L4 Concepts for implementing a quality management system

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Objectives

- This lecture will present a step by step introduction into the task of implementing a quality management system.

WHY ?

- to demonstrate ability to deliver a product that consistently meets customer and applicable regulatory requirements and
- to address customer satisfaction through the effective application of the system, including processes for continual improvement and the prevention of non-conformity.

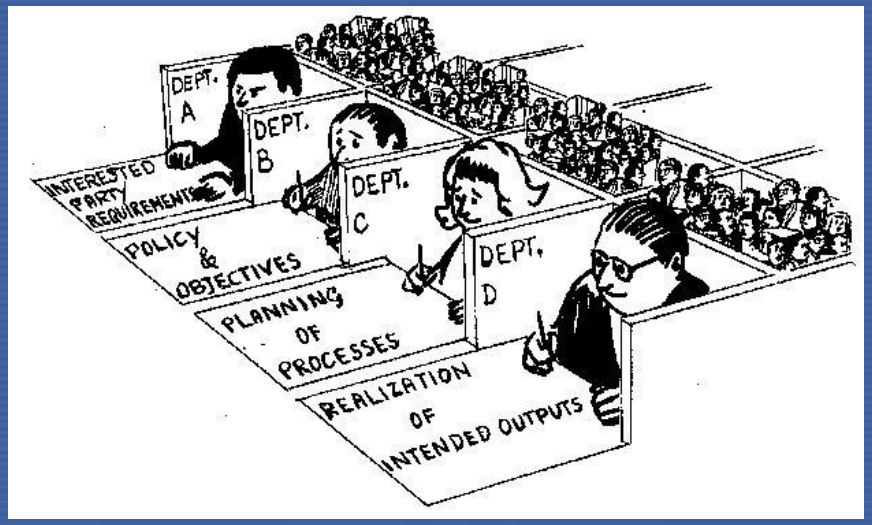
Customer

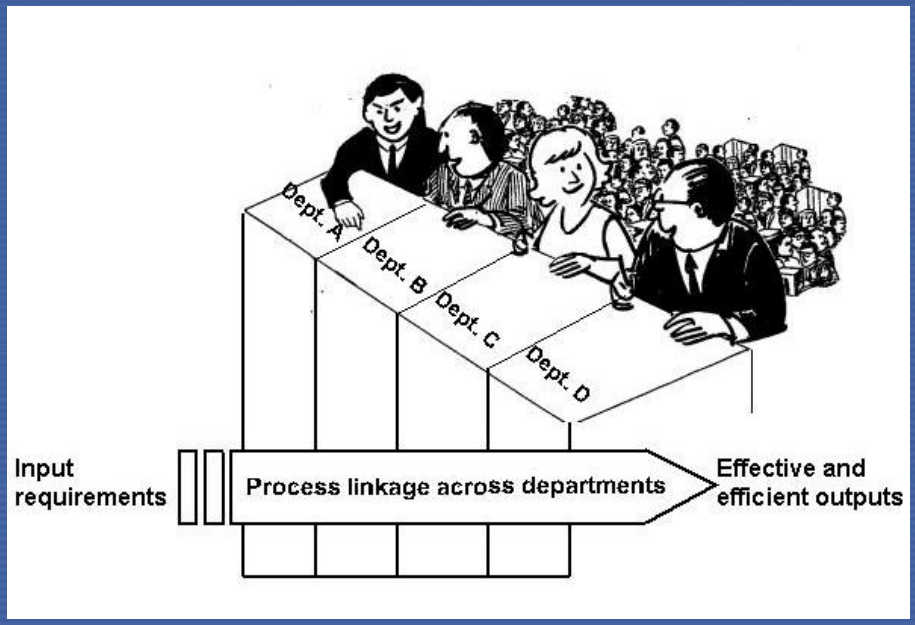
- The concept of „CUSTOMER“ is mainly applied to EXTERNAL customers: they position orders and bring in money.

- Never forget the INTERNAL customers in your organization. They keep the workflow going and support the quality of your product.

