FOCUS ON QUALITY.

Exploring the Benefits and Structure of an ISO 9001 Quality Management System

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What is ISO 9001:2015

ISO - The International Standard Organization is an independent, non-governmental organization developer of voluntary international standards. More than twenty thousand standards have been set, covering everything from manufactured products and technology to food safety, agriculture, and healthcare.

ISO 9001:2015 - Is the international standard specifying requirements for quality management systems and is the most prominent approach to quality management systems.

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What is a Quality Management System (QMS)?

Broadly, a quality management system…
- *Organizes and improves the efficiency of processes*
- *Delivers customer satisfaction*
- *Controls quality of product and service*
- *Guarantees of uniformity of product and services across borders, languages, and cultures*

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What a Quality Management System is *NOT*

- *Just extra paperwork*
- *Make a form for everything*
    - *2008 – 39 required documents*
    - *2015 – 18 required documents*
- *Only product quality*
- *Only for the quality department*

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How does it benefit Manufacturers?

Quality management systems serve many purposes, including:

- *Improving processes*
- *Improving communications*
- *Reducing waste*
- *Lowering costs*
- *Facilitating and identifying training opportunities*
- *Engaging staff*
- *Setting organization-wide direction*

Source: www.asq.org

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ISO 9001 Structure

No 1 person/process is responsible for ALL ISO clauses
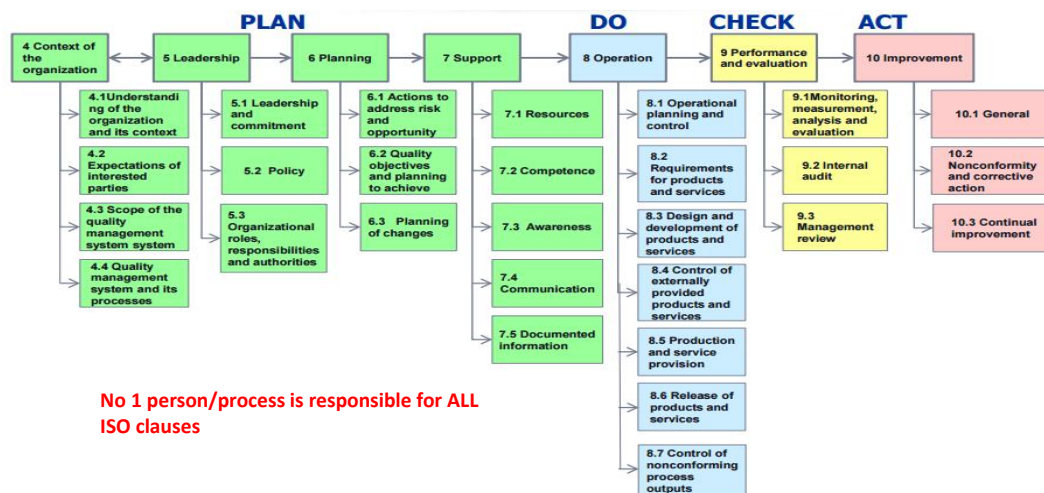
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Key Terminology within the QMS

Shall: **An organization needs evidence to prove they are following the ISO Standards**

Objective: **result to be achieved**

Organization: **Person or group of people that has its own functions with responsibilities, authorizations and relationships to achieve objectives**

Contents of the Organization (COTO): **combination of internal and external issues that can have an effect on an organization's approach to developing and achieving its objectives**

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Key Terminology within the QMS

Interested Party: **Person or organization that can affect, be affected by, or perceive itself to be affected by a decision of activity**

Top Management: **person or group of people who directs and controls an organization at the highest level.**

Risk-based thinking: **Organizations to evaluate risk when establishing processes, controls and improvements within the QMS**

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4 - Context of the Organization

Understanding the Organization –The organization must identify issues that are relevant to its purpose and strategic direction . The organization also must monitor the review information regarding issues, both internal and external

Needs and expectations of Interested Parties- Organization must determine relevant interested parties to the QMS (not just customers)

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4 - Context of the Organization

Scope – Organization identifies the limits and applicability of its QMS to establish its scope

