L9 Documentation

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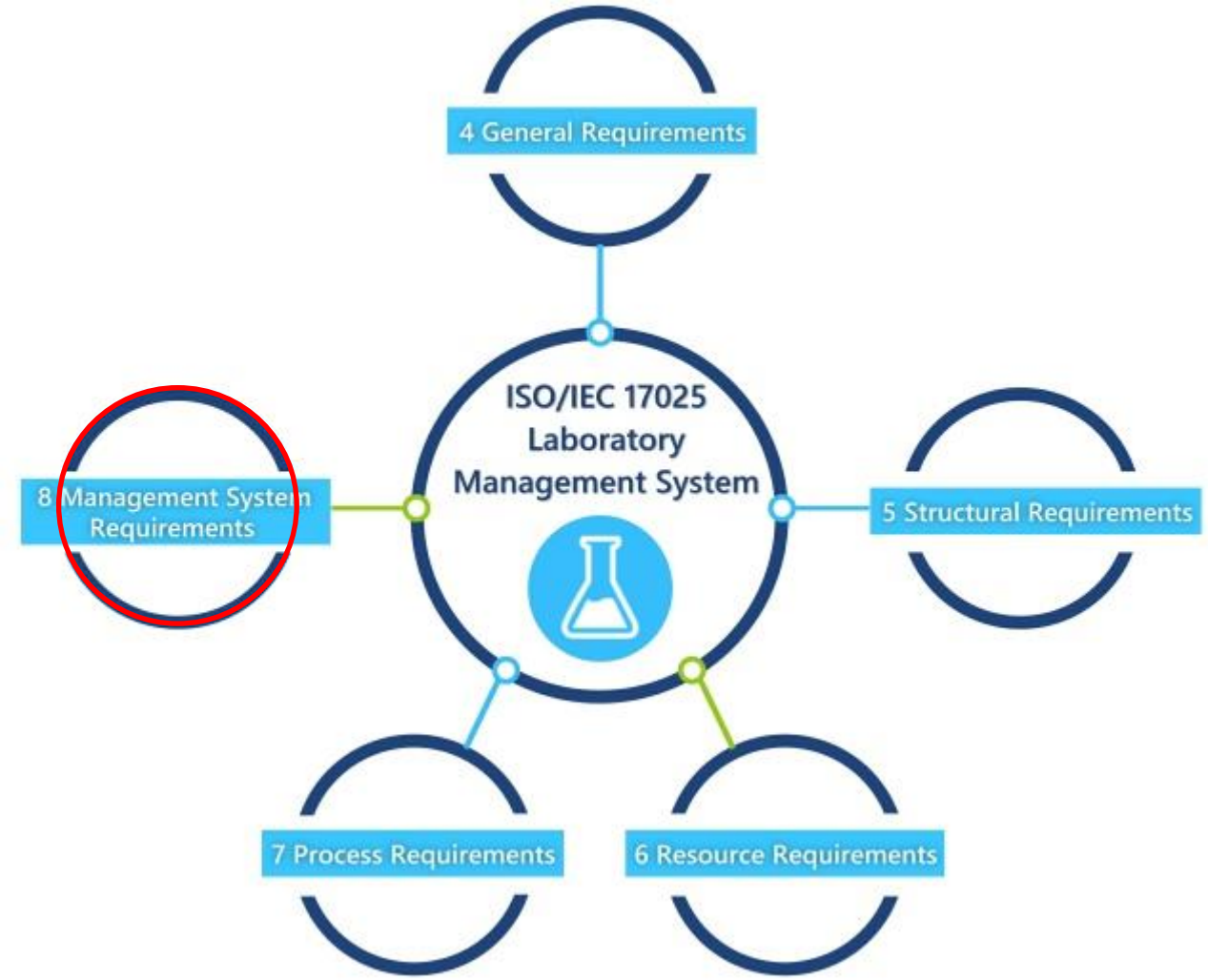
International Atomic Energy Agency

