



QUALITY MANAGEMENT & ISO 9001 STANDARD

AIM SINGLE ECAR QMS – 14TH MARCH, 2016 (ANTIGUA)



Definition of Key Terms

Term	Meaning
Quality	Conformance to requirements
Quality Control (QC)	<p>‘A part of quality management focused on fulfilling quality requirements’ A corrective tool focused on the quality of output. Example: Validation/software testing, inspection, peer reviews.</p>
Quality Assurance (QA)	<p>A part of quality management focused on providing confidence that quality requirements will be fulfilled’ A managerial tool focused on the process of quality Example: Verification activities, process checklists, project audits and methodology and standards development.</p>

Definition of Key Terms

Term	Meaning
Quality Management	Management activities and functions involved in determination of quality policy and its implementation through means such as quality planning, quality assurance and quality control)
Quality Management System	A system comprised of quality planning and quality improvement activities, the establishment of a set of quality policies and objectives that will act as guidelines within an organization, and QA and QC.
Process	Any activity or set of activities that uses resources to transform inputs into outputs

Definition of Key Terms

Term	Meaning
Procedure	An outline of how to perform a process e.g. 'Purchasing'
Work Instruction	Description of how to perform a task which is a more detailed portion of the procedure e.g. 'Completing a PO'

Quality Management vs Quality Assurance vs Quality Control



QUALITY MANAGEMENT PRINCIPLES

The following Quality Management Principles apply to the broader sphere of Business Management which underlies the ISO 9000 series of Quality Assurance Standards:

- Customer focus
- Leadership
- Involvement of people
- Process approach
- Systems approach to management
- Continual Improvement
- Factual Approach to decision-making
- Mutually beneficial supplier relationships

See the [following document](#) for explanation of the principles.

The ISO 9001 Standard is based on these principles



ISO 9001:2008 AWARENESS PRESENTATION



ISO 9001:2008 is a Business Management System.

ISO 9001:2008 AWARENESS PRESENTATION



BUSINESS MANAGEMENT SYSTEMS

Management Systems means what an organization does to manage its processes or activities in order to:

- Ensure its products or services meet the organization's objectives
- Satisfy customers' requirements
- Comply with regulations
- Enhance customer satisfaction
- Achieve continual improvement of its performance

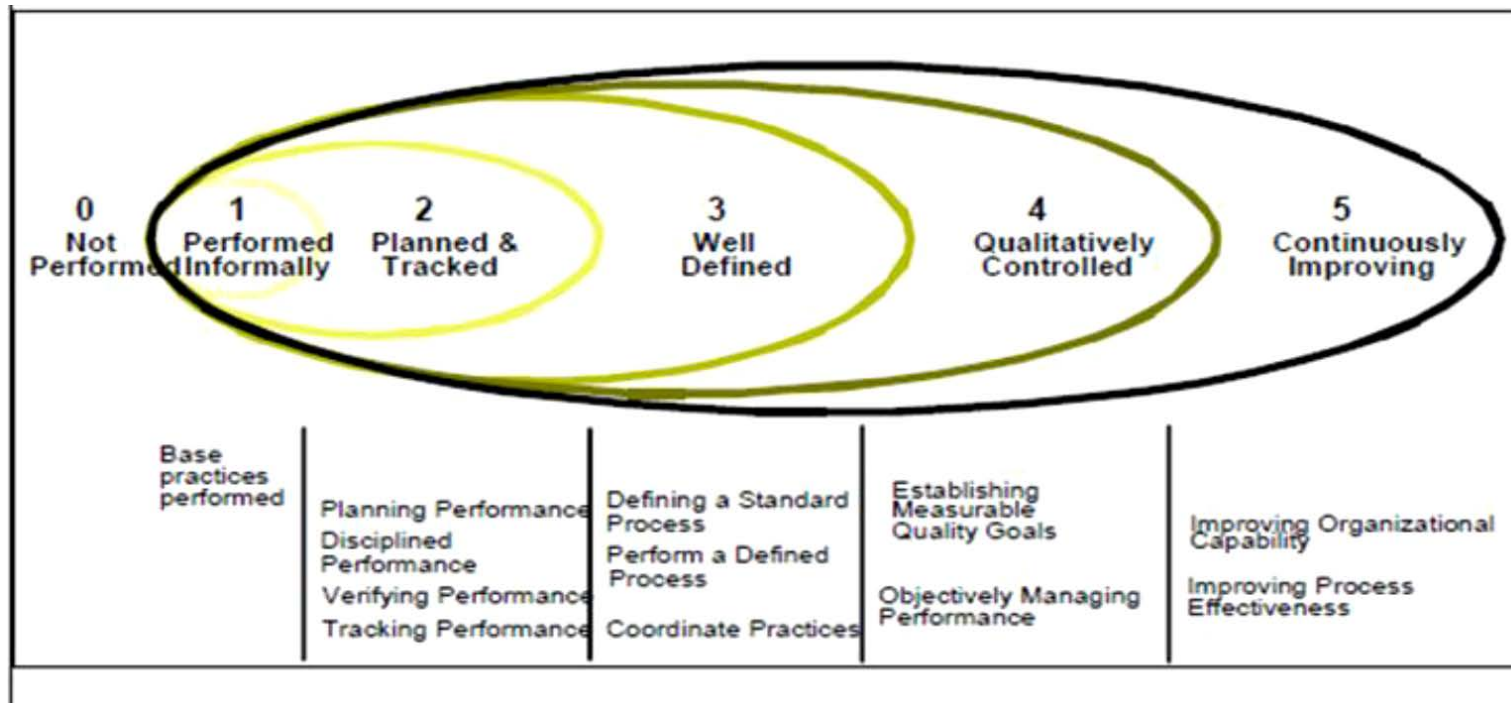
BUSINESS MANAGEMENT SYSTEMS

- Formal management systems instill process ownership which drives excellence.
- Companies in the field of aerospace, automotive and defense have been operating management systems all based on the ISO 9001 Standard for years.
- The ISO 9001 management system standard makes these successful practices available for all organizations large and small.



BUSINESS MANAGEMENT SYSTEMS

As your management system matures, effective use of the PDCA cycle will ensure continual improvement.



WHAT IS THE ISO 9000 SERIES?

A set of generic, internationally recognized standards for quality management.

*They are used by both manufacturing
and service industries*

ISO **9001:2008** is the only standard in the series that specifies the **requirements** of a quality management system.

ISO 9001 FAMILY OF STANDARDS

- a) ISO 9001:2008 Quality Management Systems – Requirements
- b) ISO 9000:2005 Fundamentals and vocabulary
- c) ISO 19011:2011 Guidelines for auditing management systems
- d) ISO 9004:2009 Managing for the sustained success of an organization — A quality management approach

Only ISO 9001:2008 is auditable. The rest serve as references only.

