Competence, Training, and Awareness

Dan O'Leary CBA, CQA, CQE, CRE, SSBB, CIRM
President
Ombu Enterprises, LLC
Dan@OmbuEnterprises.com
www.OmbuEnterprises.com
603-209-0600

Outline

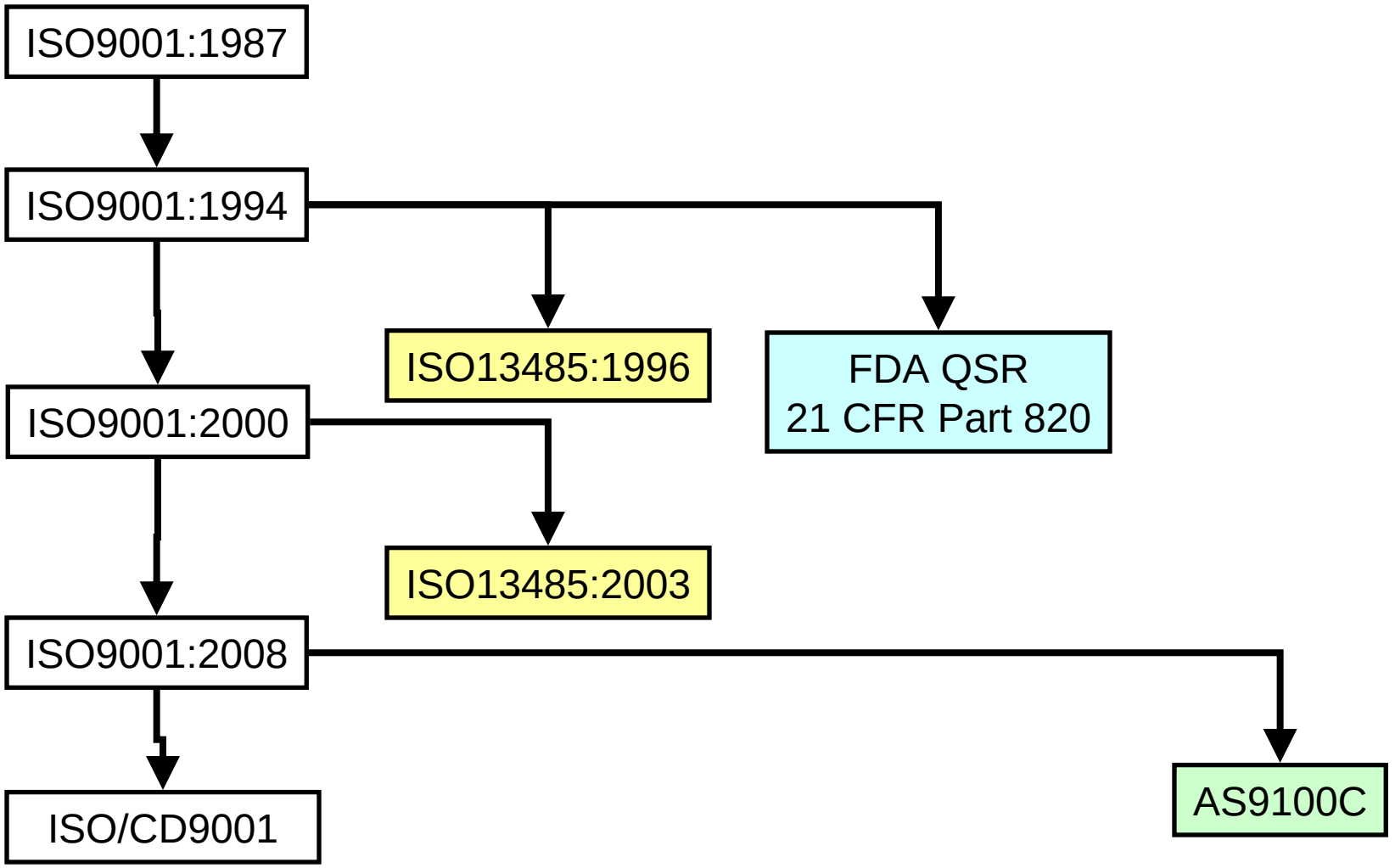
- The Competency Dimensions
- The Regulatory Requirements
- The Position Description
- Conducting A Gap Analysis
- Training
- Special Competence
- Maturity Models
- Questions

The Standards

- The medical device standards (FDA QSR and ISO 13485) are built on ISO9001.
- These standards all have requirements for Competency, Training, and Awareness
- The requirements have a core set of competency and training that evolved over time
- The current versions of the medical device standards share many common concepts

The Genealogy of Some QMS Standards

Selected QMS Genealogy



Comparison Chart
Competence, Training, and Awareness

ISO9001:2008 & AS9100C	ISO13485:2003	FDA QSR (21 CFR Part 820)	ISO/CD9001
6.2.2 Competence, training and awareness The organization shall a) determine the necessary competence for personnel performing work affecting conformity to product requirements, b) where applicable, provide training or take other actions to achieve the necessary competence, c) evaluate the effectiveness of the actions taken, d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and e) maintain appropriate records of education, training, skills and experience (see 4.2.4).	**6.2.2 Competence, awareness and training** The organization shall a) determine the necessary competence for personnel performing work affecting product quality, b) provide training or take other actions to satisfy these needs, c) evaluate the effectiveness of the actions taken, d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and e) maintain appropriate records of education, training, skills and experience (see 4.2.4). *NOTE National or regional regulations might require the organization to establish documented procedures for identifying training needs.*	**Sec. 820.25 Personnel** (a) General Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed. (b) Training Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented. (1) As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs. (2) Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions.	**7.2 Competence** The organization shall: a) determine the necessary competence of person(s) doing work under its control that affects its quality performance, and b) ensure that these persons are competent on the basis of appropriate education, training, or experience; c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken, and d) retain appropriate documented information as evidence of competence. NOTE Applicable actions may include, for example: the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons. **7.3 Awareness** Persons doing work under the organization‘s control shall be aware of a) the quality policy, b) relevant quality objectives, c) their contribution to the effectiveness of the quality management system, including the benefits of improved quality performance, and d) the implications of not conforming with the quality management system requirements.

