



ISO 9001 Auditing Practices Group

Guidance on:

Auditing Competence

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INTRODUCTION

This paper covers relevant ISO 9001 requirements which deal directly with competences and provides information on other relevant standards that auditors might consider in developing their own competence on this subject.

The following guidelines are provided to support the audit activity when addressing the competency requirements of persons doing work under the organization's control, and within the organization's quality management system.

The competence requirements are documented in clause 7.2 of ISO 9001:2015 and refer to the competences needed "*that affects the performance and effectiveness of the quality management system*". Effectiveness is the extent to which planned activities are realized and planned results are achieved (ISO 9000:2015, 3.7.11). The performance and effectiveness of the QMS relates to the ability of the organization to achieve the intended outcomes of the QMS as stated in ISO 9001 scope (ISO 9001:2015 Cl 1.0), which refers to "*consistently provide products and services that meet customer and applicable statutory and regulatory requirements*", and "*aim to enhance customer satisfaction, through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements*".

A QMS is a set of interrelated processes and competence should be evaluated within all QMS processes and not as an isolated set of requirements in a specific process.

Competence is defined as the: "*ability to apply knowledge and skills to achieve intended results.*" (see ISO 9000:2015, 3.10.4).

Some organizations use human resource processes to manage these requirements and provide evidence of conformance.

People under the organization's control may include individuals at providers of externally provided processes, products and services.

The organization is responsible for determining the necessary competences, including qualifications for specific functions or processes when applicable. The auditor should be able to:

- assess the process for determining the competences
- observe if competences were appropriately determined
- review, how actions required to achieve these competencies are identified and provided
- and, how evaluation of the effectiveness of those actions is performed.

Each process presents its own demand for competence requirements. Audit team members are assigned to audit different QMS processes. Since information on competence is being gathered by each auditor at different processes, it is important that audit team members share information found on this topic during the audit. Competence topics are important items for discussion by the audit team during scheduled daily meetings.



ISO 9001:2015 clause 7.2.d requires to "*retain appropriate documented information as evidence of competence.*" The word "appropriate" provides the necessary leeway for the organization to decide what documented information related to competence has value for the organization.

Based upon the industry codes for which auditors are qualified, they should have the expertise to assess if the organization has effectively determined what competences are appropriate, if actions taken are adequate, and what documented information relating to competence should be maintained and retained.

CONTROL OF PRODUCTION AND SERVICE PROVISION (ISO 9001, 8.5)

ISO 9001 requires the organization to provide controlled conditions for the control of production and service provision. One of these controlled conditions is the appointment of competent personnel, including any required qualifications. The qualifications are not always required, but the competencies are.

When auditing production or service provision, the auditor can sample functions, including the persons that are key for the processes involved.

The auditor should be given the opportunity:

- to obtain information on the necessary competences by interviewing process leaders or other personnel responsible for defining competence requirements (such as from human resource departments) and by reviewing any documented information on competences determined by the organization.
- to observe the performance of persons regarding objectives and job expectations,
- to interview a sample of those persons to evaluate if they are aware of the competence requirements for the activities they perform
- to confirm if these persons are able to perform their duties.
- to verify if when the usual persons who perform specific duties are absent, whether there are persons with an adequate level of competence available to replace them.

For third party audits, the auditors should be competent and approved for the organization's sector activity. They should have knowledge of any competencies and qualifications for specific process functions, required either by statutes, regulations or other means. Examples of where qualifications are required include: medical staff in a hospital; lawyers; welders for specific welding conditions; or service maintenance personnel for specialized equipment. These persons are often required to have specific qualifications attributed by a qualified authority, agency, or institution. The organization should determine such qualification requirements and be able to demonstrate the persons have acquired and maintain those qualifications.

CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES (ISO 9001, 8.4)

When dealing with externally provided processes, products and services, the organization may need to determine and communicate to external providers its



requirements for competence, including any required qualifications. This is particularly relevant when organizations are outsourcing processes and activities, or making collaboration agreements, because they need to have access to competences they do not have internally. In these cases, the suppliers' personnel competence and qualifications may have a significant impact on the outcome of the product or service provided.

