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Review Article

Quality management systems & ISO 9000 effectiveness: A review

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ABSTRACT

ISO 9000 is a widely used quality management standard in the world. The review of literature has shown the Overview of ISO 9000 series of standards.ISO 9000 application oppose the philosophy of Quality Management Systems (QMS) Approach, control an organization in order to continually improve the effectiveness and efficiency of its performance is known as quality management system. The principles of Quality management systems Fundamentals and vocabulary and in ISO 9004:2000 and Guidelines for performance improvements.

1. Introduction

ISO is a non- governmental organization formed in 23 February 1947. Its headquarters is in Geneva, Switzerland. ISO is an international standard-setting body composed of representatives from various national standards organizations and as of 2013 works in 164 countries. [1,2]

Some popular standards are-

1. ISO 9000 Quality Management
2. ISO 14000 Environmental Management
3. ISO 3166 Country codes
4. ISO 26000 Social Responsibility
5. ISO 50001 Energy Management
6. ISO 31000 Risk Management
7. ISO 22000 Food Safety Management
8. ISO 27001 Information Security Management
9. ISO 20121 Sustainable Events.

2. ISO 9000

The ISO 9000 is a series of international standards on Quality management and Quality assurance system which can be adopted by all types of organization involved in production and supply of all kinds of goods, services, software etc. [3,4]

ISO itself constitutes of series of standards namely ISO 9000, ISO 9001, ISO 9002, ISO 9003 and 9004. [3,4]

The three quality system models for external quality assurance are ISO 9001, 9002, 9003. [5]

1. ISO 9001 is the most comprehensive standard that covers the design, manufacturing, installation and servicing systems.
2. ISO 9002 covers manufacturing and installation.
3. ISO 9003 covers only final product inspection and test.
4. ISO 9004 provides guidelines to manufacturer for internal use who is developing its own quality system to achieve the business needs.

In order to attain ISO 9000 registration the manufacture must provide the objective evidence which shows that its quality process are properly managed and that all the determined requirements are understood properly and achieved and that the company's internal procedure text shows that the customer service and the product quality are maintained up to the mark.

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The ISO 9000 standards also require that a company maintain control of its documented procedures that describe its method for design, production, inspection, handling, storage and delivery of all materials and products as well as defining the system that assures continuous employee training and development.[6] The Figure 1 shows that Overview of ISO 9000 series of standards.

2.1. Quality management systems (QMS) approach

"A set of co-ordinated activities between the organization and customer to direct and control an organization in order to continually improve the effectiveness and efficiency of its performance is known as quality management system."[7–9]

An approach to QMS includes following steps:-

1. For developing QMS the customer needs and expectations should be determined.
2. The quality policy and quality objectives of the organization should be established.
3. The processes and responsibilities necessary to attain the quality objectives should be determined.
4. The resources which are necessary to attain the quality objectives should be determined and provided specifically.
5. Methods should be established to measure the effectiveness and efficiency of each process.
6. Proper measures are applied in order to determine the effectiveness and effiency of each process.
7. In Measures are determined to prevent the nonconformities and thereby eliminating their cause.
8. Order to improve the existing management practices valid process is determined and applied specifically.

An organization that follows QMS or process approach generates a confidence in the capability of its processes and subsequently increases the quality of the product and hence results in continuous improvement. This leads to increased customer satisfaction and to the success of the organization.[10]

2.2. The process approach

The Transformation of one or more inputs into valuable outputs that serves to customer is considered as Process approach.[8,9]

Effective and successful running of any organization depends on how they identify and manage the various interrelated and interacting processes. The output from one input directly gets convert into input for next process. Adoption of process approach by every organization in order to manage their quality and service is the main objective of this international standard. The process based QMS as described by the ISO 9000 series is explained in the following Figure 2 shows A Model of a Process-based Quality Management System.[9,11]

For the development of the quality management system the supplier organization should maintain the following documents:[11,12]

1. Quality policy statement and quality objectives, there are important for the achievement of quality policy.
2. Quality Manual.
3. Operational Procedures SOPS, Protocols, these instruction are given by the Organization.
4. Instructions to operators
5. Formats are the documents which necessary to record the data.
6. Records are used to signify the application status of organization activities.
7. The documentation cam is either a manuscript or an electronic type.