The Competency Dimensions

Competence

- One important point is understanding the terms
- ISO9000:2005 *Quality management systems – Fundamentals and vocabulary define many terms*
- *Competence* means demonstrated ability to apply knowledge and skills [Clause 3.1.6]

The Competency Dimensions

FDA QSR	ISO13485:2003	ISO9001:2008 & AS9100C	ISO/CD9001
Background	--	--	--
Education	Education	Education	Education
Experience	Experience	Experience	Experience
--	Skills	Skills	--
Training	Training	Training	Training

Notice that there are five terms here. We take background and skills as equivalent in this setting.

Our Sources for Definitions

- FDA QSR 820.3 Definitions
- ISO9000:2005 *Quality management systems – Fundamentals and vocabulary define many terms*
- ISO/TC176/SC1/WG1 N318:2012 *Guidance on some of the frequently used words found in the ISO9000 family of standards*

Definitions

- Background
  - Not defined in any of our sources
- Education
  - Not defined in any of our sources
- Experience
  - practical contact with and observation of facts and events (N318)
- Skills
  - Not defined in any of our sources
- Training
  - act of developing a particular skill or type of behavior through demonstration, instruction, and practice (N318)

The Problem

- Many of the competency dimensions use undefined terms in the quality standards
- The lack of definitions can cause some confusion
- We rely on colloquial language and guidance documents for help

The Competencies Described

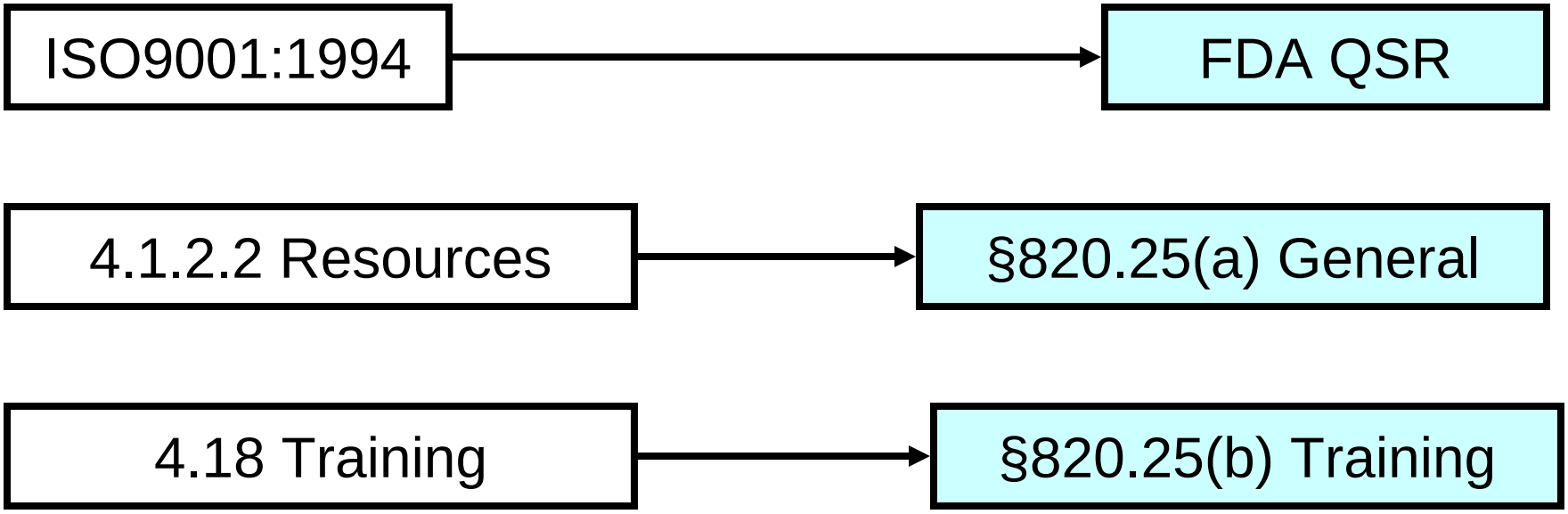
- Education
  - Formal knowledge usually delivered by a school (high school, college, *etc*.)
- Experience
  - Participation in a job or activity, often with exposure to a variety of subjects
- Skill
  - The ability to perform well in a certain area, often derived through education and experience. (Mary is a skilled welder. Fred is a skilled data analyst.)
- Training
  - Learning focused on a specific activity, often related to a specific task or job.

FDA QSR

Background

- Congress required FDA to develop device regulations that “harmonized” with a global approach
- FDA used ISO9001:1994 and a draft version of ISO13485 as the basis
- FDA published a draft version and asked for comments
- FDA’s analysis of the comments and its response is in the preamble to the regulation

ISO9001:1994 → FDA QSR



§820.25(a) General

Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed.

