

ISO 9001:2000 Requirements Explained - An Adobe PDF File for Use on a Network System

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ISO 9001:2000 - List of all requirement clauses [Click on clause name to go to clause.](#) *(Links are not active in this example.)*

Contents page for ALL personnel: Shaded clauses contain requirements that should be known by everyone in the organization.

You may need to know additional requirements depending on the type of work that you do.

4	Quality management system (title only)	
4.1	General requirements	identify processes, their sequence and interaction, resources needed, how processes are controlled, and monitor, measure, analyze and improve processes
4.2.1	Documentation requirements - General	defines what should be included in quality management system documentation
4.2.2	Quality manual	defines requirements for the Quality Manual and what should be included
4.2.3	Control of documents	requirements for documents, documents must be kept current, and how to request a document change
4.2.4	Control of records	requirements for identification, storage, protection, retrieval, retention time and disposal of records
5	Management responsibility (title only)	
5.1	Management commitment	evidence mgt. committed to quality system, customer / legal requirements, and continual improvement
5.2	Customer focus	Top management must ensure that customer requirements are determined and are met
5.3	Quality policy	requirements for the quality policy, must commit to meet requirements and continually improve QMS
5.4	Planning (title only)	
5.4.1	Quality objectives	Top mgt. must ensure measurable quality objectives are established at relevant levels in the organization
5.4.2	Quality management system planning	use 4.1 requirements to plan processes & quality objectives, plan system changes
5.5	Responsibility, authority and communication (title only)	
5.5.1	Responsibility and authority	who is responsible for activities and who has authority to take what action must be known
5.5.2	Management representative	a member of mgt. is Mgt. Rep respon. for QMS; reports to Top Mgt. on performance & needs of QMS
5.5.3	Internal communication	Top Mgt. ensures communication processes of the QMS are established and effective
5.6	Management review (title only)	
5.6.1	General	Top mgt. must review quality system to determine if changes are needed to improve system effectiveness
5.6.2	Review input	review must include audit results, customer feedback, conformance of product and processes, status of actions, etc.
5.6.3	Review output	determine actions needed to achieve objectives, improve product and processes; allocate resources for actions
6	Resource management (title only)	
6.1	Provision of resources	processes must have the resources required to perform the work
6.2	Human resources (title only)	
6.2.1	General	people must be competent to do work based on education, training, skills and experience
6.2.2	Competence, awareness and training	determining competency requirements, providing and evaluating training, people must know the importance of their work and how they contribute to meeting quality objectives
6.3	Infrastructure	identify, supply and maintain buildings, work areas, and services needed to meet conformity to requirements
6.4	Work environment	manage work environment so conditions allow workers to meet product requirements
7	Product realization (title only)	
7.1	Planning of product realization	what must be included when planning for a specific project, contract or order
7.2	Customer-related processes (title only)	
7.2.1	Determination of requirements related to the product	determine all customer requirements related to the order or contract
7.2.2	Review of requirements related to the product	review requirements, clarify differences, confirm requirements when no document
7.2.3	Customer communication	establish effective communication with customers about product, amendments, feedback, & complaints
7.3	Design and development (title only)	
7.3.1	Design and development planning	plan stages, reviews, verification, validation, responsibilities, authorities, info. flows, updates
7.3.2	Design and development inputs	what should be considered when defining design requirements for a product or service
7.3.3	Design and development outputs	must meet input req., provide info. for purchasing, prod. and servicing, acceptance criteria, etc.
7.3.4	Design and development review	hold design reviews to ensure requirements met and to id problems (incl. reps. from all functions)
7.3.5	Design and development verification	verify outputs meet input requirements, keep records of verif. results and necessary actions
7.3.6	Design and development validation	validate product meets use requirements before product delivered; keep validation records
7.3.7	Control of design and development changes	review of design changes must include effect on other parts and delivered product
7.4	Purchasing (title only)	
7.4.1	Purchasing process	purchased items must meet requirements, requirements for selection/evaluation & re-evaluation of suppliers
7.4.2	Purchasing information	requirements for submitting a request for purchased products or services
7.4.3	Verification of purchased product	ensure purchased product meets specified purchase requirements
7.5	Production and service provision (title only)	
7.5.1	Control of production and service provision	work performed under controlled conditions - work instructions avail. where needed
7.5.2	Validation of processes for production and service provision	establish your requirements for validating special processes
7.5.3	Identification and traceability	product must be identifiable throughout product realization, and inspection and test status known
7.5.4	Customer property	identify, verify, protect and safeguard customer property; report any unsuitable lost or damaged property
7.5.5	Preservation of product	preserve product - considerations for identification, handling, packaging, storage, and protection
7.6	Control of monitoring and measuring devices	determine measurements required; calibrate and verify measurement devices
8	Measurement, analysis and improvement (title only)	
8.1	General	identify monitoring, meas., analysis and improvement processes needed to meet requirements, & control & improve QMS
8.2	Monitoring and measurement (title only)	
8.2.1	Customer satisfaction	monitor information related to customer satisfaction
8.2.2	Internal audit	audit product/service plans and the organization's documentation; take corrective action on nonconformities
8.2.3	Monitoring and measurement of processes	monitor, and where appropriate, measure processes - take action and corrective action when planned results are not achieved
8.2.4	Monitoring and measurement of product	monitor and measure product at appropriate stages to verify requirements are met
8.3	Control of nonconforming product	identify, segregate and determine what will be done with nonconforming product
8.4	Analysis of data	collect and analyze data and information to demonstrate system effectiveness and where to improve system
8.5	Improvement (title only)	
8.5.1	Continual improvement	identify where improvements can be made to the quality management system
8.5.2	Corrective action	review/evaluate nonconformities, determine if action needed, plan action/implement/record results on CPAR form
8.5.3	Preventive action	determine action to eliminate potential nonconformities/action must be appropriate to effects of potential problem

