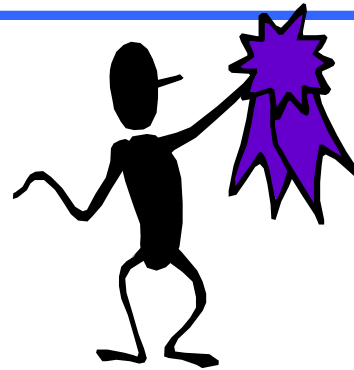


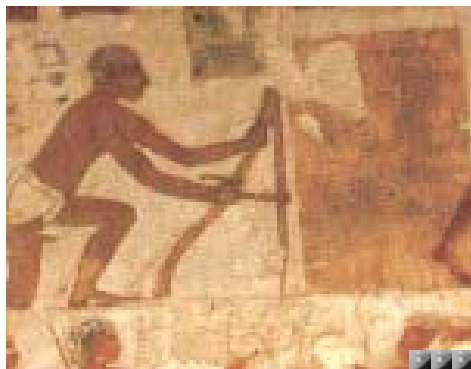
OBJECTIVES OF QUALITY ASSURANCE SYSTEMS BASED IN THE RULES:
GLP Good Laboratory Practices
ISO17020 Inspection
ISO17025 Assay & Calibration
ISO9001



Joan Rabasseda
Head of Projects
Laboratori Agroalimentari - DARP

Ljubljana, April 18th 2006

QUALITY CONTROL vs QUALITY ASSURANCE



Why do we need a Quality Management System?

- To **demonstrate** the validity of the results
- To ensure that the **quality** of the results is **under control**
- To keep procedures for identification, collection, indexing, access, storage, maintenance and disposal of all significant / important **records**
- The records for each analysis shall contain sufficient information
- **Traceability**
- . . .

FREE TRADE

How do we get our work?

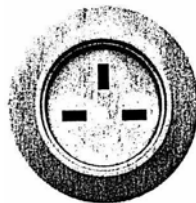
SAME PROCEDURES?

CORRECTNESS?
RELIABILITY?

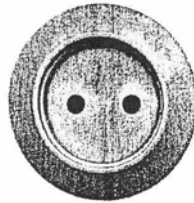
COMPARABILITY?

"ALL" RECORDED?

QUALITY SYSTEM
REQUIREMENTS?



LONDON



HELSINKI



SYDNEY

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SAME TERMS?
VOCABULARY?

SAME EQUIPMENT?

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RELAIBLE RESULTS



DEMONSTRATE
TECHNICAL COMPETENCE

Main Quality Rules

- 1962 FDA "Good Manufacturing Practices"
- 1976 FDA "Good Laboratory Practice Regulations for Nonclinical Laboratory Studies" (Mandatory legal framework since 22/07/1979).
- 1981 OEDC principles of GLP
- 1989 EN45001
- 1992 EFQM
- 1997 OECD Principles of Good Laboratory Practice
- 1998 ISO17020 and EN45011
- 1999 ISO17025
- 2000 ISO9001
- 2002 CAF Model
- 2005 ISO17025

Quality framework

ISO9000	ISO17025	GLP
Pattern for quality assurance	To get quality analytical results	Assessment of potential risk on health & environment
For any kind of company or sector	For laboratories	For laboratories
For products and services	Mutual acceptance of results	Non clinical assays with legal purpose (registry)
Voluntary scope	Voluntary and compulsory scope	Compulsory scope

Quality framework

ISO9001:2000	ISO17025:12005	Cross-references
6.1 b)	4.4.1, 4.7, 5.4.2, 5.4.3, 5.4.4, 5.10.1	Review of requests, tenders and contracts Service to the client Test and calibration methods and method validation Reporting the results
6.2.1, 6.2.2 a), 6.2.2 b), 6.2.2 c), e)	5.2.1, 5.2.2, 5.5.3, 5.2.1, 5.2.2, 5.2.2, 5.2.5	Personnel Equipment
6.2.2 d), 6.3.1 a)	4.1.5 k) 4.1.3, 4.12.1.2, 4.12.1.3, 5.3	Organization Preventive actions Accommodation and environmental conditions
6.3.1 b)	4.12.1.4, 5.4.7.2, 5.5, 5.6	Control of data Equipment Measurement of traceability