8 Management System Requirements



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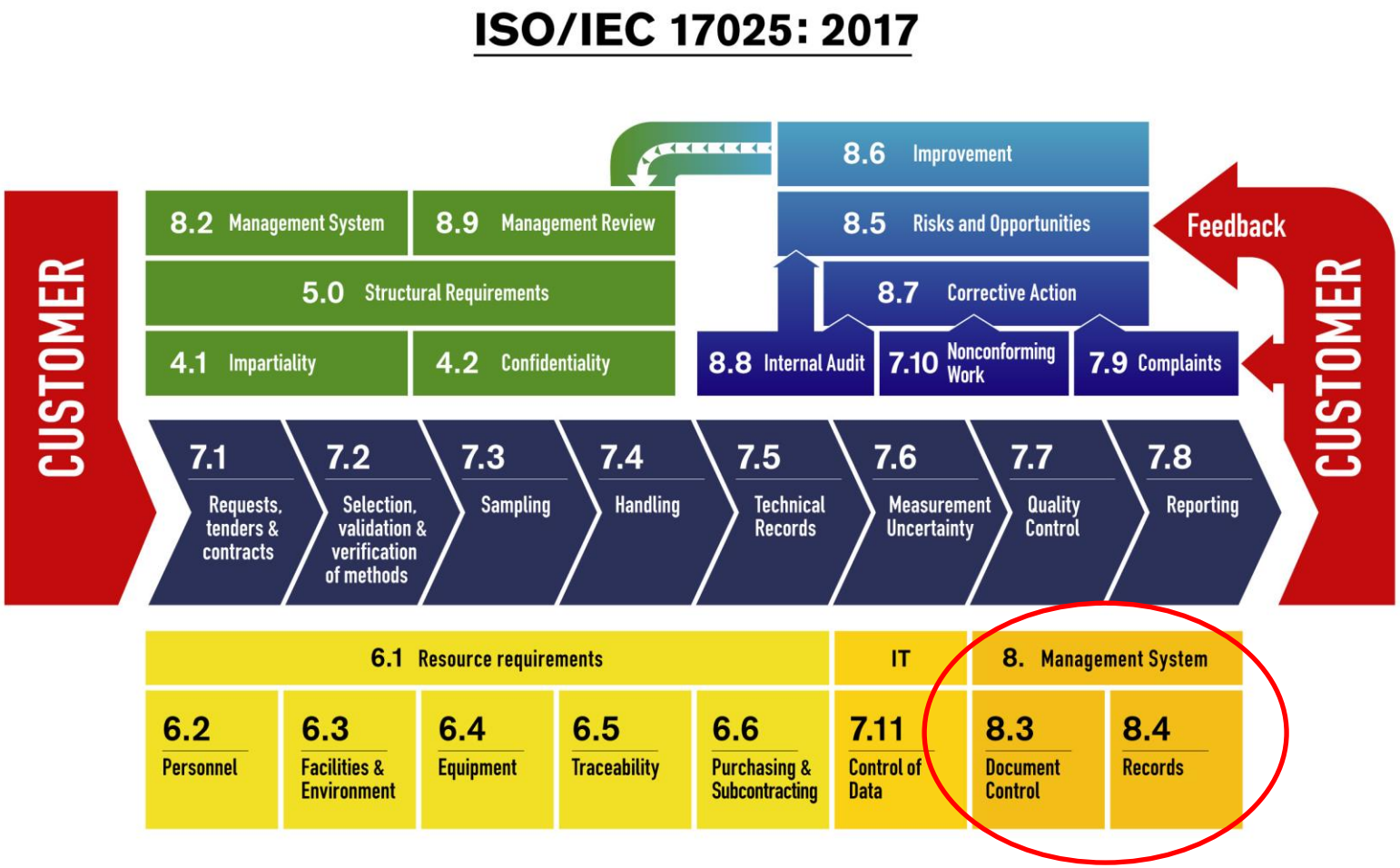
Structure


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
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CUSTOMER
7.1 Requests, tenders & contracts
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IT
8. Management System
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6.6 Purchasing & Subcontracting
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8.3 Document Control
8.4 Records

Objectives

In this lecture we will discuss about necessary documentation needed for operating the quality management system and the way to manage it:

- Documented procedures describing how a process shall be enacted and
- Records coming out of enacting the processes described in the procedures.

What is a document?

- It is information and its supporting medium.

Examples: Specification, procedures, Good practices photographs and records

The medium of document could be papers, magnetic, electronic, optical disc, photograph or a sample

Documentation

Documentation in quality management is the sum of

- documents = instructions that lead to an action
- records = annotation of the results of a process

8.2 Management system documentation

- 8.2.1 Laboratory management shall establish, document, and maintain policies and objectives for the fulfilment of the purposes of ISO/IEC 17025 and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization.
- 8.2.2 The policies and objectives shall address the competence, impartiality and consistent operation of the laboratory.
- 8.2.3 Laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.
- 8.2.4 All documentation, processes, systems, records, related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system.
- 8.2.5 All personnel involved in laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

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Quality policy

This should be made on the authority of the most senior management body for the laboratory.

This must be at the level where decisions on resource allocation are made

A quality system has a pyramidal structure

- Why? (including Quality policy)
- Quality manual – how are standards applied?
- What (when, where, who)? – the processes
- How to do it? Specific technical details
- How was it done? The proof

