

Human Resources in ISO 13485:2016

In ISO 13485:2003, Clause 6.2 covers Human Resources and includes two sub-clauses:

6.2.1 General

6.2.2 Competence, awareness, and training

In ISO 13485:2016, the structure changed to eliminate the sub-clauses.

Both versions have the same dimension for competency: education, training, skills, and experience. They require the manufacturer to determine the necessary competence for people who perform work that affects product quality.

ISO 13485:2016 adds additional requirements:

- Document the process for establishing competence
- Document the process for providing needed training
- Provide training or take other action to achieve or maintain the competence needs
- Develop a methodology to check effectiveness that is proportionate to the risk associated with the work performed

This article discusses each of these requirements and provide recommendations for implementation.

Dimensions for Competency

The concept is that people who perform work that affects quality must be competent to do the work. The standard identifies four dimensions for competence, but doesn't define them. Practical descriptions are:

- 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.
- Training – Learning focused on a specific activity, often related to a specific task or job.

In addition, some jobs may have other dimensions. A common one is physical strength, such as the ability to lift 50 pounds while performing the job. Another common requirement is that a person not be color-blind.

Document the Process for Establishing Competence

Most companies have a process, but it may be informal. The most common method develops a job description that identifies the job and the competencies. The job description might have some standard elements.

Job Title

Document date

Description of the job

The department or function associated with the position

The competence elements:

Education

Training
Skills
Experience
Physical attributes required
Ability to lift 50 pounds
Not colorblind

Write a procedure that explain the method, responsibility, and authority for preparing job descriptions. In addition, ensure they are included in the document control system.

Job Description Examples

Education

A Production Assembler may need a High School Diploma

A Design Engineer may need a Bachelor's Degree in a technical field

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 of experience in medical device manufacturing

Determine the Competence of People Who Perform Work That Affects Product Quality

With the job description approved, identify the people who perform that job. Then determine if the person in that job meets the competence requirements. A useful tool is a gap analysis, as shown below.

Identify each requirement from job description. Then document the objective evidence that the person meets the requirement. It could be diploma for education, a training certificate from an external course, years of experience document on a resume, *etc.*

Determine any gaps between the requirement and the objective evidence. Based on gap, formulate a plan to close it.

In some companies, this information could be part of a professional development plan.

Notice in the example, that one doesn't need experience as an internal quality auditor at the start of the assignment. The competency develops as part of the training program and evaluation.

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	<ul style="list-style-type: none"> • 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

Provide Training or Take Other Action

Having identified a gap, the manufacturer needs to train the employee, or take other action. The gap analysis provides a simple plan, but in some cases, it may be more extensive.

For example, a given employee may need training on a number of procedures and work instructions. In other cases, the employee may need to demonstrate a skill. For example, an operator of a validated process may demonstrate the skill by:

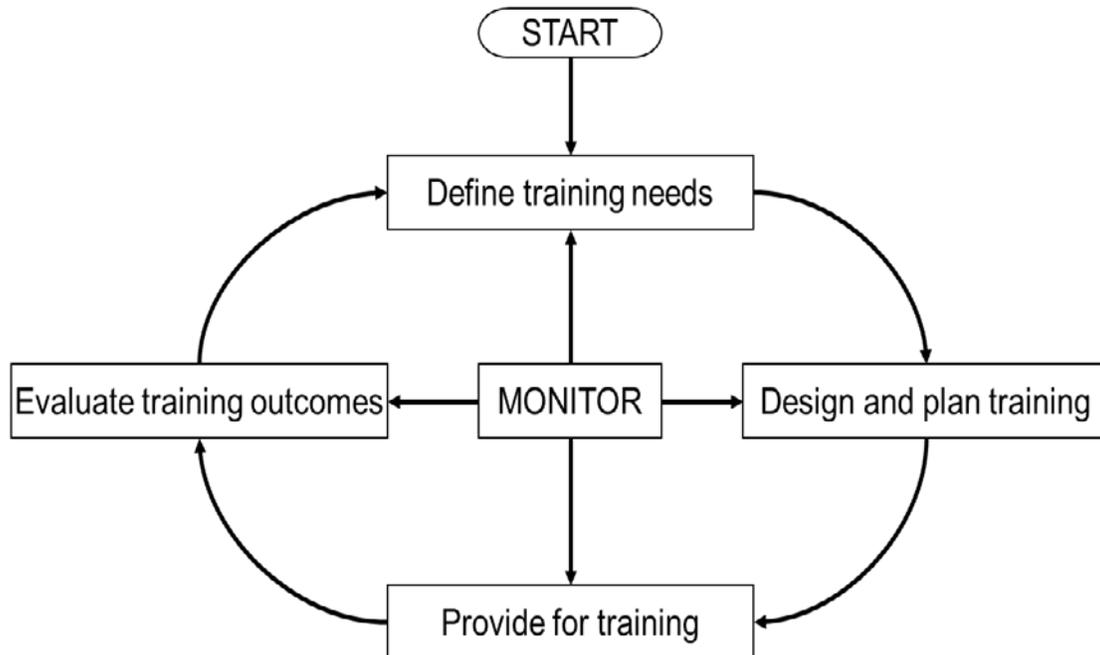
- Reading the procedure and work instruction and answer some questions
- Observe a skilled operator perform the process
- Perform the process under observation of a skilled operator
- Perform the process “solo”

Document the Process for Providing Needed Training

One good source for setting up a training program is ISO 10015:1999 *Quality management – Guidelines for training*. This document covers the development, implementation, maintenance, and improvement of strategies and systems for training.

The standard provides a training cycle as shown in the figure below.

Develop a procedure to implement the standard following the training cycle.



Check Training Effectiveness

ISO 10015:1999 *Quality management – Guidelines for training* suggests conducting evaluations on both a short-term and a long-term basis:

- In the short term, obtain trainee feedback information on the training methods, resources used, and knowledge and skills gained as a result of the training
- In the long term, assess trainee job performance and productivity improvement

ISO ISO/TR 14969:2004 *Medical devices – Quality management systems – Guidance on the application of ISO 13485: 2003* provides some recommendations on training effectiveness. This technical report is obsolete; ISO has not published its anticipated replacement, a handbook.

The technical report offers some methods to evaluate training effectiveness:

- Poll the trained employee to assess whether he or she feels they have learned the required information
- Evaluate the work performance of the trained individual
- Review the trainer assessment of training effectiveness.