6.2 Human resources (title only)

6.2.1 Human resources — General	Comply	
	Y	N
Personnel whose work affects product and service quality must be competent on the basis of appropriate education, training, skills and experience.		

Text of ANSI/ISO/ASQ Q9001-2000 paraphrased with permission of the American Society for Quality.

[Next clause](#)

Guidance

6.2.1 Human resources — General

competence - the demonstrated ability to apply skills and knowledge (ISO 9000:2000 definition)

The standard requires that

personnel whose work affects product and service quality must be competent on the basis of appropriate education, training, skills and experience.

This requirement states that the basis (criteria that you use) to determine competency should be that the person has the appropriate education, training, skills and experience that are defined as requirements for the work to be performed.

This requirement makes a distinction between those personnel whose work affects product and service quality and those whose work does not affect product and service quality.

Personnel whose work affects product quality includes personnel involved in:

1. top management
2. resource management
3. product and service realization
4. measurement-analysis-improvement processes

It is not clear why the standard limits this competency requirement to personnel whose work affects product quality. This possibly relates to defining the scope of the quality management system to processes that affect product and service quality. Organizations that want all personnel to be competent may want to extend this requirement to include all personnel.

To meet this requirement, it will be necessary to:

1. have written job requirements that describe the competence needed for the job
2. describe qualification criteria based on education, training, skills and experience required in order to do the work
3. demonstrate that a **competence assessment process is used** to validate that the person is competent for the job.

Audit: 6.2.1 Human resources — General

- ___ 1. Review organization charts, job descriptions and records to verify that personnel whose work affects product and service quality are **competent** to perform their work assignments based on:
 - ___ appropriate education
 - ___ training
 - ___ skills
 - ___ experience
 - ___ demonstrated capability to achieve required results

- ___ 2. Are there written job requirements that describe the competence needed for the job?
- ___ 3. Do employee records indicate that an assessment is performed to validate that the person is competent to perform the required work?