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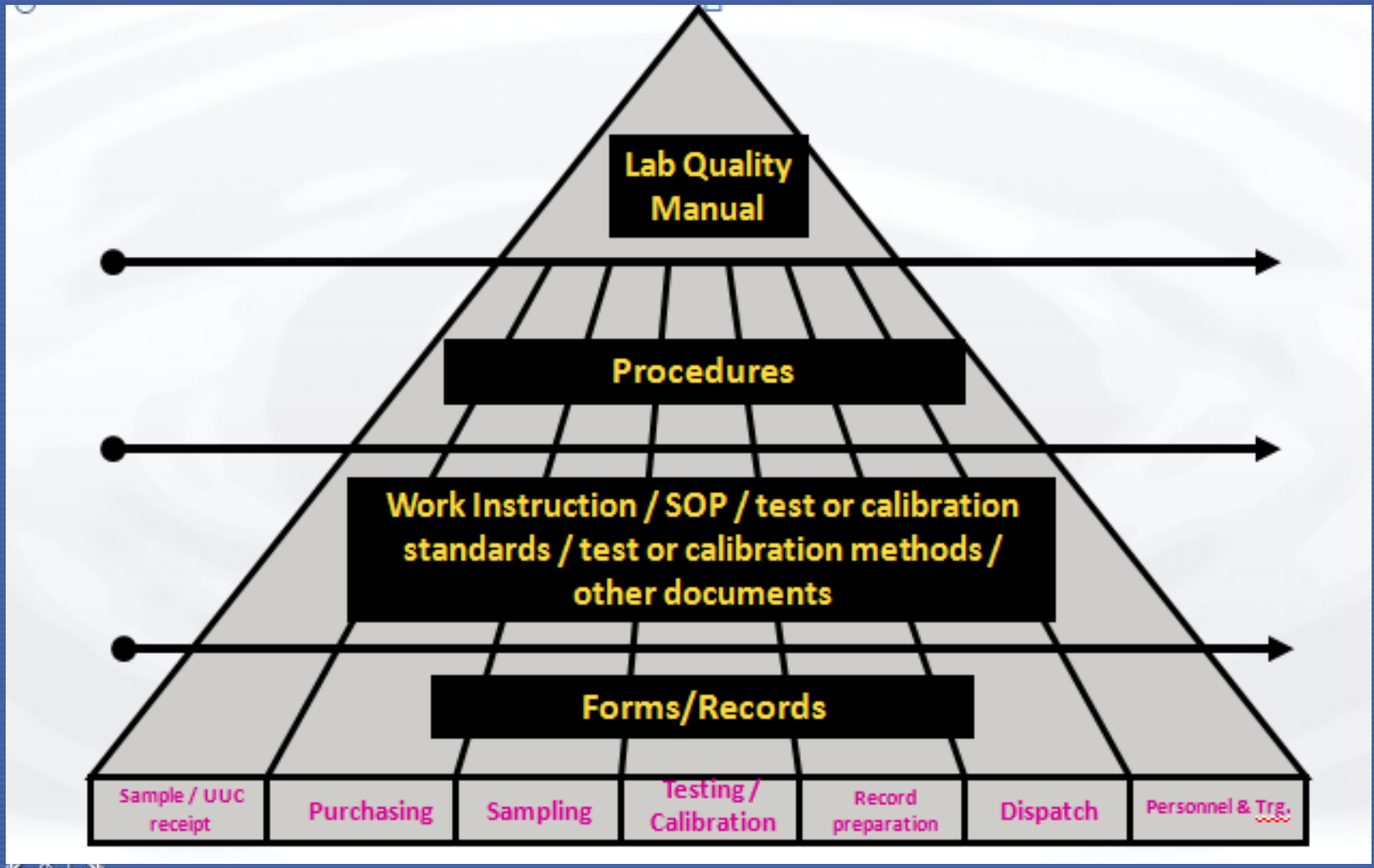
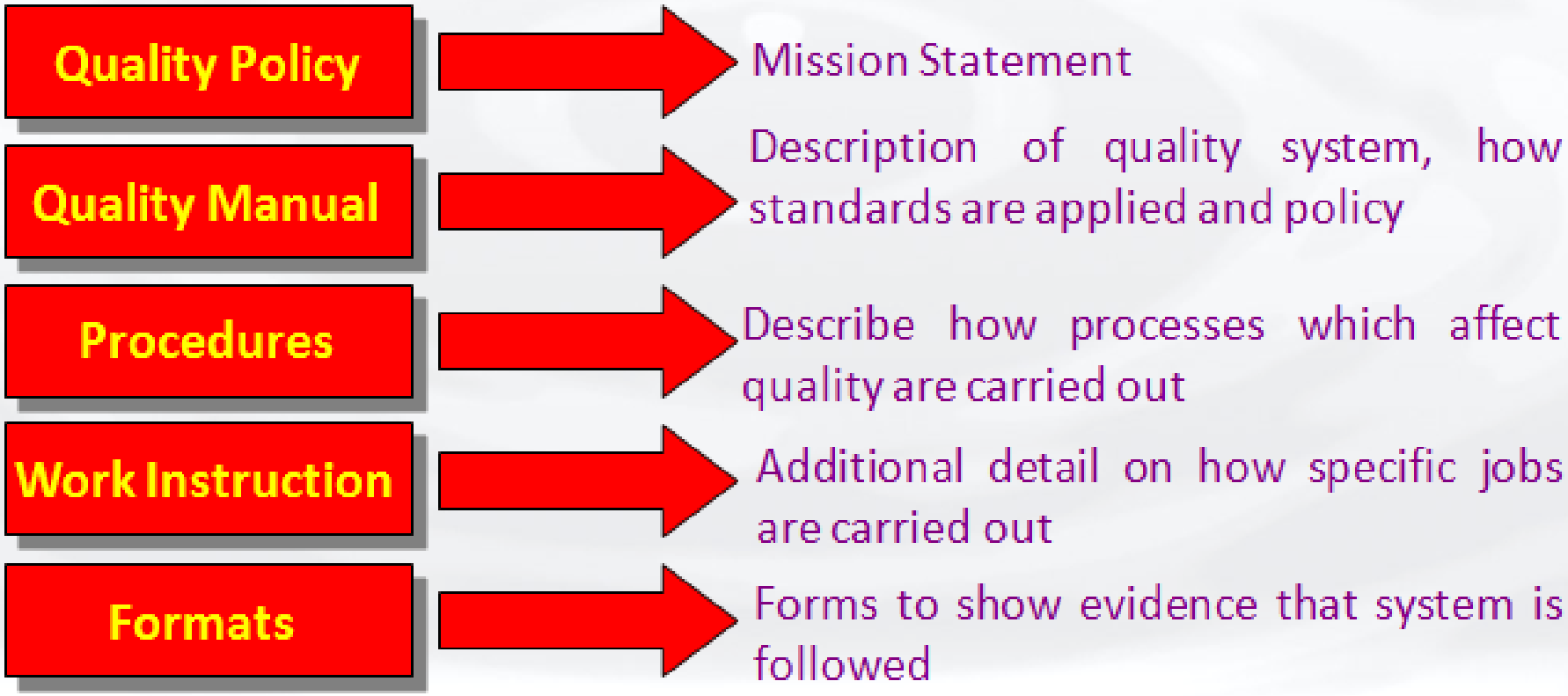
Documentation Structure for Labs under revised ISO/IEC 17025:2017 Standard



