NSAI

ISO 9001 Quality Management Systems

INFORMATION GUIDE

ISO 9001 Background

ISO 9001:2015 is the world's foremost quality management standard, used by hundreds of thousands of organisations in over 170 countries around the globe.

It sets out the essential requirements for a practical and effective Quality Management System (QMS) which is, in essence, a system for minimizing risk and maximizing opportunity. ISO 9001 is suitable for any organisation regardless of its size and industry. While it can be used to focus on improving performance in a particular department or site ISO 9001 is generally most effective when implemented throughout an organisation at every level.

ISO 9001:2015 is an update of ISO 9001:2008 and is part of a series of quality management system standards, sometimes referred to as ISO 9000. These currently comprise of the following standards and guidelines:

- ISO 9000:2015 – Fundamentals and Vocabulary, this standard describes the fundamental concepts and principles of quality management
- ISO 9001:2015 – Requirements, which specifies the criteria for certification
- ISO/TS 9002:2016 – Guidelines for the application of ISO 9001:2015
- ISO 9001:2015 for Small Enterprises - What to do? - This handbook was written by a group of experts from ISO/TC 176/SC 2, and features useful information on everything from how to get started right through to guidance for those who choose to seek certification.

Benefits for your organisation include:

- **Increase in your organisation's performance and productivity** – certification improves efficiency through reduction of waste and systematic measurement of performance. Having a robust system in place gives more time to invest in performance & productivity
- **Enhanced customer satisfaction** – Customers know what to expect from a quality certified company. ISO 9001 systematically tracks errors and prevents them thus reducing the number of customer complaints
- **Global recognition** – ISO 9001 is a globally recognised quality standard that can open new market opportunities or help to maintain current market share. Certification also attracts investment
- **Employee engagement** – An ISO 9001 Quality management system encourages communication and increases morale among the employees
- **Competitive advantage** – certification provides an advantage over competitors or the opportunity to compete on the same basis as larger organisations (e.g. ability to tender or submit price quotations)
- **Focus on objectives and customer expectations** – greater emphasis on meeting customer requirements and implied needs through continuous incremental improvement
- **Ease of integration with other management systems**

Key Principles Behind ISO 9001

The seven principles below are fundamental attributes of any quality management system. They have been taken from ISO 9000:2015 Quality Management Systems – Fundamentals and Vocabulary and have served as a basis for the new ISO 9001:2015 standard.

The seven key quality principles set out the rationale behind how a good organisation is managed. They guide the organisation on a path of continual improvement to ensure sustainability, particularly in changing times. The seven key principles themselves are not directly auditable, but their application within the standard is.

1. Customer Focus

It is essential for your organisation to understand current and future customer needs. You should strive to meet customer requirements and exceed customer expectations. This could be done by communication throughout the organisation, measuring customer satisfaction and systematically managing customer relationships. Ensuring a balanced approach and acting on findings is vital.

2. Leadership

Leaders should provide a clear vision of your organisation's future and set challenging goals and targets. It is only through unity of purpose and direction of employees an organisation's objectives are achieved. Leaders should maintain an internal environment where people can get fully involved by establishing trust and eliminating fear.

3. Engagement of People

People should be a core competency of every company. Involving people and their abilities at all levels can only benefit your organisation. Motivating people, holding them accountable for their own performance and involving them in decision making inspires innovation and creativity.

4. Process Approach

Managing activities and resources as a process gives clear indications of what all the inputs and outputs are and thus gives a clearer idea of how to achieve your desired outcomes.

5. Improvement

Continuously improving your processes and systems and thus improving the organisational overall performance should be a permanent organisational objective.

6. Evidence-based Decision Making

Decisions should be based on the analysis of reliable and accurate data and information. Analysis combined with experience and intuition is a powerful decision making tool.

7. Relationship Management

The enhancement of the ability to create value depends on the relationships with suppliers. There should be a balance between short term gains and long term considerations which then results in increased flexibility and optimisation of costs and resources.

Fundamental Elements of ISO 9001

The Plan – Do – Check – Act (PDCA) cycle is the foundation of all ISO management system standards. The PDCA cycle enables an organisation to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on.

Risk based thinking enables an organisation to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimise negative effects and to make maximum use of opportunities as they arise.

It consists of the following:

Plan – establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organisation's policies, and identify and address risks and opportunities

Do – implement what was planned

Check – monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results

Act – take actions to improve performance, as necessary

This process then continues, thereby driving continual improvement at every level of the organisation.

It is most likely that an organisation already has a quality management system but it is probably informal and not well documented. ISO 9001 provides a more systematic approach to achieving organisation's objectives. It should not result in excessive bureaucracy, paperwork or lack of flexibility nor should it be a financial burden. Quality management systems should be considered an investment as the return on investment will be in terms of the previously mentioned benefits and improvements.