Processes- Organizations implements, maintains and continually improves the QMS, including all the processes needed and their interactions. Documented information is maintained to support processes are being executed as planned
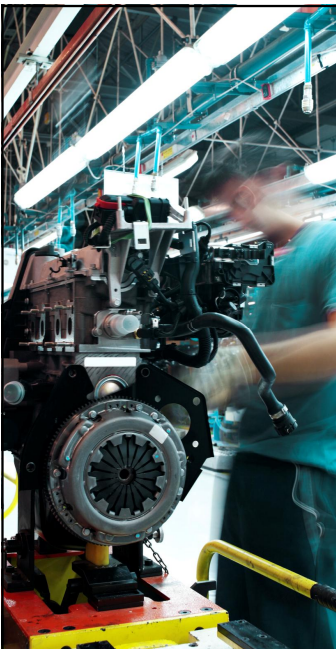
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5 - Leadership

Focus on Top Management's role regarding the QMS

Top Management- accountable for QMS effectiveness including needed resources, communication of importance and promoting improvement

Customer Focus- Top Management ensures customer applicable requirements are determined, understood and consistently met

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5 - Leadership

Quality Policy – Organization must establish a Quality Policy. The Quality Policy must be appropriate to the context of the organization, provide a framework for quality objectives and include statements on commitment to satisfy requirements and continual improvement of the QMS.

Roles and Responsibilities – Top Management ensures responsibilities and authorities are assigned, communicated and understood within the organization to ensure the QMS is effective

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6 - Planning

Risks & Opportunities- The Organization shall determine the risks and opportunities regarding the identified internal, external and interested parties.

Track on the COTO and discuss and document in the Management Review meeting

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6 - Planning

Quality Objectives- Organization will plan how to meet its Quality Objectives including:

-What will be done

-What Resources Required

-Who will be responsible

-when will it be completed

-How to evaluate the results

OBJECTIVES MUST BE MEASURABLE

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6 - Planning

Planning of Changes –Changes needed by the organization are carried out in a planned and systematic manner and will consider all risks and opportunities with the Context of the Organization

When considering changes, organization must include:

-Purpose of changes and their potential consequences

-Integrity of the QMS

-Availability of resources

-Allocation/reallocation of responsibilities and

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7 - Support

Resources (Do we have what we need to operate our QMS?)

- *People*
- *Infrastructure*
- *Environment*
- *Monitoring & Measuring Devices*

Competence

- *Who needs to be competent on what?*
- *How do we determine competence?*
- *Is competence documented?*

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7 - Support

Awareness

- **Are employees aware of the Quality Policy and relevant Quality Objectives?**

Communication

- **How do we handle internal and external communications?**

Documented Information

- **Creating/Updating/Approving Documents**
- **Controlling documentation**
- **Authority levels**

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8 - Operation

Operational Planning

Plan, Implement & Control processes to meet requirements

Criteria
- **Processes**
- **Acceptance of Products/Services**

Product/Service Requirements
- **How do we capture requirements?**

Design
- **Planning**
- **Inputs**
- **Controls**
- **Outputs**
- **Changes**

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8 - Operation

Control of Externally Provided Products/Services

- *Ensuring outsourced process, product & services meet requirements.*
- *Establishing criteria to evaluate, select & monitor performance.*

Production and Service Provision

- *Control*
- *ID/Traceability*
- *Customer/External Provider Property*
- *Preservation*
- *Post Delivery Activities*

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8 - Operation

Release of Products/Services

- *How do we know we are meeting requirements?*
  - *Release Authority?*
  - *Documentation of Release*

Control of Nonconforming Products/Services

- *What do we do when products/services don't meet requirements?*
  - *Correction (Rework/Repair)*
    - *Conformity to requirements shall be verified when nonconforming outputs are corrected.*
  - *Concession*
- *Documentation of Nonconformance*

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9 - Performance Evaluation

Monitoring, Measurement, Analysis & Evaluation

- ***Evaluation of the QMS performance and effectiveness.***

Customer Satisfaction

- ***How do we capture customer satisfaction?***
- ***What are we doing to enhance satisfaction?***

Internal Audit

- ***Plan, establish, implement and maintain an internal audit program***
- ***Who (competence)***
- ***When***