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6.2.2 Competence, awareness and training	Comply	
	Y	N
The organization must take the following actions a) determine the competency necessary for personnel who perform work that affects product and service quality, b) provide training or take other actions to satisfy training needs, c) evaluate the effectiveness of the actions taken to achieve competency, d) ensure that personnel are aware of the relevance and importance of the activities they perform and how they contribute to achieving the quality objectives, e) maintain records of each person's education, training, skills and experience (see 4.2.4).		

Text of ANSI/ISO/ASQ Q9001-2000 paraphrased with permission of the American Society for Quality.

Guidance

Documents related to this clause

[Click on blue text](#) to view illustration documents. Other documents and methods may be used.

The blue text links are not active in this example. They are active in the actual product. The product description web page has links to 5 of the 7 Exhibits that illustrate this clause.

Competence Evaluation Form — This product contains a Competence Evaluation Form. Usually several abilities are required to achieve the needed outcome. Each ability is defined as a **unit** of competence. The Competence Evaluation Form is used to 1) identify the units of competence required for an activity, 2) define the performance standard for the activity, 3) identify education, training or behavioral development activities to meet competency requirements, and 4) record an evaluation of competence results.

See form: Competence Evaluation Form for (name activity) - **Directory:** Forms/ file: competence evaluation for (name activity).doc

Personal Development Plan form — This product contains a Personal Development Plan form that may be used to maintain records of the education, training, skills and experience of the employee. The form identifies the actions taken by the organization to satisfy training needs and whether the needed level of competence has been attained for the activities the person performs.

This form is located in **Directory:** Forms/ file: personal development plan.doc

Qualified Personnel Database — This database may be used to list the activities performed in the organization and who has passed the qualification requirements to perform these activities. There should be a Competence Evaluation Form for each activity listed in the database.

This database is located in **Directory:** Forms/ file: qualified personnel database.xls

Training Record Documents

The following 4 documents relate to establishing an employee training record. These documents may be edited to match the specific training requirements of the organization. This set of documents was provided by Susan West of West Management Services.

Training Record — This form identifies training requirements, the date training occurred, when effectiveness will be assessed, the manager's initials and the date of assessment.

This form is located in **Directory:** Sample Documents/ file: training record.doc

Training Matrix — This matrix allows you to identify the Standard Operating Procedures and Work Instructions that should be included in the employee's training.

This form is located in **Directory**: Sample Documents/ file: training matrix.xls

OJT Training for Manufacturing and Shipping — This form identifies activities to include in an On-the-Job training program.

This form is located in **Directory**: Sample Documents/ file: OJT training matrix.doc

Semi Annual Assessment of Training Effectiveness and Needs — This form is used to perform a 6 month review of the effectiveness of employee training and to identify training that should take place in the next 6 months.

This form is located in **Directory**: Sample Documents/ file: semi annual training assessment.doc

6.2.2 Competence, awareness and training

This requirement pertains to all personnel at all levels within the scope of your business system that is to be certified. It addresses all training and other actions needed to ensure competency for accomplishing assigned work.

ISO 9000:2000 defines competence as **the demonstrated ability to apply skills and knowledge**. The competence-based approach presented in the ISO 9001:2000 standard focuses on the **results** that a person is expected to achieve. A person is either competent, or not yet competent, based on the performance criteria defined for a position. Grades, percentages and ratings do not apply to competence — a person is only competent when the person has demonstrated performance that meets all the requirements for the activity that must be performed.

The standard requires that the organization

a) determine the competency necessary for personnel who perform work that affects product and service quality.

Competency requirements must be determined for each individual job-type based on the skills, experience and knowledge needed to perform the required tasks, and the results that must be achieved.