A documented quality manual is optional. However, an organisation must provide documented information as required by the standard (ISO 9001:2015)

Understanding the Details
Plan, Do, Check, Act (PDCA)

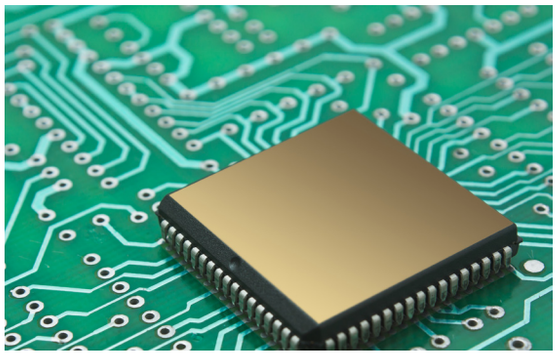
Plan – Management responsibility

The PDCA cycle starts with management as it is up to them to identify appropriate processes and relevant areas of focus.

Process identification:

Appropriate process identification is essential to a practical system and the key is to start with two processes (Management and Operations) and then decide if sub-processes are necessary rather than working "bottom up". Each process has to also have an "owner" that is responsible for the activities that relate to the success criteria of the process.

Planning and review:



The organisation is required to set out clear plans as to how they will achieve the quality objectives. The purpose of this planning process is to insure you meet your objectives and targets including customer requirements and prevent non-conformities occurring - for both product and services.

You determine the risks and opportunities that confront your organisation in delivering its products or services and plan actions to address them.

An organisation may utilise various types of documented information to capture their planned actions such as:

- Quality Policy, mission, vision, goals and purpose statements
- Strategy, business plans and operations plan
- Operating procedures, work instructions, flow charts including KPI's
- Software programmes and schedules, drawings, registers and checklists
- Internal audits, non-conformance analysis, customer feedback loops

Fundamental direction:

Owners or managers of your organisation should establish the fundamental direction of the QMS using the Quality Policy. There are several aspects that have to be thought through while designing the Quality Policy:

- **Leadership** - Top management shall demonstrate leadership and commitment with respect to the QMS
- **Context** - the organisation shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its QMS
- **Strategy** – should follow from the Quality Policy and the business environment
- **Risks and Opportunities** - When planning for the QMS, the organisation shall determine the risks and opportunities that need to be addressed to give assurance that the QMS can achieve it's intended result(s), enhance its desirable effects, prevent or reduce undesired effects and achieve improvement
- **Customer focus** – system processes have to be designed to ensure customer satisfaction
- **Support** – The organisation shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the QMS

Do – implementation and use

Having established the system it has to be used to ascertain it works in the way it was intended. It will be necessary to use documented information such as forms, checklists and work instructions in the way the system was planned.

The direction from your management and the assigned resources should make this part of the process fairly easy to implement. It is important to plan and define the processes all along the supply chain, this might include:

- Sales
- Purchasing
- Research and Development
- Manufacturing
- Delivery

Don't worry if some of the steps don't apply to you. ISO 9001 certification is designed for every type of organisation, just work on the aspects that are relevant to you.

Check – review of results

At appropriate intervals, the results of QMS should be reviewed. The intervals will be short when the system is new but can be longer once the QMS becomes mature. The reporting of results against the process success criteria should be regular and be used by management to ensure that the business is on track. Records should be designed to facilitate prompt recording as well as the early detection of problems.

Don't worry if your organisation has some problems (or "challenges" as we call them), every organisation has them but a successful one will identify these at an early stage and deal with them in an effective manner.

A key milestone in evaluating the QMS is the management review, a meeting which assesses whether the QMS has succeeded in meeting:

- Strategic objectives
- Process success criteria including Risks & Opportunities
- ISO 9001 requirements

Reviewing perceived customer satisfaction is a key metric that has to be reviewed. It is recognised that the handling of complaints is not enough; customers may just move their business to a competitor.

Probably the most important characteristic of a successful QMS is internal audits. Internal audits are a key tool to enable an Organisation to review whether its system is effective and to drive continual improvement.

Understanding the Details
Plan, Do, Check, Act (PDCA)

Act – continual improvement

Your organisation determines opportunities for improvement, as well as plans and actually implements actions in order to achieve the intended results and to enhance customer satisfaction. Improvements can help it to keep meeting customer requirements and expectations by improving its products and services, correcting or preventing undesired effects, and improving the performance and effectiveness of your QMS.

There are differenct methods to conduct improvement, such as:

- taking actions to avoid the recurrence of nonconformities
- small-step ongoing improvement activities conducted withing existing processes, products or services
- projects which can lead to significant changes to existing processes, the implementation of new processes, products or services, or the introduction of disruptive new technologies or innovations.

