



# How to conduct an audit ?

Prof dr Elisabeth Dequeker  
UZ-KULeuven, Belgium

# Agenda

- **Requirements of an auditor**
- **Process of an audit**

# Requirements of an auditor

1. Character
2. Knowledgeable
3. General qualities
4. Technical qualities
5. Responsibilities
6. Talent



# Requirements of an auditor

## 1. Character of an auditor

- Fair
- Calm
- Logical
- Sensitive
- Intelligent
- Analytical
- Tenacious
- Respectful
- Trustworthy
- Open-minded
- ...



# Requirements of an auditor

## 2. Knowledge of an auditor

- The auditor must be **knowledgeable**.
- His/her understanding of quality systems, standards, and audit procedures should be current and accurate.

# Requirements of an auditor

## 3. General qualities

- Be convinced of the value of a quality system
- Communicative in oral and in written
- Sufficient sense of responsibility
- Ability of examination, questioning, evaluation and reporting
- Able to work within a team, be pleasant, well educated and positive



# Requirements of an auditor

## 4. Technical qualities

- Up to date **knowledge of methods**, instruments in specific fields
- Being able **to judge the competence** of the lab
- Differentiate between simple and more complex tests
- **Knowledge about calibration** and traceability towards standards to judge the suitability of a method or an instrument
- **Good observation** of the work performance of personnel during the audit



# Requirements of an auditor

## 5. Responsibilities

- Perform the audit with regard to the requirements and the procedures
- Communicate and explain the audit requirements
- Plan and perform the imposed task in an efficient and effective way
- Document the findings
- Report the results in a constructive way with quantitative elements
- Keep confidentiality
- Ensure co-operation within and support of the team





# Requirements of an auditor

## 6. Talent

- Think in general terms
- Make a realistic evaluations
- Analyse complex systems
- Stay on track and finish the job
- Respect the feelings of all participants
- Resist the pressure to change the truth
- Manage personnel and interpersonal stress
- Draw rational conclusions on the basis of evidence
- Evaluate evidence in a fair and impartial manner

# Process of an audit

1. Responsibilities during an audit
2. Types and Methods
3. Phases of an audit
4. Areas to audit
5. Questioning

# Process of an audit

## 1. Responsibilities during an audit

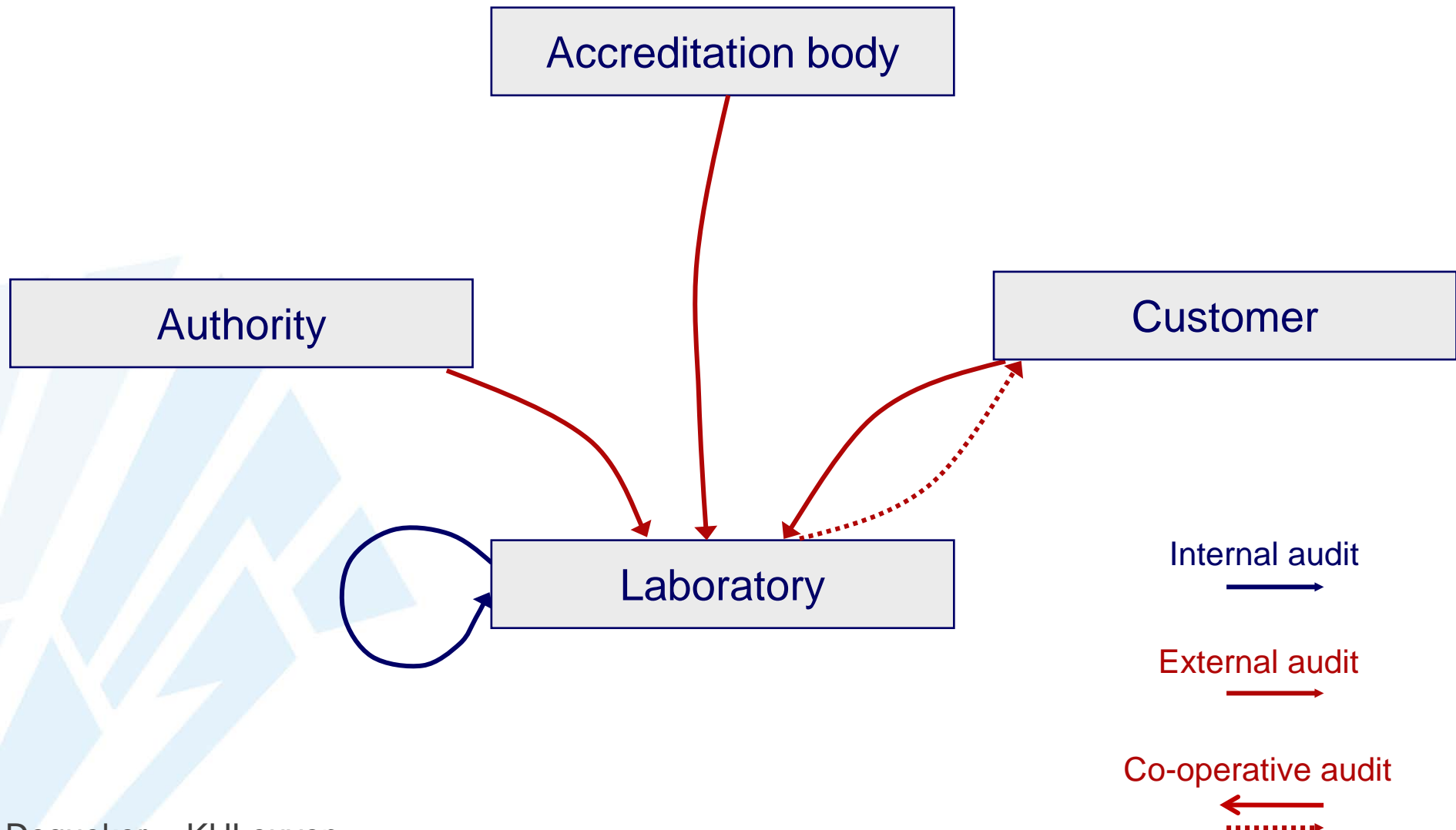
Most important task = **gathering objective evidences of the functioning of the system**