WHAT IS ISO 9001?

- It is a quality management model that can be adopted by any kind of organization
- The system is focused towards the meeting of customer requirements and enhancing of customer satisfaction

Keywords:

1. Quality
2. Management system
3. Customer requirements
4. Customer satisfaction



WHAT IS ISO 9001:2008 QMS - REQUIREMENTS?

- Quality : degree to which customer requirements have been met
- Management : coordinated activities to direct and control an organization
- System : set of interrelated or interacting elements
- Quality management system : a system to direct and control an organization with regard to quality
- Requirements : a set of management parameters for your QMS



THE ISO 9001:2008 STANDARD

The ISO 9001 Standard is modelled for Quality Management with 5 major clauses:

4.0 Quality Management System

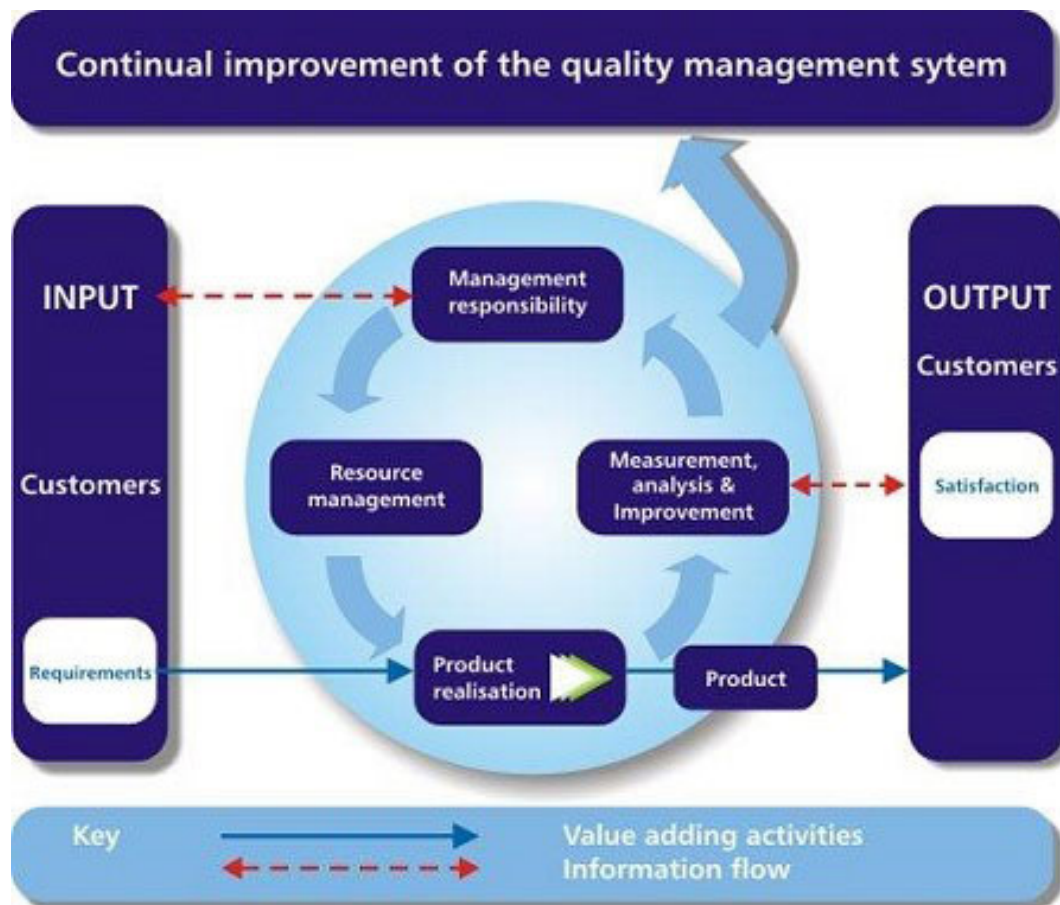
5.0 Management Responsibility

6.0 Resource Management

7.0 Product Realization

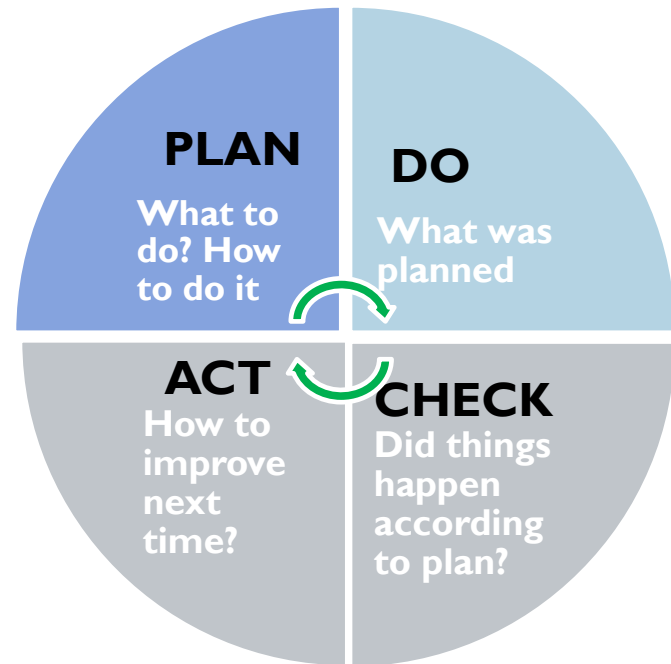
8.0 Measurement, Analysis &
Improvement

THE PROCESS MODEL



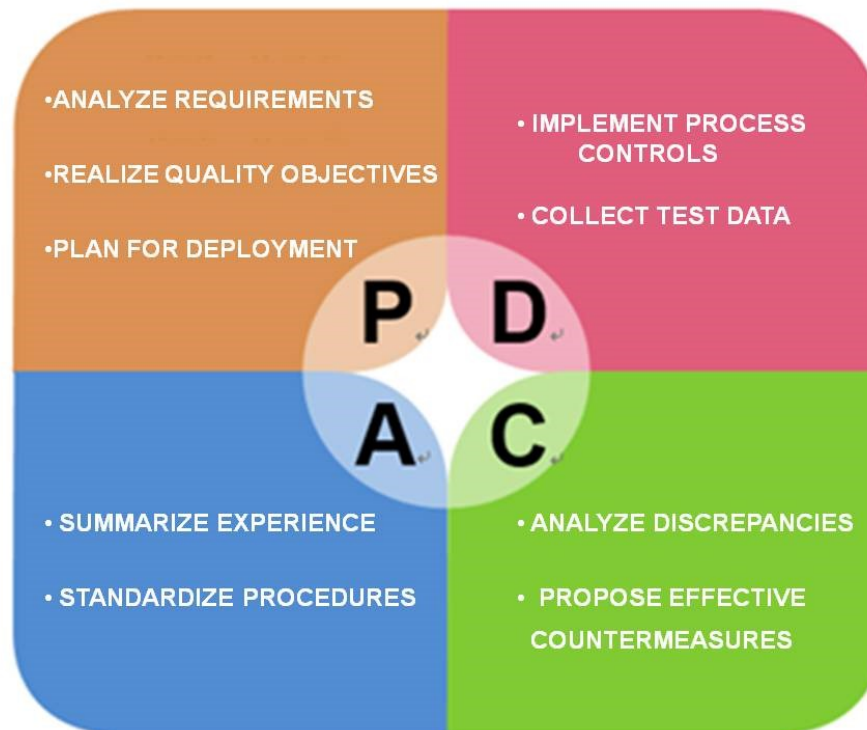
