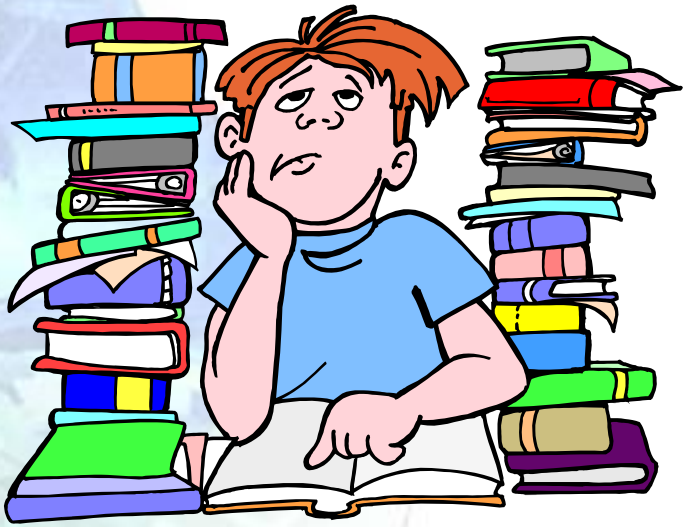
MODULE 2

Review on MS ISO/IEC 17025:2005 Requirements



MS ISO/IEC 17025 : 2005

GENERAL REQUIREMENTS FOR THE COMPETENCE OF TESTING AND CALIBRATION LABORATORIES

An international standard specifying the elements and operation of a quality management system for laboratories performing calibration or testing work.

QUALITY MANAGEMENT SYSTEM

Management system to direct and control an organisation with regard to quality.

Management System:
system to establish policy and objectives and to achieve those objectives.