When auditing the process for purchases or acquisitions, there is an opportunity to inquire about the competences needed for delivering the process, product, or service, (such as for: a gas company outsourcing gas equipment installation; a hospital outsourcing catering and laundry; an organization outsourcing training of staff; a construction company outsourcing landscaping to an agency which uses controlled chemicals; a manufacturing facility outsourcing welding and non-destructive testing, which require specific qualifications; a fabrication company outsourcing a project design). Auditors should follow up on the communication methods by which any requirements for competence are agreed between both parties.

Vendors' competence requirements may be requested by the purchaser or presented by the vendor. It is important to understand how those requirements are being communicated and agreed to. Is the communication by verbal means? Or by mail or email? By purchase order? By acquisition form? By website or catalogue? Is it specified in a contract? What other means of communication are established? In order to determine the influence of outsourced competencies, auditors can compare the competence requirements agreed during the purchase process with the results of the evaluation of the outsourced processes and services' performance.

DOCUMENTED INFORMATION (ISO 9001, 7.5)

The competence of persons is one of several factors cited that may influence the extent and need for documented information of the quality management system. Not every activity needs to be supported by documented information, because people may be capable of performing their tasks due to a combination of their experience, education, and on-the-job training and the complexity and impact of the activities itself. Therefore, when evaluating "*documented information determined by the organization as being necessary for the effectiveness of the quality management system*" (ISO 9001:2015, 7.5.1 b)) the auditors need to evaluate the balance between the documented information determined by the organization, the competences of personnel as well as the risks to the intended outcomes of the QMS.

Auditors should keep in mind the definition of competence, which calls for the ability to apply knowledge and skills for an intended result. Therefore, auditors should be careful when raising the findings that documented information is needed, without first considering the influence of the existing competencies of personnel. The need for documented information on required competencies will also vary across different organizations, depending on their complexity, size, the products and services provided, the statutory and regulatory context of their activity (including those related to qualifications) and type of personnel already employed by the organization, as well as the importance of competences for the achievement of objectives.

COMPETENCE FOR PEOPLE DOING WORK UNDER THE ORGANIZATION'S CONTROL THAT AFFECTS THE PERFORMANCE AND EFFECTIVENESS OF THE QMS (ISO 9001, 7.2)