THE SYSTEM APPROACH

- Quality must be managed by a system to be effective
- This system is done for you, as represented by the ISO 9001:2008 standard
- A system is a set of interrelated or interacting elements
- The System Approach is described in Clause 4.1
- The description of Clause 4.1 matches the PDCA approach to process management - Plan, Do, Check, Act



THE PDCA CONTINUAL IMPROVEMENT CYCLE

The ISO 9001:2008 Standard is based on the PDCA (Deming) Cycle often referred to as the 'cycle of continual improvement'.



THE SYSTEM AND PROCESS APPROACH

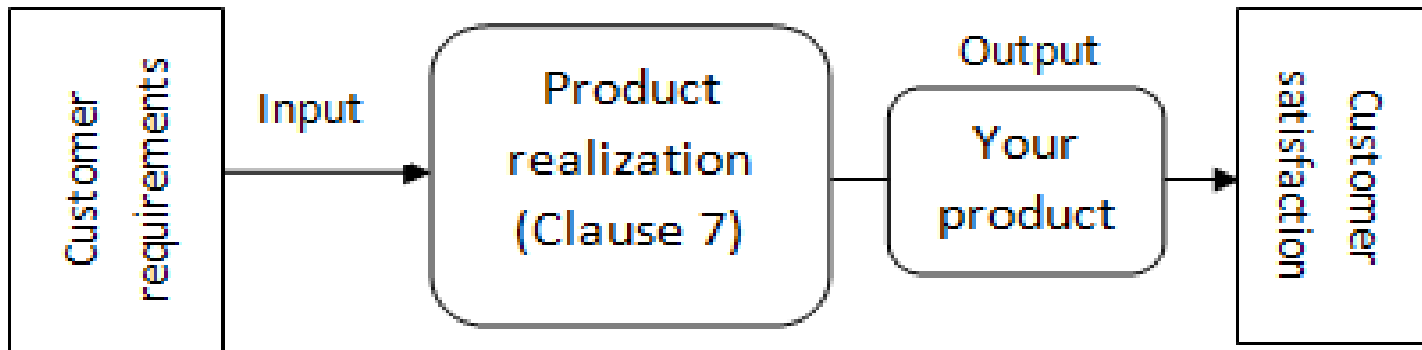
- Quality must be managed by a system.
- The system must be managed using the process approach because the system is made up of processes.
- These processes are linked to each other.
- A process has inputs , resources, activities, outputs and customers. Manage them all.

ISO LINGO



- Product = Any output- physical product or services
- Output = product
- Product = result of a process
- Process = a set of inter-relating activities focused towards producing the output
- Input = requirements

