ISO Quality Management System Implementation for Small to Medium Manufacturing Firms Kenya

George Guchu and ZSumbah Mwanaongoro

***Abstract*—**ISO 9000 standards represent a global consensus on quality management practices. It consists of standards and guidelines relating to quality management systems and related supporting standards. ISO 9001:2008 is the standard that provides a set of standardized requirements for a quality management system, and applies to any organization whether in the private, or public sector. It is the only standard in the family against which organizations can be certified. The quality management system must be checked if it works through, organization auditing itself, inviting clients to audit the system or engage independent quality system certification body to obtain certificate of conformity. In this paper focus on the approach to obtain ISO certification for small to medium sheet metal manufacturing firms in Kenya is outlined. The paper formulates steps that can be taken used to obtain certification by third party certifying bodies in Kenya. The purpose of the article is to provide overview of ISO 90001:2008, its benefits for small to medium firms in Kenya, third party certifying bodies in Kenya and description how of ISO certification can be implemented

***Keywords*—** ISO 9000, ISO 9000:2008, Quality System, Audit

I. Introduction

Quality system can be defined as a process that combines with manufacturing or service provision to ensure quality perfect products and services. ISO refers to international organization for standards. ISO 9000 series is an international family of generic quality standards, originally published by ISO in 1987, and updated in 1994 and again in 2000 and 2008. This international standard has been adopted by over 100 countries worldwide including Kenya. The idea behind the standards is defects can be prevented through the planning and application of best practices at every stage of business from design through manufacturing and then installation and servicing. ISO 9000 defines quality management system as "Management system to direct and Control an organization with regard to quality". ISO 9000:1994 series consisted of three standards namely:

ISO 9001: Design, development, production, installation and servicing.
ISO 9002: Production, installation and servicing
ISO 9003: Inspection and testing.

ISO 9000:2000 combined the three standards 9001, 9002 and 9003 into one called 9001 based on eight management principles;

- Customer focus
- Leadership
- Involvement of people
- Process approach
- System approach to management
- Continual improvement
- Factual approach to decision making
- Mutual beneficial supplier relationships

Major change involved shift from the 20 clauses requirement to a plan-do-check-act type of structure and alignment with ISO 14001:1996 which followed a process based approach[1]. ISO 9001:2008 (revised 2008) didn't introduce new requirements but important clarifications were made. ISO 9000 has four core standards that is,

ISO 9000:2008 provides quality management principles and fundamentals, describes what the series is all about, and lists definitions of terms for the use by any organization

ISO 9001:2008 states requirements for quality management systems when it is necessary to demonstrate that an organization is capable of meeting customer and regulatory requirement.

ISO 9004:2008 provides guidance for establishing quality management system that goes beyond ISO 9001 to meet and exceed customer requirements.

ISO 19011 provides guidance on planning and conducting quality audits.

ISO 9001:2008 consists of five clauses that contain 23 sub clauses [Appendix A] that specify what an organization must do to conform to the standard. The standard emphasizes on

- Greater focus on the customer- determine customer needs and expectations and monitor customer satisfaction
- Measurable objectives must be established-Role of top management to develop and improve system
- Measurement and continual improvement is required
- Training effectiveness must be evaluated

These standards ask a company to first document and implement its systems for quality management and then to verify by means of an audit conducted by an independent accredited third party, for compliance of those systems to the requirements of the standards. In Kenya the accredited third party auditors include

- Kenya Bureau of Standards
- SGS
- Bureau Veritas Quality international
- CVA international

Reasons for certification

The reasons for seeking ISO registration are many and vary between companies. According to Lipovatz [2] reasons for certification falls in two categories, market related and improvement of internal procedures. Jones [3] et all categorized reasons for certification into;

- Developmental, desire to improve company's internal procedures and overall competitiveness.
- Non developmental, requirement of major customers
- Combination of development and non developmental reasons

Benefits of ISO certification

Motwani et all [4] have summarized the benefits of ISO into six categories.

G.Guchu, Department of Mechanical Engineering, JKUAT (e-mail: gguchu@yahoo.com).
S.Mwanaongoro, Department of Mechanical Engineering, JKUAT (e-mail: mwanaongoro@yahoo.com).

(1) Assurance of business relations with most Nations, some countries especially the European Community insist on conducting business with ISO certified firms only.
(2) Worldwide recognition, because the standards are considered a Universally accepted quality standard;
(3) Use of certification label in marketing;
(4) A listing in the international "certified supplier" directory;
(5) Improved quality and productivity, and reduced costs associated with a basic quality system.
(6) Elimination of expensive, time-consuming, second-party audits by Prospective customers.

