

Auditing 'competence' and the 'effectiveness of actions taken'

The following information is provided to guide auditors performing certification audits in understanding the ISO 9001 clause 6.2.2 requirements for 'competence' and 'effectiveness of actions taken', e.g. training. These requirements are usually audited as part of a product realization process audit and not in isolation. However, it is recognized that some organizations will have separate human resource processes, where most of the evidence needed can be found. This document identifies typical activities performed by organizations to ensure the competence of their personnel and to evaluate the effectiveness of actions taken to satisfy those competence needs, and gives guidance to auditors regarding the types of evidence they should aim to find, and provide examples where appropriate.

To satisfy the competence/effectiveness requirements of ISO 9001, an organization will typically need to do several things:

- identify what competencies are required by personnel performing work which affects quality
- identify which personnel already performing the work have the required competencies
- decide what additional competencies are required
- decide how these additional competencies are to be obtained – training of personnel (external or internal), theoretical or practical training, hiring of new competent personnel, assignment of existing competent personnel to different work
- train, hire or reassign personnel
- review the effectiveness of actions taken to satisfy competence needs
- periodically review competence of personnel

Throughout the process, the organization is required to maintain appropriate records of education, training, skills and experience. However, ISO 9001 does not specify how the process will be established or the exact nature of the records to be maintained.

In auditing an organization's compliance with the competence and training evaluation requirements, an auditor would typically be seeking evidence that the following issues are addressed:

1. An organization needs to identify what competencies are required by personnel performing work that affects quality.

Guidance

The objective of the auditor should be to determine whether there is a systematic approach in place to identify these competencies and to verify that the approach is effective. The outcome of the process may be a list, register, database, human resources plan, competencies development plan, contract, project or product plan etc.

Discussions could initially be held with top management to ensure they understand the importance of identifying the competencies required. These may also be a potential source of information regarding new or changed activities or processes, which may lead to different competency requirements in the organization.

A review of competencies might also be needed when a new tender or contract is being considered. Evidence of this could be found in related records. Competence requirements may be included in contract documents where the activities of subcontractors can have an impact on processes and/or product quality characteristics.

Auditors need to determine whether the organization has identified new or changed competence needs during surveillance audits.

2. Are competent people assigned to those work place activities necessary to control the quality characteristics of its processes and products?

Guidance

Verify that some form of evaluation process is in place to ensure that the competencies are appropriate to the organization's activities, and that the personnel selected as competent are demonstrating these competencies. Also, the process should ensure that any deficiencies are being acted upon and the effectiveness of personnel is being measured.

Verify that the activities that affect quality are performed by persons selected as competent. Evidence may be obtained throughout the audit with an emphasis on those processes, activities, task and products where human intervention may have the greatest impact. The auditor may review job descriptions, testing or inspection activities, monitoring activities, records of management reviews, definition of responsibilities and authorities, nonconformity records, audit reports, customer complaints, processes validation records etc.

3. The organization should evaluate the effectiveness of the actions taken to satisfy the competence needs.

Guidance

The organization may use a number of techniques including role-play, peer review, observation, reviews of training and employment records and/or interviews (see ISO 19011, table two, for further examples). The appropriateness of a particular evaluation method will depend on many factors. For example, training records could be viewed to verify that a training course had been successfully completed (but note, this alone would not provide evidence that the trainee is competent). However, this same method would not be acceptable to evaluate whether an auditor performed satisfactorily during an audit. Instead, this may require observation, peer review, interviews etc. The organization may need to demonstrate the attainment of competence of its personnel through a combination of education, training and/or work experience.

4. Maintenance of competence.

Guidance

The auditor needs to verify that some form of effective monitoring process is in place and being acted upon. Ways of doing this include a continuing professional development process (such as the one described in ISO 19011), regular appraisals of personnel and their performance, or the regular inspection, testing or auditing of product for which individuals or groups are responsible. Ongoing changes in competence requirements may indicate that an organization is proactive in maintaining personnel performance levels.

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The ISO 9001 Auditing Practices Group is an informal group of QMS experts, auditors and practitioners drawn from the ISO Technical Committee 176 Quality Management and Quality Assurance (ISO/TC 176) and the IAF. It has developed a number of guidance papers and presentations that contain explanations about the auditing of QMSs. These reflect the process-based approach that is essential for auditing the requirements of ISO 9001.

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