

ISO 9001:2015 QUALITY MANAGEMENT SYSTEM (QMS)

*General Staff Awareness
Mentorship Programme*



February, 2023



INTRODUCTION

At the end of this program, you will have a better understanding of the following:

- The concepts and principles of ISO 9001:2015 standard;
- The requirements of the ISO 9001:2015 Standard;
- How the ISO 9001:2015 implementation is done;
- Who is responsible for the implementation of ISO 9001:2015 Standard.

WHAT IS ISO?

ISO MEANS:



- ESTABLISHED IN 1947
- HEADQUARTERS IN GENEVA
- IT IS NON-GOVERNMENTAL
- EQUAL VOTES

Nigeria is represented by Standards Organization of Nigeria (SON).

WHAT IS QUALITY

The degree to which a set of **inherent characteristics** fulfills **requirements**.

OTHER DEFINITIONS OF QUALITY:

- **Quality is conformance to specified requirements.**
- **Consistency**
- **Absence of variation**
- **Doing right the first time**



QUALITY COSTS are the **costs** associated with preventing, detecting, and remediating product issues related to **quality**.

- **Prevention:** The cost of trying to do it right first time.
- **Appraisal:** The cost of checking whether it was done right the first time.
- **Failure:** The cost incurred because it wasn't done right the first time.

BASIC DEFINITIONS...

- **Product:** the result of activities in process.
- **Process:** a set of interrelated or interacting activities that use inputs to deliver an intended result.
- **Procedure:** the specified way to perform an activity.
- **System:** set of detailed methods, procedures and routines created to carry out a specific activity, perform a duty, or solve a problem.

CUSTOMER SATISFACTION

Customer's **perception** of the **degree** to which the **customer's requirements** have been **fulfilled**.

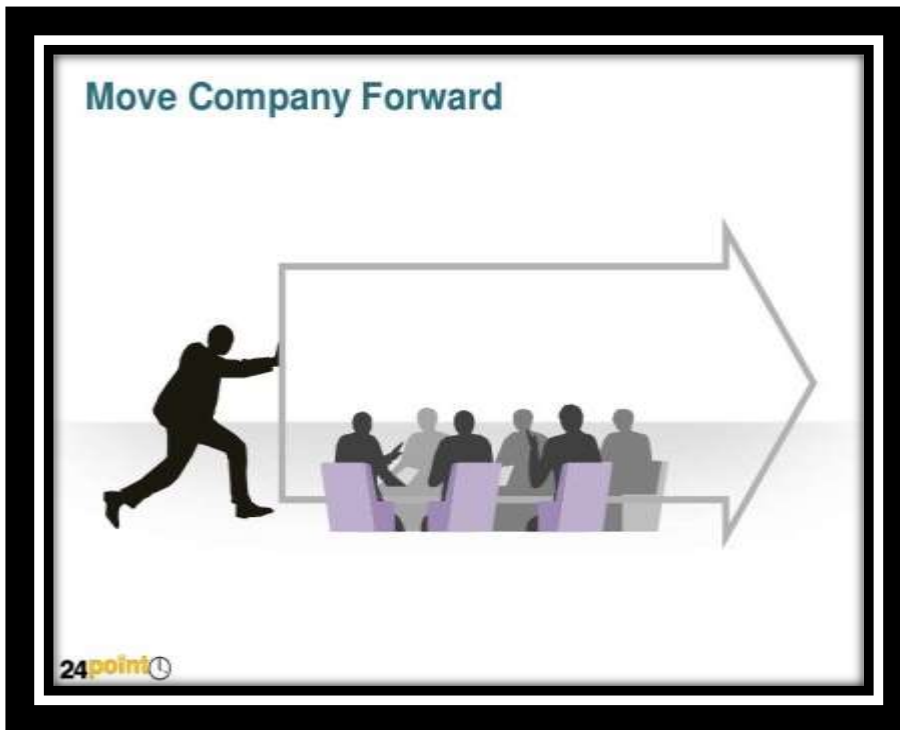
Quality management means what the organization does to:

- Ensure that its products or services satisfy the **customer's quality requirements.**
- Comply with any **regulations** applicable to those products or services.
- Enhance **customer satisfaction.**
- Achieve **continual improvement** of its performance.



