The quickest way to understand and implement International Standards

iguru Store

White Paper of
Quality Management System

ISO 9001:2015

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ABSTRACT

White Paper of 'Document Kit of ISO 9001:2015' has been established by iguru store for the users to understand its values through benefits and expected recourses to be utilized by the organization.
The ISO 9001:2015 standard is one of the most widely known standard for quality management system to achieve customer satisfaction as outcome, is implemented by over 850,000 organizations in 163 countries.

The ISO 9001 standard has become an international reference of Quality Management requirements in business-to-business relationships.

ISO 9001 helps organizations of any type and size with "Quality Management System" including:

- Fulfilling interested parties' quality requirements
- Following applicable regulatory requirements
- Enhancement of PDCA cycle
- Achieving improvement through risk based strategy
- Reduce the cost of nonconformities

The standard has earned a worldwide reputation known as the "Quality Management System Standard", which can be applied to any organization, large or small, whatever its business, products or services.

"Management system" refers to the organization's structure for managing its processes or business activities.

This structure transforms input of resources into a product or service that meets the organization's business objectives, satisfies the customer's quality requirements and complies with regulations.

ISO 9001 provides a framework of requirements for management to address customer focus, process the management approach, and pursue continual performance improvement.

The aim of iguru is to ensure the availability of resources to the user form the apart of professional documentation for intended use of any management system that is required during internal and external/ certification audits.

Those kits can also be used for second party/ customer audit requirements reference to the proper use of guidelines. Refer to 'Kit of Implementation'.

WHAT IS THE CHANGE

STRUCTURE

ISO 9001:2015 will be based on Annex L – a high level structure (HLS) that brings a common framework to all ISO management systems. This helps to keep consistency, align different management system standards, offer matching sub-clauses against the top-level structure and apply common language across all standards.

