

# 1 Introduction

Your organization has developed and implemented a quality management system (QMS), which uses ISO 9001:2015 as a framework that allows our organization to document and improve our practices in order to better satisfy the needs and expectations of our customers, stakeholders and interested parties.

This manual describes the quality management system, delineates authorities, inter relationships and responsibilities of personnel operating within the management system. The manual also provides references to procedures and activities that also comprise our quality management system.

The manual is used to familiarise customers and other external organizations or individuals with the controls that have been implemented and to assure them that the integrity of our quality management system is maintained and is focused on customer satisfaction and continual improvement.

Our quality management system meets the requirements of ISO 9001:2015 and uses the Plan, Do, Check and Act approach to process planning. Our QMS addresses and supports our strategies for the <design, development, manufacturing, installation and servicing of our products>. <insert your scope statement here. This should succinctly summarize your products and/or services. A single sentence is all that is required, as this will be shown your ISO 9001:2015 certificate>.

<Also insert the registered address of your organization here>

The following table identifies any ISO 9001:2015 requirements, from Section 8.0, that are not applicable to our organization as well as providing a brief narrative to justify their omission from the scope of our QMS:

| Clause | Justification for Exclusion |
|--------|-----------------------------|
|        |                             |
|        |                             |
|        |                             |

# 2 References

In addition to ISO 9001:2015 we also make reference to other relevant British and/or international standards as well as customer specifications appropriate to our products and market.

| Standard             | Title                       | Description                             |
|----------------------|-----------------------------|---|
| BS EN ISO 9000:2015  | Quality management systems  | Fundamentals and vocabulary             |
| BS EN ISO 9004:2000  | Quality management systems  | Guidelines for performance improvements |
| BS EN ISO 19011:2011 | Auditing management systems | Guidelines for auditing                 |

# 3 Definitions

This document does not introduce any new definitions but rather relies on the following:

1. Definitions typically used by our customers, stakeholders or marketplace;
2. Terms typically used in standards and regulations as they relate to our QMS or products;
3. Standard business terminology;
4. Terms and vocabulary commonly used in quality and <engineering> practices.

## 4 About Our Organisation

### 4.1 Organizational Context

Your organization is committed to defining our position in the marketplace and understanding how relevant factors arising from legal, political, economic, social and technological issues influence our strategic direction and our organizational context.

Your organization identifies, analyzes, monitors and reviews factors that may affect our ability to satisfy our customers and stakeholders, as well as; factors that may adversely affect the stability of our process, or our management system's integrity.

To ensure that our QMS is aligned with our strategy, whilst taking account of relevant internal and external factors; we initially collate and analyze pertinent information in order to determine potential impact on our context and subsequent business strategy.

Your organization then monitors and reviews this information to ensure that a continual understanding of each group's requirements is derived and maintained. To facilitate the understanding of our context, we regularly consider issues that influence our context during management review meetings and are conveyed via minutes and business planning documents.

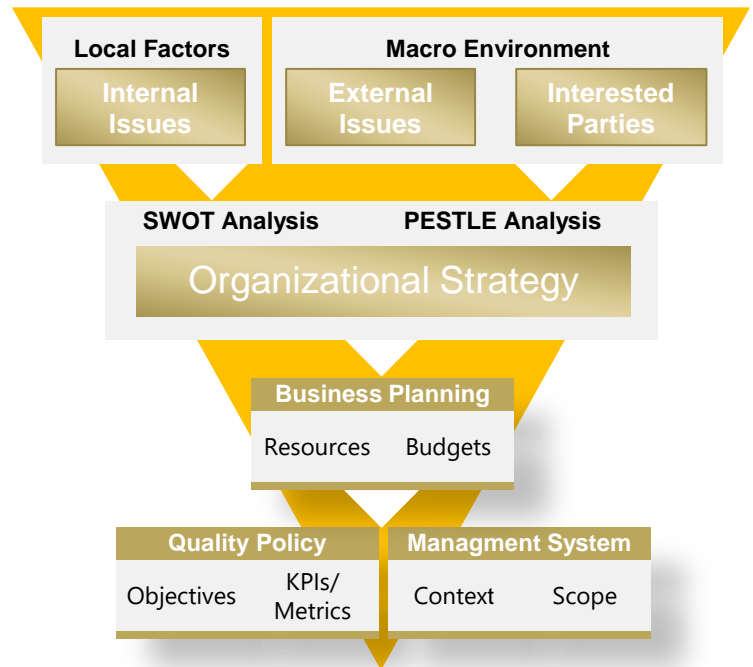
| Internal Issues        | External Issues        |
|------------------------|------------------------|
| Market share           | Customers & suppliers  |
| Employees              | Markets & competition  |
| Performance            | Regulatory & statutory |
| Values & culture       | Technological          |
| Innovation & knowledge | Cultural & social      |

The output from this activity is evident as an input to the consideration of risks and opportunities, and the actions that we take to address them. Refer to Section 6.1 for more information about our risk and opportunity management framework.