The principles are integrated in the five clauses of the standard. Quality management systems Fundamentals and vocabulary, and in ISO 9004:2000, Quality management systems Guidelines for performance improvements.[8,9,13–17] The principles are discussed in details followings are:

3. Customer Focus

In order to direct the organization Quality policy and Quality objectives are designed. These two tools determine the desired result and assist the organization so that they can apply their resources in right direction and achieve the desired results. The quality process provides a suitable framework for the enforcement of quality objectives. The quality objectives need to be consistent with the quality policy and the commitment to continual improvement, and their achievement needs to be measurable. The positive impact on product quality, operational effectiveness and financial performance can be attained by the achievement of quality objectives which leads to the customer satisfaction.

3.1. Responsibility, authority and communication

The responsibility of the top management is to frame the quality objectives in order to achieve Quality Policy. The top management should also establish the "Organization Chart" which should include the reporting hierarchy in the Organization. The responsibilities of personnel should be documented. The responsibilities of personnel need to be stated clearly and should be communicated to all personnel within the organization.

3.2. Management review

To achieve the business goal the activities of the Organization should be reviewed time to time by the Management so as to know the current status of activities and for this purpose "Management Review" is required.

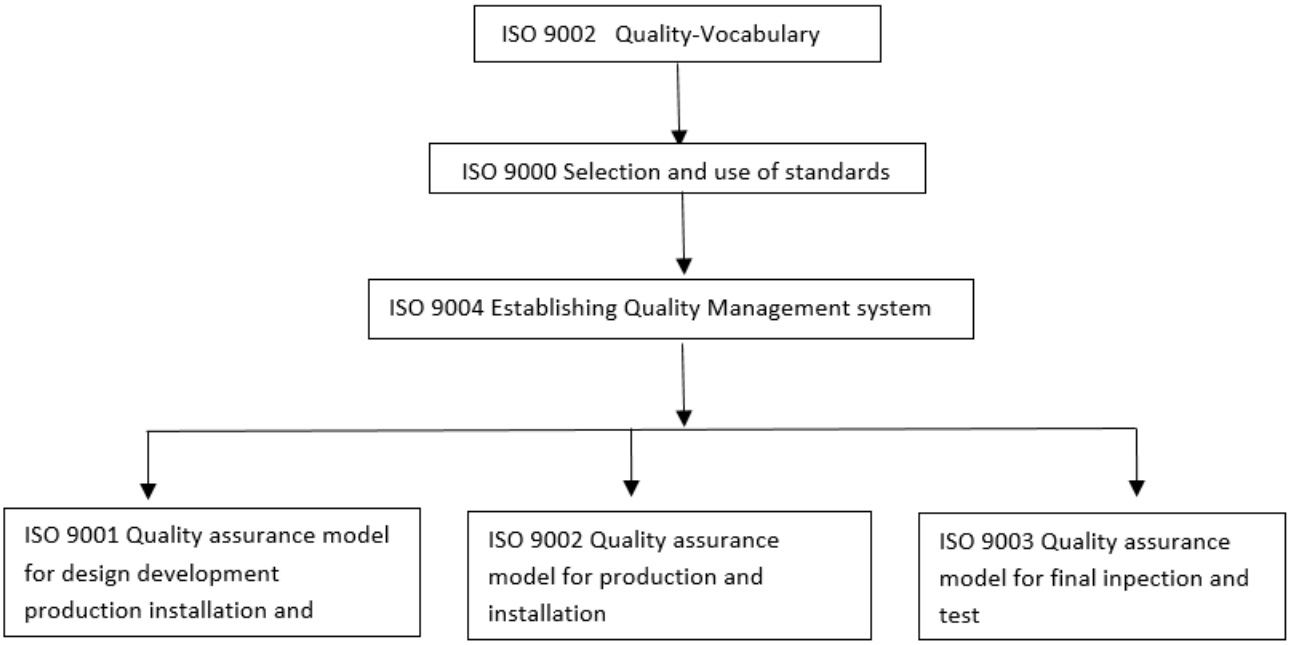

Fig. 1: Overview of ISO 9000 series of standards.[6]

