ISO/IEC 17025:2017(EN) GENERAL REQUIREMENTS FOR THE COMPETENCE OF TESTING AND CALIBRATION LABORATORIES

สถาบันมาตรวิทยาแห่งชาติ
National Institute of Metrology (Thailand)

Ajchara Charoensook

ISO/IEC 17025 :2017

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Ajchara Charoensook

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The main changes

— the risk-based thinking applied in this edition has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements;

— there is greater flexibility than in the previous edition in the requirements for processes, procedures, documented information and organizational responsibilities;

— a definition of "laboratory" has been added in definition.

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In this document, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability.

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WHAT IS RISK-BASED THINKING?

The concept of risk has always been implicit in ISO 9001 –the 2015 revision makes it more explicit and builds it into the whole management system

Risk-based thinking is already part of the process approach.

Risk-based thinking makes preventive action part of the routine.

Risk is often thought of only in the negative sense .

Risk-based thinking can also help to identify opportunities. This can be considered to be the positive side of risk.

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1. SCOPE

This document specifies the general requirements for the competence, impartiality and consistent operation of laboratories.

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

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

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2 NORMATIVE REFERENCES

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*[1]

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

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3 TERMS AND DEFINITIONS

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:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

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3 TERMS AND DEFINITIONS

3.1 impartiality

presence of objectivity

Note 1 Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the laboratory (3.6).

Note 2 Other terms that are useful in conveying the element of impartiality include "freedom from conflict of interests", "freedom from bias", "lack of prejudice", "neutrality", "fairness", "open-mindedness", "even-handedness", "detachment", "balance".

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3 TERMS AND DEFINITIONS

3.2 complaint

expression of dissatisfaction by any person or organization to a laboratory (3.6), relating to the activities or results of that laboratory, where a response is expected

3.3 interlaboratory comparison

organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

3.4 intralaboratory comparison

organization, performance and evaluation of measurements or tests on the same or similar items within the same laboratory (3.6) in accordance with predetermined conditions

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3 TERMS AND DEFINITIONS

3.5 Proficiency testing

Evaluation of participants performance against pre-established criteria by means of interlabolatory comparison.

3.6 Laboratory

Body that performs one or more of the following activities;

- testing
- calibration
- sampling associated with subsequent testing or calibration

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3 TERMS AND DEFINITIONS

3.7 decision rule

rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

3.8 verification

provision of objective evidence that a given item fulfils specified requirements

3.9 validation

verification (3.8), where the specified requirements are adequate for an intended use

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RISK MANAGEMENT

Requires the laboratory to plan and implement actions to address risks and opportunities.

Establishes a basis for increasing the effectiveness of the quality management system, achieving improved results and preventing negative effects.

The laboratory is responsible for deciding which risks and opportunities need to be addressed

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WHAT SHOULD WE DO ?

1. Identify what the risks and opportunities are in your organization
2. Plan actions to address the risks
   - *how can I avoid or eliminate the risk?*
   - *how can I mitigate the risk ?*
3. Implement the plan – *take action*
4. Check the effectiveness of the actions – *does it work?*

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IMPARTIALITY (4.1)

In order to safeguard impartiality

- Establish structure
- Mitigate pressures

- Identify & manage risks (ongoing basis)

Risks may come from…….

- its activities
- its relationship
- the relationship of its personnel

- Demonstrate how to minimize or eliminate Risks

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CONFIDENTIALITY (4.2)

Legally enforceable commitment for management of information obtained or created during the performance of laboratory activities.

- Inform customer of if public exposure of information
- Third party communication requirement

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STRUCTURAL REQUIREMENTS (5)

Legal entity

Identify management

Define and document the laboratory activities

Meet the requirements of
- ISO/IEC 17025 :2017
- Customers
- Regulatory authorities and organizations providing recognitions

Laboratory activities can be ;
- Permanent facilities
- At sites away from its permanent facilities
- Temporary
- Mobile facilities
- Customer's facility.

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STRUCTURAL REQUIREMENTS (5)

- Define organization and management structure and relationships between management , technical operations and support services;
- Specify responsibility ,authority and interrelationship of all personnel who manage , perform or verify works;
- Document its procedures to ensure consistency of works and validity of the results.
- Have personnel with authority and resources needed to carry out laboratory activities including: implementation, maintenance,improvement, identification of deviations , initiation of actions to prevent or minimize deviations ,reporting to management on the performance of management system .

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STRUCTURAL REQUIREMENTS (5)

Ensuring …

- the effectiveness of laboratory activities.
- Communication take place regarding the effective of the management system and the importance of meeting customers and other requirements;
- Integrity of management system is maintained when changed to the management system are planned and implemented.