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PURPOSE OF QMS



***THIS IS A
MANAGEMENT
TOOL
NECESSARY TO
MOVE AN
ORGANISATION
FORWARD***

PURPOSE OF QMS

- To ensure consistent quality of services or products that meets customer and applicable regulatory requirements.
- Compliance with requirements including customer and regulatory.
- To enhance customer satisfaction with services or products of an organization.

1. PROCESS APPROACH

2. RISK BASED THINKING

3. PLAN - DO - CHECK - ACT (PDCA)

PROCESS APPROACH

Understanding and planning the interaction of processes in a system.

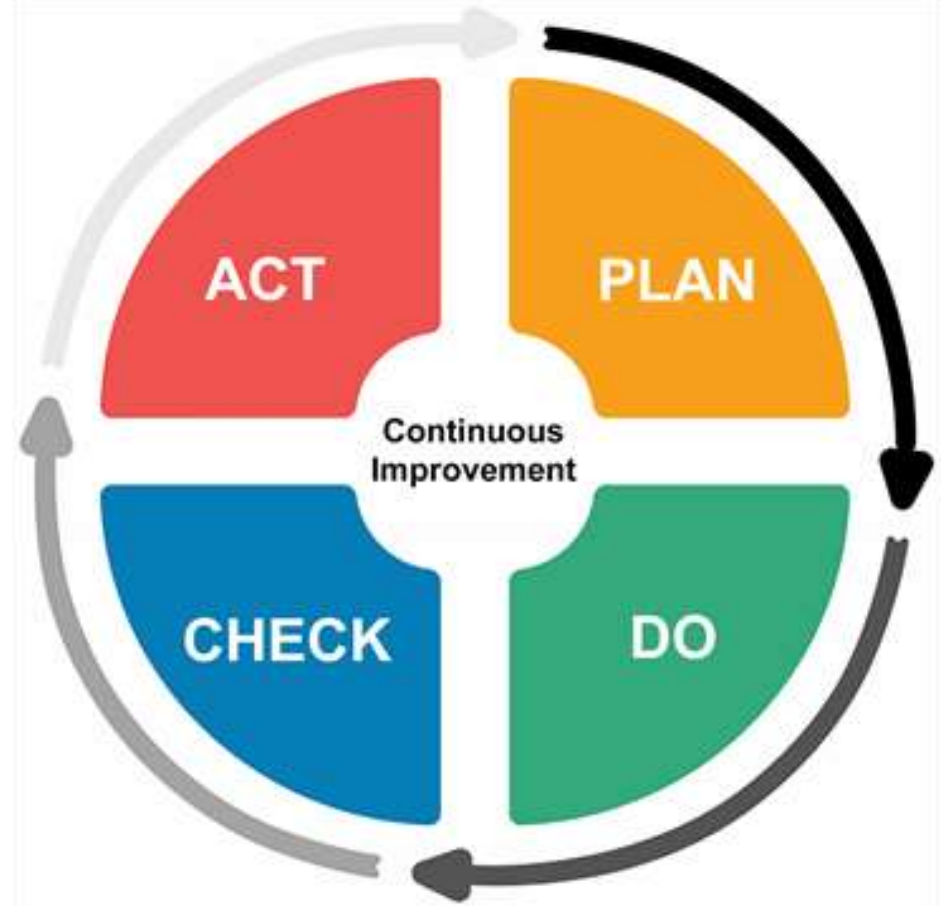


RISK BASED THINKING

- A risk is the effect of uncertainty on an expected result.
- Risk based thinking is a coordinated set of activities and methods that organizations use to manage and control the many risks that affect their ability to achieve objectives.

Plan-Do-Check-Act (PDCA)

A model that enables organizations to continually improve their processes, products or services.



