

ISO 9001 Documentation

Competences and Qualifications

1. Purpose

The purpose of this document is to define the process for identifying, assessing, developing, and maintaining the competences and qualifications of personnel whose work affects the quality of products, services, or the performance of the Quality Management System (QMS), in accordance with ISO 9001:2015. This ensures that all employees are competent based on appropriate education, training, or experience, and that their qualifications are maintained and aligned with organizational and quality requirements.

2. Scope

This procedure applies to all personnel (including full-time, part-time, temporary, contract, and outsourced workers) whose activities or responsibilities can impact:

- ❖ The quality of products or services
- ❖ Customer satisfaction
- ❖ Compliance with regulatory or statutory requirements
- ❖ The effectiveness of the QMS processes
- ❖ It covers the management of:
- ❖ Competence requirements for each role
- ❖ Identification of competence gaps
- ❖ Training and development activities
- ❖ Assessment of competence
- ❖ Recordkeeping of qualifications and competence evaluations

3. References

- ❖ ISO 9001:2015 – Quality management systems – Requirements
(Clauses: 5.1, 5.3, 6.2, 7.2, 7.3, 8.5.1, 9.1, 10.2)
- ❖ Organization's Quality Manual
- ❖ Human Resource Policies

- ❖ Job Descriptions / Role Specifications
- ❖ Risk Management Procedure
- ❖ Employee Training and Awareness Procedure
- ❖ Control of Nonconforming Outputs Procedure
- ❖ Document Control Procedure

4. Definitions

Term	Definition
Competence	The ability to apply knowledge and skills to achieve intended results.
Qualification	Formal recognition of a person's skills, knowledge, or experience, often in the form of education, certifications, licenses, or accreditations.
Competence Assessment	The process of evaluating whether an individual possesses the required knowledge, skills, and experience to perform a task or role effectively.
Training	A structured activity to develop or enhance an individual's skills, knowledge, or behavior.
Experience	Practical involvement in tasks or roles that contributes to the development of competence.
Role-Specific Competence	The specific knowledge, skills, and attributes required to perform a particular job or function that affects quality.

5. Responsibilities

Role	Responsibility
Management / Department Heads	Define competence requirements for roles, identify competence gaps, ensure appropriate training or support is provided, and confirm that personnel are competent.
Human Resources	Maintain employee qualification records, support recruitment based on competence criteria, and coordinate training planning.
Supervisors / Team Leaders	Assess the day-to-day performance and competence of team members, identify training needs, and ensure that only competent personnel perform critical tasks.
Employees	Take responsibility for maintaining and developing their own competence, participating in required training, and applying their knowledge and skills effectively.
Quality Manager / Management Representative	Ensures that the competence management process aligns with ISO 9001 requirements, monitors effectiveness, and supports continual improvement.

6. Competence Management Process (ISO 9001:2015 Clause 6.2 & 7.2)

6.1 Determining Competence Requirements

The organization identifies the competence needed for each role that affects the QMS by considering:

- ❖ Job descriptions and role responsibilities
- ❖ Customer and regulatory requirements
- ❖ Risks associated with the role or process
- ❖ Process complexity and criticality
- ❖ Technical, legal, or safety requirements
- ❖ Organizational quality objectives

Competence requirements are documented, either as part of job descriptions, role profiles, or competence matrices.

6.2 Identifying Competence Gaps

Gap analysis is performed by comparing the current competence of employees (based on qualifications, experience, and performance) with the defined requirements.

- ❖ Gaps may be identified through:
- ❖ Performance evaluations
- ❖ Internal audits
- ❖ Incident or nonconformity investigations
- ❖ Changes in processes, technology, or regulations
- ❖ New employee onboarding

6.3 Planning to Achieve Competence

For identified gaps, the organization plans actions to ensure competence is achieved or maintained. Actions may include:

- ❖ Training (internal or external)
- ❖ Coaching or mentoring
- ❖ Job shadowing or on-the-job learning
- ❖ Work experience or rotation
- ❖ Certification or qualification acquisition
- ❖ External courses or professional development
- ❖ Recruitment of qualified personnel

The planned actions are documented, tracked, and implemented within defined timelines.

6.4 Developing Competence

Development activities are carried out based on the planned actions. These may include:

- ❖ Structured training programs
- ❖ Technical skill development
- ❖ Soft skills or leadership training
- ❖ Cross-functional or job-specific workshops
- ❖ E-learning or digital training modules
- ❖ Attendance at conferences or seminars

Development is aligned with both individual career growth and organizational quality goals.

