QCS MANAGEMENT PVT LTD

WHITE PAPER ON ISO 9001 : 2015 QUALITY MANAGEMENT SYSTEM REQUIREMENTS

CONTENTS: INTRODUCTION, QUALITY MANAGEMENT PRINCIPLES, PROCESS APPROACH, RISK BASED THINKINGS. 1. SCOPE, 2.NORMATIVE REFERENCE,3.TERMS& DEFINATIONS, 4. CONTEXT OF THE ORGANISATION,5.LEADERSHIP,6. PLANNING, 7.SUPPORT, 8. OPERATIONS, 9. PERFORMANCE EVALUATION, 10. IMPROVEMENT.

Introduction

Complying with ISO 9001 ensures customers get consistent, good quality products and services, which in turn brings many business benefits. ISO 9001 defines the criteria for a Quality Management System and is the only standard in the family that can be audited against with the goal of voluntary compliance or to become 3rd party registered. In fact, there are over one million companies and organizations in over 170 countries certified to ISO 9001. All the requirements of ISO 9001 are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides. The ISO 9001 standard is based on a series of ISO 9000 standards:

- ISO 9001 – defines the requirements of a quality management system
- ISO 9000 – covers the basic concepts and language
- ISO 9004 – focuses on how to make a quality management system more efficient and effective
- ISO 19011 – provides guidance on internal and external audits of quality management systems

The standard is based on **seven Quality Management Principles,** including a strong customer focus, the motivation and implication of top management, the process approach and continual improvement.

These Quality Management Principles are identified as follows:

1. Customer focus
2. Leadership
3. Engagement of people
4. Process approach
5. Improvement
6. Evidence-based decision making
7. Relationship management

Process Approach

Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system' –

The process approach is a management strategy which incorporates the plan-do-check-act cycle and risk-based thinking. It means that processes are managed and controlled. It also means that we not only understand what the core processes are, but we also consider how they fit together.

ISO 9001:2015 employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking. This means the organisation needs to:

1. determine required process inputs and expected outputs,
2. assign responsibilities and authorities for processes,
3. identify risks and opportunities for processes, and plan to address these.

Risk-based thinking

The revised ISO 9001 standard has moved away from what it called "preventive action" towards a "risk-based approach". Preventive action was found to be lacking when it came to driving change and continuous improvement. The risk-based approach is likely to be much more effective in allowing organisations to become stronger, fitter businesses.

Taking a risk-based approach means:

- Determining the risks and opportunities
- Planning actions to address them
- Implementing them in a quality management system
- Evaluating their effectiveness

All this ensures your organisation is proactive rather than reactive, preventing potentially damaging events and promoting improvement. Once a management system is risk-based, preventive action is automatic. Though we commonly understand risk to be negative, risk-based thinking has a more positive slant in that it provides opportunities for improvement and enables businesses to make strategic decisions.

1.SCOPE : The aim or **'Scope' of ISO 9001:2015** is to specify the requirements for a QMS that can be used by organisations that want to: **a)** Demonstrate their ability to consistently provide products or services that meet customer and applicable statutory and regulatory requirements **&b)** Enhance customer satisfaction through the application of such a system, including processes for improvement and the assurance of conformity to those customer and applicable statutory and regulatory requirements.

2.NORMATIVE REFRENCES : ISO 9000: 2015, Quality Management System - Fundamental and vocabulary is referenced and provides valuable guidance.

3.TERMINOLGY : All the terms and definitions are contained in **ISO 9000:2015 – Quality Management – Fundamentals and vocabulary.**

4. CONTEXT OF THE ORGANISATION : Firstly, the organization will need to determine external and internal issues that are relevant to its purpose, i.e. what are the relevant issues, both internal and external, that have an impact on what the organization does, or that would affect its ability to achieve the intended outcome(s) of its management system. In fulfilling this clause, one should focus only on issues that can affect the customer satisfaction and delivery of quality product and/or services. An organization's internal context is the environment in which it aims to achieve its objectives. **Internal context can include;** its approach to governance & its contractual relationships with customers, and its interested parties. Things that need to be considered are related to the culture, beliefs, values, or principles inside the organization, as well as complexity of processes and organizational structure. To determine external context, one should consider issues arising from its social, technological, environmental, ethical, political, legal, and economic environment. **Examples of external context may include**: government regulations and changes in the law ,economic shifts in the organization's market, the organization's competition, events that may affect corporate image , changes in technology.

