การอบรมความรู้

ISO/IEC 17025 : 2005

คณะเภสัชศาสตร์

มหาวิทยาลัยหัวเฉียวเฉลิมพระเกียรติ

นวลตา ม่วงน้อยเจริญ

ศิริพร พันธุวนิช

สุวรรณา จารุนุช

17 กรกฎาคม 2557

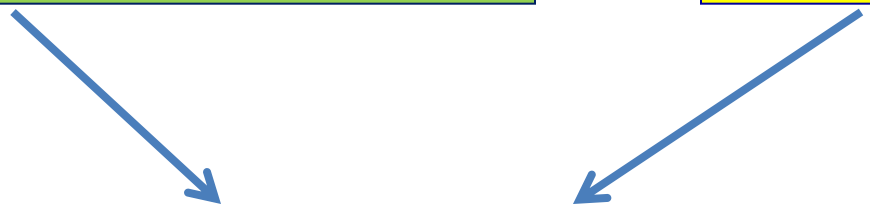
เรามาหารือกันดีกว่า
จะเริ่มอย่างไรดี

เริ่มต้นอย่างไร ?

ปรึกษาหารือ เห็นพ้อง ต้องทำ กำหนดหน้าที่

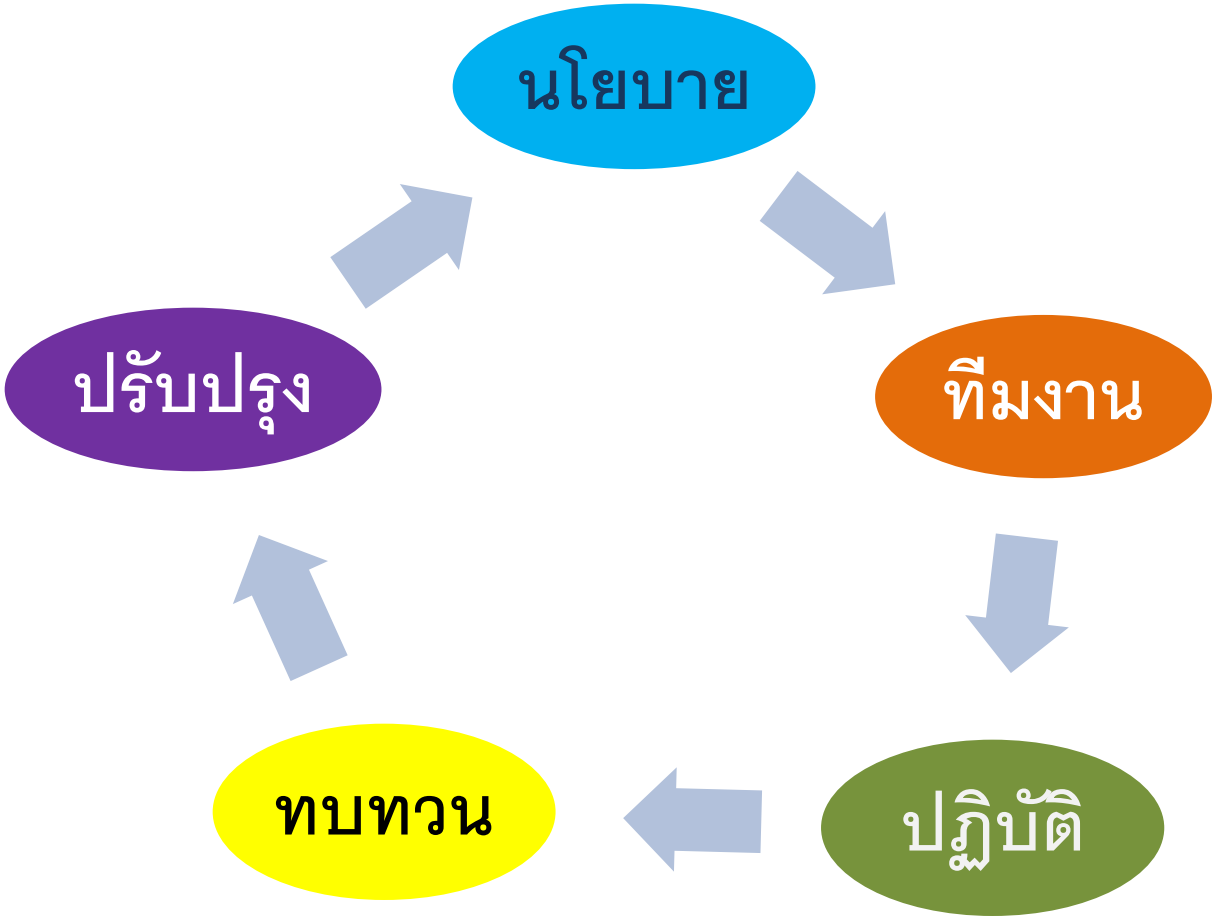
ศึกษาเอกสารมาตรฐานที่เกี่ยวข้อง

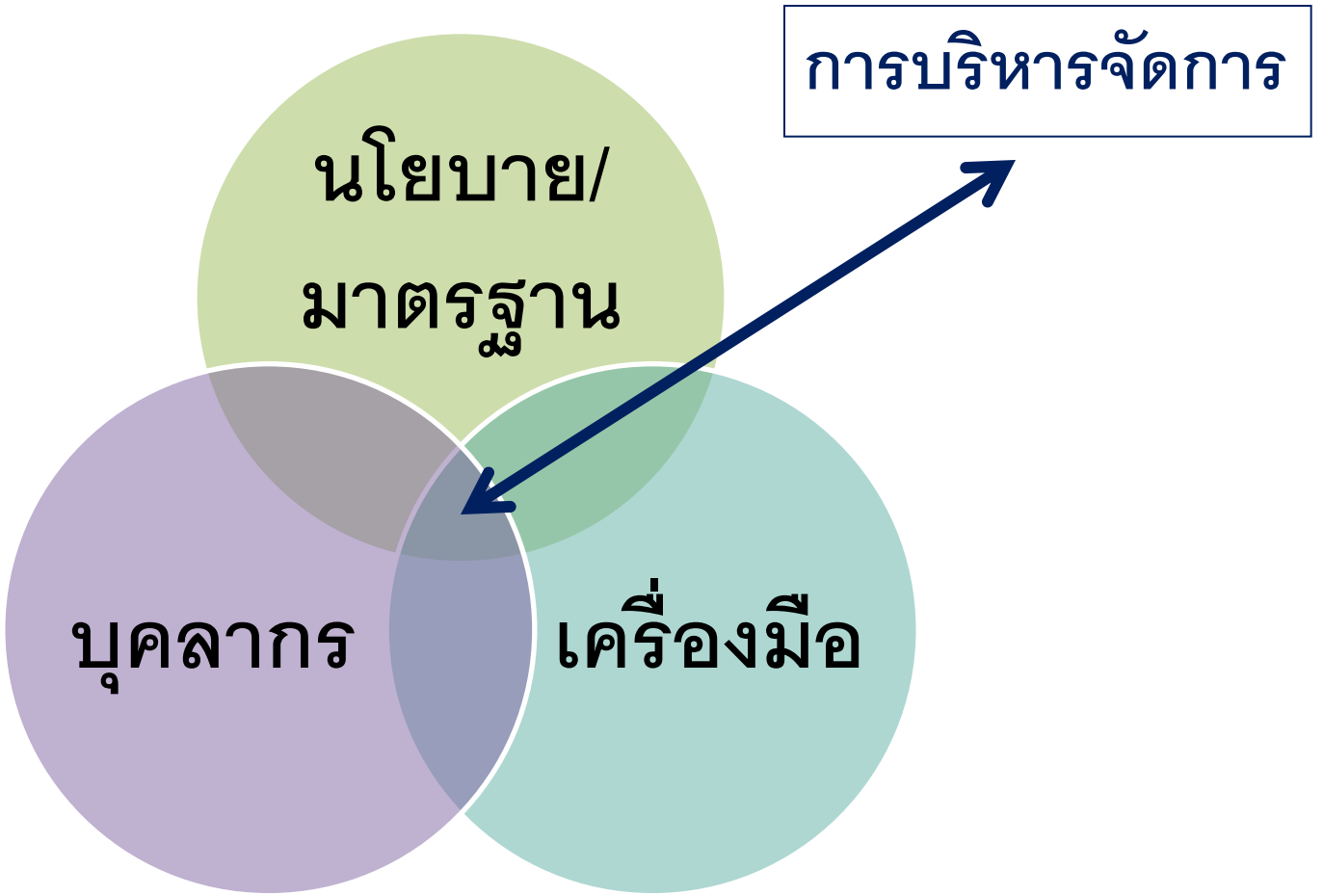
สำรวจตนเอง



เปรียบเทียบเพื่อหาส่วนขาด

เริ่มต้นอย่างไร

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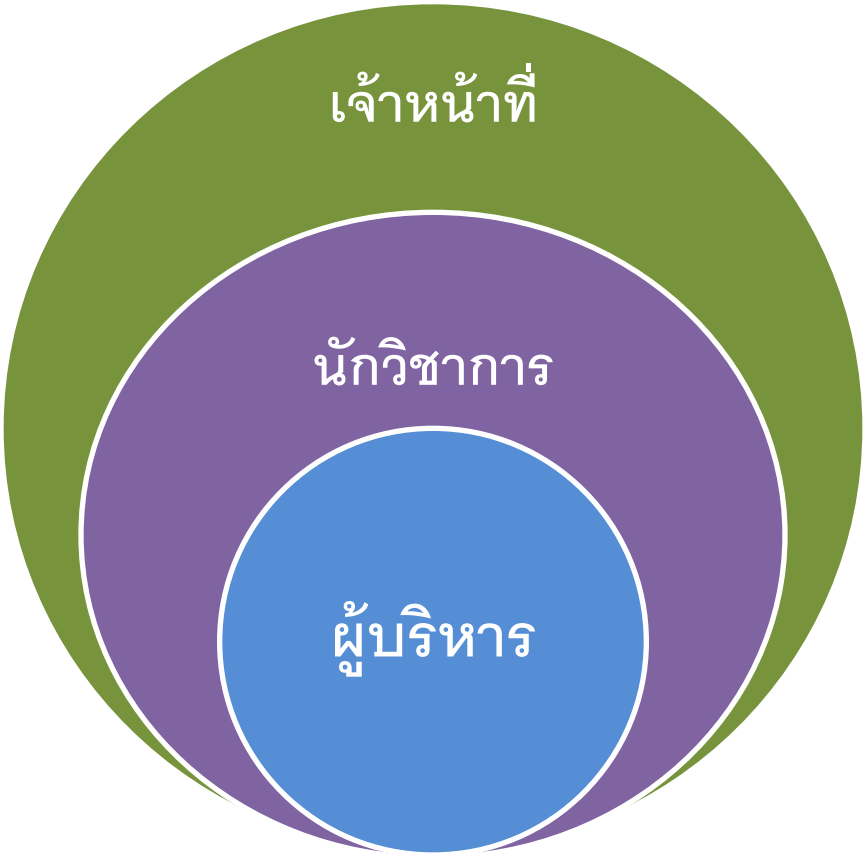

ISO/IEC 17025 : 2005

General requirements for the competence of testing and calibration laboratories

หัวข้อสำคัญ

Management requirement **15 ข้อ**

Technical requirement **10 ข้อ**

4. Management requirement

4.1 Organization

4.1.1 legally responsible.

4.1.2 meet the requirements of ISO/IEC 17025 and satisfy the needs of the customers

4.1.3 cover work carried out in the laboratory's permanent facilities, or mobile facilities.

4.1.4 If the laboratory is part of an organization performing activities other than testing shall be defined in order to identify potential conflicts of interest.

4.1.5 The laboratory shall

4.1.5 (a) have managerial and technical personnel who carry out their duties, including the implementation, maintenance and improvement of the management system