How?

- Interviews
- Documentation checking
- Observations
- Cross-checks

# Process of an audit

## 2. Types and Methods



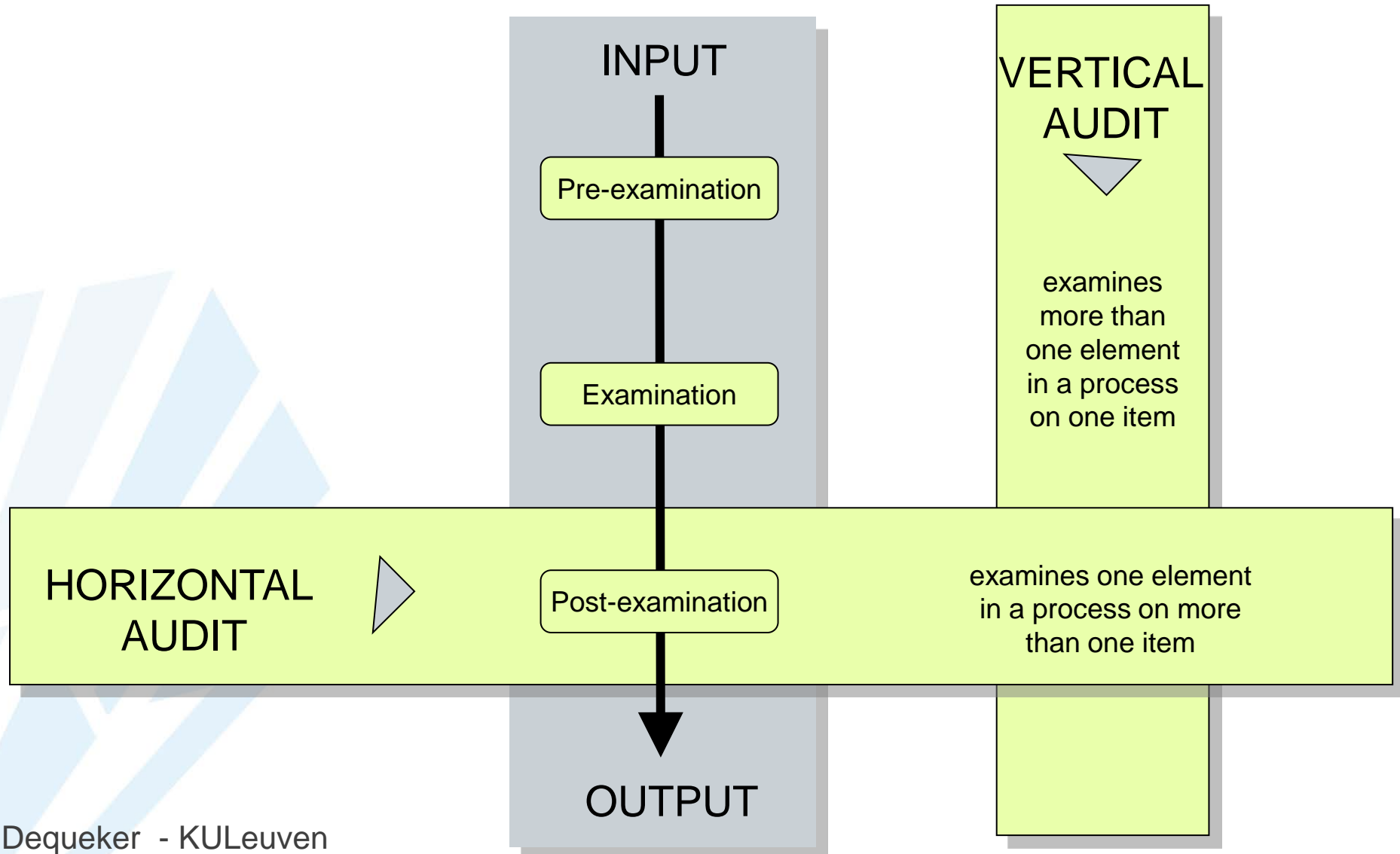
# Process of an audit

## 2. Types and Methods

- Horizontal audit
- Vertical audit
- Mixed audit
- Witness / examination audit
- Document audit
- ...