Quality framework

ISO9001:2000	ISO17025:12005	Cross-references
6.3.1 c)	4.6, 5.5.6, 5.6.3.4, 5.8, 5.10	Purchasing services and supplies Equipment Transport and storage (MRC) Handling of test items Reporting the results
6.4)	5.3.1, 5.3.2, 5.3.3, 5.3.4, 5.3.5	Accommodation and environmental conditions
7.1, 7.1 a), 7.1 b)	5.1, 4.2.2, 4.1.5 a), 4.2.1, 4.2.3	General Quality system policies and objectives Quality manual Laboratory duties
7.1 c), 7.1 d)	5.4, 5.9, 4.1, 5.4, 5.9	Test methods and method validation Assuring the quality of tests results

Quality framework

ISO9001:2000	ISO17025:12005	Cross-references
7.2.1 7.2.2 7.2.3	4.4.1, 4.4.2., 4.4.3, 4.4.4, 4.4.5, 5.4, 5.9, 5.10 4.4.1, 4.4.2, 4.4.3, 4.4.4, 4.4.5, 5.4, 5.9, 5.10 4.4.2, 4.4.4, 4.5, 4.7, 4.8	Review of requests, tenders and contracts Test methods and method validation Assuring the quality of tests results Reporting the results
7.3	5. 5.4, 5.9	Technical requirements Test methods and method validation Assuring the quality of tests results
7.4.1, 7.4.2, 7.4.3	4.6.1, 4.6.2, 4.6.4, 4.6.3, 4.6.2	Purchasing services and supplies
7.5.1, 7.5.2, 7.5.3, 7.5.4	5.1, 5.2, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9 5.2.5, 5.4.2, 5.4.5 5.8.2 4.1.5 c), 5.8	Technical requirements Test methods and method validation Equipment Measurement traceability Assuring the quality of tests results

Quality framework

ISO9001:2000	ISO17025:12005	Cross-references
7.5.5 7.6	4.6.1, 4.12, 5.8, 5.10 5.4, 5.5	Selection of purchasing services Preventive actions Handling of test items Reporting the results Test methods and method validation Equipment
8.1 8.2.1 8.2.2 8.2.3	4.10, 5.4, 5.9 4.10 4.11.5, 4.14 4.11.5, 4.14, 5.9	Improvement Test methods and method validation Assuring the quality of tests results Corrective actions Internal audits
8.2.4, 8.3, 8.4, 8.5.1, 8.5.2, 8.5.3	4.5, 4.6, 4.9, 5.5.2, 5.5.9, 5.8, 5.8.3, 5.8.4, 5.9, 4.9, 4.10, 5.9, 4.10, 4.12, 4.11, 4.12, 4.9, 4.11, 4.12	Subcontracting Purchasing services and supplies Control of non conforming work Preventive actions


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Quality framework

ISO17020	EN45011	GLPs
<ul style="list-style-type: none"> ▪ Independence, impartiality and integrity ▪ Confidentiality ▪ Organization/ management: responsibilities documented, job description, supervision, training... ▪ Quality System: Policy and objectives Quality manual (<i>content</i>) Control of documents Internal quality audits Corrective actions Review of quality system ▪ Personnel ▪ Facilities and equipment 	<ul style="list-style-type: none"> ▪ General provisions non-discriminatory criteria ▪ Organization: management impartiality documented structure formal rules and structures resolution of complaints ▪ Operations ▪ Quality System authority and responsibility management review administrative procedures personnel 	<ul style="list-style-type: none"> ▪ Responsibilities: test facility management study director principal investigator study personnel's ▪ Quality Assurance Programme ▪ Facilities: test system handling test and reference items archive waste disposal ▪ Apparatus, Material, and Reagents ▪ Test system ▪ Test and reference items