4.1.5 (b) free from any undue internal and external commercial, financial and other pressure and influences that may adversely affect the quality of their work.

4.1.5 (c) to ensure the protection of its customers'confidential information

4.1.5 (d) have policies and procedures to avoid the activities that would diminish confidence in its competence, impartiality, judgement or operational integrity

4.1.5 (e) define the organization and management structure of the laboratory, its place in any parent organization,and the relationships between quality management, technical operations and support services

4.1.5 (f) specify the responsibility, authority and interrelationships of all personnel

4.1.5 (g) provide adequate supervision of staff

4.1.5(h) have technical management which has overall responsibility for the technical operations

4.1.5 (i) appoint a member of staff as quality manager who direct access to the top management

4.1.5 (j) appoint deputies for key managerial personnel

4.1.5 (k) ensure that its personnel are aware of the relevance and importance of their activities

4.1.6 Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.

4.2 Management system

4.2.1 establish, implement and maintain a management system appropriate to the scope of its activities.

documented policies, systems, programmes, procedures and instructions shall be communicated

4.2.2 The laboratory's management system shall be defined in a quality manual and shall be reviewed during management review.

(หัวข้อที่จำเป็น)

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

4.2.2 (b) the management’s statement of the laboratory's standard of service;

4.2.2 (c) the purpose of the management system related to quality.

4.2.2 (d) all personnel concerned with testing activities

4.2.2(e)

- commitment to comply with ISO/IEC 17025

-continually improve the effectiveness of the management system.

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

4.2.4 Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.

4.2.5 The quality manual shall make reference to the supporting procedures and outline the structure of the documentation used.

4.2.6 The roles and responsibilities of technical management and the quality manager.

4.2.7 Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.

4.3 Document control

4.3.1 General

-establish and maintain procedures to control all documents (internally / external sources)

4.3.2 Document approval and issue

4.3.2.1 -All documents issued to personnel shall be reviewed and approved for use by authorized personnel prior to issue.