AUDITABLE CLAUSES

4- Context of Organization

5- Leadership

6- Planning

7- Support

8- Operation

9- Performance Evaluation

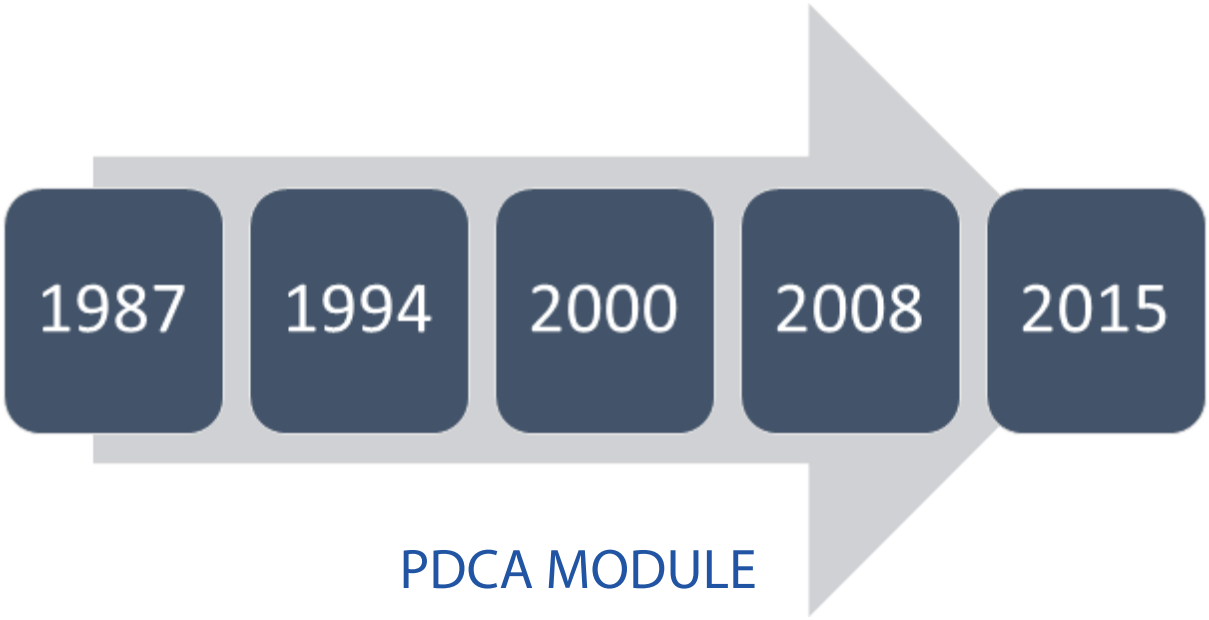
10- Improvement

DOCUMENTED INFORMATION

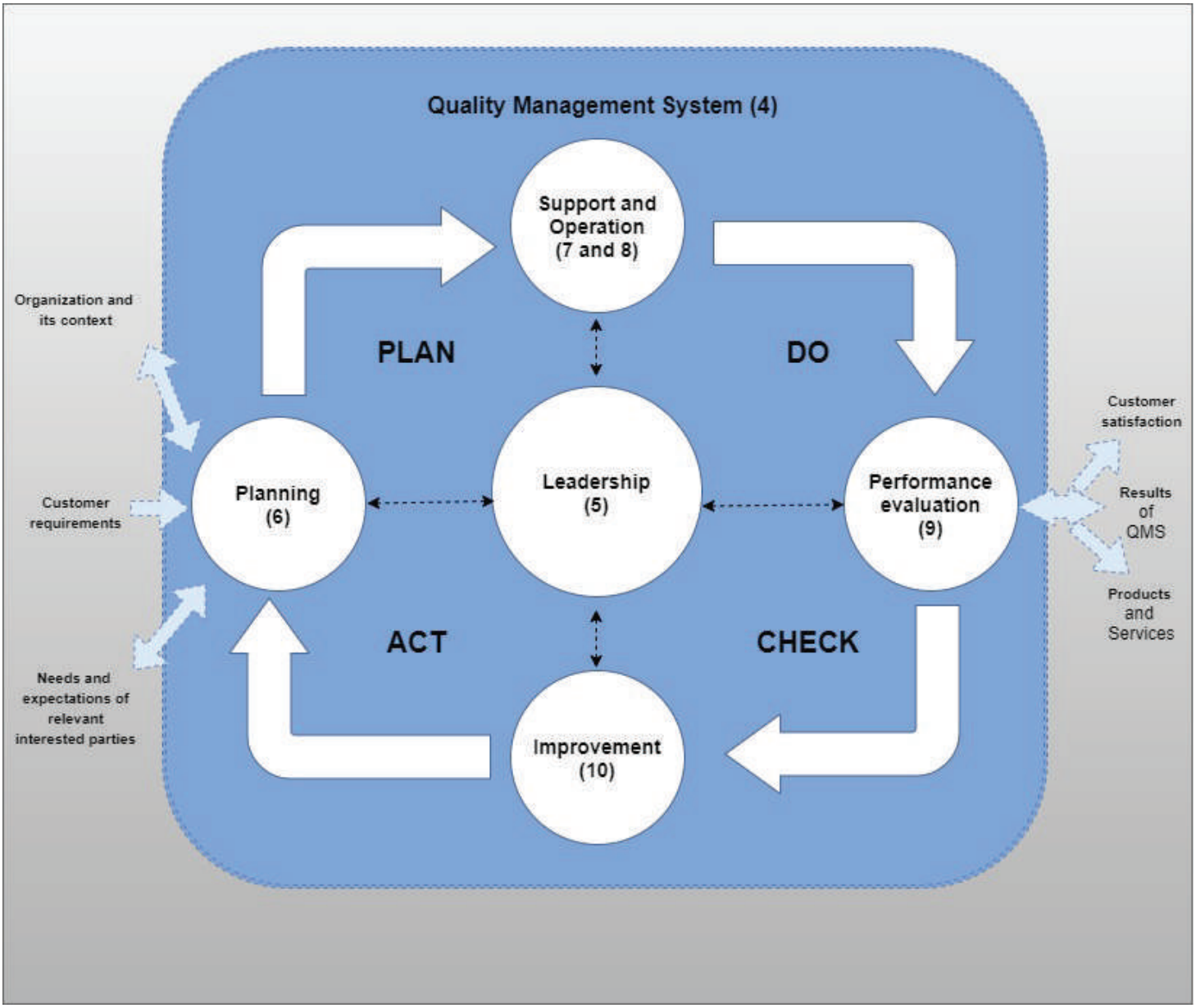
As part of the alignment with other management system standards a common clause on 'Documented Information' has been adopted. The terms "documented procedure" and "record" have both been replaced throughout the requirements text by "documented information". Where ISO 9001:2008 would have referred to documented procedures (e.g. to define, control or support a process) this is now expressed as a requirement to maintain documented information.

