ISO STANDARD REQUIREMENTS

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International Standard

- An International Standard is a document containing practical information and best practice
- It often describes an agreed way of doing something or a solution to a global problem.

International Organization for Standardization (**ISO**)

ISO is derived from the Greek *isos*, meaning equal.

Why ISO?

- **ISO develops and publish International Standards.**
- ISO creates documents that provide requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.

ISO

- ISO is an independent, non-governmental international organization with a membership of 163 national standards bodies.
- Through its members, it brings together experts to share knowledge and develop voluntary, consensus-based, market relevant International Standards that support innovation and provide solutions to global challenges.

ISO

- In 1946, delegates from 25 countries met at the Institute of Civil Engineers in London and decided to create a new international organization ‘to facilitate the international coordination and unification of industrial standards’.
- On 23 February 1947 the new organization, ISO, officially began operations.
- Today ISO has members from 163 countries and 779 technical bodies to take care of standards development.
- ISO’s Central Secretariat is located in Geneva, Switzerland.

Benefits of ISO International Standards

- ISO International Standards ensure that products and services are safe, reliable and of good quality.
- For business, they are strategic tools that reduce costs by minimizing waste and errors and increasing productivity.
- They help companies to access new markets, level the playing field for developing countries and facilitate free and fair global trade.

Development of ISO standards

- ISO standards are developed by users through a consensus process.
- Experts from all over the world develop the standards that are required by their sector.
- This means they reflect a wealth of international experience and knowledge.

ISO 9000 - Quality management

- The ISO 9000 family addresses various aspects of quality management.
- The standards provide guidance and tools for companies and organizations who want to ensure that their products and services consistently meet customer's requirements, and that quality is consistently improved.

ISO 9001

- ISO 9001 is a standard within the ISO 9000 family of standards.
- It is the international standard for **Quality Management Systems (QMS)**, published by ISO (the International Organization for Standardization).
- The standard was most recently updated in 2015, and is referred to as ISO 9001:2015.

Quality Management System

- The Quality Management System, which is often referred to as a QMS, is a collection of policies, processes, documented procedures and records.
- This collection of documentation defines the set of internal rules that will govern how your company creates and delivers your product or service to your customers.
- The QMS must be tailored to the needs of your company and the product or service you provide, but the ISO 9001 standard provides a set of guidelines to help make sure that you do not miss any important elements that a QMS needs to be successful.

Sector-specific applications of ISO 9001

- ISO has a range of standards for quality management systems that are based on ISO 9001 and adapted to specific sectors and industries. These include:
- ISO/TS 29001 – Petroleum, petrochemical and natural gas industries
  ISO 13485 – Medical devices
  ISO/IEC 90003 – Software engineering
  ISO 17582 – Electoral organizations at all levels of government
  ISO 18091 - Local government

ISO 9001 Requirements

4 Quality management system

- **4.1. General Requirements**
- The Quality Management System (QMS) is the collection of processes, documents, resources, and monitoring systems that direct the work of an organization regarding product and service quality.

ISO 9001 Requirements

- **4.2 Documentation requirements**
- **4.2.1 General**
- The organization needs to document – either electronically or on paper – the quality policy, quality objectives, and quality manual.
- Written procedure, plans, and operations need to describe how product and service quality is attained.
- Certain records, providing evidence of activities that were carried out (i.e. purchase orders, sales contracts, inspection records, design review notes, etc.), have to be retained.

ISO 9001 Requirements

- **4.2.2 Quality manual**
- The quality manual describes the extent of the QMS and may exclude certain sections of the Standard that don't pertain to the organization.
- All of the quality procedures are either included in the quality manual or are referenced by it.

ISO 9001 Requirements

- **4.2.3 Control of documents**
- All of the documents in your QMS must be legible, identified, reviewed, authorized, up-to-date, issued, distributed, and periodically updated.
- Obsolete documents have to be identified and protected from unintended use.
- Documents that come from outside the organization also have to be identified and controlled.

ISO 9001 Requirements

- **4.2.4 Control of records**
- Certain records need to be kept to demonstrate how the QMS is operating.
- These records must be legible, and easy to identify and retrieve.
- A written procedure must describe how they are identified, stored, protected, retrievable, and define their retention and disposal times.

ISO 9001 Requirements

5. Management responsibility

5.1 Management commitment

- The Standard recognizes that an effective quality program requires the involvement and commitment of the organization's top management.