II. QUALITY MANAGEMENT SYSTEM

Quality management system constitutes of four processes figure 1.1 that is;

- Management processes including strategic decisions, determination of quality policy and quality objectives and other management tasks.
- Product realization processes - describes the activities needed to produce the products and services to internal and external customers.
- Resource management – includes determination and allocation of human resources, infrastructure and work environment.
- Measurement, analysis and improvement process- ensure the product and quality management system meet the requirement and the system is continually improved.

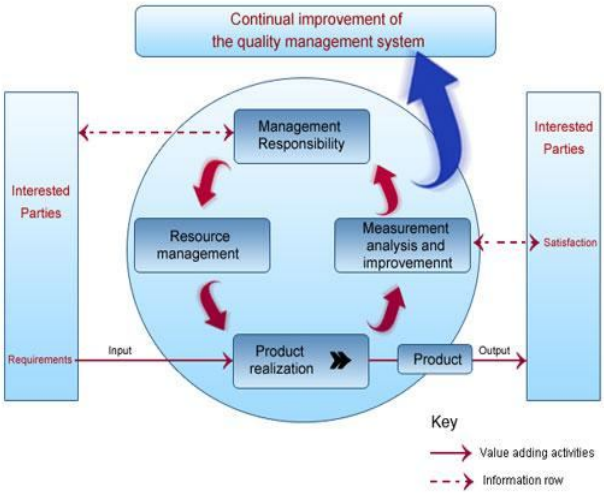


Fig 1.1 Process that constitute Quality Management System

III. IMPLEMENTATION METHODOLOGY

The design and implementation of organizations quality management system is based on objectives, products, process employed and structure of the organization [5]. Common strategies in establishing and maintaining an effective documented quality system in order to achieve ISO 9000 registration entails the following.

1. Management commitment and project team.
Management should believe in the benefits of registration be actively involved in registration process. Quality policy and objectives have to be specified by management and made clear to all levels of the organization. ISO project team should be formed for developing and implementing an effective quality management system. The size of team depends on the size of the factory, a team of three members is sufficient. One member to be the management representative and the second his assistant .The team should maintain the quality manual, schedule internal audits and management review meetings.

2. Self assessment (Gap analysis)
This involves evaluation of existing quality manual so as to formalize the way things are done, demonstrate the way things are done, demonstrate things are done right, monitor what is being done and improve. This evaluation is also referred to as baseline audit and consists of adequacy and compliance audits defined as follows [6]

- *Adequacy audit*. The adequacy audit is defined as the audit that determines the extent to which the documented quality system, represented by the quality manual and the associated procedures, meets the requirements of the applicable standard.
- *Compliance audit.* The compliance audit is defined as the audit which seeks to establish the extent to which the documented system is implemented and observed by the workforce; that is, are the people complying with the documented system?

3. Awareness and training
All personnel involved in tasks that affect quality must be trained on development of quality manuals, procedures, identification and implementation of improvement processes and on how to audit compliance with the QMS.

4. Develop action plan
Implementation plan is developed which may include the following items: Review of ISO 9000 requirements; discuss audit questions; evaluate compliance of individual units; discuss adequacy of existing systems; generate specific actions needed; assign responsibilities; obtain commitment; audit actions taken.

5. Define processes and documents
Multiple-tiered quality management documentation is commonly adopted, as shown in Figure 1.2 [7]. The top tier include the company quality manual reflecting the applicable ISO standard and the company's quality policy. Quality manual is the ISO 9000 standard, clause by clause stating how each part of the standard will be achieved [8]. ISO defines quality manual as a document specifying the quality management system of an organization [9]. Clause 7 of ISO 9001:2008 relating to product realization should be reviewed to determine how the requirements apply or don't apply to the company for example in case of production firm the clause applicable is 7.5 production and service provision. The other clauses can be excluded from QMS and reasons given in the quality manual.
The quality manual should;

- Include how QMS applies to products, processes and departments of organizations.
- Exclude any requirement and justification
- Refer to or include documented procedures for QMS
- Describe interactions between the processes of the QMS for example product realization and measurement and improvement.
- Draft quality policy and quality objectives of the organization.

ISO 9001:2008 requires organization to have documented procedures that is specified way to carry out a process for; control of documents, control of records, internal audit, and control of non conforming product, corrective action and preventive action. Other procedures and work instructions though not mentioned add value to QMS and demonstrate conformity and are included. The departmental manual shows company policy and the organizational responsibilities to accomplish that policy. Each departmental manual is supported by documented procedures which explain what quality activities are to be performed and by whom. Examples include operating procedures, engineering procedures and purchasing procedures. The third tier of documentation is work instructions intended to define the details of how a task is to be performed, including flow charts, standard forms,

calibration instructions and inspection/test instructions. The fourth tier of documentation is forms and records, which serves to demonstrate the achievement of results and provide evidence of activities performed; for example, inspection reports, audit reports and material review reports, etc. It is recommended that all documents are designed by the responsible engineers and supervisors familiar with the daily practices. The records required by ISO 9001:2008 are shown in annex B.