To determine what competence is necessary for a position is a matter of determining:

1. what outcomes are required
2. what abilities (competencies) are required to achieve the outcome
3. the performance criteria or standard to be achieved
4. the method of obtaining the evidence
5. the evidence required to demonstrate competence

(continued)

Thus, to determine competency you must answer the following questions:

Questions for Determining Competency Requirements

Key question	What this is called	What must be defined
1. What must be achieved?	Outcome	Define outcome — Conforming product or other result
2. What must be done to achieve the outcome?	Unit of competence Usually several abilities are required to achieve the needed outcome. Each ability is defined as a unit of competence.	Define the units of competence needed to achieve the outcome. Ex.: To pay bills, you must know how to use a computer + how to use the organization's accounting software to pay bills.
3. How well must this be done?	Performance criteria <the standard>	Define the performance criteria that must be achieved.
4. What assessment method will be used?	Assessment method	Define what performance must be observed, or what other method will be used to assess whether the performance standard has been met.
5. What evidence should be collected?	Evidence required	Define what evidence (see Note 1 below) must be collected that proves that each unit of competence has been achieved .

Note 1: Some organizations include training records in the same file that contains employee Performance Reviews (where the employee's overall job performance is rated). Most Registrars and businesses do not allow their auditors to view Performance Reviews (that evaluate the actual performance of an employee) because this information is considered personal. Therefore, to allow auditors to view training records, most companies have a separate sheet that is kept in the person's training folder that only records that the employee has achieved competence, the date, and the authorizing manager's signature. The Personal Development Plan form and the Competence Evaluation Form included in this product use this method and only indicate if the person has or has not achieved the requirements for competency.

Defining competency requirements for all job-types

When the standard is implemented, it is not strictly necessary to have competency requirements established for all types of work performed. When an experienced workforce is in place, personnel can be "grandfathered in" (i.e. considered qualified and competent) for the tasks they perform based on their previous experience. Training records for those "grandfathered in" should indicate what tasks they are qualified to perform. Competency requirements can be established as new personnel are hired.

Competence Evaluation Form

This product contains a Competence Evaluation Form that is used to:

1. identify the units of competence required for an activity
2. define the performance standard for the activity
3. identify education, training or behavioral development activities to meet competency requirements, and
4. record an evaluation of competence results

See form: [Competence Evaluation Form for \(name activity\)](#) in **Directory**: Forms/ file: competence evaluation for (name activity).doc
This file name says (name activity). You may develop a form like this for each activity that is included in a job description.

The standard requires the organization to

b) provide training or take other actions to satisfy training needs.

This requirement addresses competence assessment and competence development.

Applying the competence-based approach to the employee selection process

It is necessary to do the following in order to establish a competence-based employee selection, development and assessment program:

1. Define the required performance criteria — the standard that must be achieved
2. Collect evidence of the person's competence
3. Compare the evidence to the required standard that must be achieved
4. Define an employee development plan for any areas in which the person is "not yet competent"

The organization may provide **internal or external training, on-the-job training**, or define **some other action** that will enable the person to achieve the standard defined for competence.

Some other methods used to develop new skills (other than a formal training class or training event) include mentoring, coaching by a more experienced person who performs the same work, and assignments where a person is given a project that provides new experiences.

The need to define new competency requirements and provide training may also occur due to:

1. establishment of a new process
2. significant changes to an existing process
3. new procedures and work instructions
4. plans for a new product or service, new equipment, or new technologies
5. situations where a customer provides customer-owned equipment (for example, test equipment), and only trained personnel are allowed to operate the equipment
6. analysis of nonconformities, customer complaints, and other problems
7. introduction of new regulatory requirements or a new standard (such as the ISO 9001:2000 standard) that requires that employees understand how the requirements of the standard apply to the work they perform

The standard requires that the organization

c) evaluate the effectiveness of the actions taken to achieve competency.

The need to evaluate the effectiveness of action taken to ensure competence is a new requirement in ISO 9001:2000 standard. The standard does not define how you should **evaluate training or other actions taken** to achieve competency, when this evaluation should take place, or who should perform the evaluation.

To assess competence, an organization would need to establish a standard of competence for **each unit of competence** that is required for an activity. Those who can demonstrate attainment of the standard defined for a specific activity are competent to perform that activity.

Methods for evaluating competency

Different types of evaluation methods can be used. If you are testing knowledge, you can use oral or written tests. When a product is produced, a demonstration of how to perform activities and an inspection of the product produced can be the method used. When a specific behavior is required, the person can be observed while performing the activity.