Developing ISO/IEC 17025 System

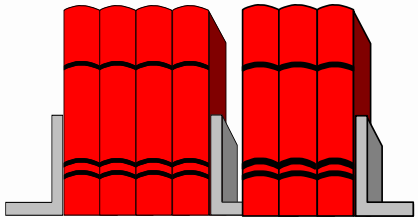
In a Quality System, work activities are described in written documents and carried out in a planned way. The structure of a documents under ISO/IEC 17025 standards are:



A quality manual

Input Requirements

- Legislation, Regulations and Codes of Practice.
- Corporate Policy and Mission Statement.
- Management System Standards, Guidelines and Practices.
- Other.



Volume 1

- Corporate Mission Statement.
- Objectives & Policy Statements.
- Management Responsibilities.
- Authorities and Accountability.
- Mandatory corporate procedures and divisional/departmental terms of reference.

Volume 2

- Divisional/departmental operating procedures.
- Processes.

Volume 3

- Work instructions.
- Operating.
- Processes.

Management System Procedures

Management system procedures may further be supplemented with detailed work instructions, forms, reports etc. termed as Level C documents.

The quantity of documented procedures, work instructions, forms, reports etc. and the nature of their format and presentation are to be determined by the individual functional units. It is preferred that each of these set of documents are arranged in the same structure and format so that the users become familiar with the consistent approach applied to each requirement.

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Why should we have procedures

- Transparency & rationalization
- To achieve comparability and harmonization and thus to avoid errors and duplication of work – communication tool
- Defines who is responsible for what
- To have a reference for discussion how things were done, early recognition of failures, problems etc
- Easier introduction of new employees
- It is a guaranteed level of work
- It's a requirement to be accredited
- It is a basis for improvement actions
- It is a knowledge management tool - it safeguards expertise and good laboratory practices

A good policy will:

- Be clear, simple and concise.
- Be relevant to the size and nature of the organization.
- State what it does and how it aims to improve.
- Be about one side of A4.
- Be balanced with general statements that detail what the company does.
- Not commit the organization to things it does not do or cannot achieve.
- It needs to belong to the company and state what the organization does. Do not copy and paste someone else's.

Quality objectives

A series of goals or targets established at different levels of the organization, which describe the desired outcome of the QMS.

These objectives should be consistent with the stated Quality Policy.

Particularly at the technical level, quality objectives should be quantifiable.

8.3 Control of management system documents

8.3.1 The laboratory shall control the documents (internal and external) that relate to the fulfilment of ISO/IEC 17025.

NOTE In this context, “documents” can be policy statements, procedures, specifications, manufacturer’s instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.

8.3 Control of management system documents

8.3.2 The laboratory shall ensure that:

a) documents are approved for adequacy prior to issue by authorized personnel

b) documents are periodically reviewed, and updated as necessary;

c) changes and the current revision status of documents are identified;