ISO 9001 Requirements

- Therefore, the Standard assigns top management the following responsibilities:
- Overseeing the creation of the Quality Management System (QMS),
- Communicating the importance of meeting requirements, including customer, legal, and regulatory requirements,
- Establishing the quality policy and the quality objectives,
- Communicating with parties responsible for product and service quality,
- Providing adequate resources for the operation of the QMS
- Reviewing the operation of the QMS.

ISO 9001 Requirements

- **5.2 Customer focus**
- Top management must ensure that customer requirements are understood and met with the goal of improving customer satisfaction.

ISO 9001 Requirements

- **5.3 Quality policy**
- The quality policy identifies the main goals of the QMS. The quality policy must be:
- Appropriate to the organization's purpose,
- Include a commitment to meet customer, legal and regulatory requirements,
- Create a background for establishing quality objectives,
- Communicated throughout the organization,
- Reviewed for ongoing suitability to the needs of the organization and its customers

ISO 9001 Requirements

- **5.4 Planning**
- **5.4.1 Quality objectives**
- Establish measurable quality objectives that support the quality policy and communicate them throughout the organization.
- **5.4.2 QMS planning**
- Plan the QMS so that the quality objectives are met and so the system continues to work as it is changed to incorporate improvements.

ISO 9001 Requirements

- **5.5 Responsibility, authority and communication**
- **5.5.1 Responsibility and authority**
- Effective work depends on a clear understanding of each persons responsibility and authority.
- Therefore responsibility and authority must be defined and communicated.

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- **5.5.2 Management representative (MR)**
- Top management must appoint a manager to have ongoing operational responsibility for the QMS. This person is referred to as the Management Representative.
- The duties of the MR include:
- Ensuring that processes needed for the QMS are established, implemented, and maintained,
- Reporting on the performance of the QMS and any improvements needed,
- Promoting awareness of customer requirements throughout the organization

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- **5.5.3 Internal communication**
- Top management needs to set up an effective system of communication to ensure effective operation of the QMS.

ISO 9001 Requirements

- **5.6 Management review**
- **5.6.1 General**
- Top management is required to regularly review certain aspects of the QMS to make sure that the goals are being achieved and to look for ways to improve the QMS.
- The review must cover suitability, adequacy, and effectiveness of the QMS.
- The review also includes assessing opportunities for improvement and needed changes to the QMS, quality policy, and quality objectives. Records of these review must be kept.

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- **5.6.2 Review input**
- These meetings must address the following areas:
- Internal audit results,
- Customer feedback,
- How well processes have been working,
- How well products have been meeting requirements,
- Status of previously identified problems,
- Items identified for follow-up in previous management reviews,
- Planned process or product changes that could affect quality,
- Recommendations for improvement generated through the operation of the QMS

ISO 9001 Requirements

- **5.6.3 Review output**
- These reviews result in decisions and actions related to:
- improving the QMS, and
- improving the product,
- the need for additional resources, including human resources.

ISO 9001 Requirements

- **6 Resource management**
- **6.1 Provision of resources**
- Provide the people, equipment, tools, and materials need to:
- build and maintain the QMS,
- continually improve the effectiveness of the QMS, and to
- meet customer requirements

ISO 9001 Requirements

- **6.2 Human resources**
- **6.2.1 General**
- People performing work affecting product and service quality must be competent to carry out that work.
- This competency is attained through a combination of education, training, skills, and experience.

ISO 9001 Requirements

- **6.2.2 Competence, awareness and training**
- The organization must:
- Identify the talents, skills, knowledge, and capabilities each person needs to carry out their assigned responsibilities,
- train or otherwise assist people to meet these identified competencies,
- assess the competency of each person to carry out their responsibilities,
- make sure each person understand how their work contributes to the quality of products and services and to meeting quality objectives.
- keep records of each person's education, training, skills, and experience

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- **6.3 Infrastructure**
- The infrastructure for a QMS includes the building, workspace, equipment, and the supporting services involved in creating the organization's products or services.
- The organization will needs to determine, provide and maintain the infrastructure needed to achieve the planned results.

- **6.4 Work environment**
- The work environment of the organization must not interfere with the ability of employees to perform effectively in order to meet quality requirements.

ISO 9001 Requirements

- **7 Product Realization Requirements**
- **7.1 Planning of product realization**
- Product realization is the term used to describe the work that the organization goes through to develop, manufacture, and deliver the finished goods or services.
- An effective Quality Management System (QMS) includes a comprehensive approach to getting from the product concept to the finished product.