Evaluating the effectiveness of actions taken can also include an evaluation by the person who participates in the training or skill development.

It is a common practice to evaluate training:

1. immediately after completing the training — to establish comprehension
2. several weeks after the training — as a follow-up to ensure that the employee retained the training content
3. several months after the training — to ensure that requirements for the activity have been achieved and are being applied, and determine if a reorientation is needed.

Providing opportunities to apply what has been learned

To ensure the effectiveness of any training, it is best to provide opportunities to use newly acquired skills as soon as possible.

Some factors to consider when evaluating the effectiveness of the actions taken to achieve competency include:

1. Evaluating the content of the training course or method used (the method used may need to be improved)
2. The scope and difficulty of the information or skill that must be achieved
3. The extent to which opportunities are needed to apply information and skills in order to achieve proficiency
4. The capability of the person who provides training
5. The intellectual and physical capability of the individual to apply the information to the work performed

The standard requires that the organization

d) ensure that personnel are aware of the relevance and importance of the activities they perform and how they contribute to achieving the quality objectives.

Why is awareness important?

When one is **aware of the importance of something**, one is better able to determine the right activities to perform and the behavior that is appropriate in a given situation.

Relevance and importance of activities

This requirement recognizes that people may not know how their work affects the final product and the contribution they make to product quality unless you tell them. This requirement also recognizes that, in the absence of a **clearly defined direction**, personnel may not know when greater attention should be given to a specific type of activity or behavior.

The contribution one makes to the product

There can be thousands of activities that contribute to features of the product that customers perceive as important, and it is the total of all activities performed by all personnel that create the end result. Explaining to personnel how their work contributes to the product and to customer satisfaction usually generates a **sense of pride** because the person knows that he or she is making a **valued contribution** and is contributing to the team effort.

The importance of activities

Are some activities and how they are performed more important than others? Yes, some activities and how they are performed may be more important than others.

It is important that personnel be made aware of how to perform activities that are of special importance to:

1. the quality of the product or service
2. important to achieving customer satisfaction (some things are more important to the customer)
3. necessary for personal safety

When personnel are made aware of the importance of an activity, they are more likely to select the right activities to perform in a given situation. It is generally the responsibility of the department manager or supervisor (who is most familiar with the person's work responsibilities) to provide this training and awareness.

Examples:

In a manufacturing situation, certain parts or components may require greater attention because they contribute to the safe operation of the product or to a critical function.

In a customer service position, it is important that personnel are accurate and polite—even when speaking to an irate customer.

Safety considerations may be of extreme importance in the performance of many types of work.

Employees can be made aware of the importance and significance of their activities during:

1. induction training upon hiring a new employee
2. training for a new or changed job
3. product briefings (point out what is important related to this product or service)
4. briefings on performance results

These methods may also be used to create awareness of the importance specific activities:

1. warning notices
2. videos that relate to performing tasks
3. managers demonstrating appropriate behavior as a model for personnel to follow

Individuals must know how they contribute to achieving quality objectives

ISO 9000:2000 defines a quality objective as "something sought or aimed for related to quality."

Based upon the above definition, the organization's quality objectives are found in:

1. the quality policy
2. specific quality objectives defined by top management (as defined in clause 5.4.1)
3. Personal Development Plans (training plans)
4. the requirements of the ISO 9001:2000 standard

Quality objectives stated in the quality policy

The organization's Quality Policy makes a commitment to **meet customer requirements** and to **continually improve the processes** that make up the quality management system. These commitments can be considered quality objectives because they state what the organization "aims for related to quality." Often the Quality Policy states other quality objectives that top management has defined for the organization.

All personnel must contribute to meeting the objectives that are in the Quality Policy. Thus, it is important that everyone in the organization know what the Quality Policy is and what significance this has to the work they perform.