PROCESS APPROACH



Can be applied to
any other process
that you manage

Input

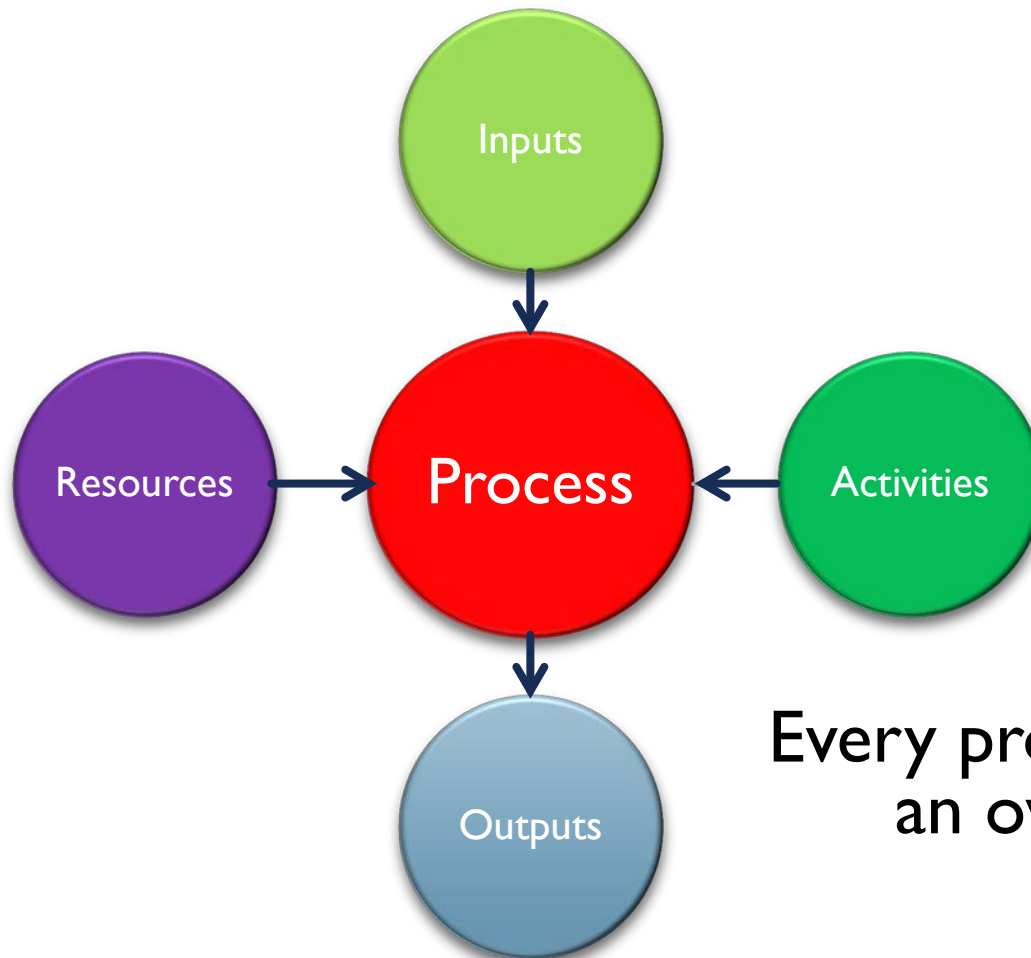
Your process

Output

PROCESS APPROACH

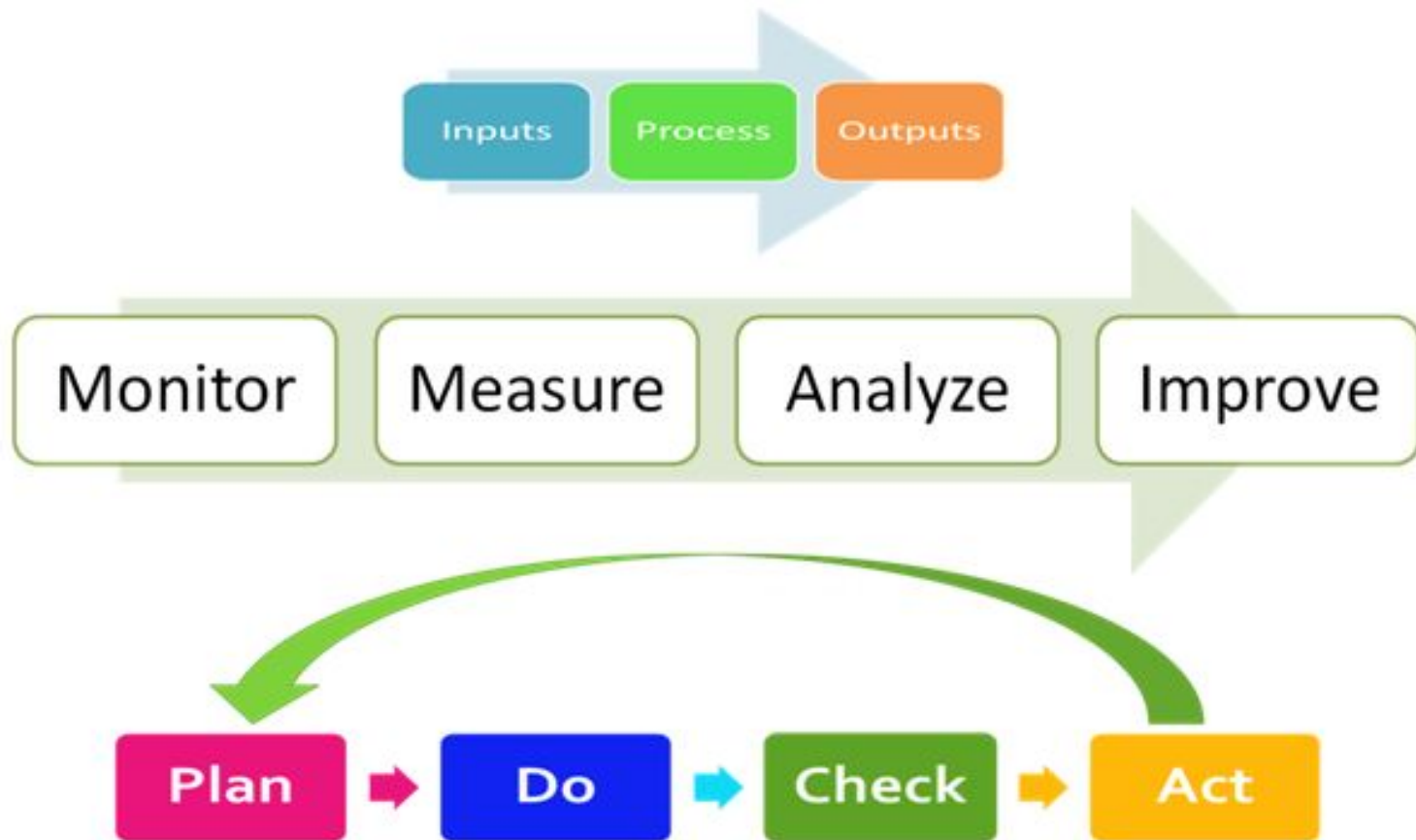
- Every process require specific inputs, resources, activities, outputs and customers
- What you can do now is:
 - Define and document the inputs
 - Define and document the kinds of resources that your processes use
 - Define and document the activities and their interactions
 - Define and document the responsibilities
 - Define and document the outputs
- You can name this document as Department Control Plan
- Then execute this plan, and monitor, measure, analyze and improve its performance using Key Performance Indicators (KPIs)
- Thus, Plan – Do - Check – Act (Dr.W. Edwards Deming)