Secondly an organization will also need to identify the "interested parties" that are relevant to their QMS. These groups could include shareholders, employees, customers, suppliers, and even pressure groups and regulatory bodies. Each organization will identify their own unique set of "interested parties" and over time these may change in line with the strategic direction of the organization.

Next the scope of the QMS must be determined. This could include the whole of the organization or specific identified functions. Any outsourced functions or processes will also need to be considered in the organization's scope if they are relevant to the QMS.

The final requirement of Clause 4 is to establish, implement, maintain and continually improve the QMS in accordance with the requirements of the standard. This requires the adoption of a process approach and although every organization will be different, documented information such as process diagrams or written procedures could be used to support this.

5.LEADERSHIP : This clause places requirements on "top management" which is the person or group of people who directs and controls the organization at the highest level. There is an increased emphasis on people "owning" the QMS rather than one individual. It is no longer the responsibility of an individual or to have a "Management Representative" who is responsible for the QMS. There is also a greater focus on top management to enhance customer satisfaction by; a. identifying and addressing risks and opportunities that could affect customer satisfaction, b. showing how they meet customer requirements, regulatory and statutory requirements, and also how the organization maintains enhanced customer satisfaction, c. In the same context, they need to have a grasp of the organizations internal strengths and weaknesses and how these could have an impact to deliver products or services. This will strengthen the concept of business process management & d. In addition, top management need to demonstrate an understanding of the key risks associated with each process and the approach taken to manage, reduce or transfer the risks. Top management now must ensure that the requirements of QMS are integrated into the organization's processes and that the policy and objectives are compatible with the strategic direction of the organization. The quality policy should be a living document, at the heart of the organization. To ensure this, top management are accountable and have a responsibility to ensure the QMS is made available, communicated, maintained and understood by all parties. Finally, the clause places requirements on top management to assign QMS relevant responsibilities and authorities , but must remain accountable for the effectiveness of the QMS.

6.PLANNING : Consider Risks and opportunities when you plan your QMS. Plan how you're going to manage risks and opportunities**.** Planning has always been a familiar element of ISO 9001, but now there is an increased focus on ensuring that it is considered with Clause 4.1 'context of the organization' and Clause 4.2 'interested parties'**.** The first part of this clause concerns risk assessment whilst the second part is concerned with risk

treatment. When determining actions to identify risks and opportunities these need to be proportionate to the potential impact they may have on the conformity of products and services. Opportunities could for example include new product launches, geographical expansion, new partnerships, or new technologies. The organization will need to plan actions to address both risks and opportunities, how to integrate and implement the actions into its management system processes and evaluate the effectiveness of these actions**.** Actions must be monitored, managed and communicated across the organization. Establish quality objectives for all relevant areas. Develop plans to achieve objectives and evaluate results. Another key element of this clause is the need to establish measurable quality objectives. Quality objectives now need to be consistent with the quality policy, relevant to the conformity of products and services as well as enhancing customer satisfaction.
The last part of the clause considers planning of changes which must be done in a planned and systemic manner. There is a need to identify the potential consequences of changes, determine who is involved, when changes are to take place, what resource needs to be allocated.