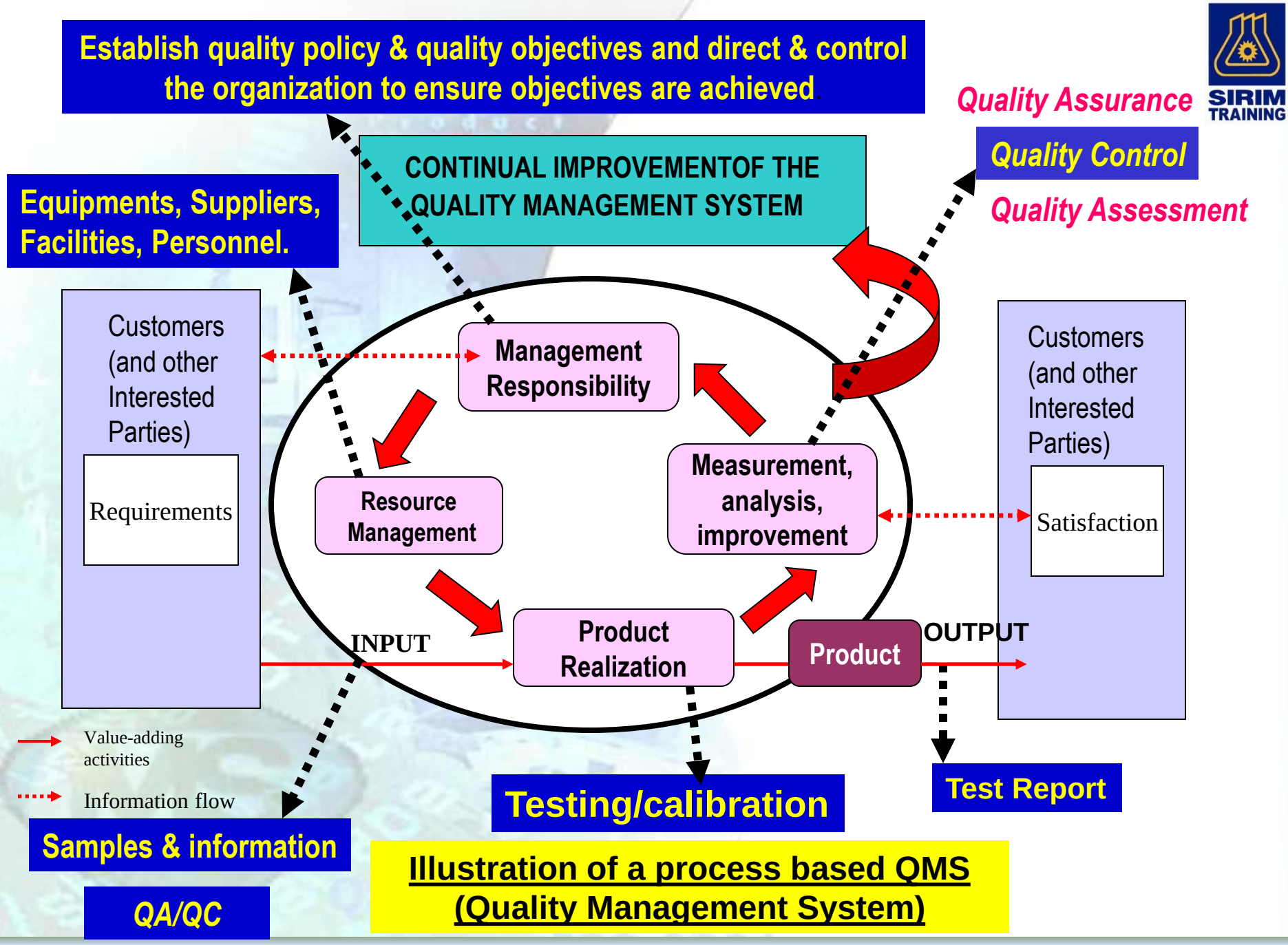


Illustration of a process based QMS (Quality Management System)

A BRIEF TOUR OF ISO 17025:2005

THERE ARE 5 PARTS TO THE STANDARD:

1. SCOPE
2. NORMATIVE REFERENCES
3. TERMS AND DEFINITIONS
4. MANAGEMENT REQUIREMENTS
5. TECHNICAL REQUIREMENTS

4. MANAGEMENT REQUIREMENTS

4.1 ORGANISATION
4.2 MANAGEMENT SYSTEM
4.3 DOCUMENT CONTROL
4.4 REVIEW OF REQUESTS, TENDERS AND CONTRACTS
4.5 SUBCONTRACTING OF TESTS
4.6 PURCHASING SERVICES AND SUPPLIES
4.7 SERVICE TO CUSTOMER
4.8 COMPLAINTS
4.9 CONTROL OF NON-CONFORMING TESTS
4.10 IMPROVEMENT
4.11 CORRECTIVE ACTIONS
4.12 PREVENTIVE ACTIONS
4.13 CONTROL OF RECORDS
4.14 INTERNAL AUDITS
4.15 MANAGEMENT REVIEWS

5. TECHNICAL REQUIREMENTS

5.1 GENERAL
5.2 PERSONNEL
5.3 ACCOMMODATION AND ENVIRONMENTAL CONDITIONS
5.4 TEST AND CALIBRATION METHODS AND METHODS VALIDATION
5.5 EQUIPMENT
5.6 MEASUREMENT TRACEABILITY
5.7 SAMPLING
5.8 HANDLING OF TEST / CALIBRATION RESULTS
5.9 ASSURING THE QUALITY OF TEST / CALIBRATION RESULTS
5.10 REPORTING THE RESULTS

4. Management Requirements

4.1 Organisation

Roles and responsibilities of the laboratory, the management and key Personnel.

4.2 Management System

Laboratory shall implement a management system appropriate to the scope of activities.

4.3 Document Control

Procedures on establishing, approval, issue and change of documents.

4.4 Review of Requests, Tenders and Contracts

The laboratory shall establish and maintain procedures for the review of requests.

4.5 Subcontracting of Tests

When a laboratory subcontracts work, this work shall be placed with a competent subcontractor i.e. one that complies with ISO 17025.