ANATOMY OF A PROCESS

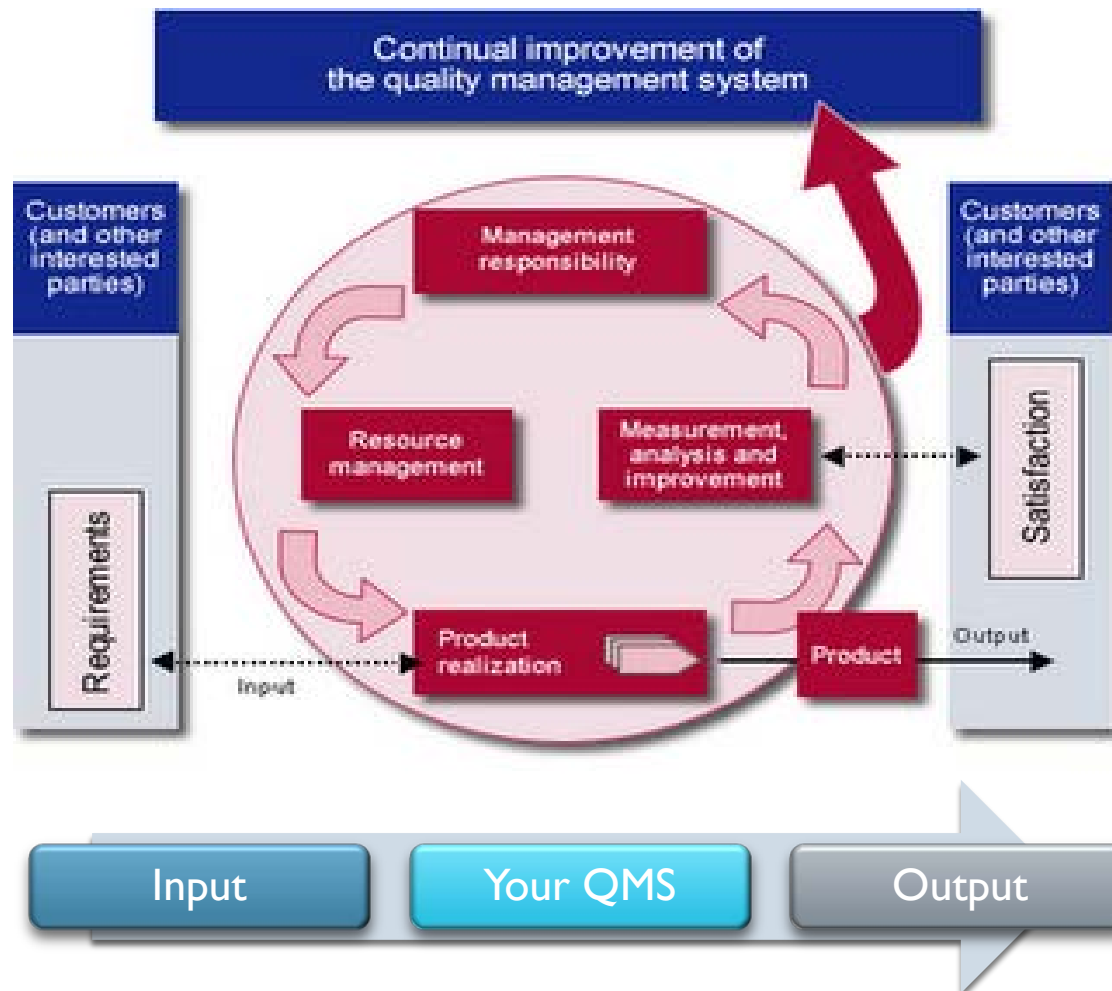


Every process has
an owner

PROCESS MANAGEMENT



ISO 9001:2008 ELEMENTS



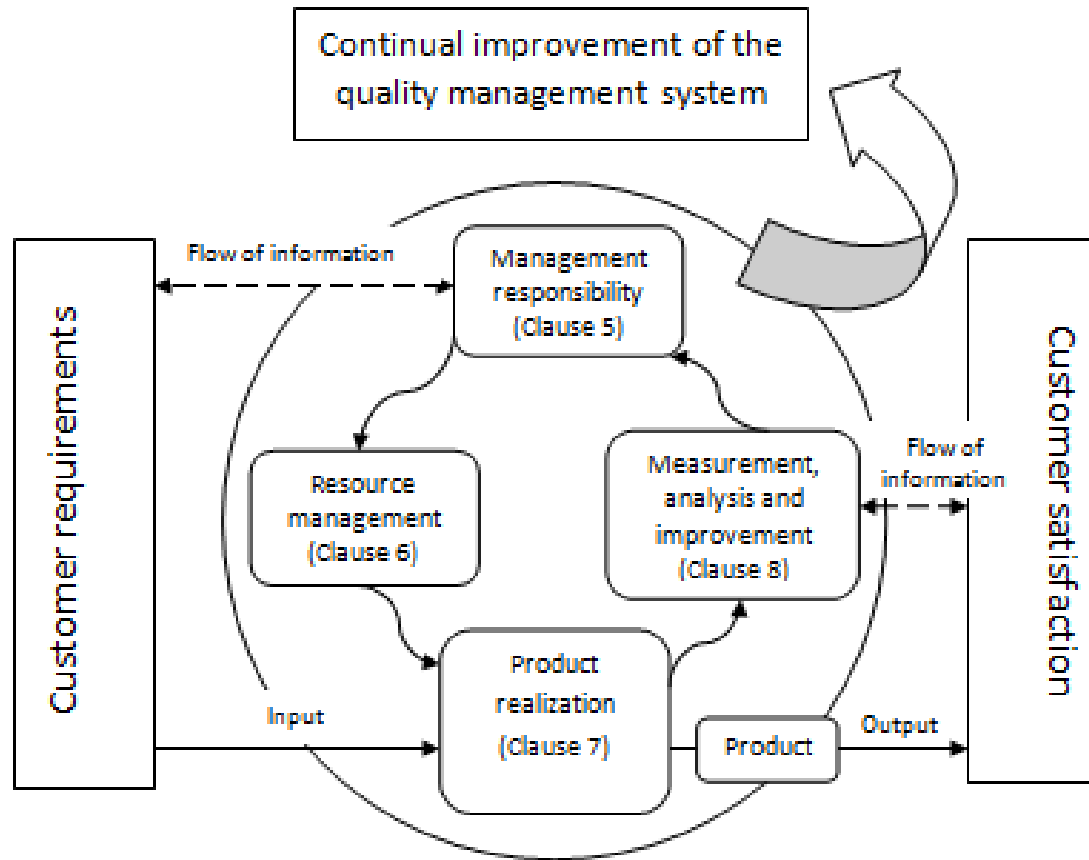
ISO 9001:2008 STRUCTURE

- Clause 1 Scope
- Clause 2 Normative references
- Clause 3 Terms and definitions
- Clause 4 Quality management system
- Clause 5 Management responsibility
- Clause 6 Resource management
- Clause 7 Product realization
- Clause 8 Measurement, analysis and improvement

CLAUSE 1 SCOPE

- Your organization should consider to adopt the ISO 9001 standard if it:
 - needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and
 - aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

QMS PROCESSES ARE IN THE CIRCLE



CLAUSES 2 & 3

Clause 2 Normative references

- This document is indispensable in the application of the ISO 9001 standard:
 - ISO 9000 – Fundamentals and vocabulary

Clause 3 Terms and definitions

- Wherever the term “product” occurs, it can also mean “service”.

