

Quality Manual Guideline V 1.1.

(Aligned with ISACO QMS Framework)

A **Quality Manual** is the foundation of a Quality Management System (QMS). It communicates your company's commitment to quality, defines responsibilities, outlines procedures, and ensures alignment with ISACO standards. Below is a structured guide to help you create a comprehensive and certification-ready manual.

Step 1 – Define Purpose and Scope

Start by explaining **why the QMS exists** and **what it covers**.

- **Purpose:** State how the QMS supports your organizational goals (e.g., consistent service delivery, compliance, customer satisfaction).
- **Scope:** Identify which **departments, processes, locations, or business units** are included.
- **Exclusions:** Clearly list any processes not covered and justify them.

Tip: Be precise. The scope determines what auditors will review.

Step 2 – Write the Company Overview

Introduce your organization and set the context for the QMS. Include:

- **Mission Statement** (your company's purpose).
- **Vision Statement** (long-term goals).
- **Core Values** (principles that guide behavior).
- **Products/Services** (what you deliver to customers).
- **Organizational Structure** (chart or description of roles and reporting lines).

Tip: Keep it short but professional. This helps auditors and employees understand who you are and what you do.

Step 3 – Define Roles and Responsibilities

Clear roles and responsibilities are the foundation of an effective Quality Management System (QMS). Regardless of the size of the organization, every quality-related activity must have ownership, accountability, and alignment with organizational objectives.

This section defines the key functions within the QMS and explains how these responsibilities can be applied across different business structures—from a sole proprietorship to SMEs and large enterprises.

Explanation

A robust QMS relies on clearly defined roles to ensure consistent implementation, monitoring, and improvement. The functions typically required in any organization include:

1. **Quality Management / QMS Coordination** – Overseeing the design, implementation, and continual improvement of the QMS, including audits, documentation, and compliance with standards.
2. **Operational Oversight / Department Heads** – Ensuring that daily processes comply with QMS requirements, procedures are followed, and corrective/preventive actions are implemented.
3. **Execution / Staff Members** – Performing tasks according to documented procedures, maintaining accurate records, and contributing to continuous improvement.
4. **Strategic Leadership / Senior Management** – Approving quality policies, setting objectives, allocating resources, and ensuring the QMS supports the organization's broader goals.

The number of people performing these roles varies by business size, but the functions themselves must always be accounted for:

- **Sole Proprietorship:** One person performs all functions. Accountability is documented to show ownership of each QMS function.
- **SMEs:** Responsibilities are distributed among a small leadership team and staff, with some individuals performing multiple roles.
- **Large Organizations:** Roles are specialized and spread across departments, with dedicated teams for quality management, auditing, and operational execution.

Examples of Roles and Responsibilities Table (All Business Sizes)

Role / Function	Responsibilities	Who Performs This Role
Quality Manager / QMS Coordinator	- Develop, implement, and maintain the QMS.- Conduct internal audits and monitor compliance.- Maintain documentation and records.- Track KPIs and initiate improvements.	Sole Prop: Owner / SMEs: Appointed Quality Manager / Large Org: Quality Department
Department Head / Operational Oversight	- Ensure processes comply with QMS.- Monitor departmental performance.- Communicate objectives and implement corrective/preventive actions.- Train and support staff.	Sole Prop: Owner /SMEs: Department Heads/ Large Org: Department Heads / Process Owners
Staff Member / Execution	- Follow documented procedures.- Maintain accurate records.- Report nonconformities and suggest improvements.- Participate in continuous improvement initiatives.	Sole Prop: Owner/ SMEs: Staff Members/ Large Org: All Operational Staff
Internal Auditor (optional for SMEs, required for large orgs)	- Conduct independent audits to assess QMS effectiveness.- Identify compliance gaps and improvement opportunities.- Report findings to management.	Sole Prop: Owner (self-audit)/ SMEs: Internal Audit Team or Quality Manager / Large Org: Internal Audit Team
Senior Management / Executive Leadership	- Approve Quality Policy and objectives.- Allocate resources for QMS implementation.- Conduct management reviews.- Promote a culture of quality across the organization.	Sole Prop: Owner/ SMEs: CEO / Executive Team/ Large Org: CEO / Executive Committee

Key Points for All Business Sizes

- Every function must be **assigned and documented**, even if performed by the same person.
- Responsibilities must be **understood by all involved**, whether internal staff or external consultants.
- Roles may be **combined in smaller businesses** but must remain clearly defined for auditing and accountability purposes.
- Periodic **review and updating** of roles ensures continued alignment with organizational growth and changes in process.

