Inspiring Innovation and Leadership

Office administrators and Clerical officers training on ISO 9001:2015-QMS

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ACRONYMS

- **ISO** - This is an acronym for the International organization for Standardization, a worldwide organization that is responsible for developing documents of “requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes, and services are fit for their purpose.”
  (Source: https://www.iso.org/standards.html)
- **Standards** - *Standards*—in relation to ISO 9001—are essentially benchmarks in quality. Businesses must meet these benchmarks to become ISO 9001 certified. The ISO 9001:2015 is the most updated standard, based on the creation and maintenance of quality management systems (QMS).

Acronyms-cntd

- **Management** - Management is the control of resources, systems and processes, and other aspects of the organization that require monitoring.
- **Management System** - The management system is a process organizations use to help set up and organize policies, objectives, and more. Management systems come in a wide variety of unique types, including:

✓ Environmental management systems

✓ Financial management systems

✓ Quality management systems

✓ Food safety management systems

✓ Occupational health and safety management systems

Acronyms-cntd

- **Management Review Meetings** - These meetings are brought together to have a proper evaluation of the management system and discuss what areas are successful, and what areas need improvement.
- **Policy** - Policies are documents that include information about a set of standards.
- **Process** - A process is a set of tasks that are completed to work towards an ultimate goal. ***Within ISO 9001, all processes are focused on satisfying the customer.***
- **Process Approach** - This term refers to how management plans strategies to improve processes.

Acronyms-cntd

- **Process-Based Quality Management System (QMS)** - This term reflects processes that are integrated within an organization to improve quality.
- **Quality** - This term is applied in a few different ways. For starters, quality can be represented by how time and energy is being used to accomplish tasks. Quality can also represent how many ISO 9001 requirements are met.
- **Quality Management** - This term refers to any activity that is being performed by an organization to maintain or improve quality. This can include the adoption of a quality policy, quality assurance, quality planning, and more.

Acronyms-cntd

- **Quality Management System (QMS)** - QMS is an organization's system which implements policies and objectives into the processes that help improve a standard of quality. Some QMS implementations include:
- ✓ Records
- ✓ Techniques
- ✓ Programs
- ✓ Rules
- ✓ Role distribution
- ✓ Responsibility distribution
- This term is by far one of the most important to be familiar with, as it is the basis of what ISO 9001 standards can help you accomplish.
- **Quality Objective** - This term represents the plan laid out to ensure that quality results are achieved properly.

Acronyms-cntd

- **Quality Policy** - The quality policy is a document that shows the standards your organization has set for itself in terms of improving and maintaining quality for customers, providers, and employees. The quality policy revolves around the quality management principles mentioned in ISO 9001. (With quality management principles, the main drive is on customers and those interested in the product/service and provide them with the resources they need.)
- **System** - A system is how a certain set of processes operate to work towards a particular goal. There are a few different systems at work when it comes to ISO 9001 — all of which have different objectives.

PREAMBLE

- This training is designed to help participants understand the ISO 9001 basic concepts of a Quality Management System (QMS) and learn how to implement and manage a Quality Management System (QMS) as specified in ISO 9001.
- During this training, the participants will be able to comprehend the different modules of a QMS, including QMS policy, procedures, performance measurements, management commitment, internal audit, management review and continual improvement:
- Understand the elements and operations of a Quality Management System and its principal processes.
- Acknowledge the correlation between ISO 9001 and other standards and regulatory frameworks.
- Understand the approaches, methods and techniques used for the implementation and management of a Quality Management System.

INTRODUCTION TO ISO 9001 AND INITIATION OF A QMS

- ISO 9001 is a standard that defines the requirements for a Quality Management System (QMS). It helps businesses and organizations be more efficient and improve customer satisfaction. The primary focus of the ISO 9001 standard is meeting customer requirements and strive to exceed customer expectations.
- **Quality Management Objectives**
- ***What is a QMS?***
- "A quality management system (QMS) is a collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction. It is aligned with an organization's purpose and strategic direction".

What is a QMS?- cntd

- A QMS is defined as an extensive system meant to document important processes and procedures and facilitate the implementation of these procedures to achieve high-quality outputs that align with a company's goals and objectives. A QMS aids in coordinating and directing the activities of a business in order to achieve customer satisfaction and meet international requirements, to enhance efficiency and work towards continual improvement.

What is the Purpose of a QMS?

