ISO 9001:2008 is the world’s foremost quality management standard, used by hundreds of thousands of organizations 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 organization regardless of their size and industry. It can be used to focus on improving performance in a particular department, plant or site. However, it is generally most effective when implemented throughout an organization at every level.

ISO 9001:2008 is an update of an earlier ISO 9001:2000 and is part of a series of quality management system standards, sometimes referred to as ISO 9000. These comprise:

- **ISO 9000** – Fundamentals and Vocabulary, which introduces the basic principles underlying management systems and explains the terminology
- **ISO 9001** – Requirements, which specifies the criteria for certification
- **ISO 9004** – Guidelines for performance improvements goes beyond ISO 9001 by identifying how ISO 9001 can be used as a springboard for improving the efficiency and effectiveness of a quality management system.

Benefits for your organization include:

- **Increase in your organization’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 making money
- **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 complains
- **Global recognition** – ISO 9001 is a globally recognized quality standard that can open new market opportunities or just maintain current market share. Certification also attracts investment
- **Employee engagement** – 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 organizations (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
The 8 principles below are not auditable but are fundamental attributes of any quality management system. They have been taken from ISO 9000:2005 Quality Management Systems – Fundamentals and Vocabulary and have served as a basis for the new ISO 9001:2008 standard.

1. **Customer Focus**

   It is essential for your organization 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 organization, 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 organization’s future and set challenging goals and targets. It is only through unity of purpose and direction of employees that achieves organization’s objectives.

   Leader should maintain internal environment where people can get fully involved by establishing trust and eliminating fear.

3. **Involvement of People**

   People should be a core competency of every company. Involving people and their abilities at all levels can only bring benefit to your organization. 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. **System Approach to Management**

   Organization’s effectiveness and efficiency depends on your ability to identify, understand and manage interrelated processes as a system. Understanding interdependencies is key.

6. **Continual Improvement**

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

7. **Factual Approach to 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.

8. **Mutually Beneficial Supplier Relationships**

   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 optimization of costs and resources.
The Plan – Do – Check – Act (PDCA) cycle is the foundation of all ISO management system standards. The cycle ensures development, continuous improvement and control of the management system in question. It is a simple tool that ensures constant monitoring of your organization’s effectiveness. It consists of the following:

**Plan** – establishing the architecture of your quality management system is covered in clause 4.1 of the standard where it requires the identification of the processes, their success criteria, the inter-relationship between processes and the system for checking your results

**Do** – implementing the plans and using the quality management system

**Check** – reviewing whether the results are satisfactory at appropriate intervals against the ISO 9001 requirements

**Act** – improving the quality management system or acting on the challenges and issues found in the reviews

It is most likely that an organization already has an effective quality management system but it is probably informal and not well documented. ISO 9001 provides a more systematic approach to achieving organization’s objectives. It should not result in excessive bureaucracy or paperwork and 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.
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:
In order to successfully plan your quality system before implementation a quality manual and a number of documents outlining procedures are required. The areas of documentation are:

- Document control
- Records control
- Internal audits
- Non-conforming product
- Corrective action
- Preventative action

Additional procedures may be required if, without them, the process might end up having variable or unpredictable results such as those caused by inexperienced staff, complicated parameters or other risks. The QMS is, after all, a system for minimizing business risks.

Fundamental direction:
Owners or managers of your organization 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:

- Strategy – should follow from the Quality Policy and the business environment
- Process criteria – should be aligned to the strategy
- Customer focus – system processes have to be designed to ensure customer satisfaction
- Resources – human, technological and environmental resources have to be put in place. The QMS requires that each company establish a way that their staff are competent
**Do – implementation and use**

Having established the system, it has to be used to see that it works in the way it was intended. It will be necessary to use the procedures, forms, equipment and instructions in the way it 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 organization, 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 organization has some problems (or “challenges” as we call them), every organization 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
- 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 quality management system is internal audits. It is expected that an organization that does not do internal audits is very likely to have their certification revoked as their system is probably out of control.
Act – continuous improvement

Improvement is another name for dealing with challenges of the organization. Challenges can be tackled either with corrective action or, preferably, with preventative action. All corrective actions need to be recorded and preventative actions designed for recurring problems.

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 organization 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?

> • **Principles** – Management should review the 8 principles mentioned earlier and how well the system delivers against these.
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 9001:2008 will allow you to keep the principles that work for you while refining those that don’t.

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

4. Ensure there are good internal communication channels and processes within the organization. Staff needs to be kept informed of what’s going on.

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

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

7. The processes should be looked at as good management practice. If your organization 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.
Key Steps To Getting Certified for ISO 9001 by NSAI

1. **Applying**

   You can make certification application through our online quotations form or by phone, fax and email. We will review all the information and provide you with a company specific quotation. Our quotations cover a three-year period corresponding to the certification cycle and are calculated to make sure that every customer receives the certification service best suited to their needs.

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
   - Prepare a report highlighting 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 normally 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 from the Preliminary Assessment.

   After the Preliminary Assessment is completed, we will produce a brief report evaluating your readiness to proceed to the next stage and identifying any areas that need to be improved before moving to Stage 2.

   If the Preliminary Assessment finds that your organization 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 organization to make sure the management system remains sound. Normally, change can be reviewed and assessed during routine surveillance visits. In cases where change leads to the breakdown of the system, NSAI reserves the right to suspend or revoke certification.
Listed below are some tools employed to assist process control and step change:

> Six sigma
> Six sigma online community
> Lean manufacturing
> Just in time manufacturing (Kanban)
> Enterprise Ireland Lean Offers
> ISO 9001 for small businesses
> ISO 9001 website

> ILI details (for purchasing standards)

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