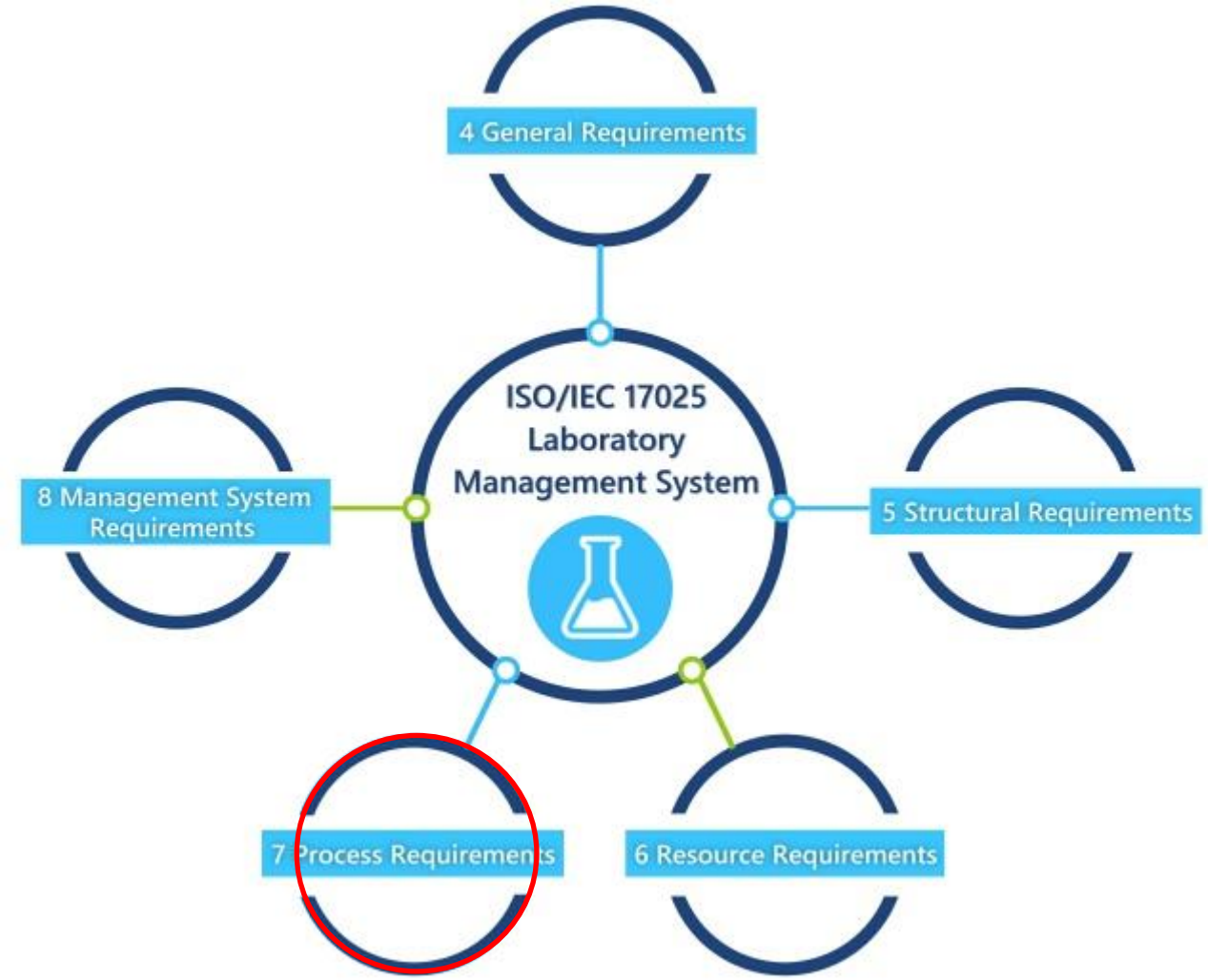
# L13 Process Requirements

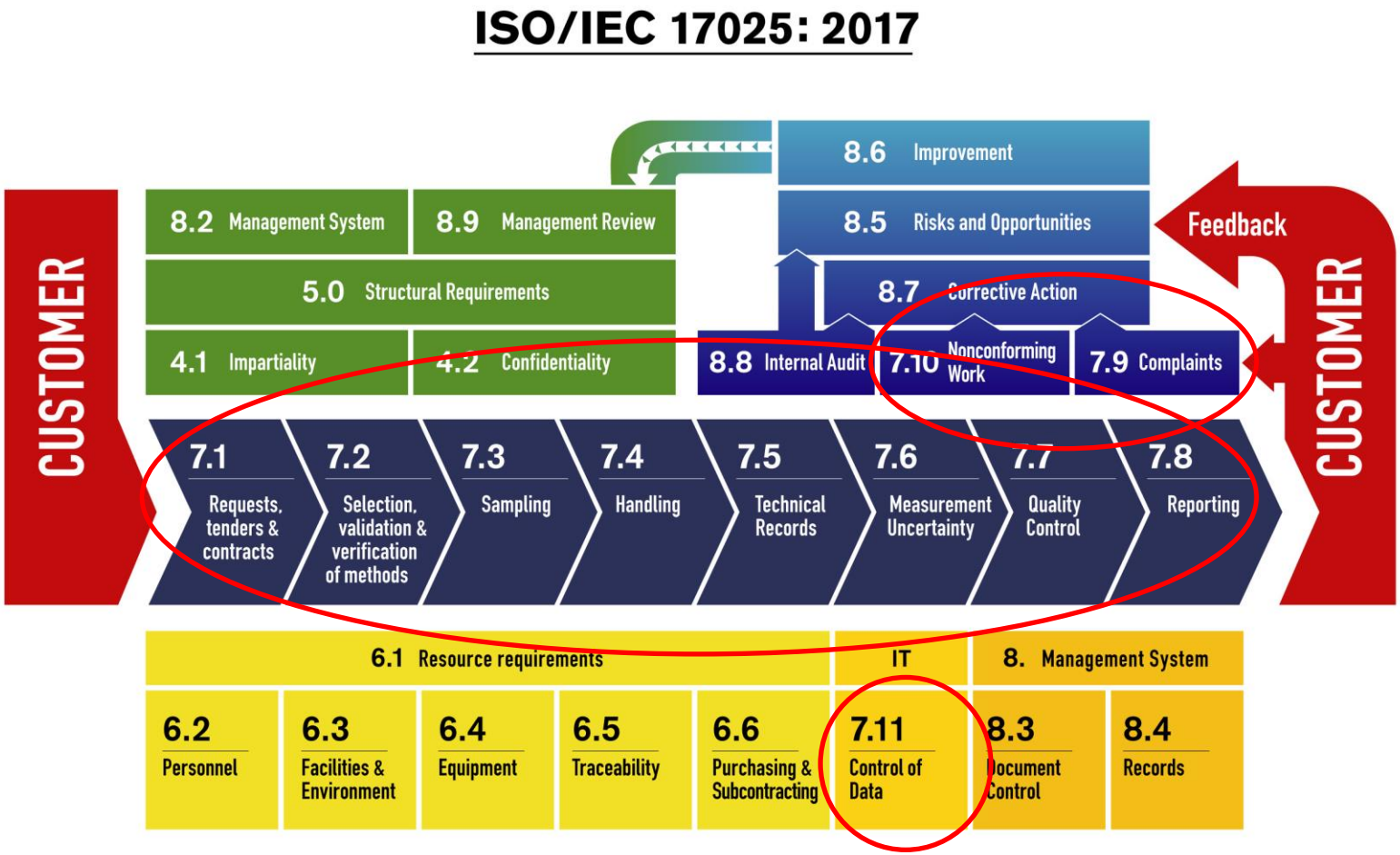
IAEA

International Atomic Energy Agency

# 7 Process Requirements



# Structure


ISO/IEC 17025: 2017
CUSTOMER
8.2 Management System
8.9 Management Review
5.0 Structural Requirements
4.1 Impartiality
4.2 Confidentiality
8.6 Improvement
8.5 Risks and Opportunities
8.7 Corrective Action
8.8 Internal Audit
7.10 Nonconforming Work
7.9 Complaints
Feedback
CUSTOMER
7.1 Requests, tenders & contracts
7.2 Selection, validation & verification of methods
7.3 Sampling
7.4 Handling
7.5 Technical Records
7.6 Measurement Uncertainty
7.7 Quality Control
7.8 Reporting
6.1 Resource requirements
IT
8. Management System
6.2 Personnel
6.3 Facilities & Environment
6.4 Equipment
6.5 Traceability
6.6 Purchasing & Subcontracting
7.11 Control of Data
8.3 Document Control
8.4 Records