§820.25(b) Training

Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented.

(1) As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs.

(2) Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions

§820.20(a) Quality Policy

Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality. Management with executive responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization.

QSR Elements

- Sufficient
  - Enough competent people to perform the requirements correctly
- Competence
  - Education
  - Background
  - Training
  - Experience
- Training
  - Identify training needs and ensure that all personnel are trained
- Training Effectiveness
  - Personnel are trained to adequately perform their assigned responsibilities
- Awareness
  - Ensure that the quality policy is understood, implemented, and maintained at all levels of the organization.
- Documentation
  - Training shall be documented.

QSR Preamble # 59

Whether “sufficient” personnel are employed will be determined by the requirements of the quality system, which must be designed to ensure that the requirements of the regulation are properly implemented. … FDA agrees that the manufacturer must determine for itself what constitutes “sufficient” personnel with proper qualification in the first instance. However, if the manufacturer does not employ sufficient personnel, … the manufacturer will be in violation of the regulation

QSR Preamble #60

- FDA amended the requirement so that the training procedure includes the identification of training needs. … FDA notes, however, that a training program to ensure personnel adequately perform their assigned responsibilities should include information about the [QSR] requirements and how particular job functions relate to the overall quality system

The QSR Manual

- When FDA published QSR it also published, in December 1996, a book to help companies implement it.
- Medical Device Quality Systems Manual: A Small Entity Compliance Guide
- It has about 20 chapters and discusses the regulation and offers sample procedures, work instructions, and forms.
- Chapter 5 covers *Personnel and Training*

QSR Manual – Employee Selection

- The initial selection of employees for a specific job is made based on a combination of education, experience, personal habits, interests, *etc*.

- New employees should be informed that they are working in a regulated industry and should be initially trained to perform their specific jobs and be made aware of any defects or problems that may occur.

QSR Manual – Production Personnel

- Employees need to be informed why certain personnel and work practices are required. Basic instructions about invisible microorganisms and particulates will make the company requirements much more meaningful.

QSR Manual – Technical Personnel

- The manufacturer should assure that they have sufficient properly trained personnel, or programs to train technical personnel, to design, validate, develop processes, and produce the new or modified device.

- New design personnel may be introduced to manufacturing methods and producibility issues by being assigned to various manufacturing areas before starting their design activities.

QSR Manual – Process Validation

- The discussion for technical personnel also applies to technical employees who perform process validation After the processes are validated, these technical personnel should use their expertise and experience to develop training methods or help train production employees on how to monitor, control, and operate validated processes.

- 820.75(b)(1) requires that validated processes be performed by qualified individuals. Obviously, operators that are trained to operate each specific validated process are needed to meet these requirements.

Warning Letter
Hammill Manufacturing Company
January 6, 2009

- 21 CFR §820.20(b) – Adequate organizational structure
- For example, your Quality Assurance Department consists of one individual, the Quality Manager, who is responsible for implementation of your CAPA system, quality audits, document control, training, developing procedures, conducting process validations, and all other aspects of your quality system for both medical and non-medical products.
- During the inspection your quality manager stated that he lacked sufficient time and resources to complete many of the Quality System requirements.

Warning Letter
Abbott Diabetes Care, Inc.
July 2, 2010

21 CFR §820.25(a) – Sufficient personnel with appropriate background

For example:

a. The job description for the Director of Quality Systems requires that the person have a Bachelor of Science/Technical/or Engineering discipline. The person holding the position does not have this type of degree, but rather a Business Administration degree.

b. The person holding the Regulatory Affairs Manager position lacks the minimum of 5 years of regulatory experience required in the job description.

c. The person holding the Quality Control Supervisor position lacks the required Bachelor degree in science or the alternative five to eight years experience in Quality Control.

d. The person holding the Calibration Coordinator position lacks the required Bachelor degree and the four years of relevant experience.

Warning Letter
Biological Controls
February 16, 2010

21 CFR §820.25(b) – Identify and document training needs

Specifically, your firm has failed to establish procedures for identifying training needs and has also failed to record personnel training so that records can be updated and gaps in training can readily be identified and filled.

Warning Letter
Caridian BCT Inc.
March 18, 2011

21 CFR §820.25(b) – Identify and document training needs

Specifically, you did not have documentation that [the] contract cleaning employees observed cleaning the "Clean room" had been trained in procedure Clean room/Controlled Environmental Access.

Warning Letter
Electric Mobility Corporation
April 14, 2011

21 CFR §820.25(b) – Identify and document training needs

There is no documentation to demonstrate that three technicians who performed the latch lock rework of the We Go power chairs were trained on the rework instruction (WI 19259400) even though the Engineering Change Notice (ECN) associated with the rework states that training is required.

Warning Letter
Laglove Sdn Bhd (M) aka LA Glove
January 20, 2011

21 CFR §820.25(b) – Identify and document training needs

For example, with regards to your employees involved in the compounding of the nitrile compound (which is used to make the nitrile sheath), a review of your firm's training procedure, entitled, "Training Needs Identification and Training Plan" … and employee training records gave no indication that employees were made aware of the defects or negative impact on the medical device that may occur from the improper performance of their job.

Warning Letter
RD Medical Manufacturing Holding Company
February 7, 2011

21 CFR §820.25(b) – Identify and document training needs

Specifically you failed to provide documentation showing that the operators performing [a certain technique] have been certified to perform [that] function. At least 2 investigations conducted in 2009 and 2010 identified [the cause for the product's failure as] inadequate operator techniques associated to the techniques mentioned above.