4. Management Requirements

4.6 Purchasing Services and Supplies

Requirement for a policy and procedure for the selection and purchasing of services and supplies it uses that affect the quality of tests. Purchased supplies, reagents shall be checked before use.
Laboratory shall evaluate suppliers of critical consumables, supplies and services.

4.7 Service to the Customer

Cooperate with customer with their requests.

4.8 Complaints

The laboratory shall have a policy and procedure for the resolution of complaints received from customers and other parties.

4. Management Requirements

4.9 Control of non-Conforming testing work

There shall be procedures in case of non-conformance to specifications.
Actions should be defined in case of such non-conformance
e.g.: could be holding the work, or notification of the client , or recall work.
If this appears to be a general problem, a corrective action plan should be developed.

4.10 Improvement

Effectiveness of the management system shall be continually improved.

4.11 Corrective Action

Should be in place in case of non-conforming work. Start with an investigation to determine the cause of the problem.
Actions shall be taken to prevent recurrence of the problem.

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4. Management Requirements

4.12 Preventive Action

Identify the need for improvements and potential sources of non-conformance. This is a pro-active process to identify opportunities of improvement rather than reaction to problems or complaints. Preventive action might involve analysis of data, including trend analysis, risk analysis and participating in proficiency testing.

4.13 Control of Records

Procedures for identification, collection, indexing, access, filing, storage, maintenance, disposal of quality and technical records. Records should be protected against damage. There should be procedures to protect and back-up records and to prevent unauthorised access. The clause also list details of contents of technical records. It also has clear requirement that records must not be erased or deleted in case of corrections.
Changes must be signed.

4. Management Requirements

4.14 Internal Audits

The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and this International Standard. Recommended audit cycle is one year.

4.15 Management Review

Management shall periodically conduct a review of the laboratory's management system and testing activities to ensure their continuing suitability and effectiveness, and to introduce the necessary changes or improvements

5. Technical requirements

5.1 General

Factors determining the correctness and reliability of tests shall be taken into account by laboratory

5.2 Personnel

Key element of personnel is appropriate training and documentation of all training activities. The training needs for all personnel whose work affects quality must be identified.

Effectiveness of training actions shall be evaluated.

5.3 Accommodation and Environmental conditions

Accommodation and environmental conditions of test areas shall facilitate correct performance of tests and shall be monitored and controlled so as not to invalidate results or adversely affect the required quality of tests.

5. Technical requirements

5.4 Test and Calibration Methods and Method validation

The laboratory shall use appropriate methods and procedures for all tests within its scope. These includes sampling, handling, transport, storage and preparation of items to be tested/calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test/calibration data.

5.5 Equipment

Equipment available for correct performance of tests/calibration including sampling, sample preparation, processing and analysis. Equipment able to achieve accuracy required and comply with tests/calibration concerned. List of records required are specified in the clause. Maintenance and calibration programmes available for equipment.

5. Technical requirements

5.6 Measurement Traceability

This clause deals with measurement traceability of test equipment and reference standards. Specific requirements are specified for calibration, testing and reference standards and reference materials.