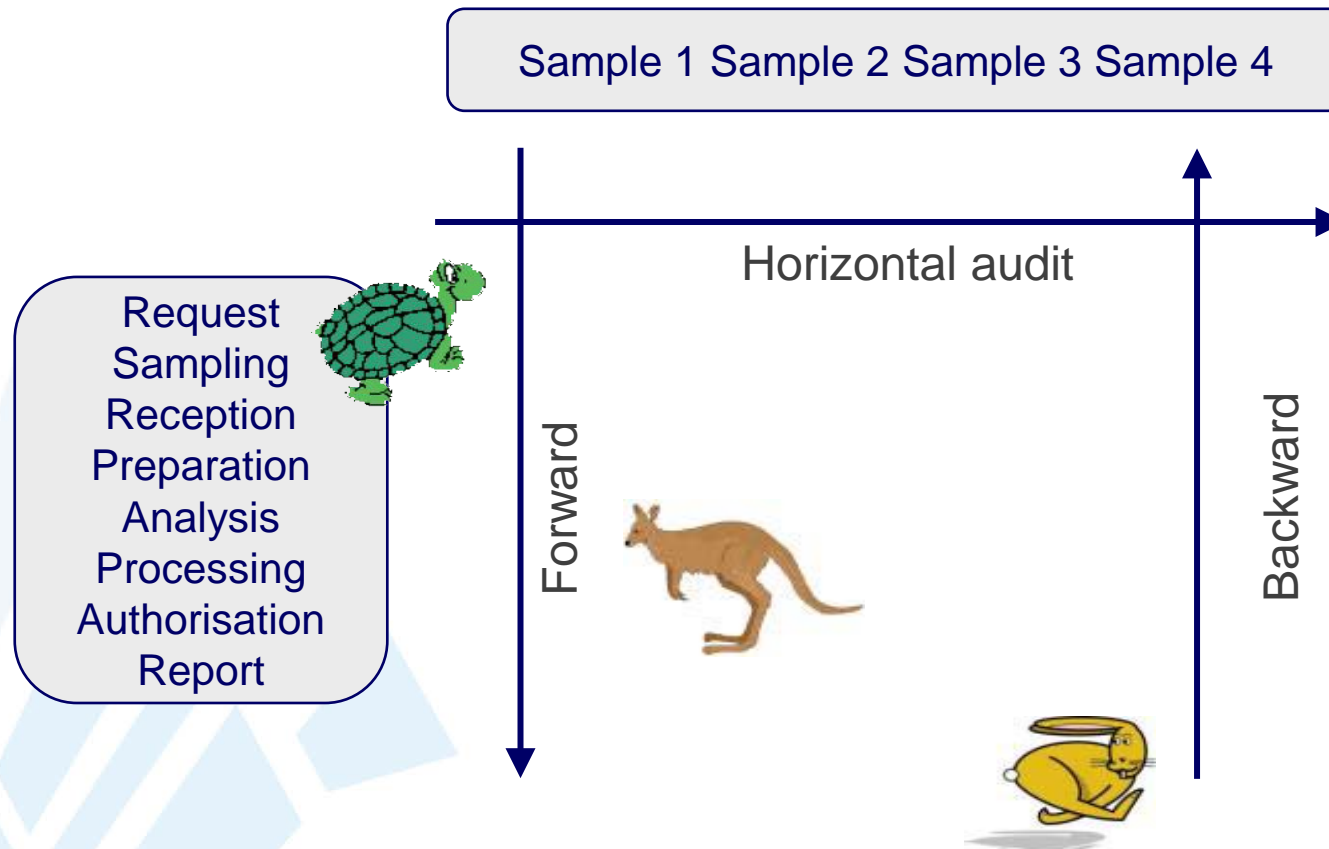
# Process of an audit

## 2. Types and Methods



# Process of an audit

## 2. Types and Methods



Try to audit forwards and backwards



# Process of an audit

## 3. Audit Phases

- Preparation
- Conducting the on-site audit
  - Introductory meeting
  - Audit
  - Summation conference
- Reporting
- Follow-up !



### 3. Audit Phases

- Preparation
  - ✓ Audit plan
  - ✓ Audit team assignments
  - ✓ Working documents

### 3. Audit Phases

- Preparation - audit plan
  - *should be flexible to permit changes*
  - *should include:*
    - *audit objectives and scope*
    - *identification of the individuals or organisation having significant direct responsibilities regarding the objectives and scope*