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Quality framework

ISO17020	EN45011	GLPs
<ul style="list-style-type: none"> ▪ Inspections methods and procedures ▪ Handling of inspections samples an items ▪ Records ▪ Inspection reports and inspection certificates ▪ Subcontracting ▪ Complaints and appeals ▪ Cooperation 	<ul style="list-style-type: none"> training personnel subcontractors handling nonconformities evaluation procedures complaints and disputes internal audits ▪ Conditions and procedures ▪ Internal audits and management reviews ▪ Documentation ▪ Records ▪ Confidentiality ▪ Personnel qualification ▪ Changes in certification requirements 	<ul style="list-style-type: none"> ▪ Standard Operation Procedures ▪ Performance study <ul style="list-style-type: none"> study plan content study plan conduct study plan ▪ Reporting of study results ▪ Storage and retention of records and materials

Quality framework

ISO17020	EN45011	GLPs
	<ul style="list-style-type: none"> ▪ Appeals complaints and disputes ▪ Information on the procedures for certification ▪ Preparation for evaluation ▪ Evaluation ▪ Decision on certification ▪ Surveillance ▪ Use of licences (conformity) 	

Quality framework

- ISO9001, ISO17025, ISO17020, EN45011, GLP:
 - Management commitment
 - Quality policies and objectives
 - Quality system documented:
 - Quality manual
 - Procedures
 - Deming circle in all activities:
 - Plan
 - Do
 - Check
 - Act

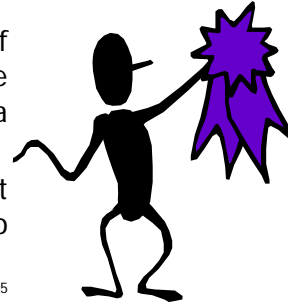
Common quality framework

- | | |
|--|---|
| 1. Request, tender and contract review | 10. Handling of test items |
| 2. <i>Sub-contracting</i> | WORK |
| 3. Purchasing services and supplies | 11. Control of nonconforming testing work |
| 4. Service to the client | 12. Corrective action |
| 5. Complaints | 13. Preventive action |
| 6. Control of data and records | 14. Internal audits |
| 7. Document control | 15. Management reviews |
| 8. Traceability | |
| 9. Personnel policies | 16. Reporting the results |

ISO9000 - ISO17025

- “Certification against ISO 9001 does not of itself demonstrate the competence of the laboratory to produce technically valid data and results.”
- Testing and calibration laboratories that comply with ISO17025 will therefore also operate in accordance with ISO 9001.

ISO/IEC 17025:2005



Voluntary

Compulsory

ISO17020 - General Criteria for the Operation of Various Types of Bodies Performing Inspection

- Accreditation for Inspection
 - Administrative requirements (Clause 3)
 - Organization and Management - Supervision (Clause 6)
 - Quality System (Clause 7.1-7.9)
 - Internal Audit (Clause 7.7 and 7.8)
 - Personnel (Clause 8)
 - Training (Clause 8.2)
 - Equipment (Clauses 9.7 and 9.8)
 - Reporting (Clause 13)
 - Sub-Contracting (Clause 14)

ISO17020 - General Criteria for the Operation of Various Types of Bodies Performing Inspection

- Administrative requirements:
 - In addition to any liability **insurance required by law** or due to contractual obligations, all types of inspection body shall have public liability insurance cover. Inspection bodies which supply services to organizations other than their own, shall also be covered by professional indemnity.