ISO13485:2003

ISO13485:2003 Information

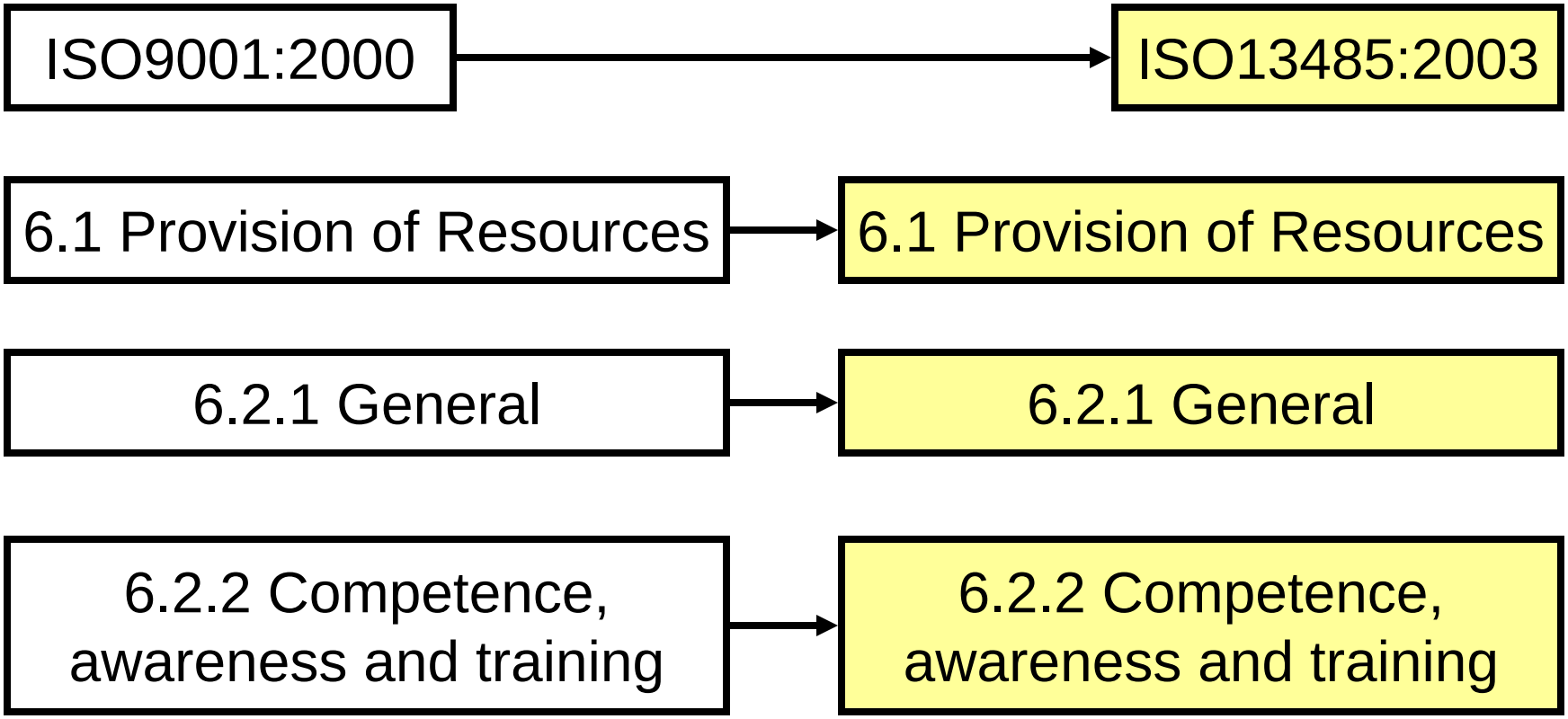
- ISO13485:2003 uses ISO9001:2000 as a basis.
- When the standard matches ISO9001, the text uses black roman font. When it differs, the standard uses blue italic font.
- In addition, there is an appendix that explains the differences between the two standards.

ISO13485:2003 Status

- ISO13485:2003 is an international standard
  - It doesn't "know" the country or region where it is used

- The proper application of ISO13485:2003 may require additional information on national or regional regulations

ISO9001:2000 → ISO13485:2003



[The text of 6.2.1 in ISO13485 is identical to that in the corresponding sub-clause of ISO9001.]

6.1 Provision of Resources

The organization shall determine and provide the resources needed

a) to implement the quality management system and to maintain its effectiveness, and

b) to meet regulatory and customer requirements.

6.2.1 General

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills, and experience.

6.2.2 Competence, Awareness, and Training

The organization shall

a) determine the necessary competence for personnel performing work affecting product quality,

b) provide training or take other actions to satisfy these needs,

c) evaluate the effectiveness of the actions taken,

d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and

e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

NOTE National or regional regulations might require the organization to establish documented procedures for identifying training needs.

National or Regional Regulations

- ISO13485:2003 is the international version
- It doesn't know the country or region where it is being used.
- The manufacturer must know if there are additional regulations.
  - National regulations could be Canada
  - Regional regulations could be the European Union

ISO/TR 14969

- ISO/TR14969:2004 *Medical devices – Quality management systems – Guidance on the application of ISO13485:2003*

- The Technical Report provides guidance to assist in the development, implementation and maintenance of quality management systems that aim to meet the requirements of ISO13485 for organizations that design and develop, produce, install and service medical devices, or that design, develop and provide related services.

