

Quality Certification & auditing systems

- ISO Standards / certified systems and major differences
- Benefits and added value versus criticism
- Structure and major elements of quality management systems
- Important guidance in developing quality management systems and process management

ISO Standards and certified systems – facts and figures

- 16500 International Standards on a variety of subjects
- 1250 new ISO standards every year
- ISO
 - Technical standards on various fields of application and products
 - Management standards

ISO Management Standards

- Provide requirements or give guidance on good management practice
- Generic: can be applied to any organization
- Model to follow in setting up and operating a management system
- Operating principle of Plan – Do – Check - Act

ISO Management Standards

- Most well known:
 - ISO 9001:2000 (Quality Management)
 - ISO 14001:2004 (Environmental Management)
- New standards based on the same generic model:
 - Information security (ISO 27001)
 - Food safety (ISO 22000)
 - Supply chain security (ISO 28000)
 - Automotive, medical devices, education, local government etc.

ISO 9000

- Quality management
- Meaning what the organization does to fulfill:
 - customer's quality requirements
 - applicable regulatory requirements
 - enhance customer satisfaction
 - achieve continual improvement of performance
- ISO 9000:2000 family:
 - ISO 9000 (QMS Fundamentals and vocabulary)
 - ISO 9001 (QMS Requirements) → external certification
 - ISO 9004 (QMS Guidelines for performance improvement)

ISO 9001:2000 certificates

ISO 9001:2000 principal results

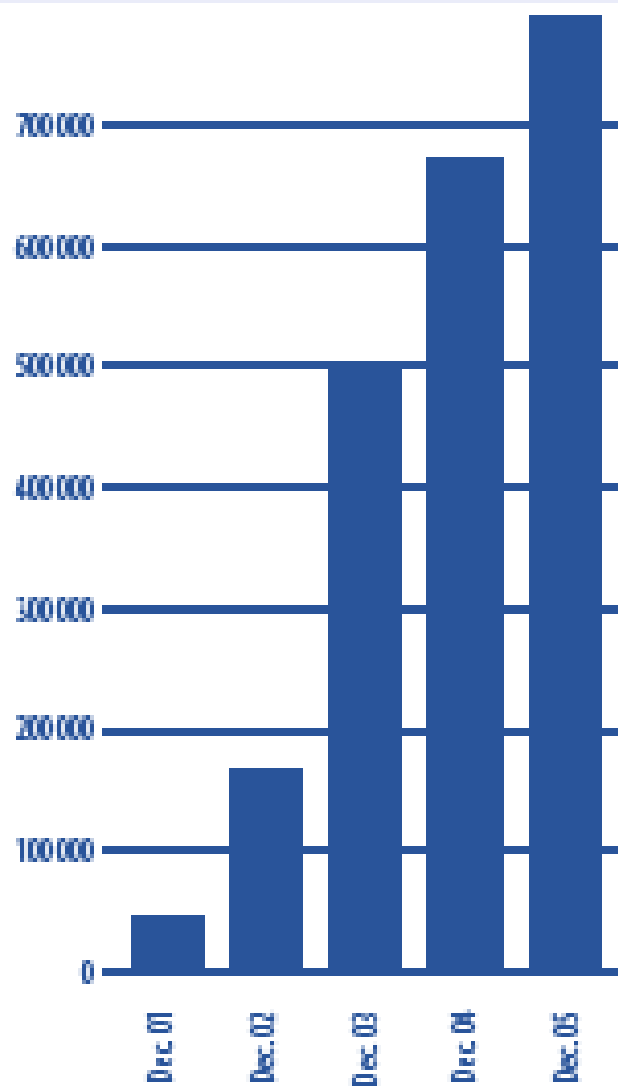
World results	Dec. 2001	Dec. 2002	Dec. 2003	Dec. 2004	Dec. 2005
World total	44 388	167 124	497 919	660 132	776 608
World growth		122 736	330 795	162 213	116 476
Number of countries/ economies	97	133	149	154	161

Source:

ISO Survey 2005 by ISO 2006/9

ISO 9001:2000 certificates

Worldwide total of
ISO 9001:2000 certificates
December 2001 to December 2005

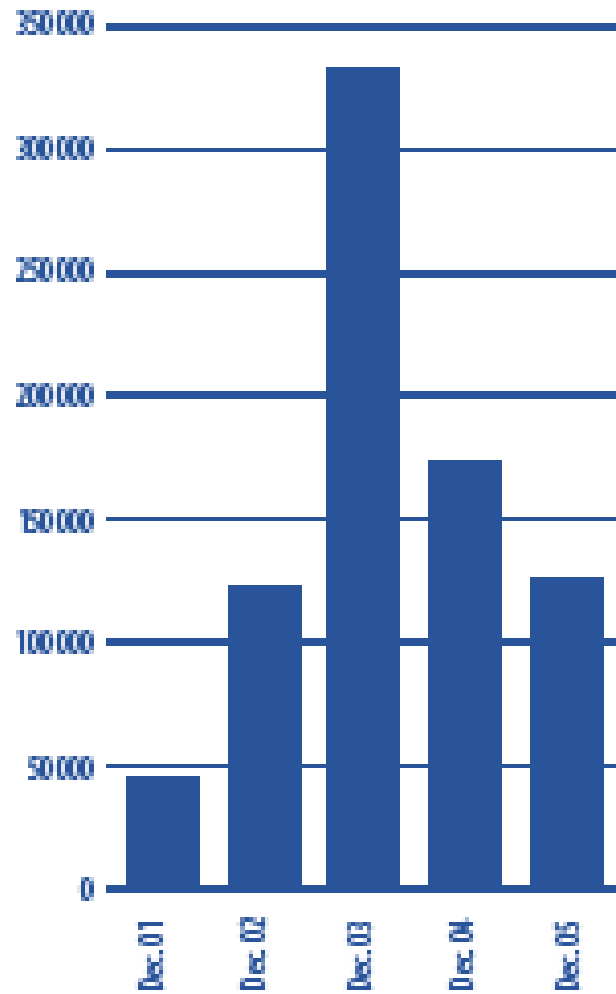


Source:

ISO Survey 2005 by ISO 2006/9

ISO 9001:2000 certificates

Annual growth of
ISO 9001:2000 certificates
December 2001 to December 2005

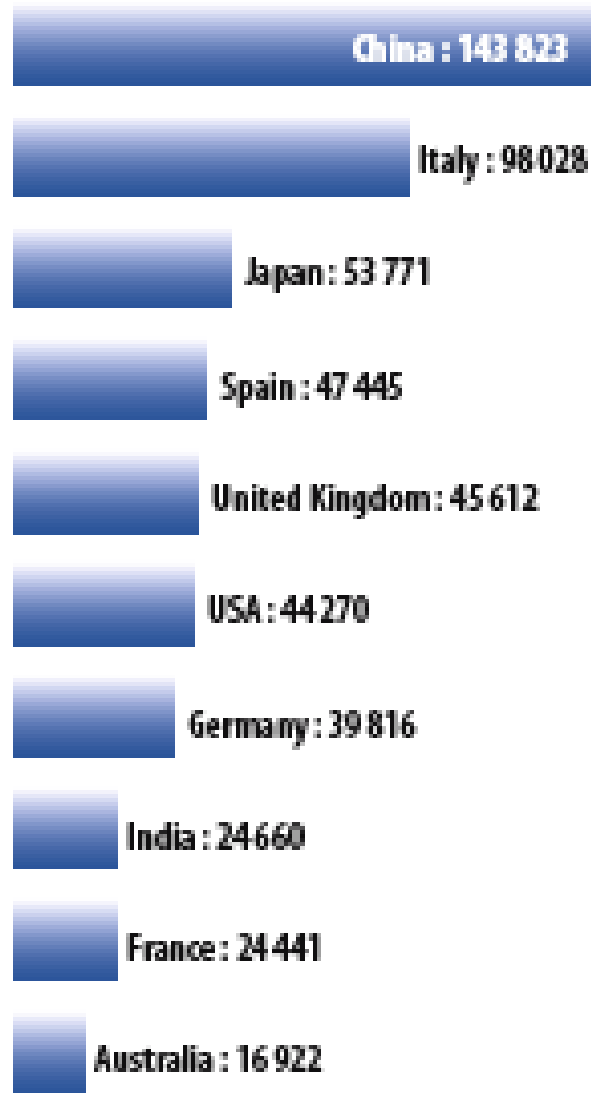


Source:

ISO Survey 2005 by ISO 2006/9

ISO 9001:2000 certificates

Top 10 countries for ISO 9001:2000 certificates



Source:

ISO Survey 2005 by ISO 2006/9

Benefits and added value

- systematic approach to manage your processes
 - systemize your way of doing things
 - time, money and resources are utilized efficiently
 - analyzing and measuring capability of key activities
- keep customers satisfied
 - meet their requirements and expectations
- review performance of QMS: check if it works!
 - internal audits (ISO requirement self-check)
 - invite clients to audit...
 - audit by certification body

Criticism

- Amount of money and time?
- Paperwork and bureaucracy?
 - failure when a company is interested in certification before quality
 - result: a paper system that has nothing to do with the way you run your business!
- Discourages free thinking?
Lose the power to develop creative solutions?

Why external certification?

- credibility of an independent assessment
- avoid multiple client audits or reduce frequency or duration
- business reference
- expert looking over your shoulder

Structure and major elements QMS

Necessary:

- Define all key processes in your organization
- Monitoring of processes to ensure they are effective (performance indicators)
- Keep adequate records
- Check output for defects
- Facilitate continual improvement: deal with past problems and potential problems (corrective and preventive actions)
- Regularly review individual processes and QMS itself for effectiveness (internal audits, management review)

ISO requirements for Quality Manual

- Scope and exclusions (ISO reference matrix)
- Quality policy and objectives
- Definition of key processes and interaction between processes
- 6 compulsory procedures/documents:
 - Control of documents
 - Control of records
 - Internal audits
 - Control of Nonconforming product/service
 - Corrective Action
 - Preventive Action

Example

Contents of a quality manual

1.1 Contents quality manual

	Version	Date of Issue	Authorisation
1. GENERAL			
1.1 Contents quality manual	0.1	01.07.2006	
1.2 Introduction, scope & distribution	0.1	01.10.2007	
1.3 Reference matrix to NEN-EN-ISO 9001:2000	0.1	01.10.2007	
1.4 Abbreviations, definitions & codes	0.1	01.10.2007	

2. MANAGEMENT RESPONSIBILITY			
2.1 Company policy & strategy	0.1	01.10.2007	
2.2 Quality policy	0.1	01.10.2007	
2.3 Quality objectives & planning	0.1	01.10.2007	

3. ORGANIZATION			
3.1 Organizational chart	0.1	21.06.2006	
3.2 Quality responsibilities and management representation	0.1	01.10.2007	
3.3 Job descriptions	0.1	21.06.2006	
3.4 Expertise & competence	0.1	21.06.2006	
3.4.1 Marketing & sales	0.1	21.06.2006	
3.4.2 Forecasting	0.1	21.06.2006	
3.4.3 IT	0.1	21.06.2006	
3.5 Authorities (financial)	0.1	21.06.2006	
3.6 Communication (internal & external)	0.1	21.06.2006	

4. CONTROL			
4.1 Control of quality management system	0.1	01.10.2007	
4.2 Control of documents (internal and external)	0.1	01.10.2007	
4.2.1 Marketing & Sales	0.1	01.10.2007	
4.2.2 Research & Development	0.1	01.10.2007	
4.2.3 Forecasting	0.1	01.10.2007	
4.2.4 IT	0.1	01.10.2007	
4.2.5 Page Production	0.1	01.10.2007	
4.2.6 Human Resources / H&S	0.1	01.10.2007	
4.3 Control of records	0.1	01.10.2007	
4.4 Control of resources and work environment	0.1	01.10.2007	

5. PROCESS EXECUTION			
<u>Primary processes</u>			
5.1 Sales & Marketing			
5.1.1 Sales budgets & targets	0.1	20.06.2006	
5.1.2 Marketing & Sales	0.1	21.06.2006	
5.1.3 Customer contracts	0.1	21.06.2006	
5.2 Product development			
5.2.1 Local projects	0.1	17.07.2006	
5.2.2 Development	0.1	05.07.2007	
5.3 Forecasting			
5.3.1 Workload	0.1	22.06.2006	
5.3.2 Hosters	0.1	22.06.2006	