ISO17020 - General Criteria for the Operation of Various Types of Bodies Performing Inspection

- Organisation and Management - Supervision
 - The Inspection Body shall be able to demonstrate that it is organised in such a way that **the work of the staff performing inspections is supervised by personnel who are familiar with the objectives of the inspections**, the inspection methods and procedures being used and the assessment of inspection results. The extent, nature and level of supervision exercised shall take into account the qualifications and experience of the inspection staff and the inspections being undertaken.
 - The supervision of inspection personnel shall also **include the regular review of inspection reports** by technical personnel to ensure that work has been carried out in accordance with relevant legislation, the Inspection Body's procedures and contractual obligations as agreed with the client.

ISO17020 - General Criteria for the Operation of Various Types of Bodies Performing Inspection

■ Quality System

- Where a company provides inspection from a number of locations, under central technical and quality control, the following criteria apply:
 - The **central quality system shall embrace each individual location** from which accredited inspection services are to be operated.
 - There shall be a **technical manager in the parent company**, supported by local deputies where necessary, who has overall technical control and can ensure that all aspects of EN 45004 are implemented at all times at each location. This control shall be clearly defined in the **quality manuals** and the **organizational charts**.

ISO17020 - General Criteria for the Operation of Various Types of Bodies Performing Inspection

■ Quality System

- Where a company provides inspection from a number of locations, under central technical and quality control, the following criteria apply:
 - There shall be a quality manager for the parent company, with **local deputies where necessary**, responsible for day-to-day implementation of the quality system. This quality manager shall have **direct access to top management** and the **responsibilities** of both the quality manager and deputies shall be **clearly defined** in the quality manual.
 - Each location shall operate to the **same technical policy and technical procedures** for a given field and type of inspection.
 - Policy on **calibration of equipment shall be controlled centrally** even though it may be performed locally.
 - Each location shall be **audited annually**

ISO17020 - General Criteria for the Operation of Various Types of Bodies Performing Inspection

■ Internal Audit

- The internal audit programme shall include the **on-site assessment** of inspection personnel carrying out inspections.
- On-site assessment shall be carried out by personnel with the relevant technical qualifications and experience who have been **trained in internal auditing** and who are **sufficiently independent** to carry out the assessment audit objectively.
- The programme shall also ensure that **each of the inspectors engaged in inspection is assessed at least once within a period of 4 years** for each of the fields in which they are active.
- The audit programme shall ensure that where inspections are managed from **locations other than a central location**, the audit programme encompasses these different locations in a systematic way over the 4 year period.

ISO17020 - General Criteria for the Operation of Various Types of Bodies Performing Inspection

■ Personnel

• Qualifications and Competence

- The Inspection Body shall ensure that only staff who have, as a minimum, the **qualifications, training, experience** (including knowledge of the inspections to be carried out)
- Supervise inspectors, resolve technical issues and perform inspections, calibrations and testing.
- The Inspection Body shall **maintain records** of **qualifications, training and experience** of all staff associated with the inspection process, together with records of how and when each member of staff was **authorized**. These records shall indicate the **fields and levels of inspection, calibration and testing considered to be within the competence of the inspector**.
- Including part-time employees or **temporary staff**

ISO17020 - General Criteria for the Operation of Various Types of Bodies Performing Inspection

- Equipment

- **All equipment** used for measurements and tests where the results of such measurements and tests **have a significant influence** on the results of the inspection, ie the conclusion about conformance with requirements, shall be readily **identifiable**, suitable for the intended purpose and **calibrated in accordance with a defined programme** so as to ensure that, wherever applicable, measurements made by the Inspection Body are **traceable** to national standards of measurement.
- Where the calibrations are performed in-house, **traceability** to national standards of measurement shall be assured
- The certificate or equivalent must detail an **uncertainty** of measurement that is **appropriate** for the equipment that is to be calibrated from the reference standard.