ISO/TR14969 – Competence, Awareness, and Training

- The organization should consider the experience, qualifications, capabilities and abilities of personnel, especially in those areas that can affect the safety and effectiveness of the medical devices being manufactured and provided to customers.

ISO/TR14969 – Competence, Awareness, and Training

- It might be necessary for people to be further qualified or formally certified for some tasks (*e.g.,* chemical or microbiological analysis, radiation activities, laser operation, welding, or soldering).

- Organizations typically provide general education and training for full-time, part-time and contract personnel, tailored to the person's assignment.

ISO/TR14969 – Competence, Awareness, and Training

- Organizations should evaluate the effectiveness of training or other actions taken in order to ensure competency.

- Evaluation can consist of polling the trained employee to assess whether he or she feels they have learned the required information, evaluating the work performance of the trained individual, and reviewing the trainer assessment of training effectiveness.

ISO/TR14969 – Competence, Awareness, and Training

- Organizations should maintain records which show what competencies an employee possesses. Records should also be kept of the training an employee has received and any results of that training.

- The records which show that the training course has been successfully completed and that competence has been achieved may be as simple or complex as necessary. At their simplest, the records may consist of ‘sign-off’ to confirm that personnel are now able to use certain equipment, carry out specific processes, or follow certain procedures.

- The records should include a clear statement that a person is now deemed to be competent to do the task for which they were trained.

- The effectiveness of any further education and training should be reevaluated, after a period, to confirm that the competence achieved is continuing.

Developing the Position Description

Job v. Role

- In a company, a person may perform many activities. Define each one using a Position Description

- Some are jobs for which a person is qualified.
  - A job is usually associated with a production process, department, *etc*.

- Others are roles, often collateral duties.
  - A role is usually associated with a specific skill or task.

Job v. Role

- Some examples of jobs include:
  - Printed Circuit Board Assembler
  - MIG/TIG Welder
  - Quality Inspector
  - Document Control Clerk
  - Accounts Payable Manager

- Some examples of roles include
  - Internal Quality Auditor
  - First Aid Team Member
  - Safety Manager

Position Description

- Develop a position description as a form in the Quality Management System
- The form will be sure you identify all the required elements for a Position Description
- A completed form describes a Job or Role
  - It is also under document control

Position Description

- The Position Description has some standard elements
  - Position Title
  - Document date
    - The Position Description should be under document control
  - Identify it as a Job or Role
  - Describe the duties of the job or role
    - Keep it short and simple
  - Identify the department or function associated with the position
  - Identify the competence elements:
    - Education
    - Training
    - Skills
    - Experience
  - Physical attributes required
  - Other attributes required
    - Ability to lift (60 pounds)
    - Not color blind

POSITION DESCRIPTION

TITLE: Date Updated:

☐ Job ☐ Role

Sec. 1	**Describe the duties of a person in this position**
Sec. 2	**Identify the function or department associated with this position**
Sec. 3	**Identify any education required to perform this position**
Sec. 4	**Identify any training required to perform this position (Do not include training on procedures or work instructions)**
Sec. 5	**Identify any skills required to perform this position (Do not include skills developed by performing the position at Select Engineering)**
Sec. 6	**Identify any experience required to perform this position (Do not include experience obtained by performing the position at Select Engineering)**
Sec. 7	**Identify any personal behavior or physical characteristics required to perform this position (This may include open minded, self reliant, ability to lift, not color blind, *etc*.)**

Other Requirements

- In some cases, a job or role may require special characteristics
  - A man required to wear a respirator may not be allowed to have beard
  - Certain jobs or roles may require the ability to lift heavy weights

Some Examples

- Education
  - A Production Assembler may need a High School Diploma
  - A Design Engineer may need a Bachelor's Degree
- Training
  - A Waste Water Treatment Operator may need external EPA regulation training
- Skill
  - A Security Guard may need skills in shooting a pistol
  - An Internal Quality Auditor may need interview skills
- Experience
  - A Quality Manager may need 5 years experience in medical device manufacturing

Exercise

- You have a handout with some exercises.
- Please take a few minutes to complete Part A.

Exercise – Internal Quality Auditor

ISO19011:2011 Guidelines for Auditing Management Systems provides information on auditing a QMS and includes auditor competency.

Part A

You are developing a Position Description for internal quality auditors. Please characterize the following representative items from ISO19011:2001. Generally, each item will apply to one and only characteristic. Put an **X** into the applicable column for each item

Item	**Education**	**Training**	**Skills**	**Experience**	**Personal Behavior or Physical Characteristics**
High school diploma or equivalent					
Contracting and liability					
Collect information through effective interviewing, listening, observing and reviewing documents, records and data					
Diplomatic, *i.e.,* tactful in dealing with people					
Confirm the sufficiency and appropriateness of audit evidence to support audit findings and conclusions					
Management system standards or other documents used as audit criteria					
Discipline-specific knowledge related to the particular sector, nature of operations or workplace being audited, sufficient for the auditor to evaluate the auditee's activities, processes, and products (goods and services)					

Gap Analysis

Identify Employees

- The Position Description describes the Job or Role

- Next, identify each person who performs the job or role
  - Any given person may have multiple jobs and roles
  - Jane is a Master Assembler, Incoming Inspector, and Internal Quality Auditor

Identify Gaps

- Each person in a Position should have all the attributes.
  - If a Design Engineer needs a Bachelor's Degree for Education, then a diploma or transcript is the objective evidence
  - If a Quality Engineer needs an ASQ CQE for Skill, then a copy of the certificate is the objective evidence
  - If a Quality Manager needs five years experience, then a resume is the objective evidence
  - If an Internal Quality Auditor needs interview skills, then a performance evaluation is the objective evidence

