What is ISO?

ISO (The International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electro technical Commission (IEC) on all matters of electro technical standardization.

What is ISO 9001:2015?

The ISO 9001 is Quality Management Systems (QMS) is a standards that helps organizations they meet customer and other stakeholder needs within statutory and regulatory requirements related to product or service. They deals with the fundamentals of QMS including the seven quality Management principles that underlie the family of standards.

ISO 9001 is the only standard in the 9000 series that requires certification. Typically, an entire organization will seek certification, but the scope of the QMS can be tailored to improve performance at a particular facility or department.

ISO 9001:2015 specifies requirements for a quality management system when an organization:

a) Needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements.

b) Enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and assurance of conformity to customer and applicable statutory and regulatory requirements.

Third-party certification bodies provide independent confirmation that organizations meet the requirements of ISO 9001. Over one million organizations worldwide are independently certified, making ISO 9001 one of the most widely used management

tools in the world. The ISO certification process has been criticized as being wasteful and not being useful for all organizations.

ISO 9001:2015 Quality management systems is a document of approximately 30 pages available from the national standards organization in each country. Only ISO 9001 is directly audited against for third-party assessment purposes.

What topic under ISO 9001:2015?

- Context of the organization
- Scope
- Normative references
- Terms and definitions
- Context of the organization
- Leadership of organization
- Planning
- Support
- Operation
- Performance evaluation
- Continual improvement

Benefits of ISO 9001:2015?

- Suitable for both small and large organizations.
- Better internal management.
- Less wastage.
- Increase in efficiency, productivity and profit.
- Improved customer retention and acquisition.
- Consistent outcomes, measured and monitored.
- Globally recognized standard.

Advantages

Proper quality management can improve business, often having a positive effect on investment, market share, sales growth, sales margins, competitive advantage, and avoidance of litigation.[46] The quality principles in ISO 9000:2000 are also sound, according to Wade [47] and Barnes, who says that "ISO 9000 guidelines provide a comprehensive model for quality management systems that can make any company

competitive".[48] Sroufe and Curkovic, (2008) found benefits ranging from registration required to remain part of a supply base, better documentation, to cost benefits, and improved involvement and communication with management.[46] According to ISO[49] the 2015 version of the standard brings the following benefits:

1. By assessing their context, organizations can define who is affected by their work and what they expect. This enables clearly stated business objectives and the identification of new business opportunities.
2. Organizations can identify and address the risks associated with their organization.
3. By putting customers first, organizations can make sure they consistently meet customer needs and enhance customer satisfaction. This can lead to more repeat customers, new clients and increased business for the organization.
4. Organizations work in a more efficient way as all their processes are aligned and understood by everyone. This increases productivity and efficiency, bringing internal costs down.
5. Organizations will meet necessary statutory and regulatory requirements.
6. Organizations can expand into new markets, as some sectors and clients require ISO 9001 before doing business.

AUDITING

Two types of auditing are required to become registered to the standard:

a) Auditing by an external certification body (external audit)
b) Auditing by internal staff trained for this process (internal audits).

The continual process of review and assessment to verify the system is working as it is supposed to, to find out where it can improve, and to correct or prevent identified problems. It is considered healthier for internal auditors to audit outside their usual management line, so as to bring a degree of independence to their judgements. Supporting papers are provided by The ISO 9001 Auditing Practices Group.

This is constituted as an informal group of quality management system (QMS) experts, auditors and practitioners, drawn from the ISO Technical Committee 176 Quality Management and Quality Assurance (ISO/TC 176) and the International Accreditation Forum (IAF).

INDUSTRY SPECIFIC INTERPRETATIONS

The ISO 9001 standard is generic; its parts must be carefully interpreted to make sense within a particular organization. Developing software is not like making cheese or offering counseling services, ISO 9001 guidelines, they are business management guidelines, can be applied Diverse organizations police departments (United States), professional soccer teams (Mexico), and city councils (UK) have successfully implemented ISO 9001:2000 systems.

CRITICISMS OF ISO 9001 CERTIFICATION

A criticism of ISO 9000 and 9001 is the amount of money, time, and paperwork required for a complete implementation, and when needed, ISO 9001 certification. Dalgleish cites the "inordinate and often unnecessary paperwork burden" of ISO, and says that "quality managers feel that ISO's overhead and paperwork are excessive and extremely inefficient. The level of minimum documentation for a minimum scope organization has been greatly reduced, going from ISO 9001:2000 to ISO 9001:2008 to ISO 9001:2015.

One study showing reasons for not adopting this standard include the risks and uncertainty of not knowing if there are direct relationships to improved quality, and what kind and how many resources will be needed. Additional risks include how much certification will cost, increased bureaucratic processes and risk of poor company image if the certification process fails. According to John Seddon, ISO 9001 promotes specification, control, and procedures rather than understanding and improvement.

ISO 9001 WITHDRAWAL

ISO 9001 certification has a three-year validity period. At the end of this period, every certified organization must renew their certificate. Unfortunately, not all organizations are successful in their renewal. Some organizations are not able to renew the certificate, because they do not conform to all requirements, and others simply decide not to renew the certificate.

Some Organization lose or decide not to renew ISO 9001 certification there several reasons:

- Some companies may think that the total cost outweighs the certification benefits. This is the most cited reason for voluntary decertification, but some

research suggests that economic underperformance is not the reason why firms lose the certification.