20 Requirements of Documented Information

- 4.4. Documented information to the extent necessary to have confidence that the processes are being carried out as planned.
- 7.1.5.1. Evidence of the basis used for calibration of the monitoring and measurement resources (when no international or national standards exist) (clause 7.1.5.2).
- 7.2. Evidence of competence of person(s) doing work under the control of the organization that affects the performance and effectiveness of the QMS.
- 8.2.3. Results of the review and new requirements for the products and services.
- 8.3.2. Records needed to demonstrate that design and development requirements have been met.
- 8.3.3. Records on design and development inputs.
- 8.3.4. Records of the activities of design and development controls.
- 8.3.5. Records of design and development outputs.
- 8.3.6. Design and development changes, including the results of the review and the authorization of the changes and necessary actions.
- 8.4.1. Records of the evaluation, selection, monitoring of performance and re-evaluation of external providers and any and actions arising from these activities.
- 8.5.2. Evidence of the unique identification of the outputs when traceability is a requirement.
- 8.5.3. Records of the property of the customer or external provider that is lost, damaged or otherwise found to be unsuitable for use and of its communication to the owner.
- 8.5.6. Results of the review of changes for production or service provision, the persons authorizing the change, and necessary actions taken.
- 8.6. Records of the authorized release of products and services for delivery to the customer including acceptance criteria and traceability to the authorizing person(s).
- 8.7. Records of nonconformities, the actions taken, concessions obtained and the identification of the authority deciding the action in respect of the nonconformity.
- 9.1.1. Results of the evaluation of the performance and the effectiveness of the QMS.
- 9.2.2. Evidence of the implementation of the audit program and the audit results.
- 9.3.3. Evidence of the results of management reviews.
- 10.2.2. Evidence of the nature of the nonconformities and any subsequent actions taken.
- 10.2.2. Results of any corrective action.


1987
1994
2000
2008
2015

PDCA MODULE


Quality Management System (4)
Support and Operation (7 and 8)
PLAN
DO
Organization and its context
Customer requirements
Needs and expectations of relevant interested parties
Planning (6)
Leadership (5)
Performance evaluation (9)
Customer satisfaction
Results of QMS
Products and Services
ACT
CHECK
Improvement (10)

ANNEX-L

A new high level structure for all management standards

Annex-L, is a type of structure that was introduced by ISO technical committee to eliminate the gap among all its management standards. This provides the framework of 'common structure' with similar use of terms, definitions, clause patterns and easy integration of standards for organization at the same
time.

The common structure of standard requirements:

Clause 1: Scope
Clause 2: Normative references
Clause 3: Terms and definitions
Clause 4: Context of the organization
Clause 5: Leadership
Clause 6: Planning
Clause 7: Support
Clause 8: Operation
Clause 9: Performance evaluation
Clause 10: Improvement

TRANSITION TIME LINE

September 2018, is the deadline for the transition. Transition should be executed timely to those who are already on ver 2008. After September 2018 no organization shall be eligible to continue ISO 9001:2008 version at all. The timely transition shall secure your continuation of certification and involvement of people to understand the new standard for the continuation of quality management system with spirit of confidence.

The quick contact to igurustore shall be in benefit to introduce your organization for true means of ver. 2015 with effective implementation. igurustore is passionate to deliver for the change and integration with similar standards.

BENEFITS OF ISO 9001:2015

- Using this standard significant growth will be observed in Profit, Cost cutting, Risk reductions, less rejections, less nonconformities and less customer complaints.
- Achieve consistency of product and service quality and compliance with legal and associated requirements of interested parties.
- Formalize good working practices through better planning.
- Assure satisfaction and added value to interested parties and feature of existing services.
- Introducing Risk based thinking approach as preventive action and to promote 'Proactive Approach'.
- Understanding and monitoring needs and expectations of interested parties.
- Be internationally recognized as a well-managed organization and business holder for quality management system.
- To increase the promotion of product and services through this standard's tools.
- Employee know what to do and how to execute.
- Better management controls through quality team.
- Monitoring of quality assured working environment.
- Increase credibility among business associates.
- Be confident through internal auditing, organizational knowledge and management reviews.
- Successful achievement of goals thorugh encouraging the continual improvement.