HIGH LEVEL STRUCTURE

- **Clauses and their significance**
- **Context of the organization**
- **Leadership**
- **Planning etc.**

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



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PDCA IN ISO 9001:2015 STRUCTURE

PLAN				DO	CHECK	ACT
4. Context of the organisation	5. Leadership	6. Planning for the QMS	7. Support	8. Operation	9. Performance evaluation	10. Improvement
4.1 Understanding the organization and its context	5.1 Leadership and commitment	6.1 Actions to address risks and opportunities	7.1 Resources	8.1 Operational planning and control	9.1 Monitoring, measurement, analysis and evaluation	10.1 General
4.2 Understanding the needs and expectations of interested parties	5.2 Quality policy	6.2 Quality objectives and planning to achieve them	7.2 Competence	8.2 Determination of requirements for products and services	9.2 Internal audit	10.2 Nonconformity and corrective action
4.3 Determining the scope of the QMS	5.3 Organizational roles, responsibilities and authorities	6.3 Planning of changes	7.3 Awareness	8.3 Design and development of products and services	9.3 Management review	10.3 Continual improvement
4.4 QMS and its processes			7.4 Communication	8.4 Control of externally provided products and services		
			7.5 Documented information	8.5 Production and service provision		
				8.6 Release of products and services		
				8.7 Control of nonconforming process outputs, products and services		

SEVEN QUALITY MANAGEMENT PRINCIPLES



CUSTOMER FOCUS

- The primary focus of quality management is to meet customer requirements and strive to exceed customer expectations.
- Organizations need customers to exist.
- Understanding their current and future needs and expectation contributes to the sustained success of the organization.

- Increase customer satisfaction.
- Improve customer loyalty.
- Expand customer base
- Increase revenue and market share

LEADERSHIP

- Leadership at all levels establishes unity of purpose and direction and creates conditions in which people are engaged in achieving the quality objectives of organization.
- Good leadership creates enabling environment.
- Helps maintain trust and eliminate fear

- Improved communication between levels, functions of the organization.
- Better coordination of the organization's processes.
- Increased effectiveness and efficiency in meeting organization's quality objectives.
- Enhance the capacity of the organization and its people to deliver desired results.

- It is essential for the organization to have competent and empowered staff that are engaged in delivering value.
- Involvement of people at all levels improves the overall performance of the organization.

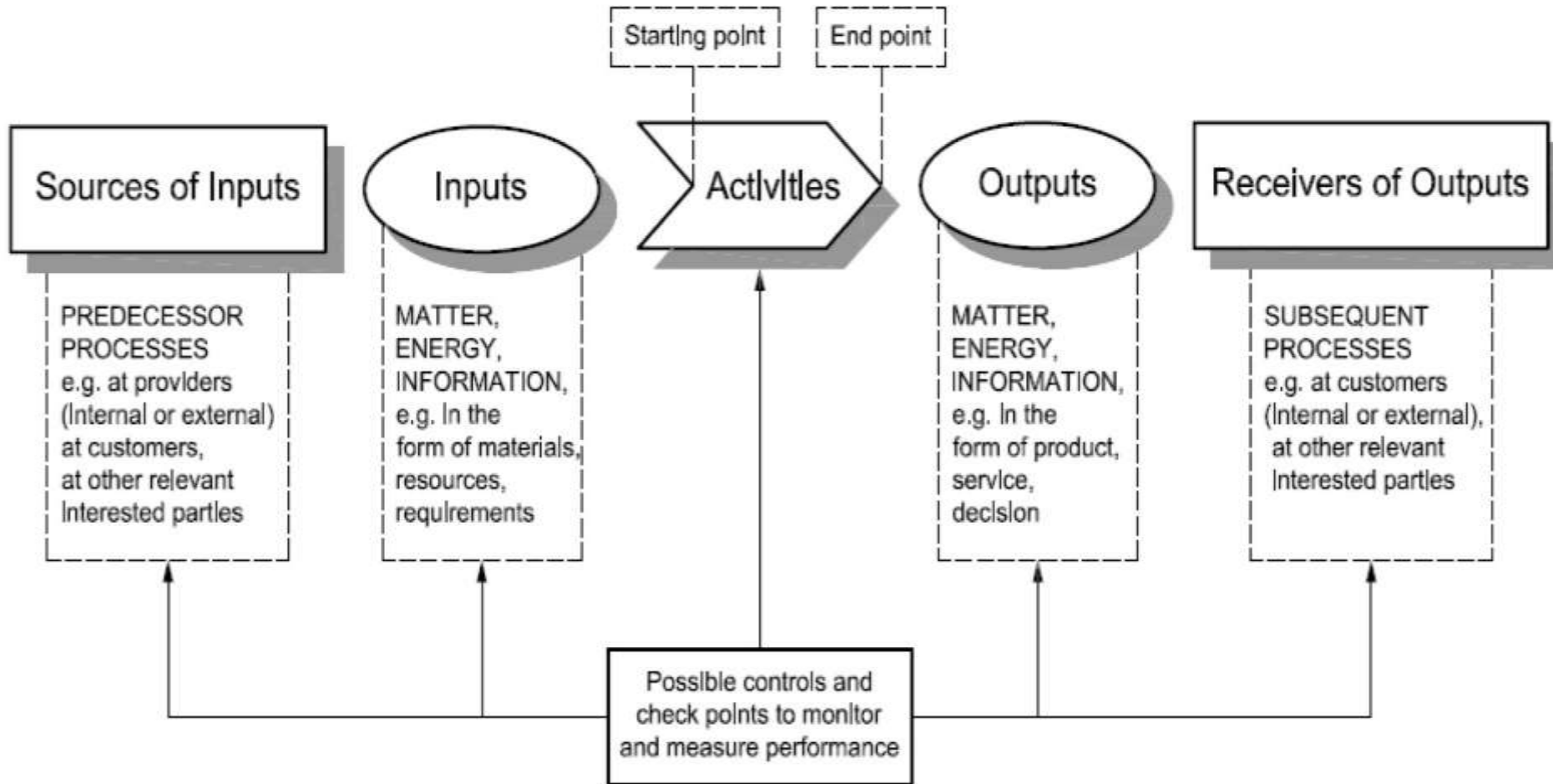
- Enhance involvement of people in improvement activities.
- Enhance trust and people's satisfaction.
- Improve understanding of the organization's quality objectives by staff and increase motivation to achieve them.
- Increase attention to shared values and culture throughout the organization.