7.SUPPORT: Clause 7 ensures there are the right resources namely environment, people and infrastructure to meet the organizational goals. It requires an organization to determine and provide the necessary resources to establish, implement, maintain and continually improve the QMS. Simply expressed, this is a very powerful requirement covering all QMS resource needs and now covers both internal and external Resources. There are additional requirements to meet applicable statutory and regulatory requirements. The sub-clauses continues to cover requirements for infrastructure and environment for the operation of processes. Monitoring and measuring has been changed to include resources, such as personnel or training. Organizational knowledge is a new requirement which deals with the requirements for competence, awareness, and communication of the QMS. Personnel must not only be aware of the quality policy, but they must also understand how they contribute to it and what the implications of not conforming are. There is a key requirement to maintain the knowledge held by an organization to ensure conformity of products and services. This could include the knowledge held by an individual as well as for example, the intellectual property of an organization. Organizations are required to examine whether the current knowledge they have is sufficient when planning changes and whether any additional knowledge is required**.** Finally there are the requirements for **"documented information".** This is a new term, which replaces the references in the 2008 standard to "documents" and "records". Organizations need to determine the level of documented information necessary to control the QMS. This will differ between organizations due to size and complexity. In line with the increased importance of information security in organizations, there is also greater emphasis on controlling access to documented information such as use of passwords. Organizations should also have systems in place to provide a back-up should IT systems crash.

8. Operational planning & control process : This clause deals with the execution of the plans and processes that enable the organization to meet customer requirements and design products and services. There is greater emphasis on the control of processes especially planned changes and review of the consequences of unintended changes, and mitigating any adverse effects as necessary. There are more explicit requirements in terms of the standards or codes of practice that the organization has committed to implement; internal and external resource needs for the design and development of products and services and finally the potential consequences of failure due to the nature of products and services. A new requirement for communicating with 'potential' customers is also included, useful for bringing new offerings or solutions to the market. The standard acknowledges the trend towards greater use of subcontractors and outsourcing. This is demonstrated by the requirement to establish criteria for monitoring the performance of these parties in addition to keeping records used to establish selection criteria. There is also a new requirement which covers post-delivery activities. This could include activities such as maintenance programmes or work carried out under warranty, and activities covering final disposal or recycling of the product.

9. PERFORMANCE EVALUATION: There is now an emphasis on directly seeking out information that relates to how customers view the organization. Organizations must actively seek out information on customer perception. This can be achieved in a number of ways including satisfaction surveys, analysis of market share, and through complaints logged. There is now an explicit requirement that organizations must show how the analysis and evaluation of this data is used, especially with regards to the need for improvements to the QMS. Internal audits must also be conducted and this is largely unchanged from those in the 2008 version. There are additional requirements relating to defining the 'audit criteria' and ensuring the results of the audits are reported to 'relevant' management'.

Management reviews are still required but there are additional requirements including the consideration of changes in external and internal issues that are relevant to the QMS. Documented information must be retained as evidence of management reviews.

10. IMPROVEMENT : This clause starts with a new section that organizations should determine and identify opportunities for improvement such as improved processes to enhance customer satisfaction. There is also a need to actively look for opportunities to improve processes, products and services, and the QMS, especially with future customer requirements in mind. Due to the new way of handling preventive actions, there are no preventive action requirements in this clause. However, there are some new corrective action requirements. Action steps are;

- The first is to react to the nonconformities and take action, as applicable, to control and correct the nonconformities and deal with the consequences.
- The second is to determine whether similar nonconformities exists or could potentially occur.

The requirement for continual improvement has been extended to cover the suitability and adequacy of the QMS as well as its effectiveness, but it no longer specifies how an organization achieves this.

Structure & terminology of ISO 9001:2015

Major differences in terminology

ISO 9001:2008	ISO 9001:2015
Products	**Products and services**
Exclusions used	**Exclusions Not used – see Clause A.5 for clarification of applicability**
Management representative used	**Management representative Not used**
Documentation, quality procedures, records-	**Documented information**
Work environment.-	**Environment for the operation of processes**
Monitoring and measuring -	**Monitoring and measuring of resources & equipments**
Purchased product -	**Externally provided products and services**
Supplier -	**External provider**
Work environment.-	**Environment for the operation of processes**
Purchased product -	**Externally provided products and services**

[END]