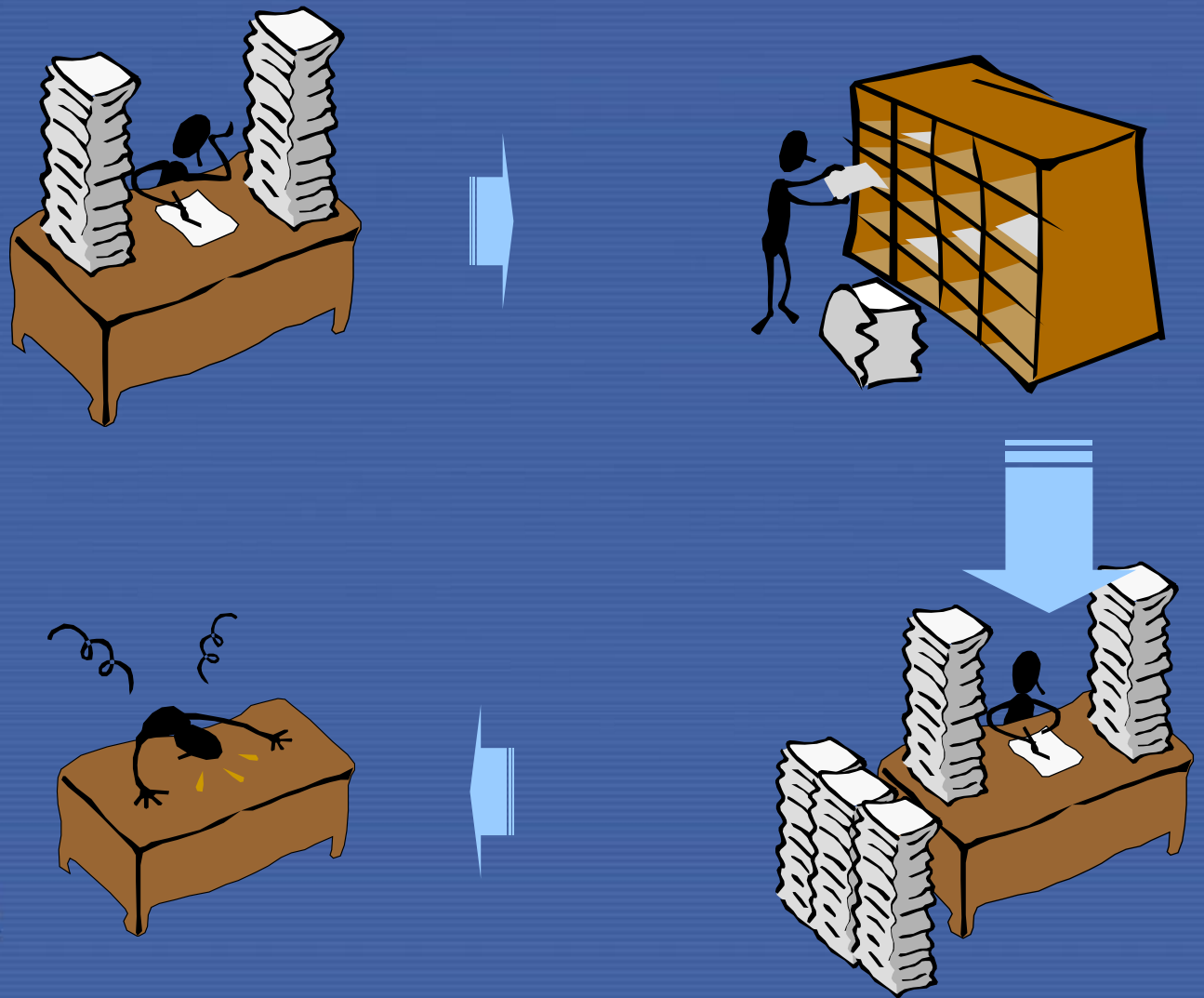
d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;

e) documents are uniquely identified;

f) the unintended use of obsolete documents is prevented, and suitable identification is applied to

g) them if they are retained for any purpose.

Document control



Control of documents

Control includes:

- creating a new document
  (who may do it, according to which procedure);
- approving a new document before it is implemented;
- implementing a new document;
- distributing of documents and marking or removing of obsolete documents ;
- reviewing implemented documents to determine whether an update (revision) may be necessary;

Control of documents

Control furthermore includes:

- discerning the current revision status of a document and identifying who is responsible for tracking the status of all documents;
- archiving documents to maintain a history of their development and revision;
- incorporating external documents into the Quality Management System;
- tracking and incorporating revisions of external documents (laws, regulations, standards).

Flexibility in Documentation

Documentation should allows flexibility to the organization in developing Good laboratory practices and Management System. Documentation which may differ from one laboratory to other due to:

- Size of the laboratory and type of its activities
- Complexity of processes and their interactions,
- Training and competence of personnel

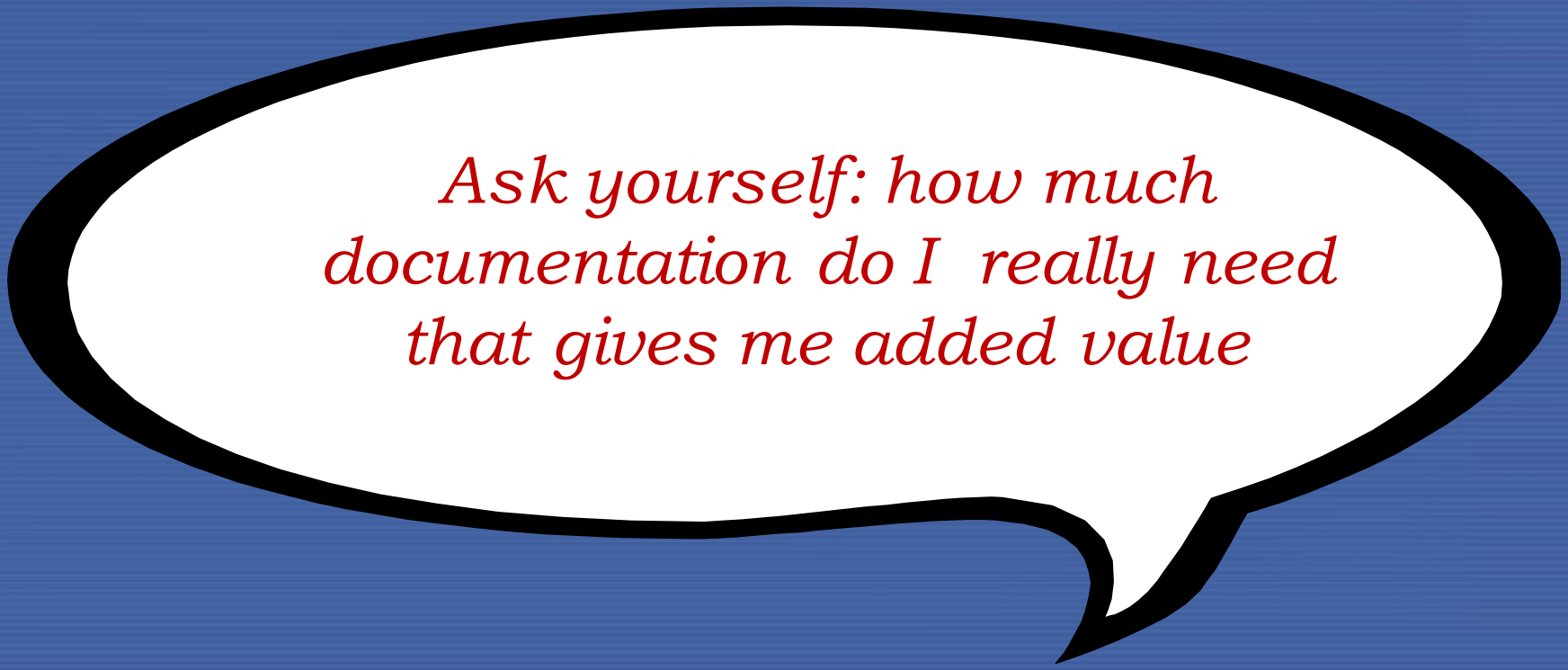
Good Documentation is:

Clear

Concise

User friendly

Have the Right Amount of Documentation



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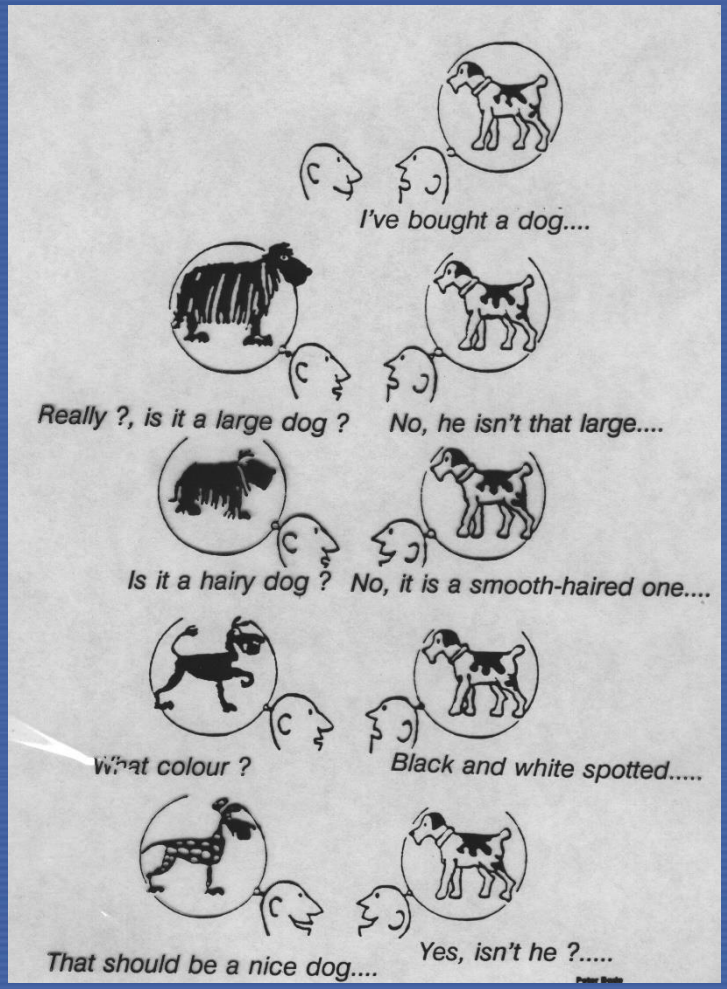
Amount of detail?



Internal documents

Documents of the quality system:

- Quality management manual
- Quality policy
- Quality objectives
- Process descriptions (procedures)

Process oriented documents:

- Procedures
- Working instructions
- Specifications
- Calibration tables
- Charts
- Drawings
- Software

External documents

These documents also have to be included into the QMS; their development has to be monitored:

- laws, decrees, governmental regulations
- standards and other normative documents
- scientific tables and calibration guidelines
- operation manuals for measurement instruments and software

The Masterlist

S. No.	Document Name	Doc. No.	Issue No.	Issue Date	Last Amend. No.	Date of last Amend.
	NABL Quality Manual	NABL 001	06	06.09.04	02	18.10.20
	NABL Operational Procedure Manual	NABL 002	06	06.09.04	08	07.04.20
	Procedure for Constituting Technical Committees for Calibration and Testing Laboratories	NABL 003	01	April 2000	02	05.11.19
	Undertaking for Maintaining Confidentiality	NABL 005	02	02.04.03	00	--
	Specific Criteria for Biological Testing laboratories	NABL 102	01	1994	02	21.10.18
	Specific Guidelines for Chemical Testing laboratories	NABL 103	02	28.02.03	01	05.07.05

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8.4 Control of records

- 8.4.1 The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in ISO/IEC 17025

- 8.4.2 The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available.