Understanding the Process Approach

The advantage of the process approach





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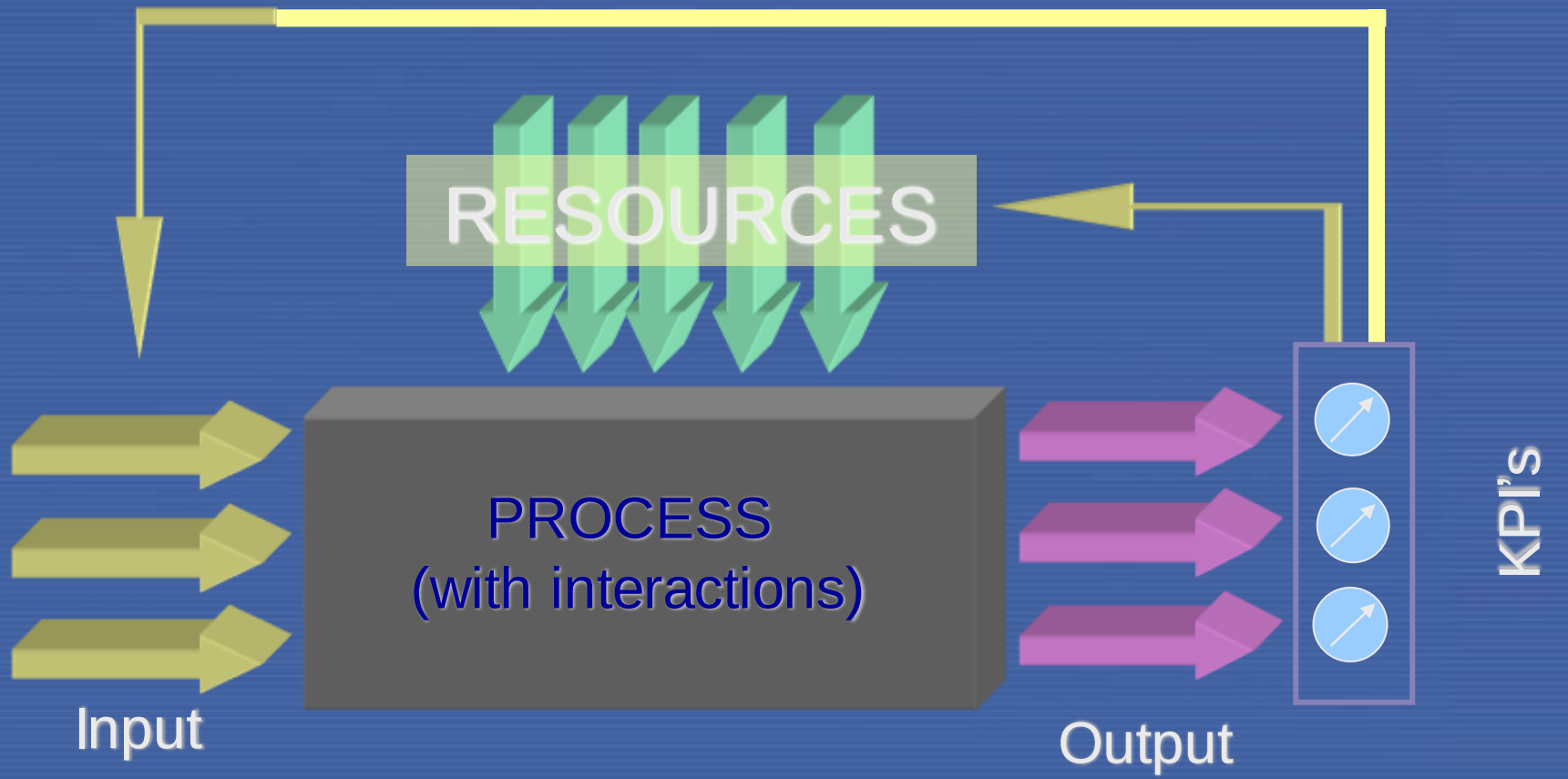
A process



Implementation basics

- identify the processes needed for the QMS;
- determine interaction of these processes;
- determine evaluation criteria for these processes;
- ensure the availability of information for these processes and
- measure, monitor and analyze the processes, and implement action necessary to achieve planned results and continual improvement.