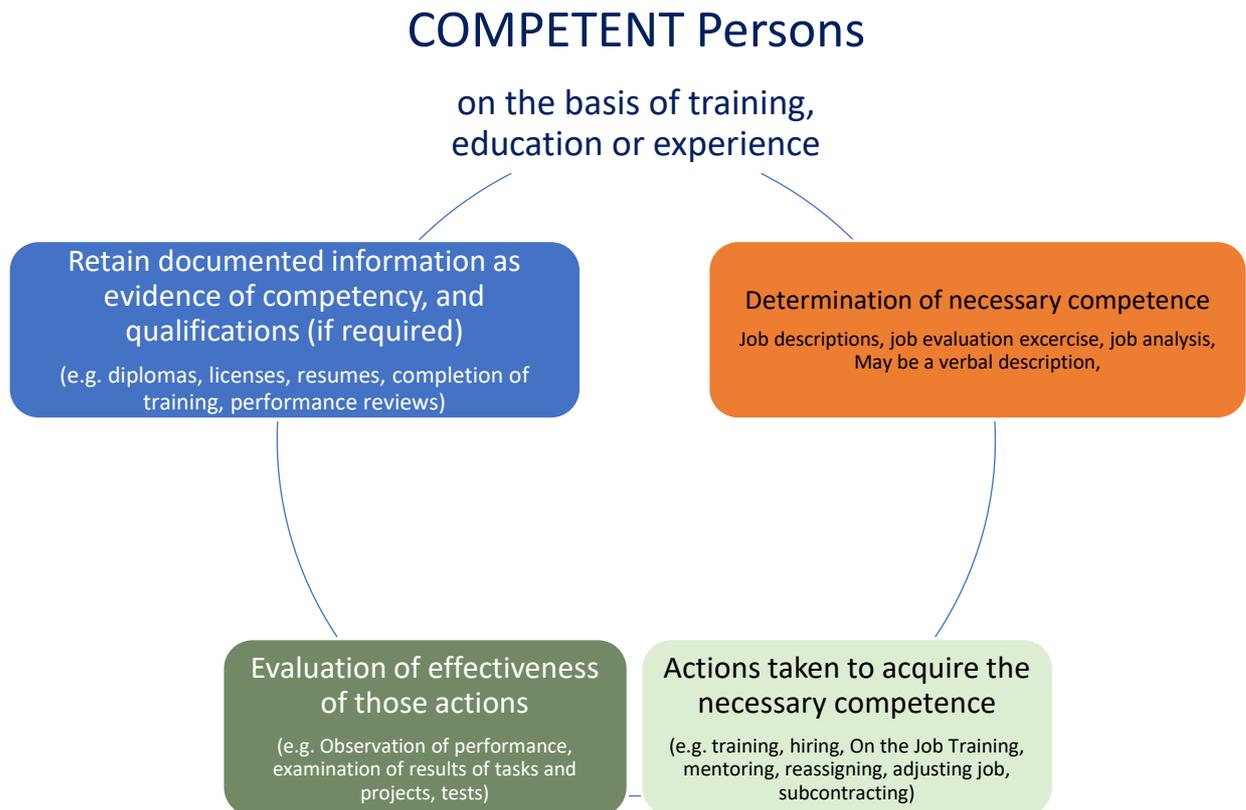


Fig 1 – The PDCA cycle of competence management

Determination of necessary competence

The objective of the auditor is to determine whether the organization being audited has a systematic approach in place to identify the competencies it needs and to verify that its approach to acquiring and utilizing competent people is effective. Auditors may find valuable information related to competence changing needs when auditing new contracts, new processes, new purchases, new products, new designs, new technology and other potential scenarios

Auditors also need to examine whether the organization's approach adequately takes account of the need to identify new or changed competence requirements. Interviews with top management, process leaders, managers, and other employees may be useful sources of information on new or changed competency needs

Determination of the competence required to achieve intended results may happen at all levels of the organization, including management and employees. In some cases, a team



or individual competence is required. Auditors should understand the context of the organization and the changes that could affect competence needs, as well as the potential impact of lack of competence. Auditors should evaluate how risk-based thinking is applied to the determination and update of risks related to competence.

Actions to acquire necessary competence

Auditors should assess how individuals' competences were determined and verified. Auditors should be aware that an organization may take several different forms of actions to acquire and utilize the necessary competences, including:

- training,
- hiring persons with specific competencies,
- on the job training,
- mentoring programs,
- re-assignment of tasks among different people,
- reassigning people,
- adjusting the scope of a job and their required competencies,
- subcontracting personnel,
- acquiring competency management services,
- collaborating and outsourcing,
- or any other actions to achieve having the right person doing the job.

Evaluating effectiveness of those actions

The auditor needs to verify what form of evaluation process the organization has in place to ensure that the competencies are appropriate to the its activities, and that the persons are demonstrating these competencies. Also, the process should ensure that any deficiencies are being acted upon.

The organization should select and apply competence evaluation techniques that are appropriate to its determined needs. These may include role-play, peer review, observation, reviews of training and employment records or interviews (see ISO 19011, Table 2, for further examples). The appropriateness of a particular evaluation method will depend on many factors. For example, training records could be verified to ensure that a training course had been successfully completed, but a participation at the course alone does not necessarily provide evidence that the trainee is competent, as it may only demonstrate that knowledge was gained, not necessarily that it is being effectively applied. A classroom course would not be acceptable to evaluate whether an auditor performed satisfactorily during an audit. Instead, evaluating auditor's performance may require observation, peer review, interviews, etc.

Documented information and maintenance of competence

The organization should be able to demonstrate the attainment and maintenance of competence of its persons through a combination of education, training and work experience. The auditor should verify that documented information exists to provide evidence of how sampled persons were deemed competent.