Step 4 – Develop Your Quality Policy

The **Quality Policy** is a formal declaration of your organization's commitment to delivering high-quality products and services while complying with applicable standards. It sets the tone for the entire Quality Management System (QMS) and provides a clear statement of the organization's quality objectives.

Key Guidelines for Your Quality Policy

1. Alignment with ISACO Principles

- Ensure your policy reflects the core ISACO values:
 - **Customer Focus:** Prioritizing the needs and satisfaction of clients.
 - **Leadership:** Demonstrating commitment to quality from top management.
 - **Continuous Improvement:** Fostering ongoing enhancement of processes and services.
 - **Evidence-Based Decision Making:** Using data and metrics to guide improvements.

2. Concise and Memorable

- Keep the policy brief, easy to remember, and meaningful.
- Avoid overly technical language; it should be understandable by all employees.

3. Communication


- Make the policy visible and accessible to all stakeholders:
 - Display in offices or production areas.
 - Include in onboarding and training programs.
 - Share during team meetings, management briefings, and internal communications.
- Ensure that every employee understands their role in upholding the policy.

4. Periodic Review

- *Review the Quality Policy regularly to ensure it remains relevant to organizational goals, customer expectations, and industry standards.*
 - *Update and re-communicate changes as needed.*
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Example of a Quality Policy Statement (Optional Template)

"Our organization is committed to delivering products and services that consistently meet or exceed customer expectations. We strive for continuous improvement in every process, guided by leadership, teamwork, and evidence-based decision making, in full compliance with applicable standards and regulations."

 **Tip:** *The Quality Policy is the foundation for all other QMS activities. It should inspire commitment across all levels of the organization and act as a reference point during audits, training, and process reviews.*

Step 5 – Document Key Procedures

List and describe the **core procedures** that support your QMS. Each should include:

- **Purpose** – Why the procedure exists.
- **Scope** – Which departments/processes it applies to.
- **Responsibility** – Who owns the process.
- **Steps / Workflow** – A clear, step-by-step guide.

Examples:

- Nonconformance Management
- Internal Audits
- Document Control
- Customer Feedback Handling
- Corrective & Preventive Actions (CAPA)

Tip: Procedures don't need to be overly complex. Focus on clarity and practicality.

Step 6 – Describe Core Processes / Add Flowcharts

Document major **business processes** (e.g., order handling, service delivery, production, procurement). For each:

- Inputs (what goes in)
- Outputs (what comes out)
- Controls/Checkpoints (how quality is checked)
- Roles involved

Tip: Use flowcharts wherever possible—they make processes easy to understand.

Step 7 – Define Performance Monitoring & Improvement

Explain **how you measure, review, and improve performance**.

- **KPIs (Key Performance Indicators):** e.g., defect rate, customer satisfaction, on-time delivery.
- **Monitoring Methods:** internal audits, customer surveys, performance dashboards.
- **Review Frequency:** monthly, quarterly, annually.
- **Continuous Improvement:** describe corrective actions, preventive actions, and employee suggestions.

Tip: Choose KPIs that matter to your business and customers, not just generic ones.

Step 8 – Manage Records & Documentation

Create a system for maintaining evidence of QMS activities.

For each record type, specify:

- **Description** (what it contains)
- **Retention Period** (how long it's kept)
- **Responsible Person/Department**

Examples: training records, audit reports, process logs, management reviews.

Tip: Auditors will check your records—make sure they're up-to-date and consistent.

Step 9 – Establish Review & Approval Process

Define how your manual will be maintained over time.

- **Manual Review:** Who checks updates (Quality Manager, Department Heads).
- **Manual Approval:** Senior Management or CEO.
- **Review Frequency:** annual, biannual, or as needed.
- **Version Control:** numbering system for tracking revisions (e.g., QMS-V1.0, QMS-V1.1).

Tip: Treat the manual as a living document—it must evolve with your company.

Step 10 – (Optional) Use Consultant Support

If desired, engage an ISACO-qualified consultant to:

- Review your manual for compliance.
- Suggest improvements for clarity and completeness.
- Conduct a pre-audit assessment.

Tip: Consultants can save time and ensure your manual is certification-ready.

Final Checklist Before Submission

Before sending your manual for ISACO certification, ensure:

- ☐ Scope is clearly defined
- ☐ Roles and responsibilities are documented
- ☐ Quality Policy is approved by management
- ☐ Key procedures are written and practical
- ☐ Core processes are described (with flowcharts if possible)
- ☐ KPIs are identified and measurable
- ☐ Record-keeping system is in place
- ☐ Review & approval process is established
- ☐ Version control is documented