ISO17020 - General Criteria for the Operation of Various Types of Bodies Performing Inspection

Reporting requirements

Sub-Contracting requirements

ISO17025 - General requirements for the competence of testing and calibration laboratories

- Organization and management
- Quality system
- Document control
- Request, tender and contract review
- Sub-contracting of tests and calibrations
- Purchasing services and supplies
- Service to the client
- Complaints
- Control of nonconforming testing and/or calibration work
- Corrective action
- Preventive action
- Records
- Internal audits
- Management reviews

Management requirements

ISO17025 - General requirements for the competence of testing and calibration laboratories

- General
- Personnel
- Accommodation and environmental conditions
- Test and calibration methods including sampling
- Method validation
- Equipment
- Measurement traceability
- Sampling
- Handling and transportation of test and calibration items
- Assuring the quality of test and calibration results
- Reporting the results

Technical requirements

Quality system management

Reflection

Planning

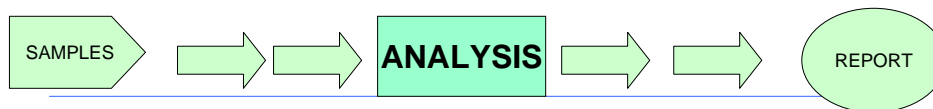
Confidence

The flow of our work

- How do I get my work?
 - How many people involved
 - Chain of custody
 - Time frame for delivery
 - ...
- What do I do with the work when I get it?
 - Plan for handling the samples?
 - Priority rules?
 - Communications with the customer?
 - ...
- What do I do with the work when It's done?
 - Follow up & communication

Process map / Flow chart

- PURPOSE
- INPUTS & OUTPUTS
- INDICATORS
- DOCUMENTS
- RECORDS
- ASSOCIATES PROCESS



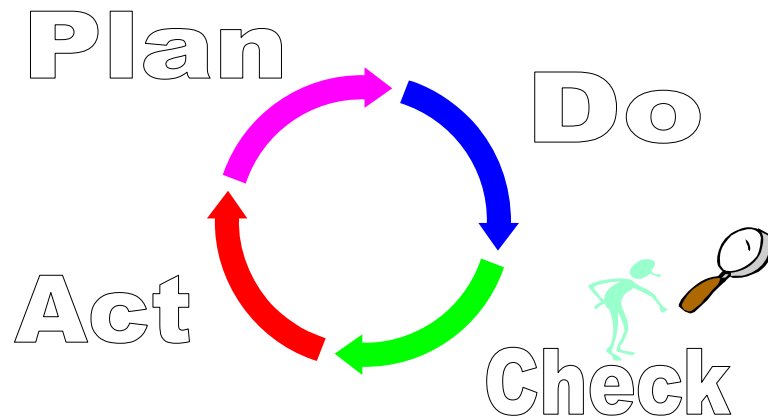
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Correctness and reliability

- **Main factors:**
 - human factors
 - accommodation and environmental conditions
 - test and calibration methods
 - method validation
 - equipment
 - measurement traceability
 - sampling
 - handling of test and calibration items
 -

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Quality Management System



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About quality...

- K. Isikawa:
 - Quality control is applicable to any company and must be **applied to all** the company
 - A company that does not practice quality control will not last
 - Quality control fails when nobody understands it
 - Quality control begins and finishes with education and training
 - People show their true capacity when their abilities are used suitably and responsibility is given to them

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About quality...

- K. Isikawa:
 - A company that does the inspection of 100 per 100 is a company that makes defective products
 - Quality is not created by means of the inspection: it is obtained by means of the design and the process
 - If the management get upset, angry, when defective units are produced, then the people will hide it
 - The normalization allows authority to be delegated

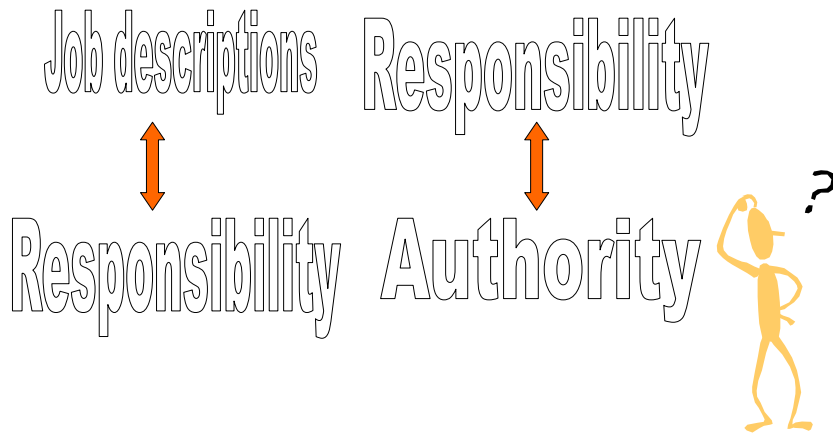
Advantages to work in accordance to a Quality Assurance System - Technical

