

## **SCRIPT – CERTIFICATION IN QUALITY ASSURANCE**

### **Cover Page – Slide 1**

This is a product of the Industrial Training Fund.... we are Nigeria's leading Human Resource development organization.

### **Learning Outcomes – Slide 2**

At the end of this session, it is my belief that we would have achieved the following Learning Outcomes:

- Explain Quality Certification.
- Discuss Quality Management System (QMS), and,
- Describe how to implement ISO 9001:2015 in a company.

### **What is Quality Certification? – Slide 3**

Quality Certification is a general term that is used for two main things: certifying the knowledge of individuals and certifying a company's system of quality management.

Certification demonstrates proficiency and understanding of the body of knowledge. It shows a mark of technical excellence. Certification may help in landing a job and increases credibility with customers.

### **Certifying a Quality Management System – Slide 4**

A Quality Management System, or QMS, is essential for improving your business's operations and enabling it to meet the requirements of customers. Whether you manage all your processes in-house or outsource to, for example, a QMS allows your organization to remain compliant with the latest standards and regulations.

A QMS is used by manufacturers as a set of policies, procedures, and processes. The direction and control of vital business activities are coordinated by the system. The QMS also focuses on the goal of continual improvements in effectiveness and efficiency.

A well implemented quality management system will assist your company in lowering costs, improving performance, reducing waste, and providing a structured training baseline for new and current employees.

A Quality Management System can be designed according to many different sets of requirements. If the QMS is certified, this means that a Certification Body (sometimes called a Registrar) has done an audit against the requirements of the QMS, and also holds ongoing routine audits of the system to ensure the QMS is maintained.

## Benefits of a Quality Management System (QMS) – Slide 5

When you have a QMS in place, you can realize important benefits such as improvements in:

- **Organizational Effectiveness:** A QMS helps establish important operational goals while providing a means to measure and review how well your organization reaches these goals.
- **Customer Satisfaction:** A business must satisfy its customers to survive; incorporating customer feedback into a QMS allows you to make customer satisfaction improvements.
- **Compliance:** Incorporating compliance into documentation, measurement and reporting, and internal auditing systems will eliminate some challenges of meeting key standards and regulations.
- **Organizational Culture:** A QMS establishes, communicates, and aligns operational activities with organizational goals and priorities, so all employees are aware of expectations.
- **Documentation:** A QMS defines how critical processes and objectives are documented, so important knowledge is available throughout the organization.

## Common Quality Management Frameworks – Slide 5

The following are some of the common quality management frameworks:

- **ISO 9001:** The most used set of requirements for designing a QMS. ISO 9001 certification is recognized worldwide.
- **AS9100:** This is a standard that is based on ISO 9001 and has additions designed for use in the Aerospace Industry. A QMS can be certified by a third party to comply with this standard.
- **ISO 13485:** This is a standard published by the ISO organization for use by companies that want to design a QMS for medical devices, and the requirements for regulatory purposes surrounding them.
- **Lean:** The core idea is to maximize value by eliminating waste. The main idea is that anything that adds cost to a product, but not value, is waste and should be controlled or eliminated. This supports a QMS but cannot be used to design or certify a QMS.
- **MBNQA:** The Malcolm Baldrige National Quality Award recognizes US organizations for performance excellence. The award has a set of requirements against which a company could design and assess a QMS, but apart from the award there is no ongoing certification against these requirements.
- **Six Sigma:** This is a set of tools and techniques used for process improvement. It is used in many organizations to support the QMS by helping to improve processes, but Six Sigma does not define a QMS, and the QMS cannot be certified to Six Sigma.
- **TQM:** Total Quality Management consists of practices designed to improve the process performance of a company. The techniques help improve efficiency, problem solving and standardization of processes. These techniques are used to aid in quality management, but do not provide a framework for a Quality Management System and cannot be certified to.
- **ISO/TS 16949:** This document includes requirements for the application of ISO 9001 for automotive production and service part organizations. A QMS designed using these requirements can also be certified against them.

**For the purpose of this session, we would be focusing ISO 9001 Certification.**

## What is ISO 9001:2015? – Slide 6

ISO 9001 is the world's most recognised Quality Management System (QMS) standard.

It aims to help organisations meet the needs of their customers and other stakeholders more effectively. This is achieved by building a framework to ensure consistent quality in the provision of goods and/or services.

The standard is based on 7 quality management principles, including having a strong customer focus, the involvement of top management, and a drive for continual improvement.

The seven quality management principles are:

- 1 – Customer focus
- 2 – Leadership
- 3 – Engagement of people
- 4 – Process approach
- 5 – Improvement
- 6 – Evidence-based decision making
- 7 – Relationship management

The principles are not ordered by priority. The relative importance of each principle varies from organization to organization and may change over time.

## Reasons to get ISO 9001 Certified – Slide 7

An ISO 9001 certification provides objective proof to your staff, your partners, your clients and the outside world that customer satisfaction is at the core of your business. If your company is ISO 9001 certified, it will benefit as follows:

- **Increased revenue:** leveraging the reputation of ISO 9001 can help you to win more tenders and contracts, whilst increasing efficiency aids customers satisfaction and retention.
- **Improvement of your credibility:** when organisations are looking for new suppliers, it is often required to have a QMS based on ISO 9001, particularly for those in the public sector.
- **Improved customer satisfaction:** by understanding your customers' needs and reducing errors, you increase customer confidence in your ability to deliver products and services.
- **Higher operating efficiency:** by following industry best-practice and focusing on quality, you can reduce costs.
- **Improved decision-making** - you can detect and identify problems in good time, which means that you can quickly take steps to avoid the same mistakes in the future.
- **Greater employee engagement:** by improving internal communications, you ensure everyone works to one agenda. Involving employees in designing process improvements makes them happier and more productive.
- **Better process integration:** by examining process interactions, you can find efficiency improvements more easily, reduce errors and make cost savings.
- **A continual improvement culture:** this is the third principle of ISO 9001. It means that you embed a systematic approach to identifying and exploiting opportunities to improve.
- **Better supplier relationships:** using best-practice processes contributes to more efficient supply chains, and certification will signpost these to your suppliers.