- A master list identifying the current revision status and distribution of documents

4.3.2.2 The procedures adopted shall ensure

4.3.2.2(a) authorized editions of appropriate documents are available at all locations.

4.3.2.2(b) documents are periodically reviewed

4.3.2.2(c) invalid or obsolete documents are promptly removed from all points of issue or use.

4.3.2.2(d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

4.3.2.3 the documents generated by the laboratory shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages

4.3.3 Document changes

4.3.3.1 Changes to documents shall be reviewed and approved by the same function.

4.3.3.2 the altered or new text shall be identified in the document or the appropriate attachments.

4.3.3.3 amendment by hand pending the re-issue of the documents, the procedures and authorities shall be defined.

4.3.3.4 Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.

4.4 Review of requests,tenders and contracts

4.4.1 The review of requests, tenders and contracts ensure that:

4.4.1(a) the requirements, the methods to be used, are adequately defined, documented and understood

4.4.1(b) the laboratory has the capability and resources to meet the requirements

4.4.1 (c) the appropriate test method is selected and met the customers‘ requirement

4.4.2 Records of reviews, including any significant changes, shall be maintained.

4.4.3 The review shall also cover any work that is subcontracted by the laboratory.

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

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

4.5 Subcontracting of tests &calibrations

4.5.1 When a laboratory subcontracts work, this work shall be placed with a competent subcontractor.

4.5.2 The laboratory shall advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer, preferably in writing.

4.5.3 The laboratory is responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.

4.5.4 The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this International Standard for the work in question.

4.6 Purchasing services and supplies

4.6.1 The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations.

4.6.2 The purchased supplies and reagents and consumable materials are not used until they have been inspected and verified.

4.6.3 Purchasing documents shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.

4.6.4 The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.

4.7 Service to the customer

4.7.1 The laboratory shall cooperate with customers in clarifying thier request and in monitoring the laboratory's performance. The laboratory ensures confidentiality to other customers.

4.7.2 The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be analysed to improve the management system, testing activities.

4.8 Complaints

The laboratory shall have a policy and procedure for the resolution of complaints received from customers or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory.

4.9 Control of nonconforming testing and/or calibration work

4.9.1 The laboratory shall have a policy and procedures that shall be implemented when testing work or the results, do not conform to its own procedures or the agreed requirements of the customer.

4.9.1 (a) the responsibilities and authorities for the management of nonconforming work are designated and actions

4.9.1(b) an evaluation of the significance of the nonconforming work is made;

4.9.1 (c) correction is taken immediately,

4.9.1 (d) where necessary, the customer is notified and work is recalled;

4.9.1 (e) the responsibility for authorizing the resumption of work is defined.

4.9.2 Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedure shall be promptly followed.

4.10 Improvement

The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

4.11 Corrective action

4.11.1 General

The laboratory shall establish a policy and a procedure for implementing corrective action when nonconforming work or departures from the policies and procedures

4.11.2 Cause analysis

The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

4.11.3 Selection and implementation of corrective action

- the laboratory shall identify, select and implement the potential action(s) most likely to eliminate the problem and to prevent recurrence.

- the laboratory shall document and implement any required changes resulting from corrective action investigations.

4.11.4 Monitoring of corrective actions

The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.

4.11.5 Additional audits

Where the identification of nonconformities or departures casts doubts on the laboratory's compliance with its own policies and procedures, or this Standard the appropriate areas of activity are audited as soon as possible.

4.12 Preventive action

4.12.1 Preventive action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

4.12.2 Procedures for preventive actions shall include the initiation of such actions and the application of controls to ensure that they are effective.

4.13 Control of records

4.13.1 General

4.13.1.1The laboratory shall establish and maintain procedures for identification, collection, indexing,access, filing, storage, maintenance and disposal of quality and technical records.

4.13.1.2 All records shall be legible and shall be stored and retained .

4.13.1.3 All records shall be held secure and in confidence.

4.13.1.4 The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records

4.13.2 Technical records

4.13.2.1 The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail for a defined period. (แล้วแต่กำหนด)

4.13.2.2 Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.

4.13.2.3 When mistakes occur in records, each mistake shall be crossed out, not erased.

4.14 Internal audits

4.14.1 The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities

The quality manager plan and organize audits as required by the schedule and requested by management.

4.14.2 When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test results, the laboratory shall take timely corrective action,

4.14.3 The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.

4.14.4 Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

4.15 Management reviews

4.15.1 The laboratory's top management shall periodically conduct a review of the laboratory's management system

4.15.2 Findings from management reviews and the actions that arise from them shall be recorded.

The management shall ensure that those actions are carried out within an appropriate and agreed timescale.

Thank you

Q & A