- 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.

- Consistent and predictable outcomes through a system of aligned processes.
- Optimized performance.



ELEMENTS OF PROCESS APPROACH



IMPROVEMENT

- Successful organizations have an ongoing focus on improvement.

BENEFITS OF IMPROVEMENT

- Improved process performance, organizational capabilities and customer satisfaction.
- Enhanced focus on root cause investigation and determination, followed by prevention and corrective actions.
- Increased drive for innovation.

- Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.
- Evidence is information that shows that something exists or is true.
- Always make decisions based on evidence.

- Improved decision-making processes.
- Improved assessment of process performance and ability to achieve objectives.
- Improved operational effectiveness and efficiency.
- Increased ability to review and challenge decisions.

- For sustained success, organizations manage their relationships with interested parties, such as exporters, partner organizations.
- Relevant interested parties influence the performance of an organization.

- Enhanced performance.
- Common understanding of objectives.
- Stable flow of products and services.

WHO IS RESPONSIBLE FOR THE QMS?

- **QUALITY IS EVERY BODY'S BUSINESS.**
- **EVERY STAFF MUST BE INVOLVED.**

- **KNOW YOUR JOB AND DO IT WELL & ON TIME;**
- **BE COMMITTED, RESPONSIBLE & REMAIN ACCOUNTABLE;**
- **ENSURE YOUR JOBS ARE DEFINED;**
- **ENSURE YOUR TOOLS ARE AVAILABLE AND WELL MAINTAINED.**
- **DON'T BE A LONE RANGER, BE A TEAM PLAYER**

- **MAINTAIN RECORDS/EVIDENCE OF ASSIGNED JOBS;**
- **BE POSITIVE AT ALL TIMES- POSSESS READY MIND TO LEARN;**
- **SUGGEST BETTER WAYS OF IMPROVING THE SYSTEM;**
- **KNOW YOUR INTERNAL CUSTOMERS AND HIS/HER NEEDS;**
- **SUPPORT THE ISO 9001 IMPLEMENTATION IN YOUR DEPARTMENT.**

- **KNOW THE QUALITY POLICY;**
- **KNOW YOUR DEPARTMENT OBJECTIVES/TARGET;**
- **BE CONSCIOUS OF OTHER PEOPLE'S NEEDS,
DON'T PROCRASTINATE;**
- **SEEK FOR WAYS OF IMPROVING THE QUALITY OF
YOUR WORK;**
- **BE CUSTOMER FOCUSED AT ALL TIMES.**

QMS in summary:

- **Say what you do**
- **Write it down**
- **Do it**
- **Check your performance**
- **Improve**

THANK YOU