Fig 1.2

Effective preparation for the documentation system requires a documentation matrix to:

- Identify which procedures are to be prepared for each ISO 9001 requirement;
- define the responsibility of the principal writer and who provides input to the corresponding procedure preparation;
- time frame for completion of the first draft of the procedure.

Examples of documentation for the firm are as shown.

Quality Policy:

Firm XXX will strive to supply sheets as per customer stated and implied quality requirements on promised date at all times.

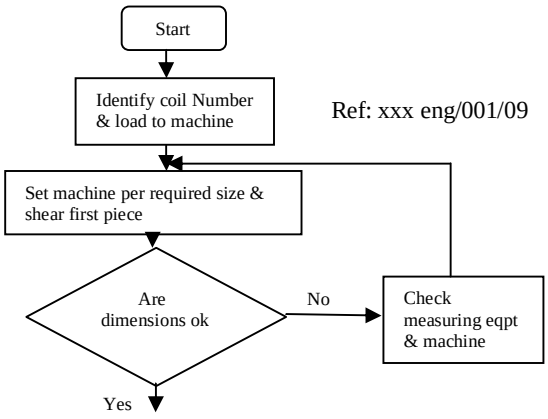
Quality objectives:

- Process control at desired quality levels to avoid production of non conforming products.
- Verification, elimination of defects through standard inspection techniques.
- Timely quality production to meet customer due dates promised.

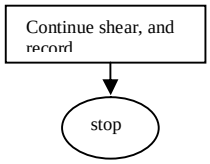
Table 1.1 Work procedure

xxx eng 001/09

Sl no	product	Dimension (mm)	input	Operation (mm)	Remarks
1	Cl 0001/09	1220x0.7	200	2440x1220x0.7	Order no 1



Ref: xxx eng/001/09



Ref: xxx prod 001/09

Fig 1.3 Shearing Work instructions

Table 1.2 Record name:xxx/prod/001/09

Date:

Sl no	Start	stop	Product id	dimensions	Input weight	Output size	Output weight	Remarks
1	0800	0850	Cl 001/08	1220X0.7	200	2440x1220x0.7	140	Order no 1

6. Select a certification body

The key elements to consider in selecting the certification body include;

- Customers expectations or preferences
- Government regulations
- International recognition
- Auditor's knowledge, experience and their qualifications.

On identifying and selecting the certification body, the company can apply for registration.

7. Establish the quality management system

Responsibilities and authority of all personnel managing, performing and verifying activities which affect the quality system should be defined. Job descriptions and specifications should be prepared for each level of staff including the operators in each section.

Besides document preparation, processes to control document distribution, approval and reissue, updating, and retrieving need to be established. Central documentation control can be considered to be adopted rather than decentralized control by individual departments/sections. This means that a core group of people should be assigned company-wide to take care of all documentation control activities. Moreover, a calibration system should be set up early in the program. Often, equipment or devices need to be calibrated against nationally recognized standards by an external calibration laboratory.

Test runs of each document on line should be performed to collect feedback from users, especially operators. Comments should be incorporated into revisions of the document to really reflect the operational practices. When the first and second tiers of documentation are prepared, they can be submitted to the certification body for adequacy audit. If the documents are accepted by the auditor, a schedule of certification audit can be confirmed by both the certification body and the company.

8. Train operators and implement the quality management system

Operators and quality inspectors should be trained to use the prepared instructions. Explanations of the basic purpose of ISO 9000 and the company quality policy should be included in the training. Once all the documentation is in place the quality management system ought to be put into operation. The certification body normally requests three to six months of implementation data recorded in all forms of appropriate quality records. The management should implement documented quality system by collecting and recording all quality data as evidence of effective implementation.

9. Conduct an internal quality audit

An internal quality audit should be performed before the certification audit to assess the effective implementation of the newly established quality assurance system. All non-conformances identified during the audit must be rectified by appropriate remedial measures. Here, management support is needed to resolve difficult issues. At this stage, the company can utilize internal auditors getting out of their departments to audit areas they don't work in. This ensures:

• Independent unbiased audit;
• Provision of relevant suggestions for preparation for the actual certification audit;
• Familiarizing operators with third-party audit.

Alternatively, the company can invite a selected certification body to perform a pre-audit. A follow-up audit should be conducted to verify the effective implementation of all committed corrective actions.

