

[Your Company]

Quality Management System Manual

Meeting BS EN ISO 9001:2008 Requirements



GUIDANCE

Navigating the Quality Manual

To aid navigation through the quality manual; the headings shown in the contents page are hyperlinked to the relevant sections of the quality manual.

- Place your mouse cursor over the heading in the contents page
- Press and hold 'CTRL'
- Then, 'left click' your mouse

Select the 'Web' toolbar within the 'Microsoft Word' and use the 'Back' and 'Forward' arrow buttons to navigate between the various sections of the manual and the contents page.

It is suggested that you also choose 'View' from the main menu and then select 'Document Map'. This will display the section headings as bookmarks on the left hand side of the screen.

It may also be useful to display the text boundaries on each page, choose 'Tools' then 'Options', click the 'View' tab, select 'Text Boundaries'.

Amending the Quality Manual, Forms & Procedure Templates

- Open the Quality Manual and Policy Template
- Review and amend the quality manual
- Review and amend the quality policy objectives
- Review and amend the procedures
- Review and amend the forms
- Replace any text to match your quality system requirements
- Blue text should be replaced with your information
- Your Company indicates that you should use your company's name in that location

Adding Value to the Quality Manual

The standard requires a minimum of six quality procedures, a quality manual and a quality policy. You'll probably want to have more procedures which are necessary to operate your specific business, but only six are mandatory:

- Document Control 4.2.3
- Control of Records 4.2.4
- Internal Audit 8.2.2
- Control of Non-conformances 8.3
- Corrective Actions 8.5.2
- Preventive Actions 8.5.3

You might want to document more procedures for other processes such as how to approve vendors, how to process sales orders, shipping and receiving inspection, things like that. But that's optional.

Also optional are work instructions. Work instructions might describe how to operate machinery, how to mix chemicals for a certain process, how to process a purchase order, or anything else that you feel is important enough to document. You want to make sure everyone is doing things the way you want them to be done. Documented procedures also make it easier to train future employees.

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5. Management Responsibilities

Top Management has the responsibility and authority for supporting development and implementation of the Quality Management System, for ensuring that it remains relevant to the company's objectives and the needs and expectations of customers, and that it promotes a continual improvement environment.

Top Management and their direct reports are responsible for communicating the Quality Policy and the importance of meeting customer as well as statutory and regulatory requirements to employees within their respective organizations. They shall ensure that it is understood and applied to the daily work of the organization through the establishment of goals and quality objectives.

Top Management is responsible for ensuring that the Quality Policy is appropriate for the goals of the business, that it promotes the continuing improvement of the effectiveness of the Quality Management System and that it is reviewed for continuing suitability.

All managers are responsible for communication of business plans and organizational goals within their respective sectors and reporting back to the organization on the performance and effectiveness of the Quality Management System.

5.1 Management Commitment

The Directors of [Your Company](#) are committed to implementing and developing the Quality Management System and this commitment is defined by the Quality Policy located in [Section 5.3](#).

We ensure that our quality policy is understood, implemented, and maintained at all levels of the organization through printed distribution of our quality policy statement, and through periodic management review of the quality policy statement and corporate level improvement objectives. In addition, our quality policy and objectives are communicated and deployed throughout the business via individual performance objectives established and reviewed during employee performance reviews.

All managers demonstrate their commitment to the development and improvement of the quality management system through the provision of necessary resources [Section 6.1](#), through their involvement in the internal audit process [Section 8.2.2](#), and through their proactive involvement in our continual improvement activities [Section 8.5](#) where emphasis is placed on improving both effectiveness and efficiency of key quality management system processes.

5.2 Customer Focus

[Your Company](#) strives to identify current and future customer needs to meet customer requirements, and exceed customer expectations. Executive management ensures that the focus on improving customer satisfaction is maintained by setting and reviewing objectives related to customer satisfaction at Management Review Meetings.

Top management ensures that customer requirements are understood and met. Customer requirements are understood, converted into internal requirements, and communicated to the appropriate personnel in our organization.

Customer complaints and other customer input/feedback are continually monitored and measured to identify opportunities for improvement. We continually look for other ways to interact directly with individual customers to ensure a proper focus to their unique needs/expectations is established and maintained.

5.3 Quality Policy

Top management ensures that the quality policy is communicated to all employees. It is included in new employee training and training on the quality management system. Management reviews the quality policy during management review meetings to determine the policy's continuing suitability for our organization.

We will achieve customer satisfaction by continually improving processes, products and services to ensure they consistently meet or exceed customer requirements

Your Company's quality policy statement indicates our commitment and focuses on what is important to us as an organization; achieving customer satisfaction and it prescribes the method by which we accomplish this; by continually improving processes, products, and services to ensure they consistently meet or exceed requirements. Moreover, our quality policy statement acts as a compass in providing the direction and a framework for establishing key corporate level performance measures and related improvement objectives [Section 5.4.1](#).

We ensure that our quality policy is communicated and understood at all levels of the organization through documented training, regular communication, and reinforcement during annual employee performance reviews.

Our quality policy statement is controlled by inclusion in this manual, and along with all policies contained in this manual, is reviewed for continuing suitability during management review meetings [Section 5.6](#).

Signed

Dated

5.4 Planning

5.4.1 Quality Objectives

Quality objectives are established to support our organization's efforts in achieving our quality policy and reviewed annually for suitability. Quality objectives are measurable, and reviewed against performance goals during management review and scheduled Management Meetings.