Implementation process

PLAN

1. Decision taking
2. Management commitment
3. Implementation team
4. Plan the implementation
5. Identify existing processes
6. Define document structure

DO

7. Write procedures
8. Initial Training of personnel
9. Implementation

CHECK

10. Internal Audit
11. Management Review

ACT

12. Improve system

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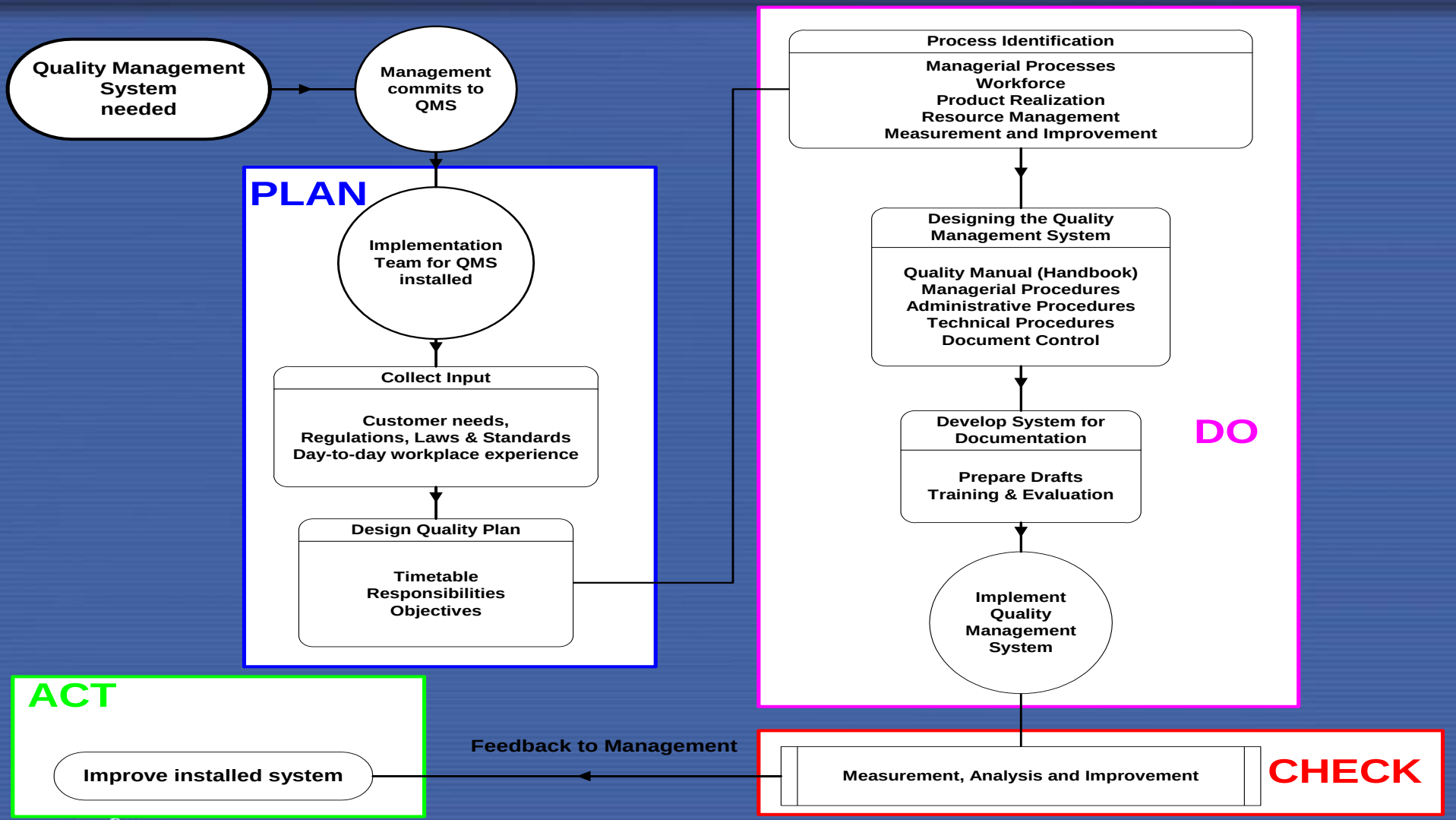
Flowchart