Document the Gaps – A Worksheet

Mary Jones Internal Quality Auditor			
Requirement	Evidence	Gap	Plan
Education High School Diploma	None	Mary did not graduate from High School	Allow a GED Enroll Mary in a GED program
Training Audit procedure & 2 supervised audits	• Training record on the audit procedure • Evaluation for two internal audits	None	None required
Skills Listening & work independently	Satisfactory performance evaluation from the Audit Manager	None	None required
Experience None required	N/A	N/A	N/A

Current Employees

- Use the plans to fill the gaps.
- ISO13485 Clause 6.2.2.b says, “The organization shall provide training or take other actions to satisfy [competence] needs”
- The plan on the worksheet identifies the training or other actions
- It should be used in conjunction with the company performance appraisal and employee development program

New Hires

- The Position Description forms the basis for the job posting or advertisement
- Evaluate potential candidates using the worksheet
- Develop a gap analysis as part of the selection process
- Use the gap analysis for the person hired

Training

Training

- Training is major issues in competence

- It is often called out explicitly the standards
  - ISO13485:2003 says to provide training or other means to satisfy competency
  - 820.25(b) says to identify training needs and ensure people are trained
- The Position Description and Gap analysis identify individual needs

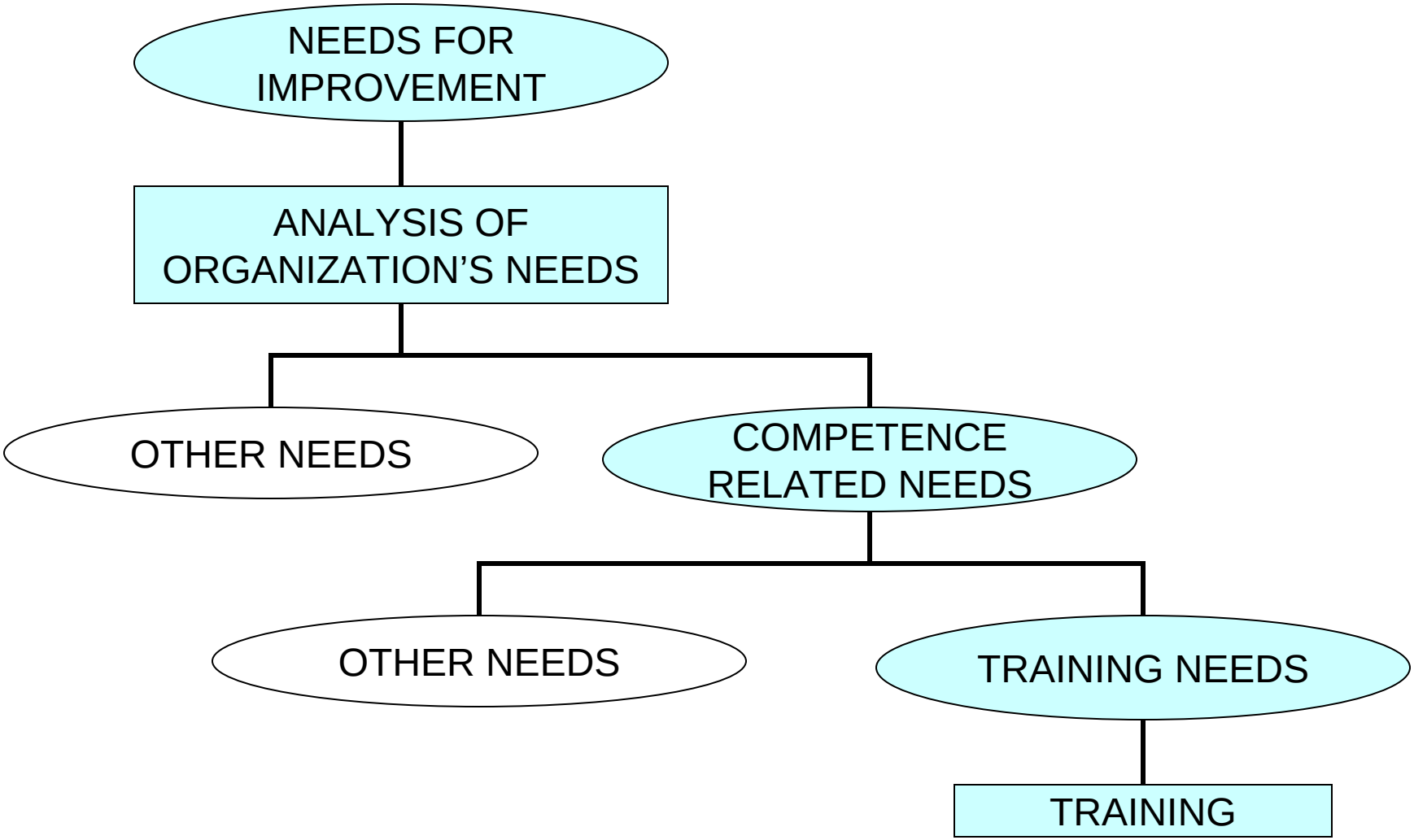
- ISO10015:1999 looks at company needs

ISO10015:1999

- ISO10015:1999 *Quality management — Guidelines for training*

- Scope: These guidelines cover the development, implementation, maintenance, and improvement of strategies and systems for training that affect the quality of the products supplied by an organization.