PRINCIPLES OF QMS

- *Principle 1 – Focus on customer and interested parties*
- *Principle 2 – Provide leadership for your organization*
- *Principle 3 – Engage and involve your people*
- *Principle 4 – Use a process approach*
- *Principle 5 – Encourage improvement*
- *Principle 6 – Use evidence to make decisions*
- *Principle 7 – Manage your corporate relationships*

igurustore ensures to provide the essence of all the core principles of ISO 9001:2015. Previously obsoleting the eight principles by intorducing seven principles to adopt QMS standard for any kind of industries, working sector, volume and irgnomics.

CONTEXT OF ORGANIZATION

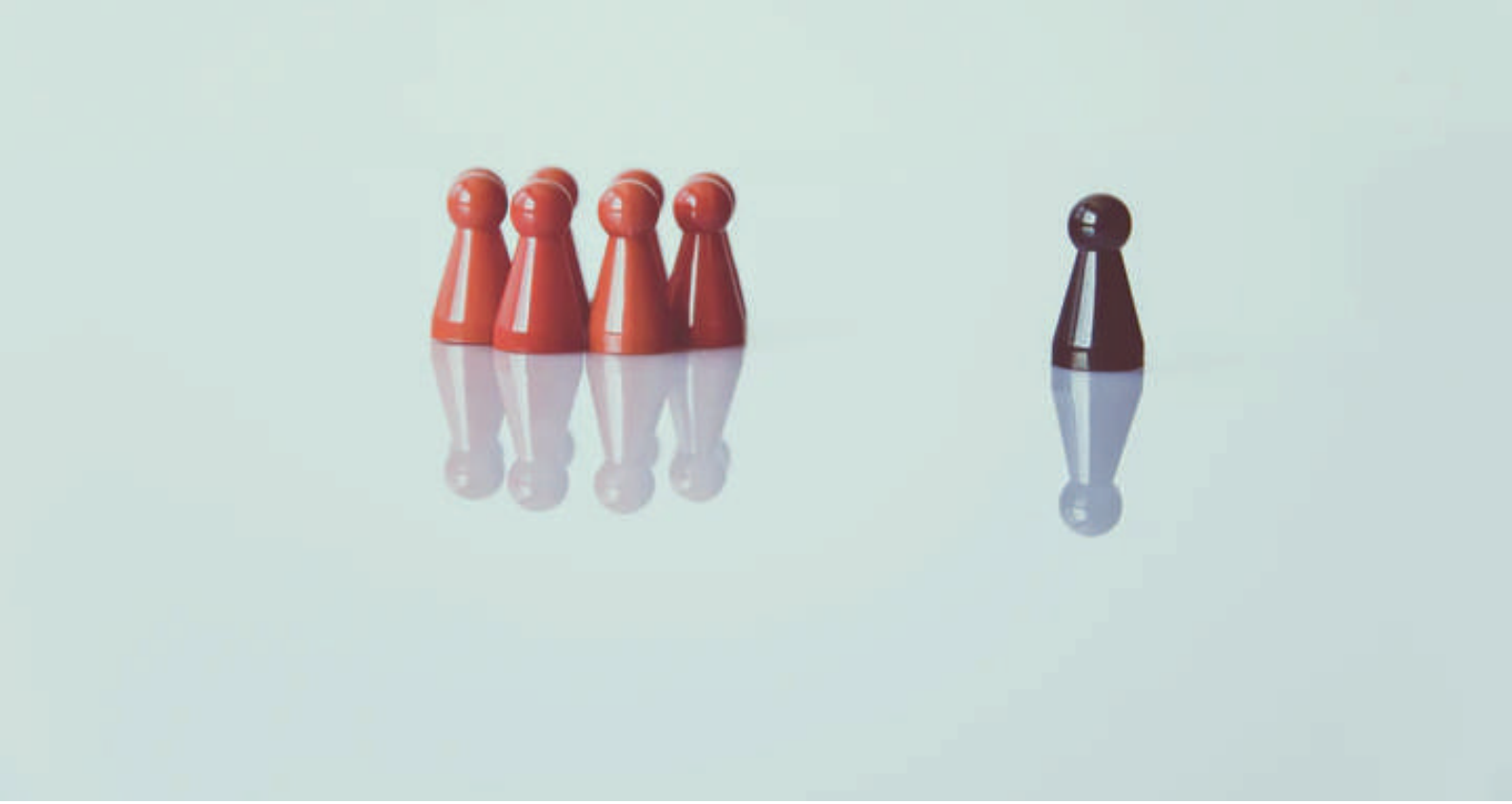
Quality Management System has its new requirements following the newest version 2015 of Annex L (HLS) which describes the requirement for the organization to establish a mechanism to describe its context of the organization with respect to the business processes including products, associated services or pure serivces are being delivered.