- A quality management system is not simply a group of documents your organization refers to, it is a whole system that aims to incorporate conformance to international standards of excellence and, through the process, takes a look at executions, costs and conveyance. In doing so, and in succeeding to continually improve upon company procedures and consequently products, the system brings about a whole array of advantages. A QMS integrates the various internal processes within the organization and intends to provide a process approach for project execution. A process-based QMS enables your organization to identify, measure, control and improve the various core business processes that will ultimately lead to improved business performance.

What is the Purpose of a QMS?- cntd

- Increasingly, top QMS have attempted to converge initiatives revolving around sustainability and transparency as they recognize that customer and investor satisfaction are tied to these factors. Out of the top regimes, the ISO 9000 family of standards is considered the top international standard and deals with both quality and sustainability integration in company values.

What are the Advantages of a QMS?

- *"A well-designed and implemented quality management system can help you plan, simplify, and control your operations"*
- The popularity of QMS can be credited to the many advantages that incorporating a quality management system into company policy has proven to bring about. Alongside showcasing an immense dedication to providing quality products and services, having a QMS in the company allows you to establish a brand identity, create consumer loyalty, and consistently meet client necessities and improve upon existing frameworks. A quality management system operates as a basic framework to help organizations manage services and document relevant changes and corrective measures for internal and external audits.

Understanding the organization and its context (Clause 4.1)

Scope of the QMS (Clause 4.3)

- ISO 9001:2015 Clause 4.3 defines the requirements of the organization's scope. The standard states that the quality management system needs to have a defined scope, which specifies its boundaries and applicability. The scope will be referenced on the ISO certificate as it states what parts of your business are within or excluded from certification.

Identifying risks and opportunities

- Risk is inherent in all aspects of a quality management system. There are risks in all systems, processes and functions. Risk-based thinking ensures these risks are identified, considered and controlled throughout the design and use of the quality management system.
- *In ISO 9001:2015 risk-based thinking needs to be considered from the beginning and throughout the system, making preventive action* inherent to planning, operation, analysis and evaluation activities.

Identifying risks and opportunities-cntd

- Not all the processes of a quality management system represent the same level of risk in terms of the organization's ability to meet its objectives. Some need more careful and formal planning and controls than others.
- *Example: To cross the road I may go directly or I may use a nearby footbridge. Which process I choose will be determined by considering the risks.*
- Risk is commonly understood to have only negative consequences; however the effects of risk can be either negative or positive.

Identifying risks and opportunities-cntd

- In ISO 9001:2015, risks and opportunities are often cited together. Opportunity is not the positive side of risk. An opportunity is a set of circumstances which makes it possible to do something. Taking or not taking an opportunity then presents different levels of risk.
- *Example:*
- *Crossing the road directly gives me an opportunity to reach the other side quickly, but if I take that opportunity there is an increased risk of injury from moving cars.*
- The concept of risk-based thinking is explained in the introduction of ISO 9001:2015 as an integral part of the process approach.
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Identifying risks and opportunities-cntd

- **ISO 9001:2015 uses risk-based thinking in the following way:**
- **Introduction** - the concept of risk-based thinking is explained
- **Clause 4 –** the organization is required to determine its QMS processes and to address its risks and opportunities
- **Clause 5 –** top management is required to
- Promote awareness of risk-based thinking
- Determine and address risks and opportunities that can affect product /service conformity

- **Clause 6** – the organization is required to identify risks and opportunities related to QMS performance and take appropriate actions to address them
- **Clause 7** – the organization is required to determine and provide necessary resources (risk is implicit whenever “suitable” or “appropriate” is mentioned)
- **Clause 8** – the organization is required to manage its operational processes (risk is implicit whenever “suitable” or “appropriate” is mentioned)
- **Clause 9** – the organization is required to monitor, measure, analyse and evaluate effectiveness of actions taken to address the risks and opportunities
- **Clause 10** – the organization is required to correct, prevent or reduce undesired effects and improve the QMS and update risks and opportunities

IMPLEMENTATION OF A QMS

Document Management

- The information required for ISO 9001 can be split into two types:
- **Documents:** These include policies or objectives that you have set that can be amended at a later date.
- **Records:** These are evidence of the results achieved. Records should not be changed or revised as they are proof of an outcome.