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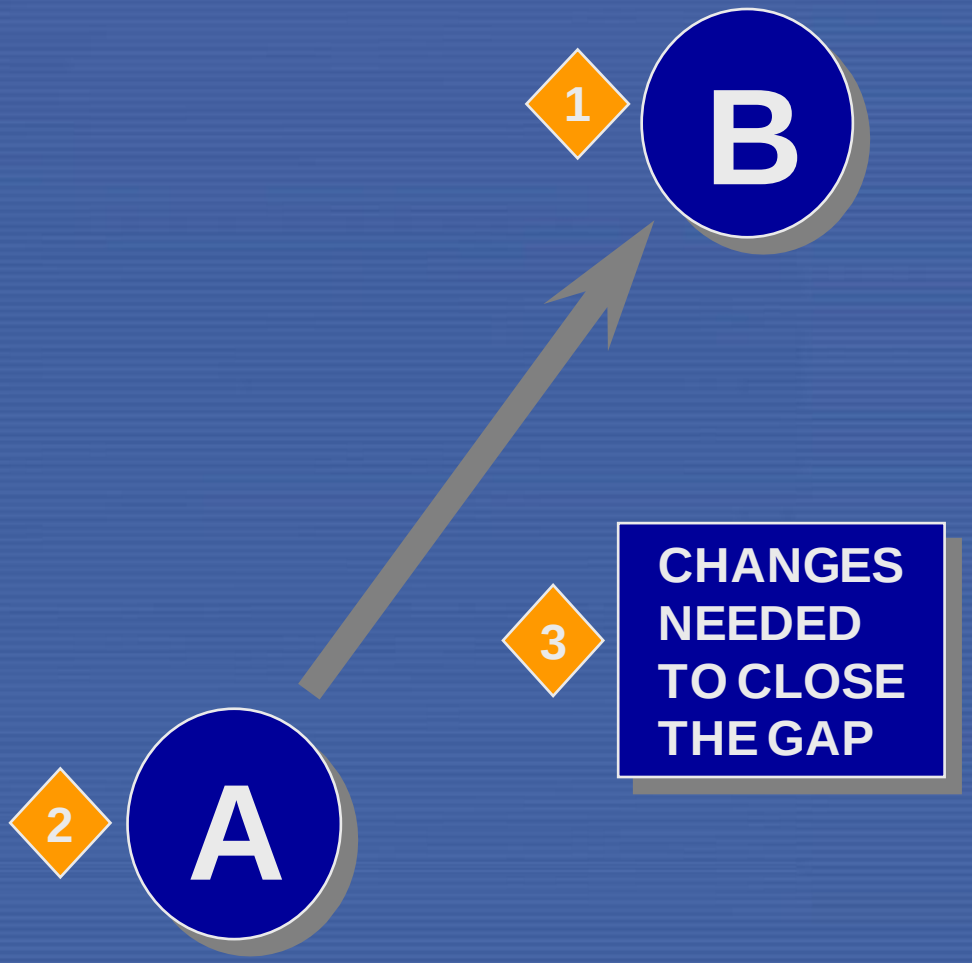
Gap analysis

There are various types of analysis that will be needed to help you define the scale, scope and potential impact of the transition to the 17025 requirements.

GAP analysis is particularly helpful here:

1. What is point B: Where are you trying to take the organisation; what does the new system look like?
2. What is the point A: Where are you now by comparison with point B?
3. What are the changes needed to close this gap?



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Documentary check or an integrated MS (IMS)

Make a link between the standards of your choice
e.g. ISO 9001, GSR part 2, ISO/IEC 17025 and
your own documents

ISO 9001	ISO 17025	IAEA GSR part 2	Document# in Quality System	To Do
§ 4.2	§ 5.5.1	§ 5.2.5	Ref. Doc # PO.606	Add § on PPC and on occupational limits

Management commitment

Top management shall:

- Take decision to implement a quality management system.
- Take the lead and manage the implementation as a TOP DOWN process.
- Show interest in completing the process in time and within the planned budget.

Decision

Two different type of factors may govern the decision to implement a quality management system.

External factors:

- demand by customers
- requirement by State or Regulatory authorities or

Internal factors:

- cost-effectiveness analysis
- need to restructure the organization due to mayor changes in work focus or workforce

Implementation team

Team members need good knowledge and experience or need to receive training in:

- Structure and workload of the organization;
- Applicable standards, laws and regulations;
- Internal processes of the organization;
- Communication methods within the company;
- Team organization and teamwork.

