration;
  - NEW i) the date of issue of the test report or calibration certificate;

# 7.8 Reporting of results

- **7.8.3 Test reports – specific requirements**
- c) where applicable, of the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent);

**7.8.4 Calibration certificates – specific requirements / no change**

# 7.8 Reporting of results

- **7.8.5 Reporting statements of conformity**
- *7.8.5.1 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)*
- **7.8.6 Reporting opinions and interpretations**
- **7.8.7 Amendments to reports**

# 7.9 Complaints

- Compulsory wordings of CASCO

- **7.10 Management of nonconforming work**
- **7.11 Control of data – Information management**

***No significant change***

# 8 Management requirements

8.1 Options

8.2 Management system documentation (Option A)

8.3 Control of management system documents (Option A)

8.4 Control of records (Option A)

8.5 Actions to address risks and opportunities (Option A)

8.6 Improvement (Option A)

8.7 Corrective action (Option A)

8.8 Internal audits (Option A)

8.9 Management reviews (Option A)

# 8 Management requirements

- Option A management system section requirements (8.2 - 8.9).
- Option B A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of clauses 4 to 7 of ISO/IEC 17025 also fulfils at least the intent of the management system section requirements (8.2 - 8.9).

# 8 Management requirements

- **NEW** 8.5 Actions to address risks and opportunities (Option A)
- 8.8 Internal audit (Option A),
  - No recommendation on frequency
- 8.9 Management review (Option A)
- **Deleted** preventive action, incorporated into "Improvement' (reference ISO 9001)

- New Revision ISO 17025
- 3 year implementation

# คำถาม