Example

Contents of a quality manual

1.1 Contents quality manual

	Version	Date of Issue	Authorisation
5.3.3 Forecasting	0.1	22.06.2006	
5.3.4 Recruitment & training forecasting	0.1	22.06.2006	
5.3.5 External training courses	0.1	22.06.2006	
5.3.6 New clients or changes winter roads	0.1	22.06.2006	
5.3.7 24 Hours monitoring winter roads	0.1	23.06.2006	
5.4 Information Technology			
5.4.1 Software development	0.1	24.04.2007	
5.4.2 Maintenance	0.1	24.04.2007	
5.4.3 Support	0.1	24.04.2007	
* All processes including monitoring & quality control			
Supporting processes (outsourced)			
5.5 Page production			
5.5.1 Page production	0.1	14.08.2006	
5.5.2 Page ready design	0.1	14.08.2006	
5.6 Human Resources			
5.6.1 Recruitment & new starters	0.1	15.08.2006	
5.6.2 Personnel evaluation & training	0.1	15.08.2006	
5.6.3 Contract changes	0.1	15.08.2006	
5.6.4 Exit process	0.1	15.08.2006	
5.7 Purchasing & outsourcing	0.1	24.04.2007	
5.8 Administration	0.1	24.04.2007	
* All processes including monitoring & quality control			

	Version	Date of Issue	Authorisation
6. MEASUREMENT, ANALYSIS AND IMPROVEMENT			
6.1 Customer satisfaction	0.1	24.04.2007	
6.2 Complaints & deviations	0.1	21.06.2006	
6.3 Quality control & verification	0.1	24.04.2007	
6.4 Supplier evaluation	0.1	01.10.2007	
6.5 Internal audits	0.1	01.10.2007	
6.6 Corrective & preventive actions	0.1	01.10.2007	
6.7 Management review	0.1	01.10.2007	

Example

Contents of a quality manual


QUALITY MANAGEMENT SYSTEM Centre for Genetic Resources, the Netherlands	
1.GENERAL 1.1 CONTENTS	Page 1 of 4

GENERAL PART

1. GENERAL	
1.0 Declaration of release and definition of scope	Version 1
1.1 Contents	Version 1
1.2 Reference matrix to NEN-FN-ISO 9001:2000	Version 1
1.3 List of amendments	Version 1
1.4 Distribution list	Version 1
1.5 Abbreviations, definitions, codes	Version 1
2. MANAGEMENT	
2.1 Establishment of policy	Version 1
2.2 Strategy memorandum CGN (abbreviated version)	Version 1
2.3 Quality policy	Version 1
2.4 Quality objectives and planning	Version 1
2.5 Budgets and finance (lump sum)	Version 1
2.6 Acceptance of assessments from third parties	Version 1
2.7 Project execution	Version 1
2.8 Acquisition of knowledge	Version 1
2.9 Knowledge transfer	Version 1
3. ORGANIZATION AND STAFF	
3.1 Organizational chart	Version 1
3.2 Responsibilities and authorities	
3.2.1 Duties, responsibilities and authorities	Version 1
3.2.2 Hierarchical structure of CGN	Version 1
3.2.3 Recruitment	Version 1
3.3 Expertise and competences	
3.3.1 Expertise matrix	Version 1
3.4 Quality responsibilities and management representation	Version 1
3.5 Explanation of function-competence profiles	Version 1
3.6 Personnel and training	Version 1
3.7 Consultation and communication	Version 1
4. ADMINISTRATION	
4.1 Document and data administration	
4.1.1 Document structure	Version 1
4.1.2 Production, amendment and release of documents	Version 1
4.1.3 Administration of internal and external documents	Version 1
4.1.4 Administration of electronic media and data	Version 1
4.1.5 Administration of confidential information	Version 1
4.1.6 Mail and archives	Version 1
4.2 Administration of (quality) registration	Version 1
4.3 Administration of means/resources	Version 1
4.3.1 maintenance/management of monitoring and measuring equipment	Version 1