7.5 Technical records

- 7.5.1 The laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.

- 7.5.2 The laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

Retention time of records

Definition of retention time for records is up to the organization. It may be governed by local laws or standards.

Generally a period of 5 - 10 years is accepted.

For records of personal dose a period of 30 years or more might be necessary according to your regulator

Quality System Documentation – The quality manual

The quality manual should normally include the following though not necessarily in the same order:

- The Document Which Communicates laboratory's Quality Policy and Objectives to Its Staff and Customers.
- Brief background of the company
- Scope of the Management System as per ISO/IEC 17025:2017 with justification for exclusions if any.

Quality System Documentation – The quality manual (2)

- Management System documentation containing list of documents such as procedures and other documents required to operate Management System.
- Organizational structure and overview of processes followed
- As quality manual can also be used as promotional material, it should not contain anything that is confidential.
- Details for each applicable elements of ISO/IEC 17025:2017

Quality System Documentation – Quality procedures

Core of Documentation System:

- Methods of Meeting Requirements of Relevant Clauses of ISO/IEC 17025:2017
- Meant for Internal Use.
- Should be protected from inadvertent Exposure.
- To be prepared by functional Heads/Management appointee

Department	NAME OF THE COMPANY QUALITY PROCEDURE	Procedure No. : PRO/OO/XY Issue No. : 1.0 Date : DD-MM-YY

1.0 PURPOSE :

Give Statement of the Specific Purpose of the Procedure to Know Why This Procedure Is Being Followed.

2.0 SCOPE :

Mention the Department and the Area of Personnel Where the Procedure Applies.

3.0 RESPONSIBILITY :

Write Down Responsibility for Different Level of Persons for Different Activities Mention in This Procedure.

4.0 DESCRIPTION OF ACTIVITIES :

This Section Should Contain Details of the Activities Step by Step With Sub Title of Paragraphs and the Action to Be Taken. They Contain How the Actions Will Be Taken.

5.0 REFERENCE :

Give Reference of Internal and External Documents Used in Procedure

6.0 ENCLOSURES :

List Out Any Tables or Flowcharts Enclosed With the Procedure As a Part of Procedure.

7.0 FORMATS / EXHIBITS :

List Out Them in Proper Manner.

Originator	Approved By	Signature	Page Of

Quality System Documentation – Work Instructions/SOPs

Test Procedures / SOPs/Work instructions: To achieve std. of workmanship

- Required where their absence affects quality.
- Details of how the specific testing activities are to be undertaken to achieve the objectives / standards.
- Define the standards of acceptability.
- Contents to be simple and easy to follow. Standards, Codes or Practice, Regulations.....

Quality System Documentation – Forms, Records

Other documents: Forms, Records, etc.

- Supporting Document. To Record and Distribute Information.
  - Forms of all kinds : test report, raw data sheet, audit, calibration, customer satisfaction .....
  - Records of activities, performance, certificates of Conformity...
- These help to prove that the quality system is operating effectively.

Procedures required by ISO/IEC 17025

List of Procedures:

- 6.2.5 Procedure for personnel
- 6.3.3 Procedure to maintain laboratory environmental conditions
- 6.4.3 Procedure for handling, transport, storage, use and planned maintenance of equipment
- 6.4.10 Intermediate checks procedure
- 6.5.2 Documented risk management process

Procedures required by ISO/IEC 17025 (2)

- 6.5.3b Results of reference measurement procedures
- 6.6.2 Procedure for externally provided products and services
- 7.1.1 Procedure for the review of requests, tenders and contracts
- 7.2.1.1 Procedure for evaluation of the measurement uncertainty and use of statistical techniques for analysis of data.

Procedures required by ISO/IEC 17025 (3)

- 7.2.2.4 Procedure for method validation
- 7.4.1 Procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items
- 7.7 Procedure for ensuring the validity of results
- 7.10 Procedure for Nonconforming work

Documents required by ISO/IEC 17025

- 5.3 Define the scope with range
- 6.2.2 document the competence requirements
- 6.4.13 documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity
- 6.5.1 maintain metrological traceability of its measurement results
- 7.1.1 Contract review requirements

Documents required by ISO/IEC 17025 (2)

- 7.6 Decision rule to give statement of conformity to a specification or standard
- 7.8.7.1 Document the basis upon which the opinions and interpretations have been made.
- 7.11 Any changes in data to be documented and authorized
- 8.1.1 Document the system to plan and implement
- 8.2.1 Document, and maintain policies and objectives

Records required by ISO/IEC 17025

- 6.2.6 Records for determining the competence requirements: . Selection, Training, Supervision, Authorization, Monitoring of competence of personnel
- 6.3 Record environmental conditions
- 6.4.13 Equipment records with manufacturer details and acceptance criteria

Records required by ISO/IEC 17025 (2)

- 6.6 Record for externally provided product and services (Selection, evaluation, reevaluation, order, inspection and action on providers)
- 7.1.8 Records of contract reviews, discussions (including any significant changes)
- 7.2.1.5 Records of the verification of methods performance
- 7.2.2.4 Records of the validation
- 7.3.3 Records of sampling data