1. Achievement of ZERO DEFECTS and 100% on time delivery ([Section 7.5.1](#)) performance.
2. Manage and control facilities, processes, quality systems and personnel to consistently and cost effectively produce products and furnish services that meet customer needs ([Section 7.5.1](#)).
3. Be committed to continuous process improvement ([Section 8.5](#)) by emphasising reduction of part-to-part variation and the elimination of all waste.
4. Conduct operations in conformance with, or to exceed, all applicable environmental laws and regulations of the jurisdictions in which we do business ([Section 6.4](#)).

5.4.2 Quality Management System Planning

The quality system has been planned and implemented to meet our quality objectives and the requirements of 4.1 of the ISO 9001:2008 standard.

The quality management system planning process involves the establishing and communicating our quality policy [Section 5.3](#) and objectives [Section 5.4.1](#) through issuance of this manual and its associated procedures, and through the provision of resources needed for its effective implementation [Section 6.1](#). Accordingly, this manual constitutes our overall plan for establishing, maintaining and improving an effective quality management system. Our management review process [Section 5.6](#) and internal audit process [Section 8.2.2](#) ensure the integrity of our quality management system is maintained when significant changes are planned and implemented that affect our key quality management system processes.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

An organizational structure has been established to show the interrelation of personnel in the organization. Job descriptions define the responsibilities and authorities of each of the positions. Job descriptions and the organizational structure are reviewed and approved by top management for adequacy.

Members of Top Management are ultimately responsible for the quality of [Your Company's](#) products and services since they control the systems and processes by which work is accomplished.

Top Management is responsible for business planning, development and communication of our quality policy [Section 5.3](#), quality management system planning [Section 5.4.2](#) including the

establishment and deployment of objectives [Section 5.4.1](#), the provision of resources needed to implement and improve the quality management system [Section 6.1](#) and management reviews [Section 5.6](#).

All managers are responsible for execution of the business plan and implementation of the policy, processes and systems described in this manual. All managers are responsible for planning and controlling quality management system processes within their area(s) of responsibility, including the establishment and deployment of operational level objectives and the provision of resources needed to implement and improve these processes.

All employees are responsible for the quality of their work and implementation of the policy and procedures applicable to processes they perform [Section 8.2.3](#). Personnel responsible for product quality have the authority to stop production to correct quality problems [Section 8.3](#). Employees are motivated and empowered to identify and report any known or potential problems and recommend related solutions through internal audits [Section 8.2.2](#) and/or the continual improvement and corrective/preventive action processes [Section 8.5](#).

5.5.2 Management representative

Your Company's Management Representative [\[insert job title of your management representative here\]](#) is appointed as management representative with delegated responsibilities for ensuring that a compliant quality management system is established, implemented, and maintained; for promoting awareness of customer requirements throughout the organization [Section 5.5.3](#); and for ensuring that the performance of the quality management system is reviewed by Top Management for effectiveness, continuing suitability and the need for improvement [Section 5.6](#). The Management Representative has the following responsibilities:

- Ensure that processes needed for the QMS are established and implemented
- Report to top management on the performance of the QMS system
- Suggest areas for performance improvement
- Promote awareness of customer requirements throughout the organization
- Act as a liaison with customers and external auditors on matters relating to the QMS

5.5.3 Internal Communication

Your Company communicates information regarding quality management system processes and their effectiveness through documented training [Section 6.2.2](#), the internal audit process [Section 8.2.2](#), continual improvement and corrective/preventive action processes [Section 8.5](#).

All managers and supervisors are responsible for establishing regular formal and informal communications as needed to convey to their employees the relevance and importance of their activities; typically this information is conveyed through team meetings and cross-functional improvement projects.

Communications regarding how employees contribute to the achievement of objectives is also conveyed and reinforced during employee performance reviews.

5.6 Management Review

5.6.1 General

Top Management conducts a management review meeting at least once annually to ensure the continuing suitability, adequacy, and effectiveness of our quality management system. The primary inputs reviewed include data that measures the conformance and performance of our quality management system and recommendations based on analysis of such data.

Conformance is primarily assured through internal audits [Section 8.2.2](#) and demonstrated through a review of internal audit results and our demonstrated ability to correct/prevent problems.

Performance is primarily assured through the deployment of corporate/operational level objectives [Section 5.4.1](#) and demonstrated through a review of our demonstrated ability to achieve desired results. The primary outputs of management review meetings are management actions taken [Section 8.5](#) to make changes or improvements to our quality management system and the provision of resources needed to implement these actions.

5.6.2 Review Input

Assessment of the Quality Management System is based on a review of information inputs to management review. These inputs include the following:

- Audit results
- Product conformity data
- Opportunities to improve
- Feedback from customers
- Process performance information
- Corrective and preventive actions
- Changes that might affect the system
- Previous quality management reviews

5.6.3 Review Output

During these review meetings, management will identify appropriate actions to be taken regarding the following issues:

- Actions to improve your quality system
- Actions to improve your products
- Actions to address resource needs
- Management meeting minutes

The primary outputs of management review meetings are management actions taken to make changes or improvements to our Quality Management System and the provision of resources needed to implement these actions.

Responsibilities for required actions are assigned to members of the management review team. Any decisions made during the meeting, assigned actions, and their due dates are recorded on the management review presentation.

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