Implementation planning

- Evaluate the workload
- Devise quality plan
- Identify existing processes
- Group processes, according to the action they are describing:
  - (Strategic) management processes;
  - Product realization (core) processes;
  - Supporting processes;
  - Management system processes.

Management processes examples

- Strategic management (quality policy)
- Finance management
- Risk & Opportunities Management
- Management of Change
- Knowledge Management
- Nuclear Safety
- Occupational Health & Safety
- Quality Management review

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Product realization processes examples

- Individual monitoring
  - e.g. TLD-dosimetry, OSL-dosimetry, Fingerdosimetry
- Calibration/Irradiation
- Workplace monitoring
- Container verification
- Contamination control
- Nuclear transport

Supporting processes examples

- Customer relation
- Marketing
- Legal support
- Procurement
- IT support
- Human Resources – Training, Competence Management
- Technical infrastructure
- Transport
- House keeping
- Maintenance
- Waste Management

Quality system processes

- Control of documents and records
- Customer complaint management
- Corrective and preventive actions
- Internal audits
- Control of nonconformities

A quality system has a pyramidal structure

Why? (including Quality policy)

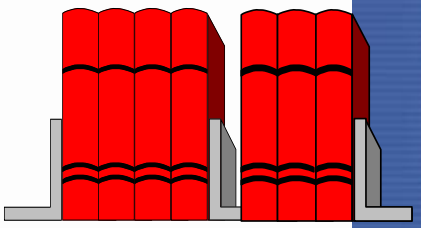
What (when, where, who)? How to do it?

How was it done? The proof

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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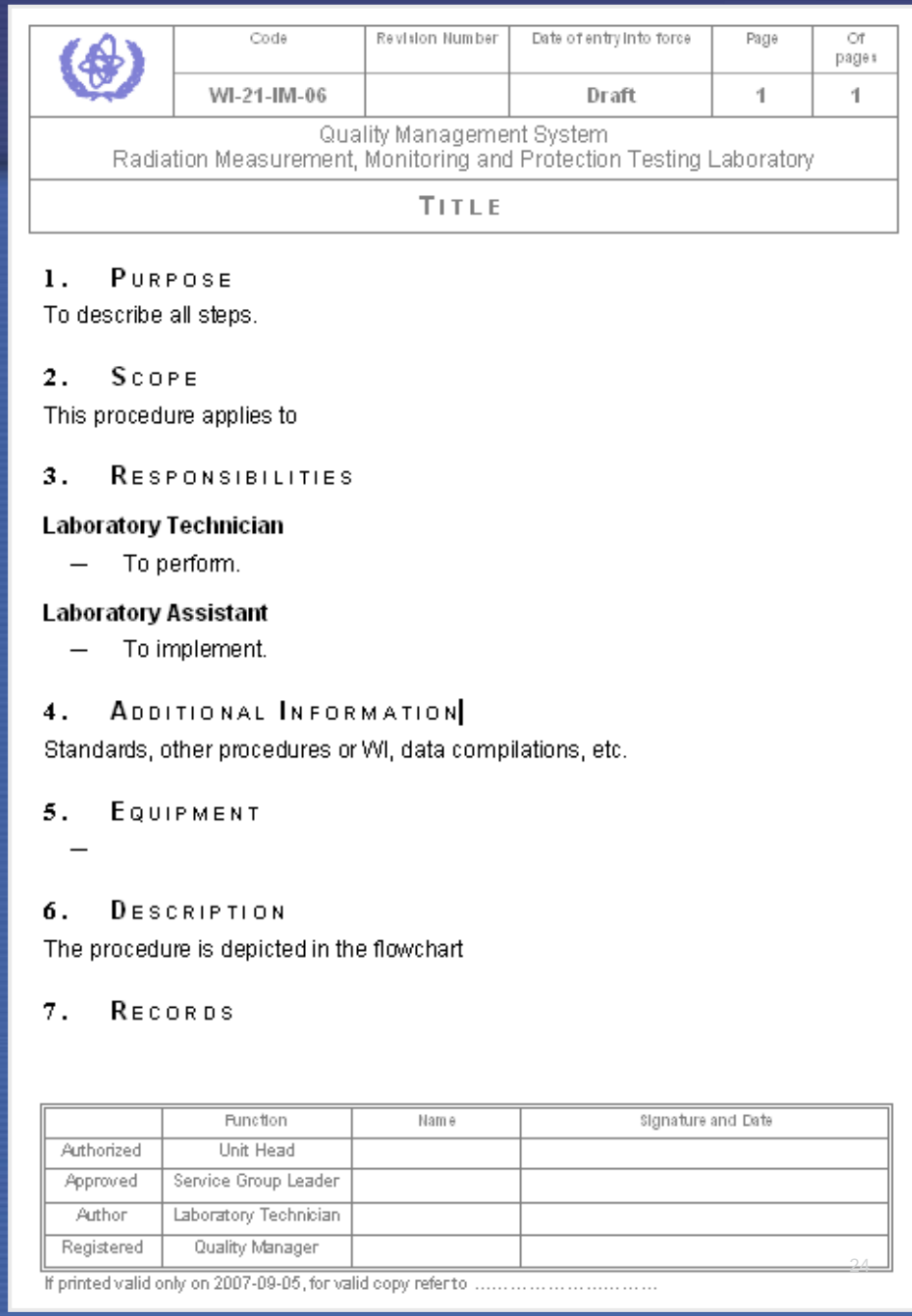
Procedure template