4.1 QMS GENERAL REQUIREMENTS

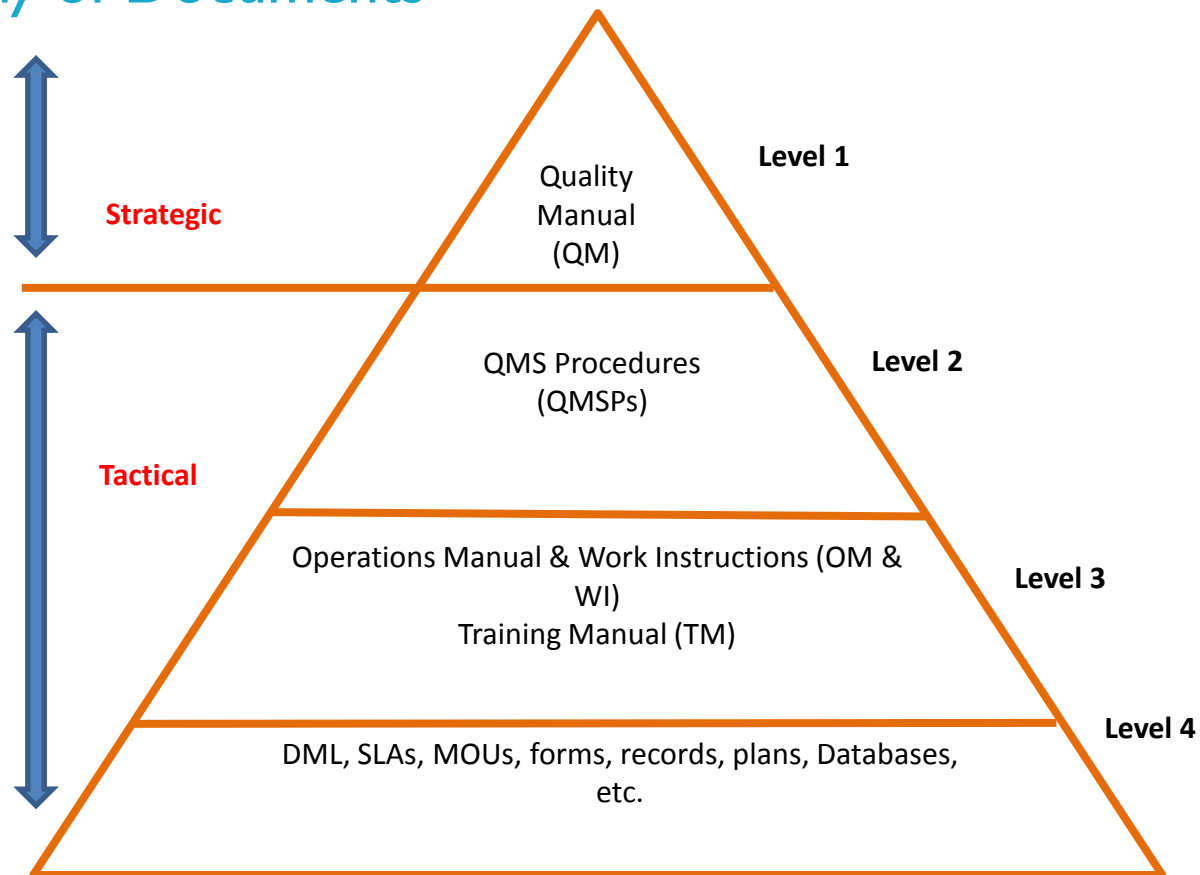
1. Determine the QMS processes
2. Determine their sequence and interactions
3. Determine the methods of operations and control
4. Provide resources to ensure effective operations (Clause 6)
5. Monitor, measure and analyze processes (Clause 8.2 to 8.4)
6. Improve the effectiveness of the processes (Clause 8.5)

CLAUSE 4.2 DOCUMENTATION REQUIREMENTS

- a) Quality Policy
- b) Quality Manual – to describe the system
- c) Quality Objectives Register – to document your quality objectives
- d) Control of Documents Procedure
- e) Control of Records Procedure
- f) Internal Audit Procedure
- g) Control of Nonconforming Product
- h) Corrective Action Procedure
- i) Preventive Action Procedure
- j) Quality Plan
- k) Control plans
- l) Other documents, as necessary
- m) Records (to show evidence of work performed in all QMS processes)

CLAUSE 4.2 DOCUMENTATION REQUIREMENTS

Hierarchy of Documents



CLAUSE 4.2.4 CONTROL OF RECORDS

- Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.
- Process owners must identify, classify and maintain all process records in good and secure conditions throughout retention period.
- Records shall remain legible, readily identifiable and retrievable.

CLAUSE 5 MANAGEMENT RESPONSIBILITY

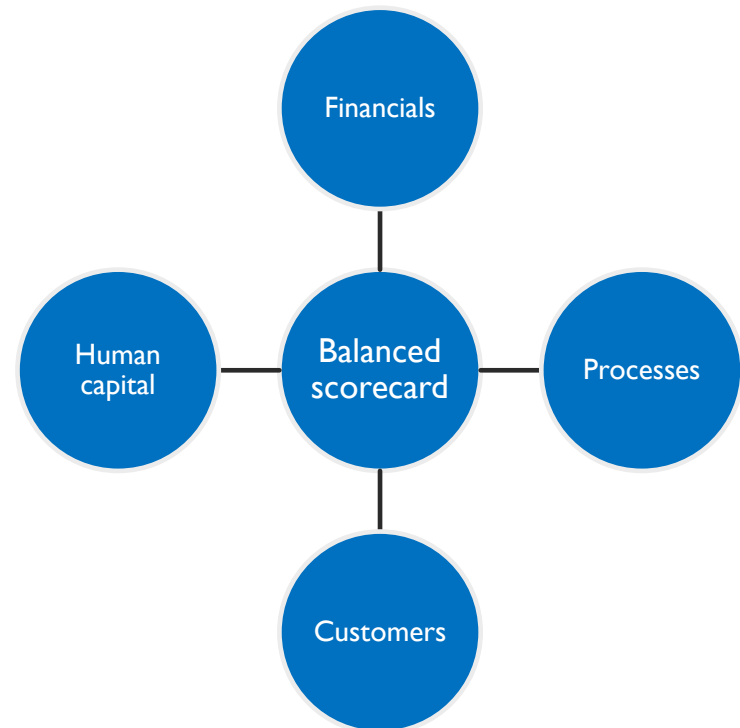
- Top management must:
 - a) Be committed to the QMS
 - b) Be customer focused
 - c) Establish a quality policy
 - d) Plan for the QMS in terms of establishing quality objectives and management of change
 - e) Assign responsibility, authority and provide suitable communication channels
 - f) Review the QMS performance

WHAT TO DO

- Read the ISO 9001:2008 Standard
- Establish a Quality Policy
- Appoint a Management Representative (from mgt. rank)
- Establish a QMS Committee
- Establish your Quality Manual
- Establish the 6 mandatory procedures (Clause 4.2)
- Establish your Quality Plan
- Establish your Department/Process Control Plans
- Establish and document your quality objectives
- Establish your KPI's and start collecting data
- Implement all the procedures

KEY PERFORMANCE INDICATORS

- Ask this question when determining KPI's:
- As the CEO/Manager of this organization, what data will instantly give me the ability to assess overall performance at any given point in time?
- Then list all them down and select your desired KPI's.



The Balanced Scorecard above provides a comprehensive set of business performance measures

Quality Objectives

- Can be used to benchmark performance based on input requirements (customer wants 100 units per month, so give them 100 units per month)
- Can be used to improve KPI performance levels – decision must be based on past performance data and existing capacity to be realistic
- You can use existing performance levels to establish your quality objectives
- Use quality objectives to improve on productivity levels, decrease errors, improve speed, reduce costs, reduce complaints, etc.