ISO 9001 Requirements

- This approach, sometimes called a *quality plan*, includes the following:
- product requirements and quality objectives,
- creation of the processes, documents, and resources needed for product realization,
- required verification, monitoring, inspection, and test activities,
- the records to be kept.

ISO 9001 Requirements

- **7.2 Customer-related processes**
- **7.2.1 Determination of requirements related to the product**
- The Standard requires the organization to determine product requirements.
- Requirements are established by standard contracts or oral agreements that the sales department uses in discussions with customers, and other sources.

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- **7.2.2 Review of requirements related to the product**
- After gathering preliminary product requirements, these requirements need to be reviewed to be sure that the customer understands them and that the organization is meeting these requirements.

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- This review must ensure:
- The requirements are known and understood,
- Any changes from the original contract or discussions is understood,
- The organization has the ability to meet the requirements
- Records are kept of this review.

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- **7.2.3 Customer communication**
- Put in place effective customer communications channels, to allow dialogue regarding:
- product information,
- questions about contracts, order handling, changes, and
- receiving customer feedback, including complaints.

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- **7.3.1 Design and development planning**
- To effectively plan the design and development process, the organization must:
- Clearly define the stages involved in the design and development process.
- Identify how the review and verification of the design will take place.
- Describe clear responsibility and authority for the people doing this work.
- Keep design and development plans up to date.

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- **7.3.2 Design and development inputs**
- Determine the product requirements, including:
- what it does and how well it must perform,
- legal and regulatory requirements,
- pertinent information from similar designs,
- other pertinent requirements.

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- **7.3.3 Design and development outputs**
- The output of design and development must include sufficient information to verify that design output meets design input requirements. In addition, it must:
- include the information need to purchase component materials, manufacture the product, and service the product.
- specify how to determine if the product has acceptable performance,
- highlight safety and usage considerations.

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- **7.3.4 Design and development review**
- Review the design and development work products to:
- determine if the design meets the design input requirements,
- identify and problems with the design,
- propose solutions to identified design problems,
- Include representatives from each function concerned with the design and development stage being reviewed. Keep records of the reviews.

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- **7.3.5 Design and development verification**
- Verify, according to your plan, that the design output meets design input requirements.
- Record the results of these verification activities.

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- **7.3.6 Design and development validation**
- Validate the operation of the resulting product under actual operating conditions.
- The methods for validation defined in the design output should be followed.
- Record the results of these validation activities.

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- **7.3.7 Control of design and development changes**
- Identify, document, review, and approve all design changes before carrying them out.
- Evaluate the impact of the changes on the present design of the product.
- Keep records of the review

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- **7.4 Purchasing**
- **7.4.1 Purchasing process**
- The organization needs to ensure that purchased products and services meet purchasing requirements.
- The purchasing group must establish criteria for how they evaluate and choose suppliers.

ISO 9001 Requirements

- **7.4.2 Purchasing information**
- Clearly describe on purchase orders the product or service being ordered.
- Consider including the following specifications:
- how products, procedures, processes, and equipment are approved for purchase,
- required competencies for contracted personnel,
- requirements for the supplier's quality management system.
- Review and approve purchasing requirements before sending them out.

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- **7.4.3 Verification of purchased product**
- Carry out a plan for verifying that purchased services and materials are adequate, i.e. meet purchase specifications

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- **7.5 Production and service provision**
- **7.5.1 Control of production and service provision**
- Plan production, installation, and service processes and provide an environment where work can proceed in an orderly fashion.

ISO 9001 Requirements

- **7.5.2 Validation of processes for production and service provision**
- Process validation demonstrates that operation of the processes achieves the planned results. When it is not possible to verify the finished good or service through monitoring or measurement the QMS must require validation. Validation is particularly important where deficiencies are not identified until the product is in use, or the service is delivered.

ISO 9001 Requirements

- **7.5.3 Identification and traceability**
- Where appropriate, establish procedures to identify a product and determine what specifications pertain to it as it moves through manufacturing, delivery, and installation. Record the inspection and measurement status of the product. Individual products or batches of products must have unique serial identification recorded if assuring product product quality requires this.

ISO 9001 Requirements

- **7.5.4 Customer property**
- Special care must be taken when a customer provides their property for use or incorporation into the product. Identify, verify, and protect customer property provided and maintain records of lost, damaged or unsuitable customer property. This may include intellectual property.

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- **7.5.5 Preservation of product**
- The standard requires the organization to preserve the product, including identification, handling, storage, packaging, protection, and delivery of parts and products throughout all processes.