Because the Quality Policy makes a commitment to meet customer requirements, personnel must be made aware of what action to take when they observe that product or service requirements are not being met. Those who perform an activity often notice that documentation requires updating because something has changed or that requirements stated in documentation are not being followed. The person may also find a way that an activity can be improved. Personnel should know how to report these situations so that documentation can be kept current and improvements can be made to the activities that are performed.

Informing personnel about what to do when they notice that requirements are not being met and how to submit suggestions for improving work processes is usually part of new employee training that relates to quality system requirements.

Specific quality objectives defined by top management

Top management sets quality objectives for the organization that typically relate to meeting the commitments and goals that are stated in the quality policy. For example, a quality objective set by top management might be to go from 90% on-time delivery to 95% on-time delivery within the next four months. Achieving this objective will require contributions from personnel located in more than one department/area of the organization. The person responsible for planning how the objective will be achieved works with department and area managers to determine how the personnel they supervise can contribute to meeting the objective. The contributions that personnel in a department or area can make toward meeting the objective become a **quality objective for the department**. There is also a plan for how each department will achieve its contribution towards meeting the higher level objective. The department plan could involve activities assigned to individuals or contributions made by the department as a whole. The department manager assigns specific activities to individuals to carry out (when this is defined in the plan) or informs all personnel of what they must do (**as individuals**) to contribute to meeting the department objective. The department could have more than one objective that it must achieve.

When audits take place, an individual can expect to be asked if there are quality objectives for the department and what contribution he or she makes toward achieving those objectives.

Personal development plans define quality objectives for individuals

Quality objectives may also be defined for individuals. Plans for achieving top-level quality objectives often involve improving the skills, knowledge and competency of employees. Quality objectives for individuals are frequently found in training plans (also called Personal Development Plans).

Individuals should know the ISO 9001:2000 requirements that apply to them

ISO 9001:2000 certified organizations make a commitment to meet the requirements of the ISO 9001:2000 standard. **Every requirement in this standard is a quality objective for the organization.** Individuals should be made aware of how requirements in the standard **specifically apply to what they do**.

Training related to the requirements of the ISO 9001 standard is usually accomplished with training sessions for each department when the standard is first put in place. A department training session explains the ISO 9001 requirements that apply to the department. Training on the requirements of the ISO standard is usually included as part of induction training for new employees after the standard is operational.

Page 2 of this document is a Table of Contents that yellow highlights the clause numbers that contain requirements that should be known by everyone in the organization. You may need to know additional requirements depending on the type of work that you do.

When audits of the organization take place personnel can expect to be asked:

1. What is the organization's Quality Policy?

Personnel are not expected to remember the exact wording of the Quality Policy, but to know what the policy says in their own words. When the organization has a lengthy Quality Policy statement, it is reasonable to expect personnel to know where a copy of the policy is located instead of expecting total recall of a long statement.

2. How does the Quality Policy relate to the work that you do?

The Quality Policy of all organizations makes a commitment to meet requirements. Thus, a standard response to this question would be to state how one reports that a requirement for the product or service is not being met. The method for doing this is most often the Corrective Action Request form.

3. Does your department presently have quality objectives assigned by top management?
 If so, are you involved in the department plan to achieve objectives? What is your participation?
 Quality objectives for the organization may or may not involve every department. There may also be assigned quality objectives that relate to activities carried out by the department.

The standard requires the organization to

e) maintain records of each person's education, training, skills and experience.

This requirement indicates that records should include the person's education, training, skills, and experience.

This requirement for records is somewhat inconsistent with these three prior clauses:

1. Clause 6.2.1 requires that personnel whose work affects product quality must be competent.
2. Clause 6.2.2 a) requires that the necessary competence for work be determined.
3. Clause 6.2.2 c) requires the evaluation of the effectiveness of actions taken to achieve competency.

Based on the above requirements, it would appear that one would need to generate competence assessment records. Competence assessment records would indicate the degree to which the person has achieved defined competence requirements for the tasks that must be performed.