EMPLOYEE RESPONSIBILITY

- Know the Quality Policy
- Be aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives
- Comply with the requirements of the QMS, as stated in the Quality Manual, procedures, Quality Plan, etc.
- Provide feedbacks or ideas about the QMS
- Report any nonconformities

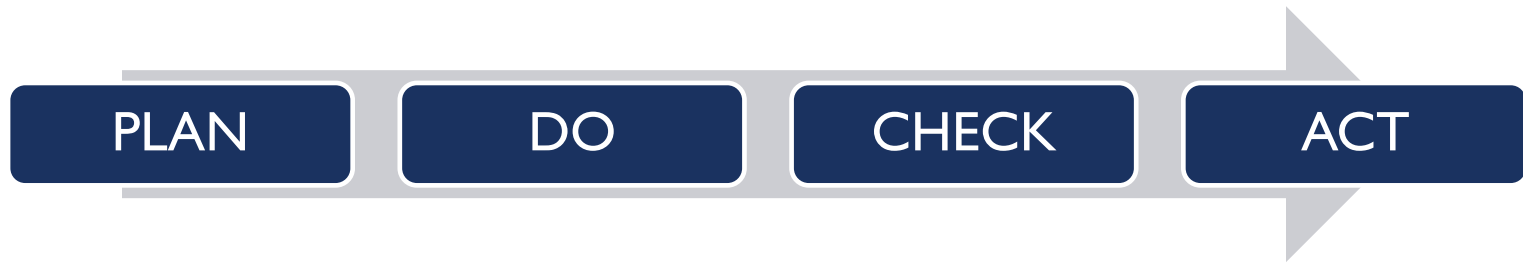


CLAUSE 6 RESOURCE MANAGEMENT

- Clause 6.1 Provision of resources
- The organization shall determine and provide the resources needed
 - a) to implement and maintain the quality management system and continually improve its effectiveness, and
 - b) to enhance customer satisfaction by meeting customer requirements.

TYPES OF RESOURCES

- Determine , provide and manage the following:
 - a) Clause 6.2 Competent human resources (competency assessment, training needs analysis)
 - b) Clause 6.3 Suitable and well-maintained infrastructures (maintenance of buildings, hardware, software, transportation, utilities)
 - c) Clause 6.4 Suitable and well-maintained work environment (5S program)
 - d) Consider including financial management in your QMS to ensure product conformity



- Clause 6.2.1
- Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

CLAUSE 7 PRODUCT REALISATION

7.1

• **Planning**

7.2

• **Determination of customer requirements**

7.3

• **Design and Development**

7.4

• **Purchasing**

7.5

• **Production/Service provision**

7.6

• **Control of monitoring and measuring equipment**

PRODUCT REALIZATION PROCESS CONTROLS

- a) Quality Plan – to document how you intend to meet your customers' requirements
- b) Customer & Legal Requirements
- c) Customer complaints handling procedure
- d) Design Plan
- e) Purchasing Procedure
- f) Production/Service Plan
- g) Monitoring & Measuring Equipment Plan (can be included in Production/Service Plan)

CLAUSE 7.1 CREATE A QUALITY PLAN

- With the following contents:
 - a) Assigned responsibilities (who's doing what)
 - b) Quality objectives (productivity/quality targets)
 - c) Customer requirements/Product characteristics, features, etc.
 - d) References to procedures to control production/creation, storage, release, delivery, etc.
 - e) Required resources- HR, materials, equipment, etc.
 - f) Required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance
 - g) Types of records needed to provide evidence that the realization processes and resulting product meet requirements

CLAUSE 8 MEASUREMENT, ANALYSIS AND IMPROVEMENT

- The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed:
 - a) to demonstrate conformity to product requirements,
 - b) to ensure conformity of the quality management system, and
 - c) to continually improve the effectiveness of the quality management system.

- This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

WHY MONITOR AND MEASURE?

- If you cannot measure it, you cannot improve it.
- *Lord Kelvin*
- Measurements provide you with a baseline to improve upon.

WHAT DO YOU MEASURE?

1. Customer satisfaction (Survey, returns rate, complaints, lost business, etc.)
2. Process conformance and effectiveness (internal audit)
3. Process performance (Key Performance Indicators and quality objectives)
4. Product characteristics (QC inspection before release to customer) where nonconforming products must be controlled

CLAUSE 8.3 CONTROL OF NON-CONFORMING PRODUCTS

- Where applicable, the organization shall deal with nonconforming product by one or more of the following ways:
 - a) by taking action to eliminate the detected nonconformity;
 - b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
 - c) by taking action to preclude its original intended use or application;
 - d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

INTERNAL AUDIT PROCESS



- Purpose is to verify whether your QMS:
 - a) Conforms to your Quality Plan,
 - b) Conforms to ISO 9001 requirements,
 - c) Conforms to your QMS requirements, and
 - d) Is effectively implemented and maintained.

AUDIT DEFINED

- Audit is a systematic and documented process for gathering audit evidence and evaluating it against the audit criteria to determine whether it has been fulfilled.
- Audit criteria is a set of policies, procedures or requirements.
- Audit evidence is records, statements of fact or other information which are relevant to the audit criteria and verifiable.
- Audit conclusion is the outcome of an audit provided by the audit team after consideration of the audit objectives and all audit findings.

WHAT TO IMPROVE?

- The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.
- All nonconformities require corrective actions.
- All potential nonconformities require preventive actions.

WHY IS ISO 9001 SO POPULAR?

The scope of the Standard specifies requirements intended to:

- Demonstrate an organization's ability to consistently provide products or services that meet customer, contractual and regulatory requirements.
- Enhance customers' satisfaction through effective application including processes for its continual improvement and assurance of conformity to the above requirements.
- Emphasis on management involvement and a system that works to achieve the goals and objectives of your business.
- ISO 9001 has become a global phenomenon and over 1 million companies are registered to date.

FOCUS OF ISO 9001

- ISO 9001 controls **processes**, not products.
- It is concerned with the way an organization carries out its business and controls processes.
- It is not a product or service standard.
- It is a **process** standard.
- Processes are what affects final products and services.
- It can be used by manufacturers and service providers.
- It can be used by large and small businesses.

THE ISO 9001:2008 STANDARD

The requirements of ISO 9001:2008 do not tell you "how" to run your business ...

... THAT'S UP TO YOU

The requirements describe "what" needs to be achieved

BIGGEST BENEFIT

- The ISO 9001:2008 Standard provides managers with a tool that is designed to continually improve their business performance.
- ISO 9001 requires you to:
 - Plan what you want to do,
 - Follow that plan,
 - Monitor, measure and analyze your execution of the plan, and
 - Improve the plan.