Context of the organization raises the opportunity for the organization to understand its internal and external environment refers to the business process and strategies in the context of “Customer Satisfaction”.

Business scope is the second vital element of this clause where the organization has to highlights the limitations of the business process and their associated risks. i.e. processes, locations, remote access, online access, supply chain location.

Monitoring the needs and expectation of interested parties to ensure the conformity of QMS at all level to avoid any noncompliances with regards of “Legal, stakeholders requirements (Shareholders, employee, suppliers, contractors, competitors).

- ***Understanding the organization and its context***
- ***Understading the needs and expectation of interested parties***
- ***Determining the scope of quality management system***
- ***Quality management system and its processes***



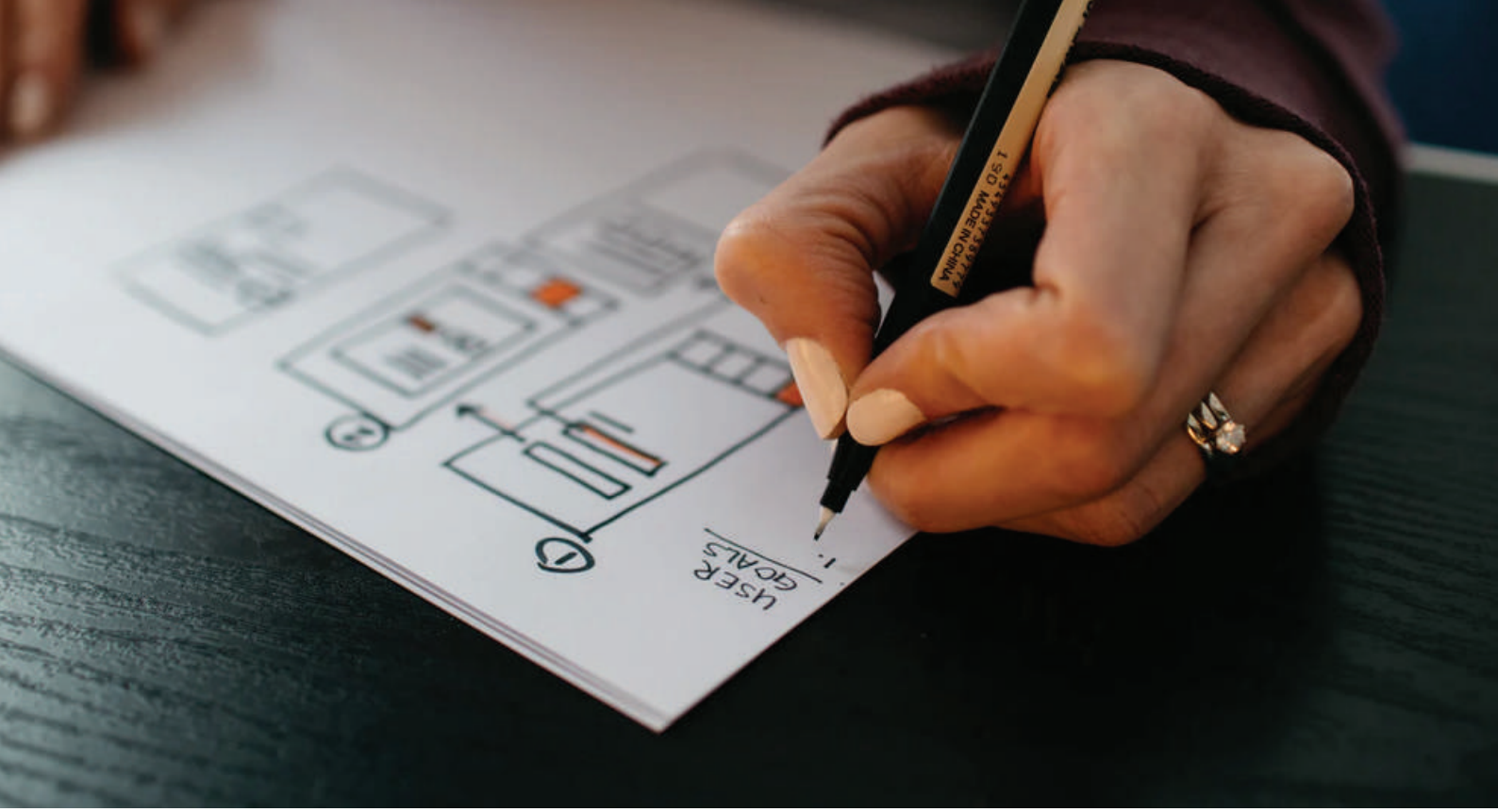
LEADERSHIP

In any organization leadership plays a vital role that creates opportunities for the growth of the organization and its interested parties. Therefore, QMS standard requires from organizations to establish a mechanism to demonstrate a working environment in the support of policy making, identifying the roles and responsibilities to the right persons for the right job and flourish the working environment of QMS conformity.

Introducing a road map for employee to direct them to achieve the goals of QMS compliances by identifying the PDCA model, creating roles and assigning them responsibilities and authorities.

Establishing the policy as a comprehensive statement to deliver the central idea of the organization for the QMS.

- ***Leadership and commitment***
- ***Quality policy***
- ***Organization roles, responsibilities and authroties***



PLANNING

In this part of the QMS standard, the organization must consider its planning using 'Proactive Approach'. A risk-based thinking strategy. i.e. designing the methodology for the mitigation of internal and external negative and positive risks associated to the business processes for both product and services.

Setting QMS objectives to achieve those mitigation actions or new milestone to achieve the goal of QMS compliances. Through the help of measurable objectives organization can identify and achieve its milestones. i.e. customer satisfaction, time delivery, quality assurance, reduce rejections.

- ***Actions to address risks and opportunities***
- ***QMS objectives and planning to achieve them***

SUPPORT

The successful implementation requires support activities that consist of resources, competent people of the organization, periodically well aware of the issues, communication channels, and documented information to maintain the records.

This organization must assign a team of skilled employee to ensure the execution of support activities.