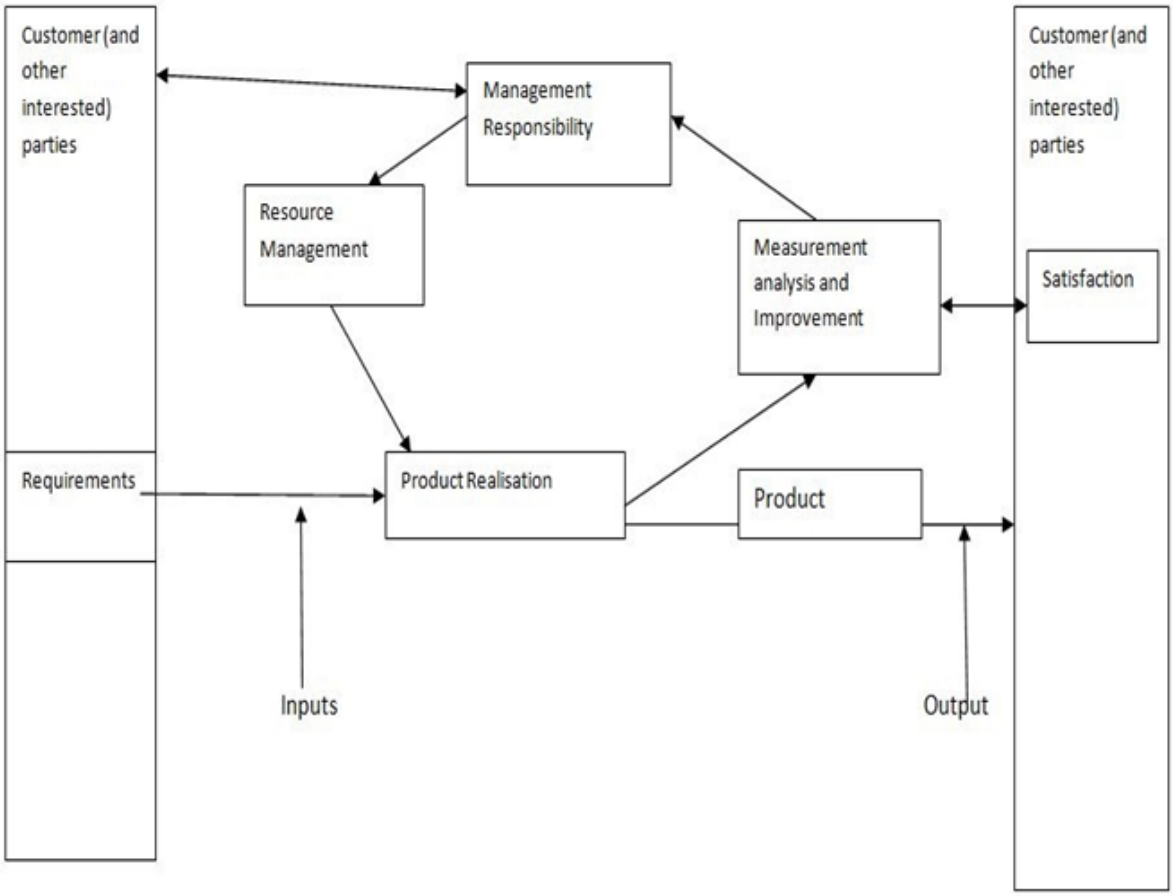

Fig. 2: A model of a process-based quality management system

4. Resource Management

4.1. Provision of resources

Certain procedures are established by the organization in order to provide necessary resources and these are:

1. Technological Resource
2. Facility Resource
3. Infrastructure Resource
4. Human Resource
5. Business development resource

These resources should be managed by Management review process.

5. Product Realisation 100 Percent Unique

For product realization the Organization should plan and develop the certain process. "Quality plan" is a document which Organization should develop and it should be either product based or project based.

5.1. Designs and development

This refers to the Research and Development function in the organization. This process is mainly for new products or process discovery or existing product process modifications or changes as necessary.

5.2. Purchasing process

The materials used within the organization should be of desired specification. The implication of the purchased material should be evaluated on the finished products manufactured by the organization. The materials supplied by the supplier or manufacture are solely responsible for the quality of the final product. Therefore, the material which is accepted for production process should be of good quality.