Example

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4.4	Statistical techniques	Version 1
4.5	Public relations	Version 1
4.6	Purchasing and outsourcing	Version 1
5. MEASUREMENT, ANALYSIS AND IMPROVEMENT		
5.1	Monitoring client and user satisfaction and client and user focus	Version 1
5.2	Complaints, deviations and improvements	Version 1
5.3	Project evaluation	Version 1
5.4	Evaluation by management	Version 1
5.5	Corrective and preventive measures	Version 1
5.5.1	Corrective measures	Version 1
5.5.2	Preventive measures	Version 1
5.6	Internal audits	Version 1
5.7	Selection and evaluation of suppliers	Version 1
SECTOR-SPECIFIC PART		
6. EXECUTION PGR		
6.0	Primary process	Version 1
6.1	Collection and conservation	
6.1.1	Acquisition	Version 1
6.1.2	Multiplication	Version 1
6.1.3	Inclusion in gene bank	Version 1
6.1.3.1	Seed processing	Version 1
6.1.3.2	Germination test	Version 1
6.1.3.3	Registration and packaging	Version 1
6.1.3.4	Seed lot meeting standards of Germination test	Version 1
6.1.4	Inventory management	Version 1
6.1.4.1	Identification and traceability	Version 1
6.1.4.2	Storage, working and handling guidelines	Version 1
6.1.4.3	Divided seed material	Version 1
6.1.4.4	Monitoring of seed quality and quantity	Version 1
6.1.4.5	Management of duplicate material from other gene banks	Version 1
6.1.4.6	Management of material from third parties	Version 1
6.1.4.7	Duplicate material in CRN collections	Version 1
6.2	Documentation	
6.2.1	Acquiring and disseminating information on collections	Version 1
6.3	Facilitation and stimulation	
6.3.1	Processing of applications and distribution	Version 1
6.3.2	Simulation of the use of collection material	Version 1

Example

Contents of a quality manual

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SECTOR-SPECIFIC PART

7. EXECUTION AnGR	
7.1 Primary process AnGR	Version 0
7.2 Gene bank	
7.2.1 Selection of genetic material and resources	Version 0
7.2.2 Acquisition, transfer and receipt	Version 0
7.2.3 Preservation, inclusion and storage	Version 0
7.2.4 Inventory management	Version 0
7.2.4.1 Identification and traceability	Version 0
7.2.4.2 Documentation and status	Version 0
7.2.4.3 Management of duplicate material in gene bank collections	Version 0
7.2.4.4 Management of genetic material from third parties	Version 0
7.3 Acquisition of knowledge AnGR	Version 0
7.4 Consultancy and knowledge transfer AnGR	Version 0

APPENDIX 1. PROTOCOLS/ INSTRUCTIONS, OVERVIEWS and FORMS - GENERAL

APPENDIX 2. PROTOCOLS/ INSTRUCTIONS, OVERVIEWS and FORMS - PGR

APPENDIX 3. PROTOCOLS/ INSTRUCTIONS, OVERVIEWS and FORMS - AnGR

Important steps

1. Focus on customer / user:
 - What are we selling/delivering?
 - Who is our customer?
 - Do we know his requirements, needs, expectations?
 - Can we measure customer satisfaction and increase it?

Important steps

2. Amount of documentation (paperwork) depends on:

- Size and kind of organization
- What business are you in
- Complexity of processes
- Competence and qualifications of personnel

Documentation: yes or no

- Effect on quality of your product / service
- Risk of unsatisfied customer/user
- Legal requirements
- (Economic) risks
- Effectiveness and efficiency

Necessary =
defining and analyzing of your processes!!