providing a procedure template early during the implementation process helps to capture all relevant information for the operated processes.



	Code	Revision Number	Date of entry into force	Page	Of pages
	WI-21-IM-06		Draft	1	1

Quality Management System
Radiation Measurement, Monitoring and Protection Testing Laboratory

TITLE

1. PURPOSE

To describe all steps.

2. SCOPE

This procedure applies to

3. RESPONSIBILITIES

Laboratory Technician

– To perform.

Laboratory Assistant

– To implement.

4. ADDITIONAL INFORMATION

Standards, other procedures or WI, data compilations, etc.

5. EQUIPMENT

–

6. DESCRIPTION

The procedure is depicted in the flowchart

7. RECORDS

	Function	Name	Signature and Date
Authorized	Unit Head		
Approved	Service Group Leader		
Author	Laboratory Technician		
Registered	Quality Manager		

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Procedures

Of great importance:

- For later acceptance of quality management system by all members of the staff
- As many staff members as possible should be included in the authoring process using the approved document template.
- Due to better training in the contents of standards and regulations, the members of the implementation team, should provide assistance in editing the procedures.

Procedures

All drafted procedures will have to be reviewed by the implementation team:

- consistency with other procedures
- compliance with the management directives and
- compliance with the applicable standards

to ensure conformity and integrity of the quality documentation.

Training

- on applying the documented procedures
- on applying quality management principles

Training period may show need to correct the documentation.

Implementation

- After the training period:
  - quality management system may be piloted for an initial testing period, typically three to six months

Internal audit

The first assessment of the newly implemented quality management system will certainly be carried through by an or with the help of an external auditor.

This may be the same person that acts as ex/in-ternal advisor during the creation phase.

Management review

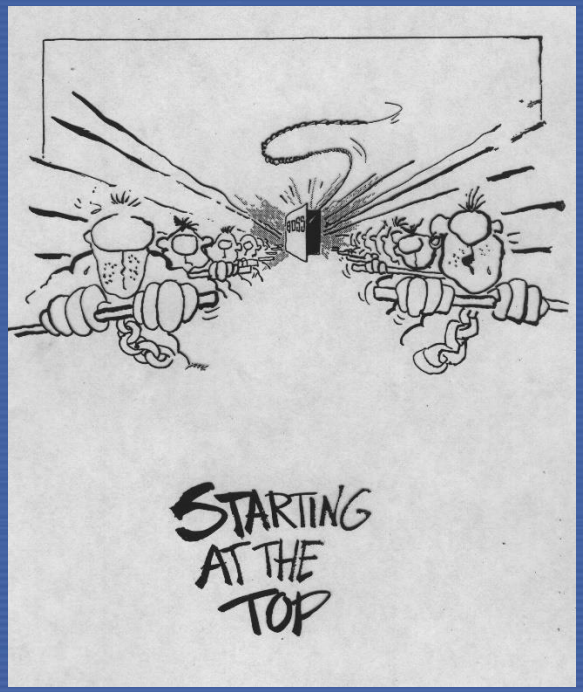
Assess the status of the quality management system from :