Document Management-cntd

- There are mandatory documents that you need to produce to become ISO 9001 certified. These include:
- Scope of the Quality Management System (clause 4.3)
- Quality policy (clause 5.2.2)
- Quality objectives and how these will be achieved (clause 6.2)

Document Management-cntd

- The mandatory records needed for ISO 9001 include:
- ✓ Criteria for evaluation and selection of suppliers (clause 8.4.1)
- ✓ Characteristics of product or service to be provided (clause 8.5.1)
- ✓ Identification and Traceability records (8.5.2)
- ✓ Records about customer property including any changes (clause 8.5.3)
- ✓ Production/service provision change control records (clause 8.5.6)
- ✓ Control of nonconforming outputs (clause 8.7.2)
- ✓ Monitoring and measurement results (clause 9.1.1)
- ✓ Internal Audit results (9.2.2)
- ✓ Results of the management review (clause 9.3.3)
- ✓ Results of corrective actions including opportunities for improvement (clause 10.2.2)

Document Management-cntd

- These are the mandatory clauses that you need to provide documents and reports for in order to become ISO 9001 certified. Your documents and records will take a variety of forms, such as spreadsheets, diagrams, videos and written content. ISO 9001 requires you have some system in place that controls your documents. Note that retention policies will need to be in place establishing the length of time that records will be kept.

- What is Document Control in ISO 9001:2015? ISO 9001:2015 **mandates 'control over documented information' to guarantee the right people have access to a QMS where and when** they need it - and to ensure that no unauthorized or unrecorded changes can be made to its required contents

Operational Planning and Control (Clause 8.1)

- Operational planning is about controlling the design and development process. The organization must ensure that all related activities take place under controlled conditions.
- Operational planning includes the following elements:
- Developing process plans that include clear, concise and detailed work instructions;
- Defining quality objectives and requirements (tolerances, surface finish, workmanship standards, etc.) for the product or service;
- Developing the capabilities, training, qualifications, procedures and work instructions necessary to execute the requirements to ensure product compliance to contract/customer requirements;

Internal Audit (Clause 9.2)

- The internal audit process is part of the continual improvement feedback loop to evaluate and improve the effectiveness of the management system. It also highlights where processes and procedures are not addressing risks adequately and where changes are needed to improve efficiency or effectiveness.

Internal Audit (Clause 9.2)

- The internal audit process should include the following activities:
- The development of a programme of internal audits which can be revised depending on the results of previous audits and the results of performance monitoring;
- The identification, selection and training of internal auditors;
- The analysis and evaluation of the results of internal audits;
- The identification of the need for corrective or improvement measures;
- The verification of the completion and effectiveness of these measures;
- The documentation pertaining to the execution and results of audits;
- The communication of the results of audits to the top management.

Management Review (Clause 9.3)

- Top management must periodically review the management system to ensure its continuing suitability, adequacy, and effectiveness. The frequency or intervals of the Top management's formal review must be defined.
- As per Clause 5.1 *(Leadership and commitment)* of the standards, it is important that a member of Top management chairs the management review meetings. It is imperative that everyone involved with the management review process fully understand and appreciate the management review requirements from Clause 9.3.
- Other attendees at management review meetings should include functional management, line management, process owners, process champions, lead process users, and action owners within the scope of the quality management system, as appropriate, and the internal auditor(s) should also attend.

Quality management review inputs

- This now includes additional requirements for your organization to have a structured management review process that includes discussion of internal and external issue changes, and its potential effect on the strategic direction of your organization. The management review process should focus on the following inputs:
- Status of follow-up actions (open/closed) from the previous management review
- Changes in internal and external issues (Clause 4.1 & Clause 4.2);
- Customer feedback (Clause 9.1.2);
- Performance indicators and objectives (Clause 6.2);

- Process performance and product conformity (Clause 8.1);
- Non-conformities and corrective actions (Clause 10.2)
- Monitoring measuring results (Clause 9.2);
- Results of audits and inspections (Clause 9.1);
- External providers (Clause 8.4);
- Resources (Clause 7.1);
- Risk and opportunities (Clause 6.1);
- Opportunities for improvement (Clause 10.1);
- Changes affecting the QMS (Clause 6.3);
- Review of QMS policy & Objectives (Clause 5.2);
- Review of action items.

Management Review outputs

- Management review results should be summarized, specifying management commitments, directives and action items. Action items should specify responsible individuals and target completion dates. Affected individuals include those impacted by or responsible for addressing findings. You should seek and record evidence of outputs from the management review process, there should be evidence of decisions regarding:

- Process improvement actions;
- Management system improvement actions;
- Product and service improvement actions;
- Resource provision actions;
- Revised business plans and budgets;
- Revised objectives and KPIs/SPIs;
- Amendments to policies;
- Management meeting minutes.

Continual Improvement (Clause 10)

- ISO 9001:2015 Clause 10 Improvement describes the requirements for continual improvement in the quality management system by identifying nonconformities and taking corrective actions to recur the nonconformity by eliminating the root cause of the non-conformance.

THANK YOU