Process management

1. Define basic elements of the process
2. Continual improvement
3. Also: a different way of auditing

Basic process elements

1. Field of application of process
2. Process responsibilities
3. Describe process and interaction with other processes
4. Process indicators (gather process information and analyze it)
5. Define objectives to improve process

Example

1. **FIELD OF APPLICATION**
PA Human Resources
MeteoGroup UK

2. **DUTIES, RESPONSIBILITIES AND AUTHORITIES**

Activity	Functions							Details
	Managing Director MeteoGroup UK	General Manager MeteoGroup UK	Head of HR	HR Business Manager	HR Administrator	Line manager Meteo Group UK	All employees MeteoGroup UK	
1. Yearly performance & development discussions						E		
2. Select necessary training or workshop available				A		E		
3. Attend available training or update programme						E		
4. Evaluation of training course or workshop						E		
5. Checking of attendance lists + evaluations			E			E		
6. Review points of action with (external) trainers			E			E		
7. Attendants receive certificate or qualification						E		
8. Attendance and qualification are updated in HR Database					E			
9. Evaluation of objectives						E		- 6 months evaluation - Forecasters grading system
10. Annual salary review	D					E	D	
11. Preparing of standard letter and salary details				E				
12. Adding of details and confirming review to employee						E		

E = executing responsibility D = Decisive authority in case of deviations A = obligation to advise **process responsibility**

3. **PROCESS INDICATORS FOR PROCESS EFFECTIVENESS AND CAUSE ANALYSIS**

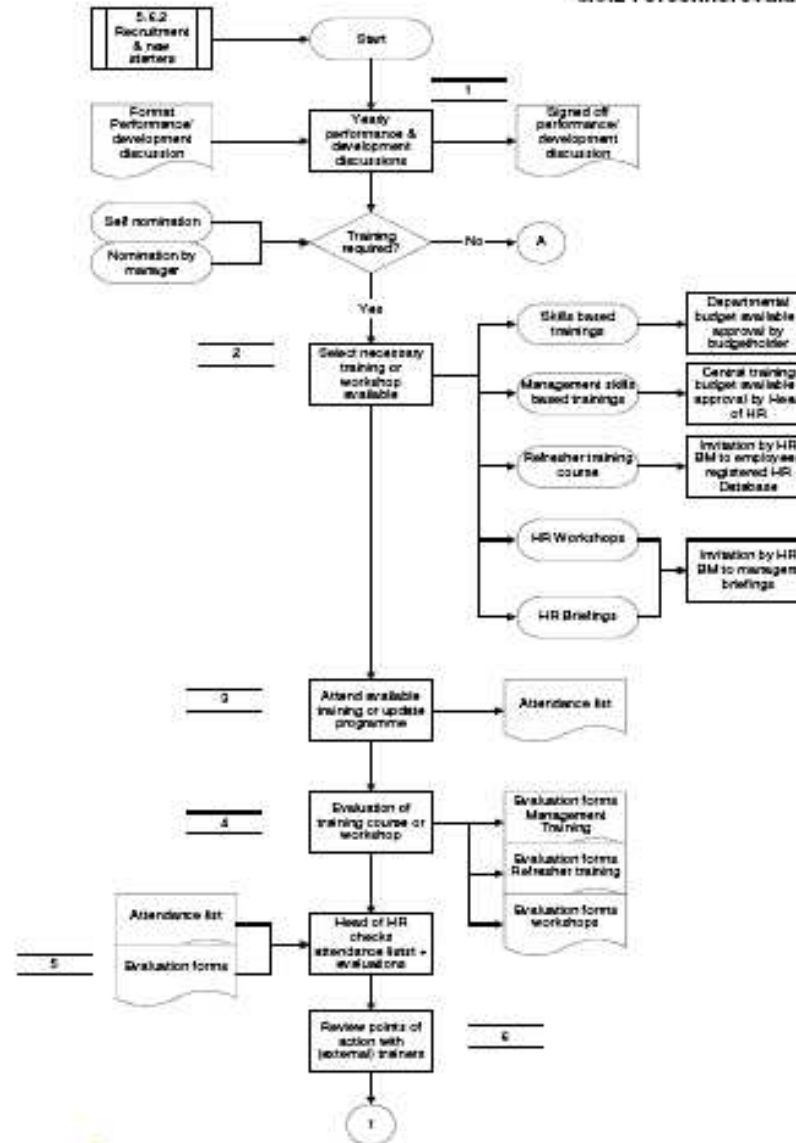
- Success of progress through forecasters grading system.
- Positive outcome from evaluations. PI = 9 out of 10.