ISO 9001 Requirements

- **7.6 Control of monitoring and measuring devices**
- Any measurement worth taking is worth taking correctly. The standard requires the organization to identify the inspection, test and measurements taken, their required accuracy, and the equipment used to make the measurements. Procedures must describe how measurements are carried out.

ISO 9001 Requirements

- Measuring equipment must be carefully cared for, including:
- timely calibration to national standards,
- identification with a calibration label,
- preventing adjustments that would invalidate the calibration,
- preserving the equipment accuracy during handling, storage and use.
- Measurements taken with equipment later found to be inaccurate must be assessed and corrected.

ISO 9001 Requirements

- **8 Measurement, analysis and improvement requirements**
- **8.1 General**
- Plan and carry out the inspection, test, measurement, analysis, and improvement activities needed to:
- assure product meets product requirements,
- assure the QMS works as planned,
- improve the operation and results from the QMS.

ISO 9001 Requirements

- **8.2.1 Customer satisfaction**
- Monitor the end customers' opinion of your product and service. Determine how to gather and use this information.

ISO 9001 Requirements

- **8.2.2 Internal audit**
- Internal audits are verification activities performed by trained auditors within the organization. Their purpose is to determine how well the plans making up the QMS are being followed. The Standard requires internal audits be carried out regularly in each area covered by the QMS. Audits address conformity with the QMS, the requirements of ISO 9001:2000, and the effectiveness of the implementation.

ISO 9001 Requirements

- Audit plans address:
- Audit criteria, and extent,
- Frequency, and methods used,
- Responsibility for conducting the audit
- Auditors are trained, objective, and never audit their own work.
- Identified problems are quickly resolved by the manager responsible for area being audited.
- Audit results are reported and recorded, follow up actions are verified.

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- **8.2.3 Monitoring and measurement of processes**
- Monitor and measure the performance of the processes that make up the QMS. Compare these actual results to the planned results. Take corrective action to make sure the product or service meets requirements.

ISO 9001 Requirements

- **8.2.4 Monitoring and measurement of product**
- During the production process, monitor and measure the product to assess if requirements are met. Keep records showing:
- The product meets acceptance criteria.
- The name of the person who authorized release of the product.
- The product has proceeded through all of the planned process steps, including all planned verifications.

ISO 9001 Requirements

- **8.3 Control of nonconforming product**
- Nonconforming product is any product or service that does not meet requirements. Have documented procedures to identify nonconforming products and to make sure they are not used by accident. Define who is responsible for deciding what to do with a bad product.

ISO 9001 Requirements

- One of the following three actions must be taken:
- fix the product as if the problem never happened,
- ask the customer to accept it, perhaps on new terms,
- discard it or clearly mark it as unsuitable for its original use.
- Keep records of nonconformities.
- Re-inspect any corrected products according to the procedures for new products.
- Mitigate potential losses, perhaps by recall, from any product that has been found to be defective after its release to the customer.

ISO 9001 Requirements

- **8.4 Analysis of data**
- The standard requires the organization to collect information on the functioning of the QMS. This information is then analyzed to evaluate the effectiveness and efficiency of your system and to identify opportunities for continual improvement of the QMS. Information collected and analyzed relates to:
- customer satisfaction,
- meeting product requirements,
- process characteristics and trends,
- product characteristics and trends,
- supplier performance.

ISO 9001 Requirements

- **8.5 Improvement**
- **8.5.1 Continual improvement**
- Make use of the quality policy, quality objectives, audit results, data analysis, corrective and preventive actions and management review to improve the QMS.

ISO 9001 Requirements

- **8.5.2 Corrective action**
- When problems occur, fix the underlying process responsible for the defect. The thoroughness of each solution depends on how costly or unsafe the actual or possible problems are.

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- Create written procedures for:
- satisfying customer complaints
- investigating and solving reported product and process problems,
- identifying the underlying cause of these nonconformities,
- understanding how to eliminate the cause of nonconformities,
- making sure corrective actions are carried out,
- keeping a record of corrective actions,
- following up on corrective actions.

ISO 9001 Requirements

- **8.5.3 Preventive action**
- The same actions described above for corrective actions must be considered for problems that have yet to occur.
- This is called preventive action.
- Effective preventive action involves identifying the potential problem, examining the root cause, putting a plan in place to prevent occurrence of the problem, evaluating the effectiveness of the plan, recording actions taken, and reviewing the preventive actions taken.
- A written procedure is required to describe the preventive action process.

THANK YOU