## ISO 9001 Certification – Slide 8

ISO 9001 is the only standard in the ISO 9000 series to which organizations can certify. Achieving ISO 9001:2015 certification means that an organization has demonstrated the following:

- Follows the guidelines of the ISO 9001 standard
- Fulfills its own requirements
- Meets customer requirements and statutory and regulatory requirements
- Maintains documentation

Certification to the ISO 9001 standard can enhance an organization's credibility by showing customers that its products and services meet expectations. In some instances, or in some industries, certification is required or legally mandated. The certification process includes implementing the requirements of ISO 9001:2015 and then completing a successful registrar's audit confirming the organization meets those requirements.

Organizations should consider the following as they begin preparing for an ISO 9001 quality management system certification:

- Registrar's costs for ISO 9001 registration, surveillance, and recertification audits
- Current level of conformance with ISO 9001 requirements
- Amount of resources that the company will dedicate to this project for development and implementation
- Amount of support that will be required from a consultant and the associated costs

## How to implement ISO 9001 in your Company – Slide 9

If your company is looking at implementing a quality management system (QMS) based on the ISO 9001 standard and becoming certified, you might be overwhelmed with figuring out where to start. To help with this, here is an overview of the 13 steps that are needed to help you make sure that nothing is missed during your implementation and preparations for certification:

**1. Management Support:** – This is critical. Without the support of management your implementation of ISO 9001 will almost certainly fail. Convince your management that ISO 9001 is a good idea, and the benefits to the company are enormous.

**2. Identify Requirements:** – Another crucial step to make sure your implementation succeeds is to make sure you have identified all the requirements that exist for your QMS. These will include customer requirements, as well as other requirements such as regulations and the needs of your company culture.

**3. Define Scope:** – Defining the scope of your QMS will help to ensure you know the limits of what needs to be done, so that you do not include areas of your business that might not have an effect on your system. The key tool to define the scope is the quality policy which will be the first document you will need to create for the QMS.

**4. Define Processes and Procedures:** – These will include the mandatory procedures defined by the ISO 9001 standard, but also any additional processes and procedures required by your company to ensure consistent and adequate results with respect to quality. The key is to define all the processes in your company and look at how they interact within your organization. It is in these interactions that problems can occur.



**5. Implement Processes and Procedures:** – Often, these processes will already be in place at your company and will just need to be adequately documented to ensure consistent results. Not all processes need to be documented procedures, but it is important to decide which ones need to be in order to ensure compliant products and services.

**6. Training and Awareness Programs:** – It is important that everyone in your organization know what you are doing with your QMS and how they fit into the equation. Employees should have training on what ISO 9001 is, so that they are aware of why you are doing this, as well as the important training of any changes to the processes they are involved in.

**7. Choose a Certification Body:** – This can be a very important step in how effective your implementation is. The certification body is the company that will ultimately come in to audit your QMS and decide if it is compliant with ISO 9001 requirements, as well as whether it is effective and improving. It is best to interview several certification bodies to decide which is right for your company.

**8. Operate the QMS and Measure the System:** – This is when you will collect the records that will be required in audits to show that your processes meet the requirements set out for them, that they are effective, and that improvements are being made in your QMS as needed. Certification bodies need this to happen over a certain length of time, which they will identify, in order to ensure that the system is mature enough to show compliance.

**9. Conduct Internal Audits:** – Before the certification body comes in to audit your system, they will first want you to audit each process internally. This will give you a chance to make sure that the processes are doing what you had planned. You will also have a chance to implement the necessary corrective actions to fix any problems that you find.

**10. Conduct Management Review:** – Just as it is important that management support the implementation of ISO 9001, it is also important that they are involved in the continued maintenance of the QMS. Management needs to review specified data from the activities of the QMS in order to ensure that the processes have adequate resources to be effective and improve.

**11. Corrective Action:** – This is the step where you find the root cause of any problems found during your measurements, internal audits and management review and take action to correct the root cause. This is the key step toward improvement, which is a main focus of having an ISO 9001 QMS.

**12. Stage 1 Certification Audit:** – This is a review of your documentation by the certification body auditors to verify that, on paper, you have addressed all the necessary requirements of the ISO 9001 standard. The auditors will issue a report outlining where you comply and where there are problems, and you will have a chance to implement any corrective actions to address the problems. This may take place during the timeframe defined for the initial operation of the QMS.

**13. Stage 2 Certification Audit:** – This is the main audit when the certification body auditors will review the records you have accumulated by operating your QMS processes, including your records of internal audits, management review and corrective actions. From this review, which will take several days, they will issue a report detailing their findings and whether they have found your QMS to be effective and in compliance with the ISO 9001 requirements. The auditors will also make a recommendation for certification if you meet all requirements. If you have any major non-conformances, then you will need to take corrective action for these problems before certification can be recommended.

## Conclusion – Slide 14

Hey, so in the past few minutes, we have been able to look at:

- Quality Certification.
- Quality Management System.
- ISO 9001:2015, and,
- Implementation of ISO 9001:2015.

***ISO 9001:2015 sets a global standard for Quality Management Systems and ensures their efficiency for products, services, and international supply chains. Whether an organization is starting down the path of a QMS or transitioning to the 2015 standard, ISO 9001:2015 embodies the best practices of Quality Management and Quality certification.***

Thank you and I will see you again in the next session. Stay Safe. Bye

