ISO 9001:2015 Readiness & Gap Assessment Checklist

A practical checklist for assessing quality management system readiness against ISO 9001

ISO 9001 · Quality Management · QMS · Internal Audit · Corrective Actions · Continual Improvement

ISO 9001 certification depends on a quality management system that is actually followed, not just documented. This checklist sets out a practical sequence for assessing QMS maturity and closing gaps before certification or recertification audit.

A Context & Scope

- [ ] Define the QMS scope, including products, services, and sites covered
- [ ] Identify interested parties and their relevant quality requirements
- [ ] Document internal and external issues that affect QMS outcomes
- [ ] Confirm the QMS scope statement is consistent with certification intent

B Leadership & Planning

- [ ] Document a quality policy approved and communicated by top management
- [ ] Assign quality management roles, responsibilities, and authorities
- [ ] Set measurable quality objectives at relevant functions and levels
- [ ] Plan actions to address risks and opportunities identified for the QMS

C Support & Resources

- [ ] Maintain competence records and training plans for QMS-relevant roles
- [ ] Control documented information with version control and approval history
- [ ] Maintain calibrated and fit-for-purpose monitoring and measuring equipment
- [ ] Ensure infrastructure and work environment support conforming products and services

D Operational Controls

- [ ] Define requirements for products and services before accepting orders
- [ ] Control design and development where applicable to the organisation
- [ ] Apply supplier evaluation and control over externally provided processes
- [ ] Maintain traceability and identification through production or service delivery
- [ ] Control nonconforming outputs and prevent unintended use or delivery

E Performance Evaluation

- ☐ Monitor customer satisfaction using a defined method and frequency
- ☐ Analyse quality data to identify trends, risks, and improvement opportunities
- ☐ Track quality objectives against targets on a set reporting cycle
- ☐ Report QMS performance to management ahead of management review

F Internal Audit

- ☐ Maintain an internal audit programme covering all QMS clauses and processes
- ☐ Assign auditors who are independent of the area being audited
- ☐ Raise nonconformities with objective evidence and clear descriptions
- ☐ Verify corrective actions close the root cause, not just the symptom

G Management Review

- ☐ Hold management review at planned intervals with a defined agenda
- ☐ Review audit results, customer feedback, and process performance
- ☐ Review the status of actions from previous management reviews
- ☐ Record decisions on resourcing, changes, and improvement opportunities

H Corrective Action & Continual Improvement

- ☐ Investigate nonconformities and determine root cause before acting
- ☐ Assign corrective actions with clear owners and realistic due dates
- ☐ Verify effectiveness of corrective actions after implementation
- ☐ Conduct a pre-certification readiness review ahead of the external audit

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