# Objectives

In this lecture we will discuss 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 Ensuring the validity of results
7.8 Reporting of results
7.9 Complaints
7.10 Management of nonconforming work
7.11 Control of data – Information management

IAEA

# 7.1 Review of requests, tenders and contracts

## 7.1.1 Establish and maintain procedure for review of requests tenders and contracts which ensure that:

- The level of understanding of requirements The requirement including the methods are adequately defined, documented and understood
- Implementation of appropriate control over external providers used (if any)
- The capability and resources to meet requirements
- The use of appropriate test methods or procedures and capability to meet the requirements
- Records for review should maintained which includes any subcontracted work and customer approval for performing such activity from external laboratory

IAEA

# 7.1 Review of requests, tenders and contracts (2)

7.1.2 Inform the customer when the method requested by the customer is considered to be inappropriate or out of date

7.1.3 If customer requests a statement of conformity to a specification or standard and decision rule which specifies pass/fail criteria) selected to be communicated to, and agreed with, the customer

7.1.4 Any differences between the request or tender and the contract is resolved before laboratory activities commence and accepted by both

.

# 7.1 Review of requests, tenders and contracts (3)

7.1.5 Inform to customer for any deviation from the contract

7.1.6 Follow contract review for amendments and Inform both for any amendments

7.1.7 Cooperate the customers

7.1.8 Maintain records for review, changes and amendments and customer discussion.

# 7.2 Selection, verification and validation of methods

See separate presentation

# 7.3 Sampling

The requirements of this clause are applicable to the laboratories which perform just sampling activities as well as for testing and calibration laboratories which are responsible also for sampling

7.3.1 Use sampling plan and method and available at place of use. Method to address the factors to be controlled to ensure the validity of results. The Sampling plans, may be based on appropriate statistical methods

7.3.2 The sampling method describe:

- the selection of samples or sites;
- the sampling plan;
- preparation and treatment of sample for subsequent testing or calibration

7.3.3 Retain records of sampling data

IAEA

# 7.3 Sampling (2)

7.3.3 Contents of Sampling records

The sampling records include ;

- Reference of the sampling method used
- Date and time of sampling
- Data to identify and describe the sample
- Identification of the personnel performing sampling
- Identification of the equipment used
- Environmental or transport conditions
- Diagrams or other equivalent means to identify the sampling location when appropriate
- Deviations, additions to or exclusions from the sampling method and sampling plan.

IAEA

# 7.4 Handling of test or calibration items

7.4.1 Document the procedure for the

- Transportation,
- Receipt,
- Handling,
- Protection,
- Storage,
- Retention and or disposal of test and calibration items
- Protection of the test or calibration items

Precautions to be taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for, testing or calibration. Handling instructions provided with the item is followed

# 7.4 Handling of test or calibration items (2)

7.4.2 Establish system for identification of test and or calibration items. The identification should be appropriate and followed for sub division of items

7.4.3 Upon receipt of the test or calibration item, deviations from specified conditions is recorded. If an item does not conform to the description provided then consult customer and record the results of this consultation. Include a disclaimer in the report indicating which results may be affected by the deviation due to specified conditions

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

IAEA

# 7.5 Technical records

See separate presentation

# 7.6 Evaluation of measurement uncertainty

See separate lecture

# 7.7 Ensuring the validity of results

See separate lecture

# 7.8 Reporting of results

See separate lecture

# 7.9 Complaints

See separate lecture

# 7.10 Nonconforming work

- See separate lecture

# 7.11 Control of data– Information management

- Sets requirements for the laboratory information management system(s) used for the:
  1. collection 2. processing 3. recording 4. reporting 5. storage 6. retrieval of data. Give access to the data and information needed to perform laboratory activities

- Information used for the collection, processing, recording, reporting, storage or retrieval of is validated for functionality and interface. For any changes in software, implement the change management including authorization, documentation and configuration management before implementation

# 7.11 Control of data– Information management (2)

- Establish controls like protection, data tempering, accuracy, integrity, immediate actions for business continuity in case of failure etc. to implement laboratory information management system
- If the laboratory information management system is managed by external provider then he also has to follow the requirements
- Ensure that instructions, manuals and reference data relevant to the laboratory information management system are made readily available to personnel
- Calculations and data transfers shall be checked in an appropriate and systematic manner.

IAEA