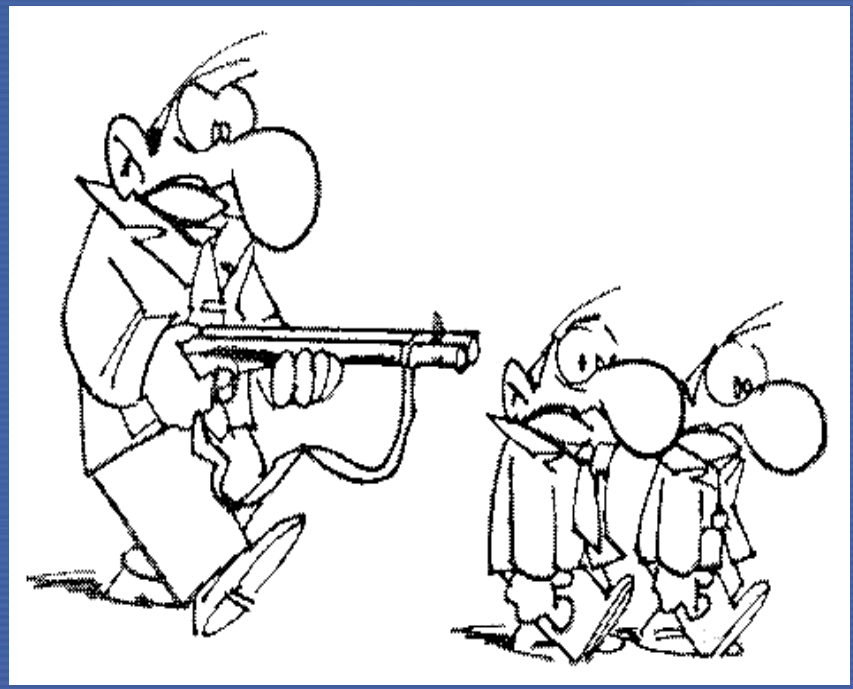
- implementation process
- staff quality training sessions and
- internal audit

Identify still necessary improvements.

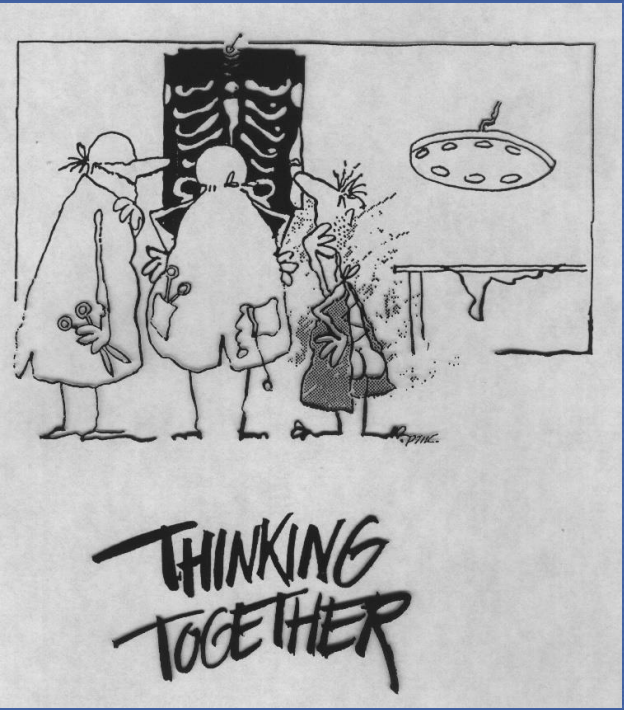
TOP-DOWN support is absolutely necessary

Top-down:
Top Management decides that a system is needed.

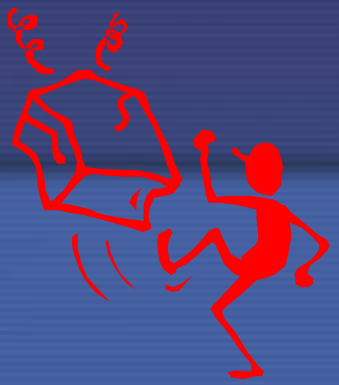




Bottom-up approach is needed to start



Pitfalls




Good idea, but
It won't work
It's not cost effective
It just isn't done
It's not in the budget
It's against our policy
It involves too much paper work
let's be practical
let's get back to reality
let's form a committee!