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Records required by ISO/IEC 17025 (3)

- 7.4.3 Records of deviations of sample conditions on receipt and customer consultation
- 7.4.4 Environmental conditions monitoring records during storage
- 7.5.1 Original observations, data and calculations
- 7.6 Evaluation of measurement uncertainty and use of statistical techniques
- 7.7.1 Monitoring results and track the trend for the validity of results (QA)

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List of Quality Procedures – Example as suggestion

Sr. No.	Document No.	Title Of Quality Procedure
1.	QP/01	Personnel and training
2.	QP/02	Maintain laboratory environmental condition
3.	QP/03	Handling, transport, storage, use and planned maintenance of equipment
4.	QP/04	Intermediate checks
5.	QP/05	Measurement traceability and calibration
6.	QP/06	Procurement of externally provided products and services
7.	QP/07	Review of requests, tenders and contracts
8.	QP/08	Method validation
9.	QP/09	Transportation, receipt, handling, protection, storage, retention, and disposal or return of test items
10.	QP/10	Evaluation of measurement uncertainty and statistical techniques for analysis of data
11.	QP/11	Ensuring and monitoring of validity of result

List of Quality Procedures – Example as suggestion

Sr. No.	Document No.	Title Of Quality Procedure
12.	QP/12	Receive, evaluate and make decisions on complaints
13.	QP/13	Control of non–conforming work
14.	QP/14	Control of data
15.	QP/15	Document and data control
16.	QP/16	Control of records
17.	QP/17	Risk assessment
18.	QP/18	Corrective action
19.	QP/19	Internal audit
20.	QP/20	Management review

List of forms– Example as suggestion

Sr. No.	Format No.	Title Of Formats
Marketing		
1.	F/MKT/01	Test Request and Sample Receipt Report
2.	F/MKT/02	Customer Feedback Form
3.	F/MKT/03	Complaint Report
4.	F/MKT/04	Inward Register
Maintenance/ Instrument Operation		
5.	F/OPN/01	Equipment History Card
6.	F/OPN/02	Preventive Maintenance Schedule
7.	F/OPN/03/xx	Equipment Wise Preventive Maintenance Checkpoints
8.	F/OPN/04	Disposal Of Non–Conforming Work
9.	F/OPN/05	Gate Pass
11.	F/TRG/05	Job description and specification
12.	F/TRG/06	Skill matrix

List of forms– Example as suggestion (2)

Sr. No.	Format No.	Title Of Formats
Purchase		
13.	F/PUR/01	Purchase Order
14.	F/PUR/02	Indent – Purchase Requisition
15.	F/PUR/03	Approved Vendor List Cum Open Purchase Order
16.	F/PUR/04	Supplier Registration Form
17.	F/PUR/05	Open Purchase Order
18.	F/PUR/06	Supplier Evaluation Report
19.	F/PUR/07	Inspection Report
Quality control		
20.	F/QCD/01	Four Year Plan for Quality Control
21.	F/QCD/02	Re–test plan / execution report
22.	F/QCD/03	Z Score Analysis Report (Standard Deviation Method)
23.	F/QCD/04	Uncertainty Of Measurement
24.	F/QCD/05	Re–test Analysis Report

List of forms– Example as suggestion (3)

Sr. No.	Format No.	Title Of Formats
25.	F/QCD/06	Intermediate check report – Weighing Balance
26.	F/QCD/07	Intermediate check report – Oven
27.	F/QCD/08	Curing Tank Temperature Monitoring Report
28.	F/QCD/09	Cement Section Environment Monitoring Report
29.	F/QCD/10	Bitumen Section Temperature Monitoring Report
30.	F/QCD/11	Intermediate check report – Humidity chamber
System		
31.	F/SYS/01	Master List Cum Distribution List of Documents
32.	F/SYS/02	Change Note
33.	F/SYS/03	Corrective Action Report
34.	F/SYS/04	Master List of Records
35.	F/SYS/05	Quality Objectives
36.	F/SYS/06	Audit plan / schedule

List of forms– Example as suggestion (4)

Sr. No.	Format No.	Title Of Formats
37.	F/SYS/07	Internal Audit Non–Conformity Report
38.	F/SYS/08	Clausewise Documentwise Audit Review Report
39.	F/SYS/09	Risk Assessment sheet
40.	F/SYS/10	Calibration Status of Equipment
41.	F/SYS/11	Clausewise audit report – Quality Manager
42.	F/SYS/12	Clausewise audit report – Technical Manager
43.	F/SYS/13	Circular
44.	F/SYS/14	Minutes of Meeting
45.	F/SYS/15	Continual improvement log
Training		
46.	F/TRG/01	Training Calendar
47.	F/TRG/02	Training Report
48.	F/TRG/03	Induction Training Report

List of forms– Example as suggestion (5)

Sr. No.	Format No.	Title Of Formats
49.	F/TRG/04	Job Description And Specification
50.	F/TRG/05	Skill Matrix
51.	F/TRG/06	Confidentiality Agreement
40.	F/TRG/07	Appointment Letter
41.	F/TRG/08	Employees Competence Report
42.	F/TRG/09	ISO/IEC 17025 Effectiveness Check Report
43.	F/TRG/10	Technical Training Effectiveness check report
44.	F/TRG/11	Interview report