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RESOURCE REQUIREMENTS (6)

Availability of personnel, facilities, equipment, systems and support services. (6.1)

Personnel (6.2)

- Act impartially, be competent and work in accordance with lab's management system
- Evidences of the competence requirements (education, qualification, training, technical knowledge ,skills and experience)
- Competence to perform laboratory activities and to evaluate the significance of deviations
- Communicate to personnel their duties, responsibilities and authorities.

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FACILITIES AND ENVIRONMENTAL CONDITIONS (6.3)

- Suitable for laboratory activities and not adversely affect the validity of results
- Documented requirements for facilities and environmental conditions
- Monitor, control and record environmental conditions
- Measures to control facilities including:
  - Access to and use of areas affecting laboratory activities;
  - Prevention of contamination, interference or adverse influences on laboratory activities;
  - Effective separation between areas with incompatible laboratory activities.
- Ensure that environmental conditions are met when performing outside its permanent control

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EQUIPMENT (6.4)

- Available and function properly
- Conform with specification before place into service
- Capable to achieve required accuracy
- Calibration of measuring equipment
- Establish calibration program
- Calibration status
- Action for out of service
- Intermediate checks
- Update/implement correction factors or reference values
- Measures to prevent unintended adjustment
- Equipement records

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METROLOGICAL TRACEABILITY (6.5)

- Establish and maintain metrological traceability of its measurement results
- Ensure that measurement results are traceable to the SI units:
  - Competent laboratory;
  - Competent producer;
  - Comparison, directly or indirectly with national or international standards.
- Demonstrate metrological traceability to an appropriate reference when not technical possible to the SI units:
  - Competent producer;
  - Suitable comparison.

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EXTERNALLY PROVIDED PRODUCTS AND SERVICES (6.6)

Ensure that <u>suitable externally provided products and services are used</u> when products and services:

- Are intended for incorporation into the laboratory's own activities;
- Are provided ,in part or in full, directly to the customer by the laboratory as received from the external provider;
- Are used to support the operation of the laboratory.

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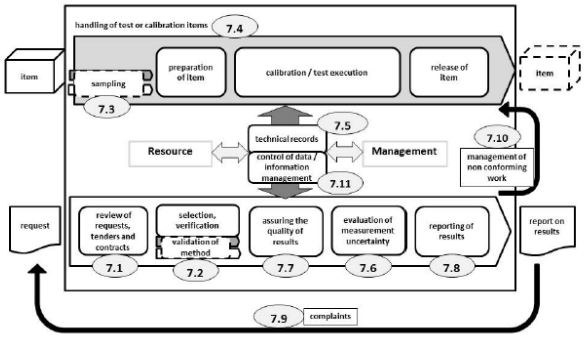
PROCESS REQUIREMENTS (7)



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REVIEW OF REQUESTS,TENDERS AND CONTRACTS (7.1)

- Have a procedure for the review
- Inform customer when method requested by the customer is not appropriate or out of date
- Clearly defined a statement of conformity when requested by the customer
- Resolve any difference between the request or tender and the contract before commencing work
- Inform customer if any deviation from the contract
- Repeat contract review if amended after work and communicate to all affected personnel
- Cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed
- Retain records of reviews

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SELECTION, VERIFICATION AND VALIDATION OF METHODS (7.2)

- Use appropriate methods and procedures for all laboratory activities
- Up to date methods, procedures and supporting documents are kept and made readily available to personnel
- Uses the latest version unless not possible to do
- Select appropriate method when customer does not specify
- Verify methods before introducing them to ensure it can achieve the required performance.
- Have Action plan for method development
- Document, technically justify, authorize and accept by the customer if any deviation from methods
- Validate non –standard methods , laboratory developed methods and standard methods used outside their intended scope or modify
- Retain records of validation

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SAMPLING (7.3)

- Sampling plan
- Sampling method
- Retain records

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HANDLING OF TEST OR CALIBRATION ITEMS (7.4)

- Have a procedure
- Have a system for unambiguous identification
- Records of the item
- Facilities to maintain items

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TECHNICAL RECORDS (7.5)

- Sufficient information
- Amendment can be tracked to previous versions or original observations

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EVALUATION OF MEASUREMENT UNCERTAINTY (7.6)

- Identify the contributions to measurement uncertainty
- Evaluate for all calibrations (calibration lab)
- Evaluate measurement uncertainty where test method precludes rigorous evaluation of measurement uncertainty

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ENSURING THE VALIDITY OF RESULTS (7.7)

- Have a procedure for monitoring the validity of results
- Monitor its performance by comparison with results of other laboratories
- Analyze and use data from monitoring to control and improve the laboratory's activities
- Take action when data from the monitoring are found to be outside pre-defined criteria

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REPORTING THE RESULTS (7.8)