5.7 Sampling

The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration

5.8 Handling test and calibration items

The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test/calibration items

5. Technical requirements

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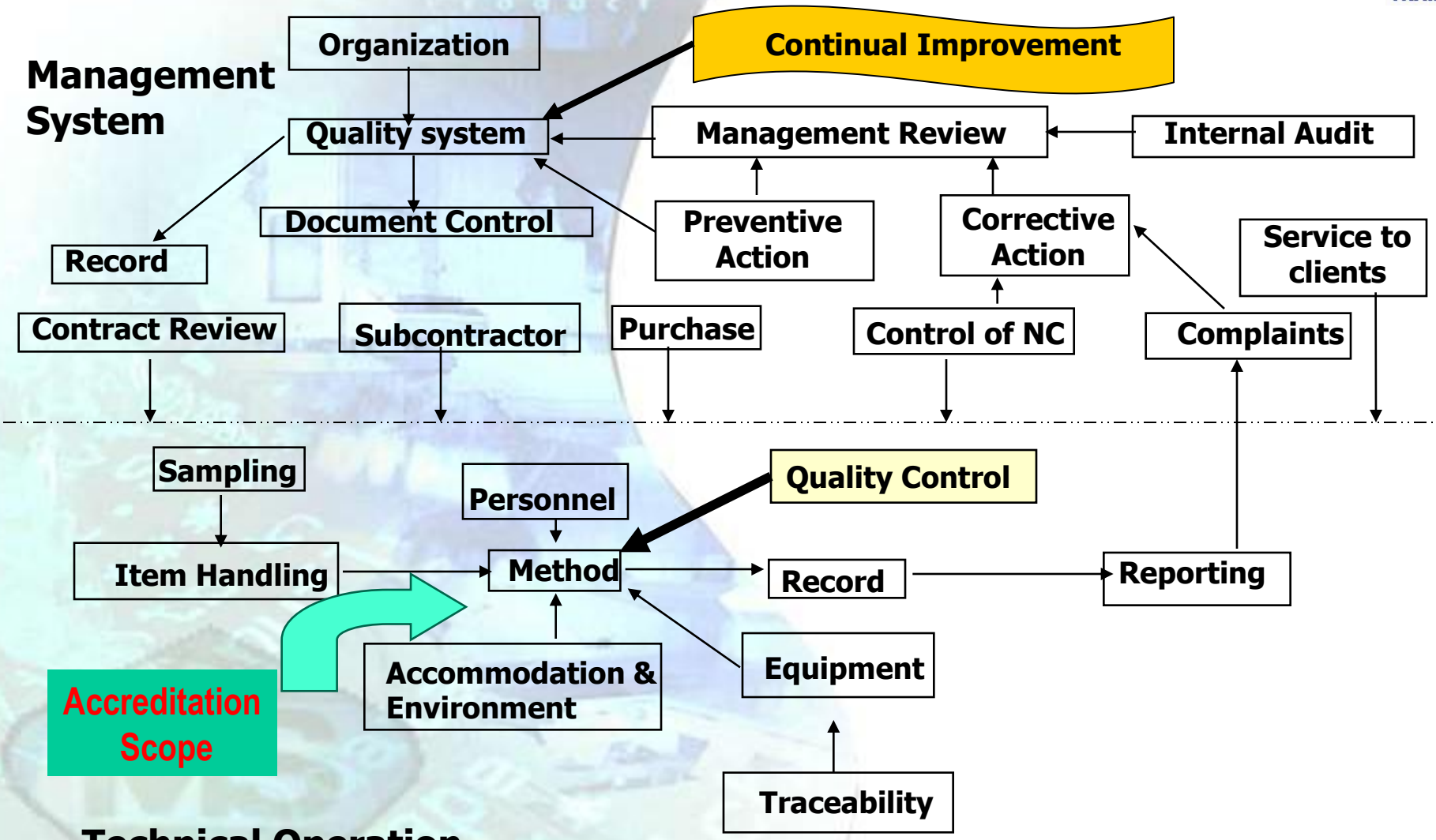
5.9 Assuring the quality of tests and calibration results

The laboratory shall have quality control procedures for monitoring the validity of tests.The monitoring shall be planned and review.