Planning is
the key



OTHER BENEFITS

A well-designed and well-implemented quality management system can and should **eliminate**:

- **INEFFECTIVENESS**
- **INEFFICIENCIES**
- **PROBLEMS**
- **ERRORS**
- **INCONSISTENCIES**
- **MALICIOUS PRACTICES**
- **UNCERTAINTIES**
- **BAD CULTURE**

BENEFITS OF AN EFFECTIVE QMS

- Improves efficiency and productivity
- Reduces variation, waste, inefficiencies and defects
- Facilitates continual improvement
- Improves process consistency and stability
- Improves supplier performance
- Improves profitability
- Improves customer confidence and satisfaction
- Improves conformity to quality requirements

BENEFITS OF AN EFFECTIVE QMS

- Increases competitive edge and market share
- Makes financial sense, which appeals to Top Management
- Improved communications and support
- Appropriate training provided
- Better understanding of job and importance
- Encouragement to report problems
- Improved morale and commitment

See 'Out of Crisis' by W.E. Deming.

IMPACT ON DAY TO DAY OPERATIONS

- Requires level of formality and structure
- Impacts nearly all functional areas
- Supports performance metrics
- Encourages employee awareness
- Impacts customers and bottom line
- Addresses silo management
- Encourages inter-department communication



IMPACT ON DAY TO DAY OPERATIONS

Process Management:

- Ensures processes are efficient and effective
- Reduces process steps leading to reduced costs
- Outputs of one department are inputs to next department

IMPACT ON CUSTOMERS

Impacts include:

- Formal identification and management of customer requirements
- Formal handling of complaints
- Closed-loop communication with customers
- Defined customer satisfaction measurements

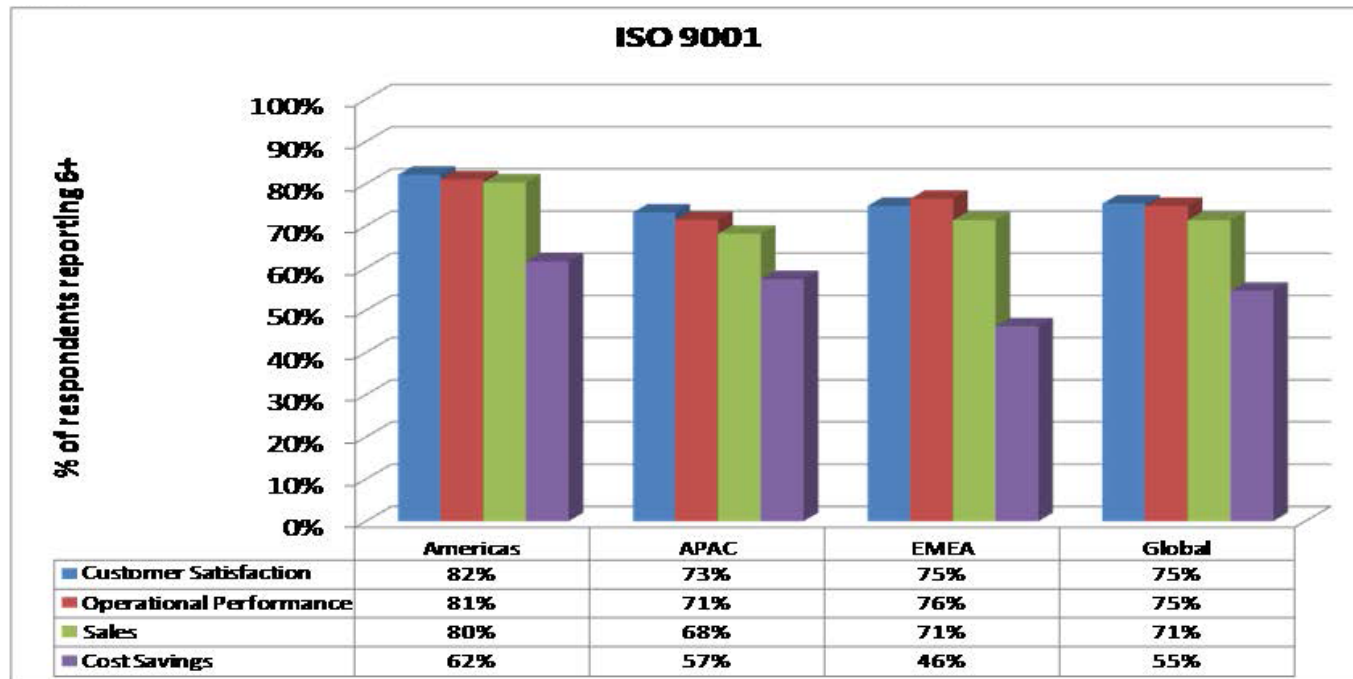
ULTIMATE GOAL

Strong relationship with customers
and improved performance

DOES ISO 9001 REALLY WORK?

The chart below shows evidence of improvements resulting from ISO 9001 implementation.

Increased Quality = Reduced Cost of Quality



ACCREDITATION AND CERTIFICATION

- Accreditation bodies (ABs) oversee the accreditation, the Certification bodies (CBs) and their audit processes.
- ABs must be certified by the International Accreditation Forum (IAF)
- The CB qualified auditor will provide third party audits and approve certification requests for organisations.



REGISTRATION/CERTIFICATION PROCESS

- Provide information and request quote.
- Select Registrar and submit application.
- Agree on audit objective, scope and date.
- Arrange for the review of documents.
- Consider optional Pre-Assessment visit.
- Participate in the Registration Audit.
- Receive your ISO 9001 certificate.
- Begin the ongoing Surveillance Audits.



See document containing a detailed comparison of the 2008 and 2015 ISO 9001 Standard requirements

ASSESSMENT & STAGES

Pre-assessment (optional)
Documentation Assessment
(Stage I)
Certification Assessment
(Stage II)

Pre-certification

- The client receives a three year renewable certificate.
- 1st Year – Certification Audit
- 2nd Year – Surveillance Audit
- 3rd Year - Surveillance Audit and/or Re-Certification

Continuing Assessment
Triennial Re-assessment

Post-certification

CERTIFICATION BENEFITS

- Increased productivity
- Reduction of waste/efficiencies
- Increased customer satisfaction and confidence
- Public demonstration of management commitment
- Measurable results from management system objectives
- Improved effectiveness of key processes
- Continued identification and resolution of problem areas
- Managed continual improvement
- Ability to market independent assessment of the organisation

The linked document gives a pictorial representation of the ISO 9001 benefits.

CONCLUSION

Implementing and certifying a formal ISO Management System will:

- Ensure awareness of and compliance with an established set of relevant internal and external guidelines, standards, policies, regulations and legislation related to managing operational resilience.
- Redundant activities and their associated costs can be eliminated.
- Staff resources can be more effectively deployed and optimised.
- Enforce focus on organisational and service missions.
- Facilitate a process that is owned by line of business and unit managers and consistently implemented across the organisation.

CONCLUSION



TRAINING



CERTIFICATION



MANAGEMENT SYSTEM SOFTWARE