**CORRECTNESS and
RELIABILITY**

TRACEABILITY



Advantages to work in accordance to a Quality Assurance System - Organization



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SAME VISION IN FRONT
THE SAME REALITY?

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Advantages of working with accordance to a Quality Assurance System – Organization

- The laboratory shall
 - have managerial and technical personnel with the **authority** and resources needed to carry out their duties and to identify the occurrence of departures from the quality system.
 - specify the **responsibility, authority** and **interrelationships** of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations
 - appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the quality system is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources

– ISO17025 (4.1.4)

Advantages of working in accordance with a Quality Assurance System

- **Accreditation:**
 - Independent recognition that the laboratory is competent
 - Give confidence to the customer
 - Confidence to laboratory staff
 - Fulfillment of legal framework



Advantages of working in accordance with a Quality Assurance System

- Document control:
 - Think over – Unify
- Management and technical records:
 - Traceability
- Qualifications and competence:
 - Training - Deputies
- Specifications control:
 - Cost - Quality
- Equipment management:
 - Planning
- Method validation:
 - Confidence in results



Quality Management System – Nonconforming work

- Usual items of nonconforming work or problems with the quality system or with testing and/or calibration activities are related to:
 - customer complaints
 - quality control
 - instrument calibration
 - checking of consumable materials
 - staff observations or supervision
 - test reports
 - management reviews and internal or external audits
 - ...



Test final report

- The Final Report shall include at least the following information
 - a title (e.g. "Test Report")
 - name and address of laboratory
 - unique identification of the test report (such as serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report
 - name and address of the client placing the order
 - description and unambiguous identification of the item(s) tested
 - date of receipt of test item(s) and date(s) of performance of the test
 - test results with units of measurement
 - ...

Test final report

- The Final Report shall include at least the following information
 - reference to sampling procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results
 - the name, function and signature of person authorizing the test report
 - a statement to the effect that the results relate only to the items tested
 - a statement specifying that the test report shall not be reproduced except in full, without written approval of the laboratory.

Test final report

- Where necessary for the interpretation of the test results, include:
 - description and condition of the test item
 - identification of the standardized test method(s) used, or unambiguous brief description of any non-standardized method used
 - deviations from, additions to or exclusions from the test method, and information on specific test conditions, such as environmental conditions
 - where relevant, a statement of compliance/non compliance with requirements and/or specifications
 - where appropriate and needed, opinions and interpretations
 - where applicable, a statement on the estimated uncertainty of measurement of the test result
 - additional information required by specific branches.

Equipment information

- The records shall include at least the following:
 - identity of the item of equipment
 - manufacturer's name, type identification, and serial number or other unique identification
 - checks that equipment complies with the specification
 - current location (if it where appropriate)
 - the manufacturer's instructions, if available, or reference to their location
 - dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and due date (or criteria) of next calibration
 - maintenance carried out to date and the maintenance plan
 - damage, malfunction, modification or repair to the equipment.