- General – review and authorize prior to release
- Common requirements for reports
- Specific requirements for test reports
- Specific requirements for calibration certificates
- Specific requirements for reporting sampling
- Reporting statements of conformity
- Reporting opinions and interpretations
- Amendments to reports

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COMPLAINTS (7.9)

- Have a documented process to receive , evaluate and make decision on complaints
- Responsible for all decisions at all levels of handling process of complaints and made availability of description of handling process for complaints to interested party
- Include at least the following elements and method:
  - Description of the process
  - Tracking and recording complaints
  - Ensuring that appropriate action is taken
- Responsible for gathering and verifying all information to validate the complaint
- Acknowledge receipt of the complaint, and provide the complainant with progress report and outcome
- Review, approve the outcomes by individual (s) not involved in the original laboratory activities in question
- Give formal notice of the end of the complaint handling to the complainant

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NONCONFORMING WORK (7.10)

- Have procedure to ensure that
  - Responsibilities and authorities for the management of NC work are defined;
  - Actions are based upon the risk levels established by the laboratory;
  - An evaluation is made of the significance of NC work, including an impact analysis on previous results;
  - A decision is taken on the acceptability of NC work;
  - Where necessary ,the customer is notified and work is recalled;
  - The responsibility for authorizing the resumption of work is defined.
- Retain records of NC work and actions taken
- Implement corrective action where the evaluation indicates that the NC work could recur or is doubt about the conformity of laboratory's operation

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CONTROL OF DATA AND INFORMATION MANAGEMENT (7.11)

- Have access to the data and information needed to perform laboratory activities
- Validate information management system for functionality
- Protect from unauthorized access, safeguard against tampering and loss, operate in suitable environment , maintain integrity of data, record system failures and corrective actions
- Ensure the provider or operator of the system complies when manage and maintain off-site or through an external provider.
- Ensure that instructions, manuals and reference data relevant to laboratory information system are made readily available to personnel
- Check calculations and data transfers in an appropriate and systematic manner

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MANAGEMENT REQUIREMENTS (8)

Option A

- At a minimum the laboratory addresses 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)

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MANAGEMENT SYSTEM DOCUMENTATION (8.2)

MS Documentation - Policies & Objectives for the fulfilment of the purpose of ISO/IEC 17025

- ✓ Establish ,document and maintain
- ✓ Acknowledge and implement at all levels of the laboratory organization
- ✓ Address the competence, impartiality and consistent of the operation
- ✓ Make reference or link to other documents
- ✓ Easy to access by relevant personnel

EVIDENCES of commitment to the development and implementation of the MS and to continually improving its effectiveness.

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CONTROL OF MANAGEMENT SYSTEM DOCUMENTATION (8.3)

Ensure

- Approve prior to issue
- Review / update
- Identification of current revision / changes
- Available at point of use
- Uniquely identify
- Unintended use of obsolete documents

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CONTROLS OF RECORDS (8.4)

- Establish and retain legible records
- Implement the controls
- Retain for a period consistent with its contractual obligations
- Readily available

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ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES(8.5)

- Action plan to address risks and opportunities
- Integrate and implement actions
- Evaluate the effectiveness of actions

❖Actions taken shall be proportional to the potential impact on the validity of laboratory results

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IMPROVEMENT (8.6)

- Identify and select opportunities for improvement
- Implementation
- Seek feed back & use and analyze feed back to improve the MS

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CORRECTIVE ACTIONS (8.7)

- React to NC
- Evaluate the need for action & implement
- Review the effectiveness
- Update risk & opportunities
- Make changes to the MS
- Retain records

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INTERNAL AUDITS (8.8)

- Conduct as planned intervals
- Plan , establish and maintain audit program
- Define the audit criteria and scope for each audit
- Report the results to relevant management
- Implement correction and corrective actions without undue delay
- Retain records

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MANAGEMENT REVIEWS(8.9)

- Review at planned intervals
- Record all inputs to the management review
- Record all decisions and actions of output

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ANNEX A (INFORMATIVE) METROLOGICAL TRACEABILITY

- Traceability established by:
  - Definition of the measurand
  - Unbroken chain of comparisons/cals
  - Measurement uncertainty
  - Performed in accordance with documented information
  - Competence
- Demonstration of Traceability
  - Evaluate the technical competence of the calibration provider and claimed metrological traceability as per the requirements of this standard
  - CMCs peer reviewed by international arrangement
  - CIPM MRA or ILAC

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ANNEX B (INFORMATIVE) MANAGEMENT SYSTEM OPTIONS

- Option A of clause 8 : operate generally in accordance with the principles of ISO 9001.
- Option B of clause 8 : allow to establish and maintain a management system in accordance with the requirements of ISO 9001.
- Both options are intended to achieve the same result in the performance system and compliance with Clauses 4 to 7.

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Ajchara Charoensook

THANK YOU

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