    - *identification of reference documents (SOPs, standards, ...)*
    - *identification of audit team members*
    - *date and expected time – duration*
    - *...*

### 3. Audit Phases

- Preparation - audit team assignment

*Each auditor should be assigned specific quality system elements or functional departments to audit*

### 3. Audit Phases

- Preparation - working documents

*The documents required to facilitate the auditor's investigations*

*Working documents may include:*

*Checklists used for evaluating QS elements*

*Forms for reporting observations*

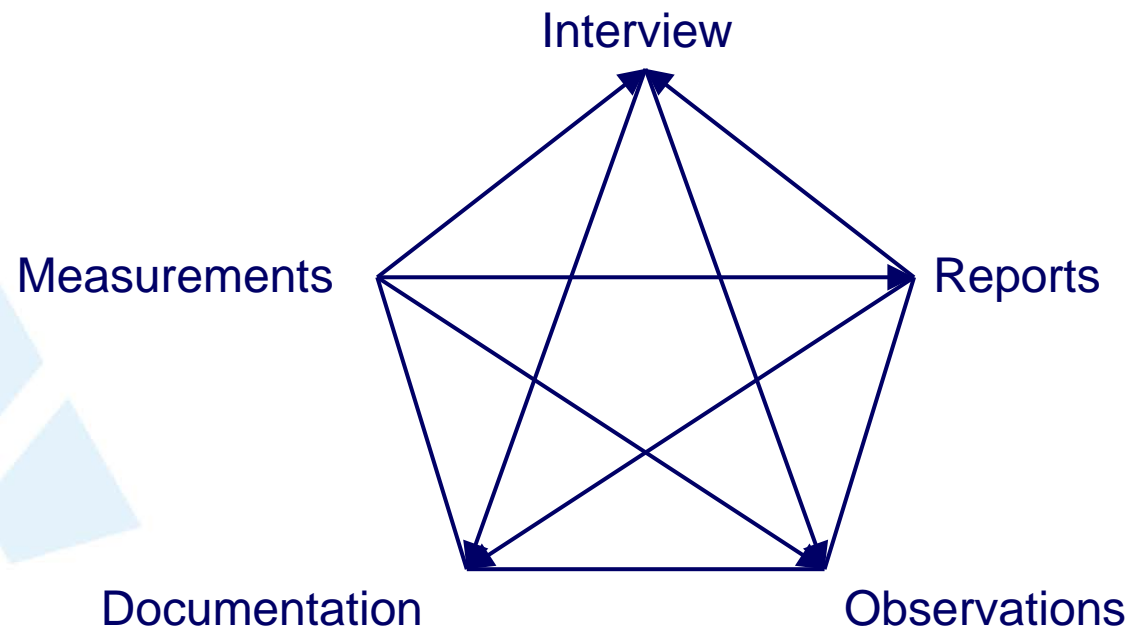
**CHECKING LIST FOR GMP ASSESSMENT**

Date : Location : Warehouse  
Auditor : Auditee :