5.3. Production and service operations

These processes are necessary to be performed during manufacturing process and it covers following:

1. Production process and service operations.
2. Validation of applicable processes.
3. Materials identification, storage and trace ability.
4. Customers property/material
5. Packaging and delivery of the product
6. Monitoring and measuring devices control and calibration.
7. Monitoring and measuring devices control and calibration.

6. Measurement, analysis and improvement

The process/activities in the manufacturing operations that are under execution should cover the phases of installation, monitoring, measurement, analysis of data and provident and this process should be identified by the organization continuously over a certain period of time.

6.1. Control of non-conforming product

For the following process the organization should develop specific procedure:

1. Product/process criteria
2. Monitoring criteria
3. Recording mechanism of non-conformities
4. Action to be taken to eliminate non-conformity
5. Re-verification of corrected product
6. Notification of changes to statutory authorities.

To prevent the entering of unauthorized or unapproved products into the manufacturing operations these process of evaluations are essential.

6.2. Analysis of data

For the following process the organization should develop specific procedure:

1. Identification of parameters
2. Collection of data
3. Analysis of data
4. Conclusions

7. Improvement

7.1. Continual improvement

It is necessary for the any Organization to observe the following process in order to maintain the Quality Management System within the organization:

1. Quality policy and objectives
2. Analysis of data Corrective and preventive actions taken especially on critical issues.
3. Internal audit reports
4. Management review reports.

8. Conclusion

This investigation gives observational proof that accreditation to ISO 9000 is related with the apparent execution of TQM theory. The organizations having ISO 9000 accreditation can perform better in contrast with non-confirmed organizations. The documentation for ISO 9000 encourages representatives having better work guidelines and techniques which subsequently improve the authoritative cycles. The execution of soul of ISO 9000 quality administration System subsequent to having the accreditation of this norm.

9. Source of Funding

None.

10. Conflict of Interest

None.

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References

1. Available from: https://www.iso.org/.
2. Available from: https://asq.org/quality-resources/iso-9000.
3. Wilson JP, Walsh MAT, Needy KL. An Examination of the Economic Benefits of ISO 9000 and the Baldrige Award to Manufacturing Firms. *Eng Manag J*. 2003;15(4):3–10.
4. Kartha CP. A comparison of ISO 9000:2000 quality system standards, QS9000, ISO/TS 16949 and Baldrige criteria. *TQM Mag*. 2004;16:331–40.
5. Byrnes D. Exploring the world of ISO 9000; 1992.
6. Todorov B. ISO 9000 required: Your worldwide passport to customer confidence. Portland: Productivity Press; 1996.
7. ISO (2008). ISO 9001:2008, Quality management systems: Requirements. Geneva, Switzerland. Geneva, Switzerland.
8. ISO (2000). ISO 9001:2000, Quality management systems: Requirements. Geneva, Switzerland.
9. ISO (2000).ISO 9001:2000, vocabulary. Geneva, Switzerland.
10. International Organisation for Standardisation. The ISO survey of certification, 2009. Geneva, Switzerland. 2011. Available from: https://asq.org/quality-resources/iso-9000.
11. Ahire SL, Dreyfus P. The impact of design management and process management on quality: an empirical investigation. *J Operations Manag*. 2000;18(5):549–75.
12. Jang WY, Lin CI. An integrated framework for ISO 9000 motivation, depth of ISO implementation and firm performance. *J Manufacturing Technol Manag*. 2008;19(2):194–216.
13. International Organisation for Standardisation. The ISO survey of certification, 2009. Geneva, Switzerland. 2011.
14. Choi TY, Eboch K. The TQM Paradox: Relations among TQM practices, plant performance, and customer satisfaction. *J Operations Manag*. 1998;17(1):59–75.
15. Dean JW, Bowen DE. Management theory and Total Quality: Improving research and practice through theory development. *Acad Manag Rev*. 1994;19(3):392–418.
16. Evans JR, Lindsay WM. Managing for quality and performance excellence. Mason: Thomson Corporation; 2008.
17. International Organisation for Standardisation. The ISO survey of certification, 2009. Geneva, Switzerland.

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