Although we acknowledge that ISO 9001:2015 does not require our organizational context to be maintained as documented information, we maintain and retain; in addition to this document, the following documented information to describe our organizational context:

1. Analysis of business plans, strategies, and statutory and regulatory commitments;
2. Analysis of technology and competitors;
3. Economic reports from relevant business sectors;
4. Technical reports from technical experts and consultants;
5. SWOT analysis reports or schedules for internal issues;
6. PESTLE analysis reports or schedules for external issues;

Figure 1: Typical QMS Input Hierarchy



## Appendices

### A.1 Correlation Matrix

This section provides a matrix to correlate the requirements of ISO 9001:2015 against the relevant sections in this document and should be used to determine where the new and amended clauses are located.

| ISO 9001:2015 |  | This Document |                                       |
|---------------|--|---------------|---------------------------------------|
| 4.0           | Context of the Organization                    | 4.0           | About our Organization                |
| 4.1           | Understanding the Organization and its Context | 4.1           | Organizational Context                |
| 4.2           | Needs and Expectations of Interested Parties   | 4.2           | Relevant Interested Parties           |
| 4.3           | Scope of the Quality Management System         | 4.3.1         | Management System Scope               |
| 4.4           | Quality Management System and its Processes    | 4.3.2         | Management System Processes           |
| 5.0           | Leadership                                     | 5.0           | Leadership & Governance               |
| 5.1           | Leadership and Commitment                      | 5.1           | Leadership & Commitment               |
| 5.1.1         | Quality Management System                      | 5.1.1         | Quality Management System             |
| 5.1.2         | Customer Focus                                 | 5.1.2         | Customer Focus                        |
| 5.2           | Quality Policy                                 | 5.1.3         | Quality Policy                        |
| 5.2.1         | Establishing the Quality Policy                | 5.1.3.1       | Establishing the Quality Policy       |
| 5.2.2         | Communicating the Quality Policy               | 5.1.3.2       | Communicating the Quality Policy      |
| 5.3           | Roles, Responsibilities and Authorities        | 5.2           | Roles, Responsibilities & Authorities |
| 6.0           | Planning for the Quality Management System     | 6.0           | Management System Planning            |
| 6.1           | Actions To Address Risks and Opportunities     | 6.1           | Addressing Risk & Opportunities       |
| 6.2           | Quality Objectives & Planning To Achieve Them  | 6.2           | Quality Objectives                    |
| 6.3           | Planning of Changes                            | 6.3           | Planning for Change                   |
| 7.0           | Support  | 7             | Support                               |
| 7.1           | Resources                                      | 7.1           | Resources                             |
| 7.1.1         | General  | 7.1.1         | General                               |
| 7.1.2         | People   | 7.1.2         | People                                |
| 7.1.3         | Infrastructure                                 | 7.1.3         | Infrastructure                        |
| 7.1.4         | Environment for the Operation Of Processes     | 7.1.4         | Operational Environment               |
| 7.1.5         | Monitoring and Measuring Resources             | 7.1.5         | Monitoring and Measuring Tools        |
| 7.1.6         | Organizational Knowledge                       | 7.1.6         | Organizational Knowledge              |
| 7.2           | Competence                                     | 7.1.2.1       | Competence                            |
| 7.3           | Awareness                                      | 7.1.2.2       | Awareness                             |
| 7.4           | Communication                                  | 5.3           | Communication                         |
| 7.5           | Documented Information                         | 4.3.4         | Documented Information                |
| 7.5.1         | General  | 4.3.4.1       | Management System Documents           |
| 7.5.2         | Creating and Updating                          | 4.3.4.2       | Creating and Updating                 |
| 7.5.3         | Control of Documented Information              | 4.3.4.3       | Controlling Documented Information    |
| 8.0           | Operation                                      | 8.0           | Product & Service Development         |
| 8.1           | Operational Planning and Control               | 8.1           | Operational Planning and Control      |
| 8.2           | Requirements for Products and Services         | 8.2           | Customer Requirements                 |
| 8.2.1         | Customer Communication                         | 8.2.1         | Customer Communication                |
| 8.2.2         | Determining Requirements Related to Products   | 8.2.2         | Determining Requirements              |

A.2 Sequence & Interaction of Processes