DESCRIPTION	GMP.REF.	PARAMETER	AUDIT FINDING
Personnel	1.2.1	- Organization structure	
	5.1.2	- Personnel hygiene	
	2.1.5	- Training record	
Storage area	10.1.1	- Design and layout of defined area	
	3.1	- Flow of personnel and goods	
	3.6	- Structure of the storage area, based on GMP	
	3.9 & 3.10	- HVAC system	
	3.12.2	- Record of monitoring parameter	
Sanitation	3.1	- Pest record program	
	5.3	- The map of bait - The cleanliness of weighing apparatus	
Documentation	4.3	- Record of maintenance and calibration of weighing apparatus	
	10.2.2.3	- The effectiveness of label system	
	10.2.2.1	- Inventory stock control	

### 3. Audit Phases

- Preparation
- Conducting the on-site audit
  - *Introductory meeting (more for external audits)*
  - *Audit – collecting information*



- *Summation conference*

# Process of an audit

## 3. Audit Phases

- Preparation
- Conducting the on-site audit
  - Introductory meeting
  - Audit
  - Summation conference
- Reporting
- Follow-up !





### 3. Audit Phases

- Reporting – general
- *Reporting within well defined time limits*
- *Report should be clear, constructive and only describing observations*
- *Follow a clear template*
- *Mention all administrative data: who, where, when, what, ...*  
(see content report)

"Internal Audit" Vs. "External Audit"

Factor	Internal audit	External audit
Objectives	sound risk management and controls	accounts = true and fair view
Scope of work	overall systems: VFM, fraud, MIS and compliance	accounts, Profit and Loss a/c, balance sheet, annual report and financial systems
Independence	from operations by professionalism and status	from company via statutory rights and APB codes
Structure	varies: CAE, managers, seniors and assistants	partners, managers, seniors and trainees
Staff	competent persons trained in internal auditing	qualified and part qualified accountants
Methodology	risk-based systems-based audits, assurances and consulting work	vouching and verification and some use of risk-based systems approach
Reports	comprehensive structured reports to management and the audit committee and brief executive summaries	brief standardized published reports to shareholders and users of accounts
Standards	IIA and/or other	various APB requirements
Legislation	generally not mandatory apart from parts of public sector, but encouraged in most sectors	companies legislation and various public sector statutes
Size	only larger organizations	all registered companies and public sector (small companies may have exemptions)

### 3. Audit Phases

- Reporting – content
  - *Information about the auditee*
  - *Summary of findings and conclusions*
  - *Examination of the application field*
  - *Evaluation of the conformity with the criteria of the guidelines, ISO standards ...*
  - *Checklists, specific reports, ...*
  - *Annexes e.g. action plan*



### 3. Audit Phases

- Follow-up !
  - *Audit leads to: corrective actions on a timely base (action plan)*
  - *Examination of the action plan*
  - *Follow-up by:*
    - *Documented proof or*
    - *Scheduling a additional audit*
  - *Follow-up of corrective actions: within certain time limits!*

# Process of an audit

## 3. Audit Phases

- Preparation
- Conducting the on-site audit
  - Introductory meeting
  - Audit
  - Summation conference
- Reporting
- Follow-up !

# Process of an audit

1. Responsibilities during an audit
2. Types and Methods
3. Phases of an audit
- 4. Areas to audit**
- 5. Questioning**

# Process of an audit

## 4. Areas

- Qualifications and responsibilities
- Physical facilities
- Test performance, quality control and performance improvement
- Specific requirements depending on the guideline used/system installed

# Process of an audit

## 5. Questioning

- *Ask clear, concise questions*
- *Use “open” questions*
- *Record observations*

*Avoid :*

- *Leading questions – the answer is in the question*
- *Question outside the scope*
- *Too much questions in the same time – you will have only one answer*



# Process of an audit

## 5. Questioning

- *Focus the discussion by briefly stating what you need*
- *Use open ended questions to expand the discussions*
- *Use closed ended questions to probe for specifics*
- *Encourage dialogue*
- *Listen carefull*

# Process of an audit

## 5. Questioning

- *Restate what you have heard to verify understanding*
- *Summarize and close the discussion: restate key points, tell what will follow, clearly express any further needs that you may have and show appreciation for their time and effort*

# Conclusion

Purpose of an audit is always to evaluate the need for improvement or corrective action.