The need to document required competences will vary considerably among different organizations in different contexts, from competence databases, formal job descriptions and qualification requirements, to a simple verbal explanation on the competences required to perform a certain task. However, when an organization needs to “*ensure that these persons are competent on the basis of appropriate education, training, or experience*” they need to retain appropriate documented information as evidence.

The same applies to actions to acquire the required competence. Records may include, identification of training needs, training plans and training records, effectiveness evaluation records, tutorials for induction training on specific matters to newcomers or for changing functions, charts that show cross-training so that risks from staff shortages can be mitigated, prompts to monitor when refresher training is due for revalidation of a qualification, collaboration agreements to access competencies external to the organization, recruitment advertisements (including organizational websites), briefs to the head-hunters and recruitment agencies, etc.

Competency verification may need to be monitored or repeated to ensure a continuous systemic effort to maintain the necessary competencies. Auditors should evaluate if an effective monitoring process is in place and being acted upon to maintain the necessary competences. Ways of doing this may include a continuing professional development process, regular appraisals of persons and their performance, or the regular inspection, testing or auditing of product and service for which individuals or groups are responsible. Results from internal audits may also provide the organization with insights if the persons doing work under its control have the acquired competence. Often corrective actions identify the need for training

COMPETENCE AND ORGANIZATIONAL KNOWLEDGE

Knowledge is an input to competence. ISO 9001, 7.1.1 requires “The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.”. When auditing competence, the auditor may also evaluate how the organization determines that knowledge by enquiring what is the knowledge relevant for a specific activity, how people have access to that knowledge, and how they are kept updated. Auditors can also enquire how specific knowledge gained by experience is captured by the organization. (See the APG paper on “Organizational Knowledge”)

CONCLUSION ON AUDITING COMPETENCE

Competence is a key resource of the quality management system, which auditors should keep in mind when auditing all processes and interviewing people in the organization.

Documented information on determined competence may exist at each process in a spread-out fashion (under local control at each process), or it may exist at a central function assigned with the competency management of the organization (e.g., a Human Resources department). The evaluation of its existence, as well as the existence of training plans and records of effectiveness evaluation of training or other actions to ensure competence (such as hiring or external collaboration), are not sufficient to



evaluate how the organization is ensuring the competencies needed for the person(s) doing work under its control that affects the performance and effectiveness of the quality management system.

Sampling, observing and interviewing personnel about their competences throughout an audit is a key audit activity to enable the auditor to arrive at informed, and valid, conclusions concerning an organization's approach to ensuring the competences needed.

DEVELOPMENT OF AUDITORS' COMPETENCE ON THIS THEME

Quality management system auditors should have knowledge on quality management related tools, methods, techniques, and their application (ISO 17021-3). One of the sources of knowledge, among others, are the ISO 10000 family of standards developed by ISO/TC 176.

ISO 10015:2019 *Quality management — Guidelines for competence management and people development* provides “*guidelines for an organization to establish, implement, maintain and improve systems for competence management and people development to positively affect outcomes related to the conformity of products and services and the needs and expectations of relevant interested parties*”. The standard describes organizational practices for competence management, starting from determination of competence needs, assessing current competence and development needs, to competence management. Although it is not a required standard and it should not be used as audit criteria in an ISO 9001:2015 audit, it can provide useful insights that can help auditors to understand management of competence in an organization. It will also enable them to audit organizations that incorporate part or all of those practices in their competence management processes.

BIBLIOGRAPHY

ISO 9000:2015 - Quality management systems — Fundamentals and vocabulary
ISO 9001:2015 - Quality management systems — Requirements
ISO 19011:2018 - Guidelines for auditing management systems
ISO 10015:2019 - Quality management — Guidelines for competence management and people
ISO 17021-3:2017 - Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 3: Competence requirements for auditing and certification of quality management systems
APG paper “Organizational Knowledge”

For further information on the ISO 9001 Auditing Practices Group, please refer to the paper: Introduction to the ISO 9001 Auditing Practices Group.



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