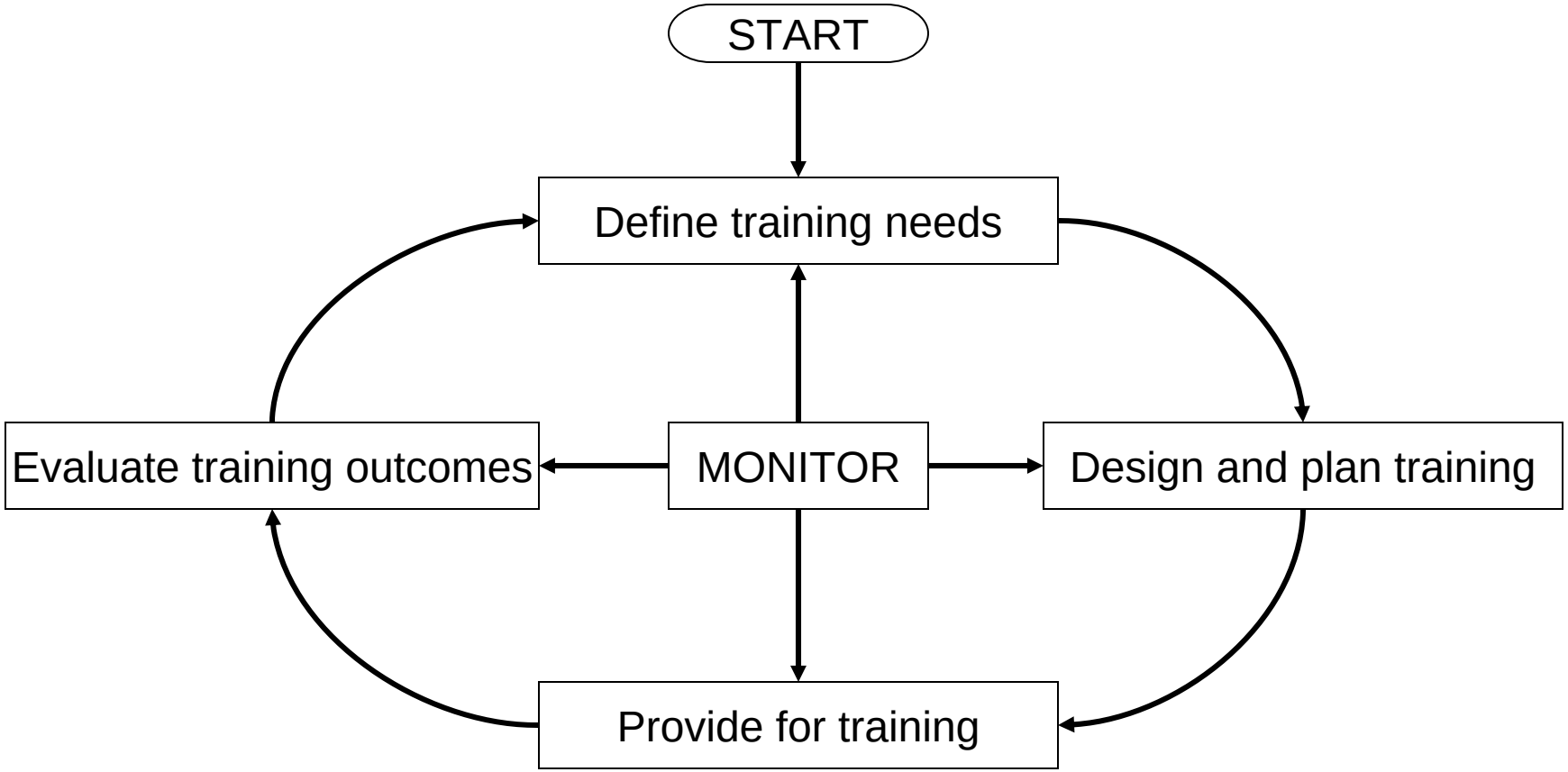
Training as an Improvement Activity



The Training Cycle

- ISO10015:1999 provides a four stage training model
  - Define training needs
  - Design and plan training
  - Provide for training
  - Evaluate training outcomes

The Training Cycle



The Training Cycle

- ISO10015:1999 provides information and methods for each step in the training cycle
- It also provides a set of tables, based on the training cycle to help manage the training process and its sub-processes

Defining the Organization's Needs			
Inputs	Process	Outputs	Record
Quality policy Training policy Quality management requirements Resource management Process design	Consider all inputs when initiating training	Decision to initiate training process	Decision to initiate training process

Determining Effectiveness

- ISO10015:1999 – Evaluating Outcomes
  - Evaluation conforms that objectives have been met, *i.e.,* training is effective
  - Evaluation inputs include training specifications and training delivery records
  - Training results often cannot be fully analyzed and validated until the trainee is observed and tested on the job
  - Within a specified time, management should perform an evaluation to verify competence

Determining Effectiveness

Evaluating Training Outcomes			
Inputs	Process	Outputs	Record
Specification for training needs Training plan specification Records from the delivery of training	Collect data and evaluate it on the basis of established criteria Analyze data and interpret results, review of budget, verify the achievement of specified competence Recommend corrective actions	Evaluation report	Evaluation report Training records

Determining Effectiveness

- ISO/TR14969:2004
- Organizations should evaluate the effectiveness of training or other actions taken in order to ensure competency.