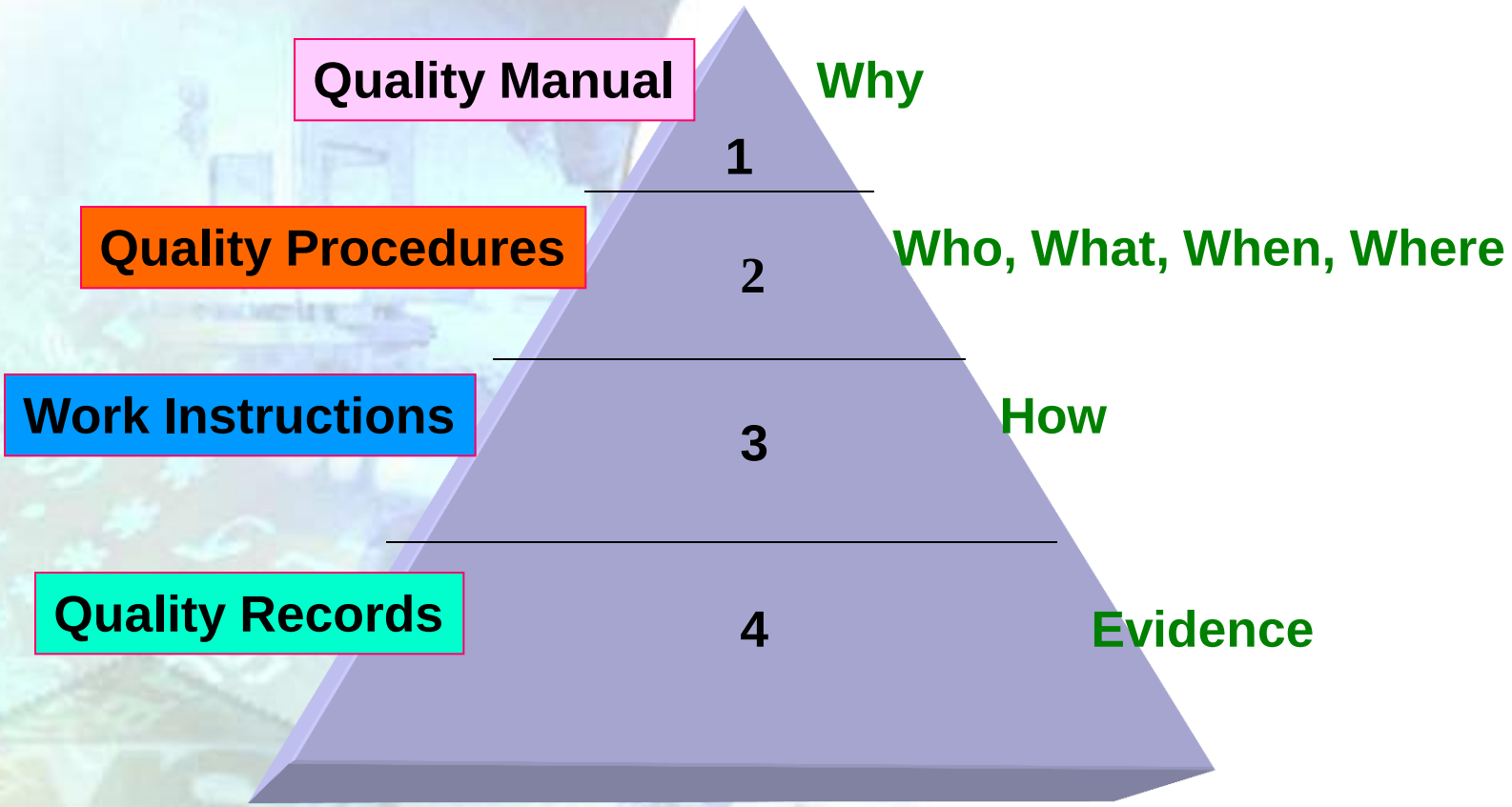
5.10 Reporting the Results

This clause describes how test results should be reported. There are general requirements on test reports like clarity and accuracy but also very detailed requirements on the contents. When opinions and interpretations are included, the laboratory shall document the basis upon which opinions and interpretations have been made.

ISO 17025 - RELATIONSHIP OF EACH REQUIREMENTS



ISO/IEC 17025 DOCUMENTATION



Document Pyramid

ISO/IEC 17025 DOCUMENTATION

- Documented statements of a quality policy & quality objectives
- A quality manual
- Documented procedures required by this international standard
- Document needed by organization to ensure effective planning, operation and control of its processes
- Records required by this International Standard

… Clause 4.2.1

End of session 2: Review on ms iso/iec17025:2005

Thank you very much