As a checklist, the following questions should be asked:

- **Customer Focus** – Have you found out what the customer's current and future need and expectations are at a strategic level?
- **Quality Policy** – Does it really suit your organisation and reflect your customer's expectations, your vision and mission – and the requirements of the standard?
- **Objectives** – Are all the objectives measurable and linked to both the processes and to the strategies?
- **Plan The System** – Have all the responsibilities been identified and communicated? Does everyone know what they need to do to contribute to the success of the business – and the QMS?
- **Review at Regular Intervals** – Are the results of the QMS being reviewed and compared against planned results? Is action being taken to improve areas where results are not quite as good as planned?
- **Review root cause of failures (or non-conformites)** - Can you establish the real cause of what went wrong? How do you put the necessary actions in place to stop it recurring?
- **Principles** – Management should review the 7 principles mentioned earlier and how well the system delivers against these.
- **Risks & Opportunities** - has your Organisation assessed risks and opportunities? These may impact the QMS

Tips

1. Top management commitment is vital if the system is to be introduced successfully.

2. Look at what system you have in place at the moment. ISO 9001:2015 will allow you maintain good current practices and further enhance them by implementing best practice.

3. Top management should determine the key processes of the organisation.

4. Ensure there are good internal communication channels and processes within the organisation. Staff need to be kept informed of what's going on.

5. Involve your staff in the processes that your organisation uses.

6. Give some thought to process interaction. It is important that the people within your organisation don't work in isolation but work as a team for the benefit of the customers and the organisation.

7. The processes should be looked at as good management practice. If your organisation is well managed, the quality should be automatically achieved.

8. Don't ignore the impact that introducing these systems will have on your customers and suppliers. Speak to them to gain insight as to how they view your service and how they feel improvements could be made.

9. Clearly lay out a well communicated plan of activities and timescale. Make sure everybody understands them and their role in achieving success.

10. Make it fun. Competitions for the first completed process that can be seen working (or similar events) will provide increased motivation.

11. Listed below are some tools employed to assist process control and step change:

    - SWOT
    - Pestel
    - Porter Five Force model
    - Cause & Effect diagram
    - Statistical Process Control (SPC)
    - Stakeholder maps
    - Lean Six Sigma
    - Kanban

Key Steps To Getting Certified for ISO 9001 by NSAI

1. Applying

The first step is to request a quotation for certification for your organisation, quotations are organisation specific and based on the NSAI request for quotation form. You will find this on our website or by contacing certification@nsai.ie for a copy. We will review all the information and provide you with a quotation. Our quotations cover the registration process and the following three-year certification cycle.

2. Gap Assessment

Applicants can proceed at their own pace, with assessment dates arranged to suit. If you are unsure whether you are ready to undergo assessment for registration, we can offer you a Gap Assessment, in which we:

- Conduct an on-site analysis of your current system
- Assess this against the relevant standard
- Issue you with a findings report which will highlight the gaps between your current system and the standard.

A gap assessment is optional and is not a requirement of the certification process.

3. Preliminary assessment – stage 1

The Preliminary Assessment involves an inspection of your documentation and a review ranging over various areas including:

- The proposed scope of your registration
- The status of implementation of your management system
- The appropriate regulatory and legal requirements
- Your management policies and objectives
- Whether the system addresses the key areas of your business
- Your site-specific activities – top level process review
- Your key management elements, e.g. internal audits, reviews and complaints procedures
- Your readiness to move onto Stage 2 of the assessment, the Registration Assessment.

The Preliminary Assessment takes place on-site. We recommend an interval of several weeks between the Preliminary Assessment and the Registration Assessment to allow time to resolve any issues arising.

When the Preliminary Assessment is complete we will produce a brief report evaluating your readiness to proceed to the next stage. This report wil also identify any areas that need to be improved before moving to the Registration Assessment (Stage 2).

NOTE: The Registration Assessment (Stage 2) must be completed within 6 months of the Preliminary Assessment (Stage 1).

If the Preliminary Assessment finds that your organisation is not ready for full Registration Assessment, it becomes, in effect, a Gap Assessment. That means that a second Preliminary Assessment will have to be carried out.

4. Registration assessment – stage 2

The Registration Assessment (Stage 2) involves a full review of your management system, including relevant records and documents. Its purpose is to confirm that your management system is properly controlled and has predictable outcomes.

At the end of the Registration Assessment, NSAI issues a detailed report, together with the outcome (whether to recommend registration or not). We will identify any issues found during the assessment. You in turn will be expected to submit an action plan detailing what changes are planned to be made to the management system to eliminate or reduce the risk of the same issues re-occurring.

5. Surveillance and re-assessment

At least once a year, NSAI visits each registered company to ensure the management system is being maintained and is achieving its expected outcomes. During each visit, part of the management system is reviewed in depth.

Certificates expire every three years, with the expiry date indicated on the certificate. Before that date, we undertake a detailed reassessment, reviewing the performance of the whole management system to make sure every element is performing satisfactorily. The results of the previous visits are taken into account.

During the period of registration, changes are inevitable. NSAI works with each registered organisation to make sure the management system remains sound. Normally, change can be reviewed and assessed during routine surveillance visits. **The QMS must be maintained during periods of change.**

Additional Material

Additional information

Enterprise Ireland Lean Offers	www.enterprise-ireland.com/en/Productivity/
ISO website	www.iso.org

To purchase a Standard or publication please contact our standard sales partner SAI Global at:

www.standards.ie
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Information on other management systems standards:

NSAI.ie/management-systems.aspx