- Evaluation can consist of:
  - polling the trained employee to assess whether he or she feels they have learned the required information,
  - evaluating the work performance of the trained individual, and
  - reviewing the trainer assessment of training effectiveness.

Monitoring – Training Process Validation

Monitoring Analysis	Procedures **not** followed	Procedures followed
Requirements met	• Review & revise procedure • Update personnel competence records	• Update personnel competence records
Requirements **not** met		• Corrective action to improve the training process • Non-training solution

Exercise

- You have a handout with some exercises.
- Please take a few minutes to complete Part B.
- Which method is, in your opinion, most reliable?
- Are any of the methods not applicable?

Exercise – Internal Quality Auditor

ISO19011:2011, Clause 7.4, offers some methods for auditor evaluation and recommends using two or more of the methods described below. The standard also notes:

Part B

- The methods area range of options and may apply in all situations
- The methods may differ in their reliability

Based on your experience, rank order the method's reliability using **1** for the most reliable method, **2** for the next, etc.

For your organization, mark the two most applicable methods with an **X**.

Method	Objectives	Examples	Reliability	Applicability
Review of records	To verify the background of the auditor	Analysis of records of education, training, employment, professional credentials and audit experience		
Feedback	To provide information about how the performance of the auditor is perceived	Surveys, questionnaires, personal references, testimonials, complaints, performance evaluation, peer review		
Interview	To evaluate personal behavior and communication skills, to verify information and test knowledge and to acquire additional information	Personal interviews		
Observation	To evaluate personal behavior and the ability to apply knowledge and skills	Role playing, witnessed audits, on-the-job performance		
Testing	To evaluate personal behavior and knowledge and skills and their application	Oral and written exams, psychometric testing		
Post-audit review	To provide information on the auditor performance during the audit activities, identify strengths and weaknesses	Review of the audit report, interviews with the audit team leader, the audit team and, if appropriate, feedback from the auditee		

Special Competencies

Verification and Validation

- FDA QSR
  - 820.25(b)(2) requires, “Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions.”

- ISO13485:2003
  - 5.5.1 requires, “*Top management shall establish the interrelation of all personnel who manage, perform and verify work affecting quality, and shall ensure the independence and authority necessary to perform these tasks.*”

Designated Individuals

- FDA QSR often calls out a “designated individual” to perform a function
  - Design input review and approval {820.30(c)}
  - Document review for adequacy and approval {820.40(a)}
  - Finished device release {820.80(d)(3)}
  - Release of labeling for storage or use {820.120(b)}
  - Review evaluation, and investigation of a complaint that might be an MDR {820.198(d)}

Risk Management

- ISO14971:2007 *Medical devices — Application of risk management to medical devices*
  - Clause 3.2 says, “Top management shall provide evidence of its commitment to the risk management process by ensuring the assignment of qualified personnel (see 3.3) for risk management.”
  - Clause 3.3 says, “Persons performing risk management tasks shall have the knowledge and experience appropriate to the tasks assigned to them. These shall include, where appropriate, knowledge and experience of the particular medical device (or similar medical devices) and its use, the technologies involved or risk management techniques. Appropriate qualification records shall be maintained.”

ISO 9004 Maturity Models

- Maturity models measure your company's implementation of a QMS
- ISO9004:2000 and ISO9004:2009 each provide a different form of the model.
- Each model have five levels

Maturity Models
Competence, Training, and Awareness

ISO 9004:2000					
Question	Maturity Level				
	Level 1	Level 2	Level 3	Level 4	Level 5
Question 10.a How does management promote involvement and support of people for improvement of the effectiveness and efficiency of the organization?	**No formal approach** No systematic approach evident, no results, poor results, or unpredictable results	**Reactive approach** Problem-based or corrective-based systematic approach; minimum data on improvement results available	**Stable formal system approach** Systematic process-based approach, early stage of systematic improvements; data available on conformance to objectives and existence of improvement trends	**Continual improvement emphasized** Improvement process in use; good results and sustained improvement trends	**Best in class performance** Strongly integrated improvement process; best-in-class benchmarked results demonstrated
Question 10 b How does management ensure that the competence of people in the organization is adequate for currants and future needs?	**No formal approach** No systematic approach evident, no results, poor results, or unpredictable results	**Reactive approach** Problem-based or corrective-based systematic approach; minimum data on improvement results available	**Stable formal system approach** Systematic process-based approach, early stage of systematic improvements; data available on conformance to objectives and existence of improvement trends	**Continual improvement emphasized** Improvement process in use; good results and sustained improvement trends	**Best in class performance** Strongly integrated improvement process; best-in-class benchmarked results demonstrated

ISO 9004:2009					
Area	Maturity Level				
	Level 1	Level 2	Level 3	Level 4	Level 5
6.3 People in the Organization	People are considered a resource, but only a few objectives are related to the strategy of the organization. Training is provided on an *ad hoc* basis, mostly at the request of individual employees. Competence reviews are performed in a few cases.	People are recognized as a resource with given objectives, which are related to the strategy of the organization. There is a program for competency review. Competences are developed as part of an overall plan, which is linked to the organization's strategy. Ideas for improvement are collected.	People have clear process responsibilities and targets and know how they link within the organization. A skills qualification system is established with mentoring and coaching.	Internal networking is widespread and provides collective knowledge for the organization. Training is provided to develop skills for creativity and improvement. People know their personal competences and where they can best contribute to organizational improvement. Career planning is well developed.	External networking involves people throughout the organization. People across the organization participate in the development of new processes. Best practices are recognized.

QUESTIONS