- Some companies may believe that they have internalized the certification benefits into their processes and do not feel the need for formal certification as they can continue to conform to the ISO 9001 standard without formal registration within a certification body.
- Some of the customers may no longer demand certification.
- Some companies may have considered their ISO 9001 certification as a first step into quality management and now want to evolve their quality management systems by advancing to other alternative certifications (e.g., IATF 16949:2016, in the automobile industry) or towards other more demanding quality management systems (e.g., TQM, six sigma, lean).
- Financial distress.
- Improper ISO 9001 implementation.

ISO 9001 series Quality Management Principles

The ISO 9000 series are based on seven quality management principles (QMP)

The seven quality management principles are:

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

Principle 1 – Customer focus

Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

Principle 2 – Leadership

Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

Principle 3 – Engagement of people

People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

Principle 4 – Process approach

A desired result is achieved more efficiently when activities and related resources are managed as a process.

Principle 5 – Improvement

Improvement of the organization's overall performance should be a permanent objective of the organization.

Principle 6 – Evidence-based decision making

Effective decisions are based on the analysis of data and information.

Principle 7 – Relationship management

An organization and its external providers (suppliers, contractors, service providers) are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

Contents of ISO 9001:2015

ISO 9001:2015 Quality management systems — Requirements is a document of approximately 30 pages available from the national standards organization in each country. Only ISO 9001 is directly audited against for third-party assessment purposes.

Contents of ISO 9001:2015 are as follows:

- Section 1: Scope
- Section 2: Normative references
- Section 3: Terms and definitions
- Section 4: Context of the organization
- Section 5: Leadership
- Section 6: Planning
- Section 7: Support

- Section 8: Operation
- Section 9: Performance evaluation
- Section 10: Continual Improvement

Essentially, the layout of the standard is similar to the previous ISO 9001:2008 standard in that it follows the Plan, Do, Check, Act cycle in a process-based approach but is now further encouraging this to have risk-based thinking (section 0.3.3 of the introduction). The purpose of the quality objectives is to determine the conformity of the requirements (customers and organizations), facilitate effective deployment and improve the quality management system.[35][36]

Before the certification body can issue or renew a certificate, the auditor must be satisfied that the company being assessed has implemented the requirements of sections 4 to 10. Sections 1 to 3 are not directly audited against, but because they provide context and definitions for the rest of the standard, not that of the organization, their contents must be taken into account.

The standard no longer specifies that the organization shall issue and maintain documented procedures, but ISO 9001:2015 requires the organization to document any other procedures required for its effective operation. The standard also requires the organization to issue and communicate a documented quality policy, a quality management system scope, and quality objectives. The standard no longer requires compliant organizations to issue a formal Quality Manual. The standard does require retention of numerous records, as specified throughout the standard. New for the 2015 release is a requirement for an organization to assess risks and opportunities (section 6.1) and to determine internal and external issues relevant to its purpose and strategic direction (section 4.1). The organization must demonstrate how the standard's requirements are being met, while the external auditor's role is to determine the quality management system's effectiveness. More detailed interpretation and implementation examples are often sought by organizations seeking more information in what can be a very technical area.

Certification

The International Organization for Standardization (ISO) does not certify organisations itself. Numerous certification bodies exist, which audit organisations and upon success, issue ISO 9001 compliance certificates. Although commonly referred to as "ISO 9000" certification, the actual standard to which an organization's quality management system can be certified is ISO 9001:2015 (ISO 9001:2008 expired around September 2018). Many countries have formed accreditation bodies to authorize ("accredit") the certification bodies. Both the accreditation bodies and the certification bodies charge fees for their services. The various accreditation

bodies have mutual agreements with each other to ensure that certificates issued by one of the accredited certification bodies (CB) are accepted worldwide. Certification bodies themselves operate under another quality standard, ISO/IEC 17021,[37] while accreditation bodies operate under ISO/IEC 17011.[38]

An organization applying for ISO 9001 certification is audited based on an extensive sample of its sites, functions, products, services, and processes. The auditor presents a list of problems (defined as "nonconformities", "observations", or "opportunities for improvement") to management. If there are no major nonconformities, the certification body issues a certificate. Where major nonconformities are identified, the organization presents an improvement plan to the certification body (e.g., corrective action reports showing how the problems will be resolved); once the certification body is satisfied that the organization has carried out sufficient corrective action, it issues a certificate. The certificate is limited by a certain scope (e.g., production of golf balls) and displays the addresses to which the certificate refers.

An ISO 9001 certificate is not a once-and-for-all award but must be renewed, in accordance with ISO 17021, at regular intervals recommended by the certification body, usually once every three years.[39] There are no grades of competence within ISO 9001: either a company is certified (meaning that it is committed to the method and model of quality management described in the standard) or it is not. In this respect, ISO 9001 certification contrasts with measurement-based quality systems.

The new ISO 9001:2015 management system standard helps ensure that consumers get reliable, desired quality goods and services. This further increases benefits for a business.[43]

The 2015 version is also less prescriptive than its predecessors and focuses on performance. This was achieved by combining the process approach with risk-based thinking, and employing the Plan-Do-Check-Act cycle at all levels in the organization.[44]

Some of the key changes include:

- High-Level Structure of 10 clauses is implemented. Now all new standards released by ISO will have this high-level structure
- Greater emphasis on building a management system suited to each organization's particular needs
- A requirement that those at the top of an organization be involved and accountable, aligning quality with wider business strategy
- Risk-based thinking throughout the standard makes the whole management system a preventive tool and encourages continuous improvement

- Less prescriptive requirements for documentation: the organization can now decide what documented information it needs and what format it should be in
- Alignment with other key management system standards through the use of a common structure and core text[45]
- Inclusion of Knowledge Management principles
- Quality Manual & Management representative (MR) are no longer mandatory