- ***Resources***
- ***Competence***
- ***Awareness***
- ***Communication***
- ***Documented information***

OPERATION

It is the only sub-clause with coverage of many requirements including operational planning, customer communication and understanding of customer requirements, design and development production provisions, identification and traceability, nonconforming outcome etc.

All the operational activities including sales, procurement, research & development, production (manufacturing or packing), quality control , labs, distribution, services or post delivery come under this sub-clause.

Organization must follow the given sub-clauses of “Operation” to meet the requirements of QMS conformity. These requirements are mandatory for all the scopes of business irrespective of product, services, the volume, size and location of the organization.

- ***Operational planning and control***
- ***Requirements for products and services***
- ***Design and development of products and services***
- ***Control of externally provided processes, products and services***
- ***Production and services provision***
- ***Release of products and services***
- ***Control of nonconforming outputs***

PERFORMANCE EVALUATION

Measuring the performance of quality management system - customer satisfaction, monitoring of external providers (suppliers), risk and opportunities identified by the organization using data, statistical analysis with the help of softwares.

To monitor overall QMS performance, an "Internal Audit" is a mandatory requirement to be met by the organization by following the documented and systematic procedure through competent and skilled auditor to get the realistic outcomes of the audit.

Management reviews to sum up the overall performance in the form of reviews in the presence of top management or leadership to investigate the matters intensely making new decisions, objectives, and through change management changing the risks treatments.

- ***Monitoring, measurement, analysis, and evaluation***
- ***Internal Audit***
- ***Management Review***

CONTINUAL IMPROVEMENT

During the execution of operational activities, QMS must face deviations against its plan, which is called non conformance, that must be resolved by this improvement clause, taking into consideration correction and corrective actions.

Encourage continual improvement to enhance quality management system by by following the polices, SOP's, safe working instructions and risk assessment control plan.

- ***General***
- ***Nonconformity and corrective action***
- ***Continual improvements***

Document Kit | Internal Audit Kit | Online Consultation

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iguru ISO 9001:2015

iguru ISO 14001:2015

iguru ISO 45001:2018

iguru ISO 50001:2018

iguru ISO 27001:2013

iguru cGMP

iguru ISO 22000:2018

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