Quality Management System

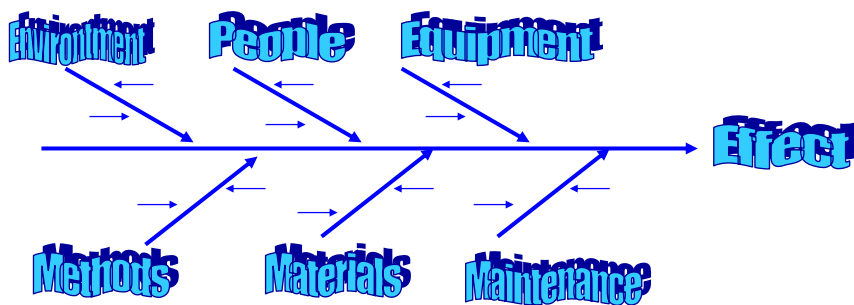
Corrective Actions

Preventive Actions

Mature System → Less corrective - More preventive

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How to establish the cause?



Ishikawa
diagram

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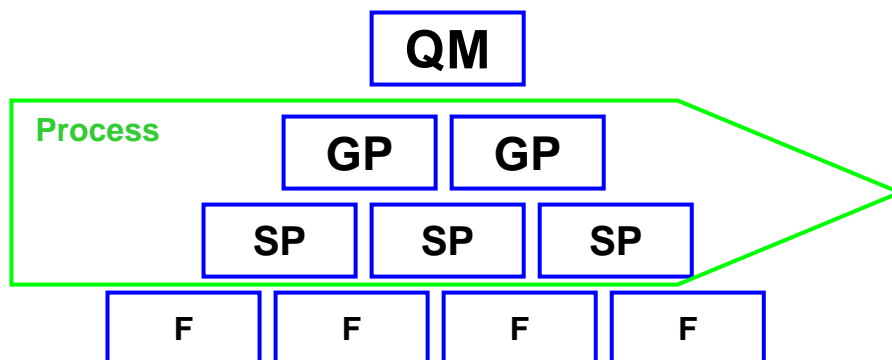
ISO17025 - General requirements for the competence of testing and calibration laboratories

- The laboratory management **shall document** its policies, systems, programmes, procedures and instructions to the **extent necessary** to enable the laboratory to assure the quality of the test and/or calibration results it generates.

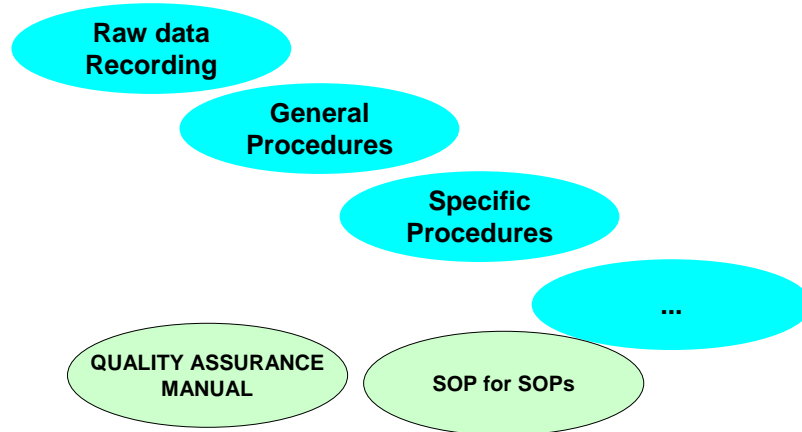
✓ ISO17025 4.2.1


Do what is written and write what you do

Documentation structure



ISO17025 - General requirements for the competence of testing and calibration laboratories

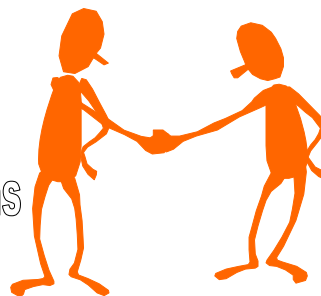


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Quality Management System

Improvement effectiveness

Avoids conflicting situations



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Conclusions

The importance of:

- Working like a team. All the jobs are important.
 - Organization
 - Disciplined work
- “Do what is written and write what you do”
- Follow the Quality Assurance Unit indications
- Follow the well qualified technicians indications
- Being a good professional