7. Assessing Competence (ISO 9001:2015 Clause 7.2)

Competence is assessed to confirm that employees have the ability to apply their knowledge and skills effectively in their role. Methods of assessment may include:

- ❖ Skills demonstration or practical tests
- ❖ Written or oral examinations
- ❖ Observation of work performance
- ❖ Supervisor or peer evaluations
- ❖ Assessment by training providers
- ❖ Performance review outcomes
- ❖ Results of certification exams or qualifications

Assessments are objective, fair, and documented, and are conducted by qualified individuals (e.g., supervisors, trainers, or HR).

Where competence is not demonstrated, corrective actions are taken, such as additional training, re-assessment, or reassignment of duties.

8. Qualifications (Formal Recognition)

Employees may hold formal qualifications such as:

- ❖ Academic degrees or diplomas
- ❖ Professional certifications (e.g., engineer, auditor, technician)
- ❖ Industry licenses or accreditations
- ❖ Safety or compliance-related credentials

- ❖ Technical or vocational qualifications

The organization ensures that:

- ❖ Required qualifications are defined for each role
- ❖ Evidence of qualifications is collected and verified (e.g., certificates, licenses)
- ❖ Qualifications are kept current and valid (e.g., renewed certifications)
- ❖ Records are maintained as part of the employee file

9. Maintaining Competence

Competence is not a one-time achievement but an ongoing requirement. The organization ensures that:

- ❖ Competence is reviewed periodically (e.g., annually or upon process change)
- ❖ Continuous learning and development opportunities are provided
- ❖ Employees are informed of new requirements or changes in regulations, technology, or processes
- ❖ Re-training or refresher courses are provided as needed
- ❖ Competence is reassessed after significant organizational or process changes

10. Records of Competence and Qualifications

The organization maintains records related to employee competence and qualifications, including:

- ❖ Job descriptions and competence requirements
- ❖ Training records (see related Training Procedure)
- ❖ Competence assessment results
- ❖ Qualification certificates or evidence
- ❖ Competence gap analysis reports
- ❖ Development or action plans
- ❖ Records of refresher or ongoing training

These records are:

- ❖ Stored securely and confidentially
- ❖ Retained in accordance with the Controlled Record Retention Policy

- ❖ Available for audit, review, and performance evaluation

11. Outsourced Personnel and Contractors

For contractors, temporary staff, or external service providers performing tasks that affect quality:

- ❖ The organization ensures that they possess the required competence or qualifications
- ❖ Evidence of competence or qualification is obtained and reviewed
- ❖ Where necessary, orientation or specific training is provided
- ❖ Competence is monitored through performance and quality outcomes

12. Compliance with ISO 9001:2015

This procedure supports compliance with the following ISO 9001:2015 clauses:

- ❖ Clause 5.1 – Leadership and commitment (ensuring competent workforce)
- ❖ Clause 5.3 – Organizational roles, responsibilities, and authorities
- ❖ Clause 6.2 – Quality objectives and planning to achieve them (including competence planning)
- ❖ Clause 7.2 – Competence (determining, providing, and assessing competence)
- ❖ Clause 8.5.1 – Control of production and service provision (ensuring competent execution)
- ❖ Clause 9.1 – Monitoring, measurement, analysis and evaluation (assessing competence effectiveness)
- ❖ Clause 10.2 – Nonconformity and corrective action (addressing competence-related issues)

13. Conclusion

Managing competence and qualifications is essential to building a capable, confident, and compliant workforce. By systematically identifying competence needs, assessing current abilities, providing targeted development, and maintaining up-to-date records, the organization ensures that all personnel are equipped to contribute to the effectiveness of the QMS, the consistency of quality, and the achievement of customer satisfaction.

A structured competence management process supports risk reduction, regulatory compliance, and continuous improvement in full alignment with ISO 9001:2015.

14. Revision History of This Document

Rev No.	Date	Revised By	Approved By	Description
v1.0	2025-10-29	John Wang	Janice Lee	Initial release of ISO 9001 Documentation - Competences and Qualifications

Note: All controlled documents must be accessed through authenticated and approved channels. Employees must notify QA/Document Control in case they identify outdated or conflicting versions.

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