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Management Review

Inputs

- ***Actions from previous MRM***
- ***Changes to Internal/External Issues***
- ***Customer Satisfaction***
- ***Quality Objectives***
- ***Process Performance***
- ***Corrective Actions***
- ***Monitoring/Measuring Results***
- ***Audit Results***
- ***Performance of External Providers***
- ***Adequacy of Resources***
- ***Risk Management Effectiveness***
- ***Opportunities for Improvement***

Outputs

- **Opportunities for Improvement**
- **Changes to the QMS**
- **Resource needs**

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10 - Improvement

Corrective Action
- *When things go wrong, how do we handle it?*
- *Systematic approach?*

Continual Improvement
- *How do we capture improvement opportunities?*
- *Systematic approach?*

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QMS Structure

Level 1   Quality Manual   Less Detail
- *Policies/Intentions; Ref Doc*

Level 2   Process ID / Map
- *What, Why*

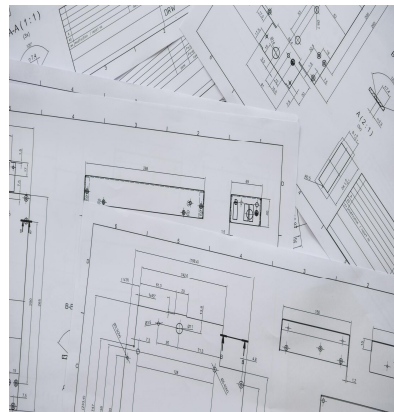*Level 3 Procedures*
- *Who, When, Where*
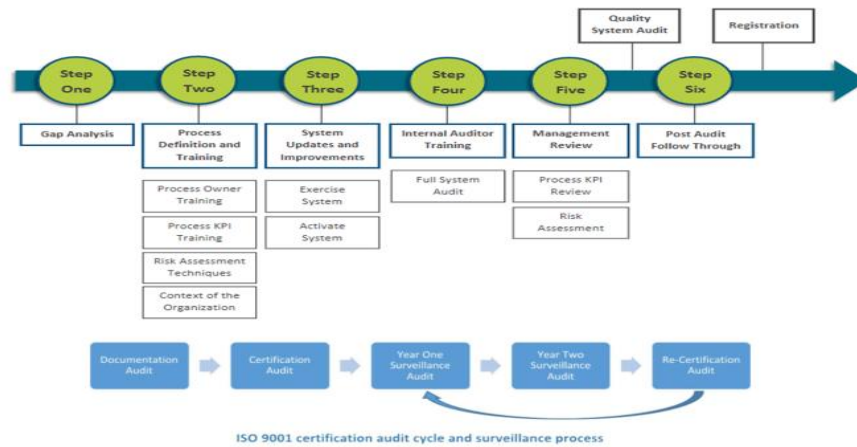
Level 4 Work Instructions
- *How*

Level 5 Forms / Records   More Detail
- *Evidence*

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ISO 9001 Implementation & Certification Process

Step One	Step Two	Step Three	Step Four	Step Five	Step Six
Gap Analysis	Process Definition and Training	System Updates and Improvements	Internal Auditor Training	Management Review	Post Audit Follow Through
	Process Owner Training	Exercise System	Full System Audit	Process KPI Review	
	Process KPI Training	Activate System		Risk Assessment	
	Risk Assessment Techniques				
	Context of the Organization				

Quality System Audit   Registration

Documentation Audit → Certification Audit → Year One Surveillance Audit → Year Two Surveillance Audit → Re-Certification Audit

ISO 9001 certification audit cycle and surveillance process

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Questions?

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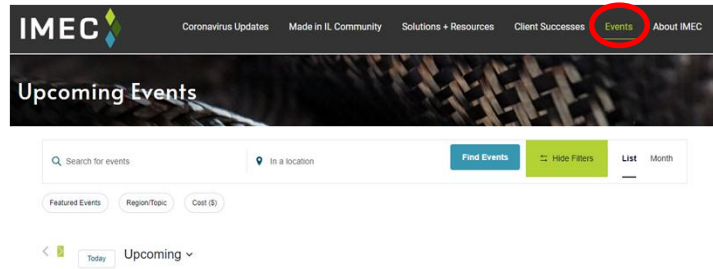
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Thank You!

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