4. **PROCESS FLOW CHART**

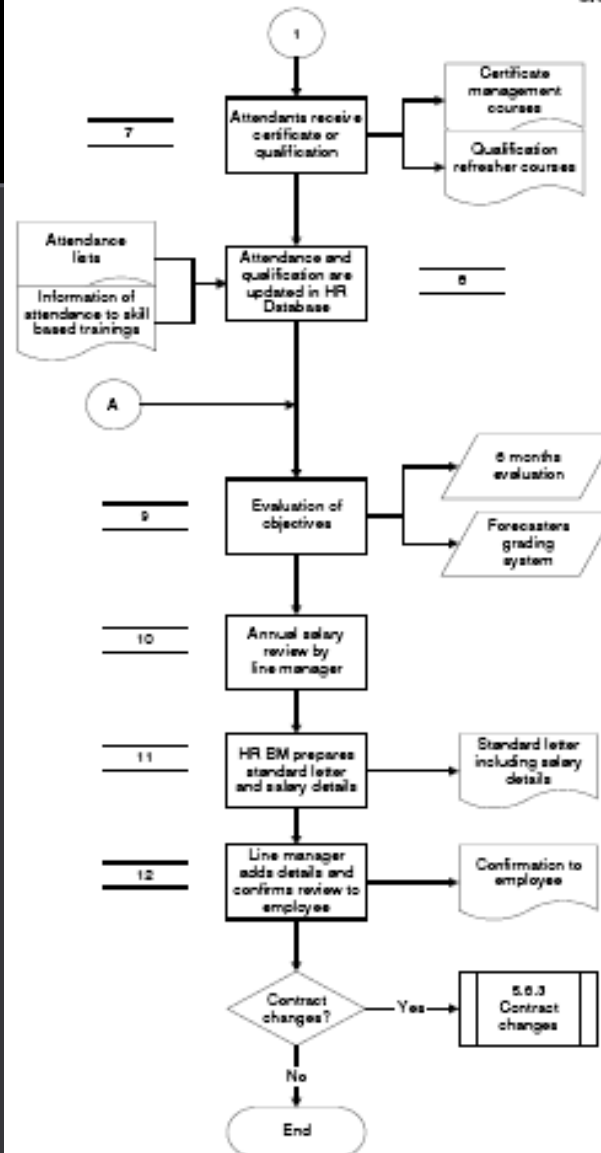
Next page.

Example

5.6 Human Resources
5.6.2 Personnel evaluation & training



Example



Continual improvement

1. Based on process effectiveness, efficiency, reduction of risks and prevention of deviations/failures.
2. Necessary:
 - a) Management commitment
 - b) Definition of key success factors and performance indicators
 - c) Process responsibility (also on higher management level)

Auditing

- History: compliance auditing
 - tell me what you do
 - show me where it says that
 - prove that that is what happened
- 9001:2000 → a new approach for auditing:
 - ISO 19011 auditing management systems
 - process approach
 - focusing on risk, status, importance
 - auditor is expected to make more judgements (more 'what is effective' than 'what is formally prescribed')

Analyzing processes

1. Based on the activities that add value to your process!
2. Criteria:
 - a) Does it add value to the customer (internal and external)?
 - b) Does it really cause a change in the process?
 - c) Can we do it right the first time? (no unnecessary checks)

Benefits of process improvement

1. Reduction of time (and cost)
2. Improvement of quality (remove activities that don't add value + concentrate on activities that really matter)
3. Better focus on the customer
4. Improved working conditions for personnel (less frustrating and time consuming activities)

Start immediately??

1. Changes in processes have to be based on facts: gather information and analyze it!
2. Don't remove check points out of processes without a reason: quality control based on risks and prevention of failures!
3. Changing of processes can only be realized by top management!

Good luck !

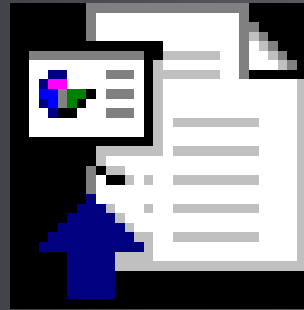


Van

Ravesteijn

Partners

**Maybe some time left for a little
'process joke'...**



FLOWCHART.pps