L9 Documentation
8 Management System Requirements
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.
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
Documentation Structure for Labs under revised ISO/IEC 17025:2017 Standard
In a Quality System, work activities are described in written documents and carried out in a planned way. The structure of documents under ISO/IEC 17025 standards are:

- **Quality Policy**
  - Mission Statement
- **Quality Manual**
  - Description of quality system, how standards are applied and policy
- **Procedures**
  - Describe how processes which affect quality are carried out
- **Work Instruction**
  - Additional detail on how specific jobs are carried out
- **Formats**
  - Forms to show evidence that system is followed
A quality manual

Input Requirements

- Legislation, Regulations and Codes of Practice.
- Corporate Policy and Mission Statement.
- 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.
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 allow 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
Ask yourself: how much documentation do I really need that gives me added value
Amount of detail?

I've bought a dog....

Really?, is it a large dog?  No, he isn't that large....

Is it a hairy dog?  No, it is a smooth-haired one....

What colour?  Black and white spotted.....

That should be a nice dog...  Yes, isn't he?.....
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

<table>
<thead>
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<td>02</td>
<td>28.02.03</td>
<td>01</td>
<td>05.07.05</td>
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</table>
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.
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
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.
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......
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
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
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)
List of Quality Procedures – Example as suggestion

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Document No.</th>
<th>Title Of Quality Procedure</th>
</tr>
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<tbody>
<tr>
<td>1.</td>
<td>QP/01</td>
<td>Personnel and training</td>
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<td>2.</td>
<td>QP/02</td>
<td>Maintain laboratory environmental condition</td>
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<td>3.</td>
<td>QP/03</td>
<td>Handling, transport, storage, use and planned maintenance of equipment</td>
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<td>4.</td>
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<td>Intermediate checks</td>
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<td>5.</td>
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<td>Measurement traceability and calibration</td>
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<td>6.</td>
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<td>Procurement of externally provided products and services</td>
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<td>7.</td>
<td>QP/07</td>
<td>Review of requests, tenders and contracts</td>
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<td>Method validation</td>
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<td>9.</td>
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<td>Transportation, receipt, handling, protection, storage, retention, and disposal or return of test items</td>
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<td>10.</td>
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<td>Evaluation of measurement uncertainty and statistical techniques for analysis of data</td>
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<td>11.</td>
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<td>Ensuring and monitoring of validity of result</td>
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List of Quality Procedures – Example as suggestion

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# List of forms—Example as suggestion

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<td>Re–test plan / execution report</td>
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<td>F/SYS/08</td>
<td>Clausewise Documentwise Audit Review Report</td>
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<td>F/SYS/11</td>
<td>Clausewise audit report – Quality Manager</td>
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<td>F/SYS/12</td>
<td>Clausewise audit report – Technical Manager</td>
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### Training

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List of forms– Example as suggestion (5)

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<td>50.</td>
<td>F/TRG/05</td>
<td>Skill Matrix</td>
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<td>51.</td>
<td>F/TRG/06</td>
<td>Confidentiality Agreement</td>
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<td>F/TRG/07</td>
<td>Appointment Letter</td>
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<td>41.</td>
<td>F/TRG/08</td>
<td>Employees Competence Report</td>
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<td>42.</td>
<td>F/TRG/09</td>
<td>ISO/IEC 17025 Effectiveness Check Report</td>
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<td>43.</td>
<td>F/TRG/10</td>
<td>Technical Training Effectiveness check report</td>
</tr>
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<td>44.</td>
<td>F/TRG/11</td>
<td>Interview report</td>
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