To meet this requirement for records — and to provide evidence of the extent to which a person meets defined competence requirements — records should be maintained that provide:

1. the person's education, training, skills and experience
2. evidence of the extent to which a person's abilities and skills meet the defined competence requirements
3. evidence of activities performed to specify, develop, or verify the abilities of a person who is intended to meet defined competence requirements

The intent of Clause 6.2.2 is that the organization should ensure that employees are competent to perform work. A job description identifies the competence needed for a position. A person's **Personal Development Plan** identifies the courses of study, training, and behavioral development (and the dates for these events) that are required to meet the competence needs of the position.

What is included in a Personal Development Plan record?

A Personal Development Plan includes:

1. the planned actions to be taken by the organization and the individual in meeting competence requirements
2. records of the actions taken, and
3. records of any measurement and verification of competence

Whenever an employee attends a training course, a record should be made on the individual's personal file, details of the course taken, the dates, duration and whether the person received a passing score on the exam if an exam was taken. A copy of a course certificate should be retained on file as evidence of training. However, having attended a course is not necessarily evidence of competence.

Records should indicate whether the needed level of competence has been attained. In order to record competence, a formal training event needs to be followed by an on-the-job assessment. Records should indicate who conducted the education, training, or behavioral development and assessment. There should also be evidence that the person or organization providing the training and assessment is competent to deliver and evaluate such activities.

There should be evidence that the effectiveness of actions taken have been evaluated. This may be accomplished by a statement of evaluation results (whether the person has or has not achieved the defined requirements for the activity) and the signature and date of the assessor.

This product contains a [Personal Development Plan](#) form that may be used to maintain records of the education, training, skills and experience of the employee. The form identifies the actions taken by the organization to satisfy training needs and whether the needed level of competence has been attained for the activities the person performs.

This form is located in **Directory**: Forms/ file: personal development plan.doc.

Competence records should be reviewed periodically to identify personnel development needs.

There are two types of records kept that relate to competency:

1. Records that relate to **individuals** (discussed above)

2. Records that relate to **specific activities / work assignments**

There should be a separate record for each type of work assignment that defines the competency requirements for that type of work.

These records list who is qualified to do the work related to the work assignment.

These records are used to select competent people for specific assignments.

You must specify who is responsible for keeping training records, and who is responsible for maintaining them. Training records can be kept in one central location or by department. It is suggested that managers and supervisors be made responsible for ensuring that training records are kept up-to-date. This is suggested because it can be difficult to have a single person keep track of all training events, unless they are kept in a central computerized location.

A log or a database assists in the fast retrieval of records that relate to competency qualifications.

Audit: 6.2.2 Competence, awareness and training

- 1. Verify that the organization defines the competency needs for personnel who perform activities that affect product or service quality.
- 2. Does the organization define any training needed by individuals to meet competency requirements?
- 3. Is the required training or other action needed to ensure competency provided by the organization?
- 4. Is completed training or other competence development action evaluated by someone who is qualified to assess its effectiveness?
- 5. Does a competence assessment take place when on-the-job training is used to satisfy training requirements?
- 6. Verify that quality management system awareness training is provided.

Are the following topics included in this training?

- ISO requirements that apply to the person
- safety requirements that apply to work
- the importance of meeting customer, legal, and regulatory requirements
- responsibilities and authorities in the organization
- the quality policy
- how the person's work relates to the quality of the product or service
- how the person contributes to achieving quality objectives
- how to complete a Corrective Action Request and Preventive Action Request.

Interview a sampling of employees and ask:

- 7. How does your work contribute to the quality of the product/service?
- 8. How do you contribute to the quality objectives for your department? (when there are defined objectives)
- 9. What is the Quality Policy?
- 10. What does the quality policy mean related to your work?

Interview supervisors and ask:

- 11. Are records of each employee's education, training, skills and experience maintained?
- 12. Do training records show that each person has completed the required training?

The questions at the end of a requirement clause match the questions on the ISO 9001:2000 Checklist that auditors use when conducting an audit.

This written explanation of the standard is part of the Auditor Training Course. It is also available as a separate purchase.

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