10. Management review the audit results

The organization should conduct at least two management reviews before the certification audit; these reviews follow internal audits. The reviews should include;

- The examination of quality objectives/goals.
- Customer complaints/returns.
- Customer survey results.
- In-process quality performances.

11. Apply for the on-site certification audit

Once everything is ready, the auditors will come to perform the on-site certification audit. The management representative from the project team should be provided to assist auditors conducting the certification audit. The company can provide any objective evidence to clarify any non-conformance found by the auditor. If any non-conformance is identified, it should be rectified promptly. If everything is acceptable, the company will be recommended to be certified.

12. Continual improvement of the quality management system

On being granted the certificate it is normally valid for three years. Semi-annual surveillance audits on parts of the established quality assurance system will be conducted by the auditors. Such audits aim to verify whether or not the documented quality system is maintained effectively. The management can put the quality system on the maintenance mode by:

(1) Conducting internal quality audits on a regular basis.
(2) Holding management review sessions focusing on the:
  • Achievement of quality policy and objectives;
  • Effectiveness of corrective and preventive actions taken;
  • The results of internal quality audits.
(3) Implementing corrective and preventive action system with focus on customer complaints and trends in quality performance.

Quality system well maintained with strong emphasis on the maintenance has great potential for continuous improvement. Internal quality audit scheduled throughout the year and interdepartmental audit with qualified auditors from each operational department plays a vital role in sustaining the quality system

IV. CONCLUSION

The paper has proposed Steps that can be used for successful certification of ISO 9000. The strategy can be adopted for SME's that seek to pursue ISO certification, leading to quality improvements and growth of business.

REFERENCES

[1] S. Yahya and W.K. Goh, "The implementation of an ISO 9000 quality system," *International Journal of quality and reliability management*, vol. 18(9), pp. 941 -966, 2001.

[2] D.Lipovatz, F. Stenos and A.Vaka, "Implementation of ISO 9000 quality systems in Greek enterprises," *International Journal of quality and reliability management*, vol. 16(6), pp. 534 -551, 1999.

[3] R.Jones, G.Arndt and R.Kustin, "ISO 9000 among Australian Companies: Impact of time and reasons for seeking certification on perceptions of benefits received," *International Journal of quality and reliability management*, vol. 14(7), pp. 650 -660, 1997.

[4] J.Motwani, A. Kumar and C.H.Cheng, "A roadmap to implementing ISO 9000," *International Journal of quality and reliability management*, vol. 13(1), pp. 72 -83, 1996.

[5] O.A. Tigani, "The impact of the implementation of ISO 9000 quality management system upon the perception of the performance of the organization's worker", *Global Journal of Management and Business research*, vol. 11(8), pp. 99 -113, 2011.

[6] Batalas training manual, Audits, January 1991, pp. 1-3.

[7] C.L. Tang, "The PCB industry in Hong Kong and China, a 14 step implementation strategy", *International Journal of quality and reliability management*, vol. 13(2), pp. 99 -113, 1996.

[8] I.W. Hall, "Using ISO 9000 to improve customer service", *Training for quality, vol.* 5(3), pp. 126-129, 1997.

[9] ISO Technical committee ISO/TC/176/SC 2/N525R2, "Introduction and support package: Guidance on the documentation requirements of ISO 9001:2008", 2008.

APPENDIX A ISO 9001:2008 CLAUSES		
Clause		Comments
4	Quality management system	
4.1	General requirements	Quality management has to be established, documented, implemented, maintained and continually improved
4.2	Documentation	Documented statements of quality policy, manuals, objectives ,records
5	Management responsibility	
5.1	Management commitment	Quality system is matter of management
5.2	Customer focus	Identify your customers' desires and expectations
5.3	Quality policy	should be written down in your QM manual and reveal which degree of customer satisfaction you aim at, in what direction the development of your employees and future improvement should head, and what resources you provide
5.4	Quality objectives & planning	Establish measurable quality objectives and production plan
5.5	Responsibility, authority and communications	Organizational structure defining authorities and responsibilities
5.6	Management review	Assess the efficiency of your QM system and its processes through regular audits. The results of internal audits, customer feedback and complains should be documented.
6	Resource management	
6.1	Provision of resources	Financial plan
6.2	Human resources	Company's qualification structure, annual training plan and training evaluation
6.3	Infrastructure	Building, work place, equipment and the corresponding service
6.4	Work environment	Work environment required to conform to product requirements
7	Product realization	
7.1	Planning and product realization	Production process planned
7.2	Customer related process	Records on order acceptance
7.3	Design and development	Fulfill if you develop products
7.4	Purchasing	List of suppliers and their evaluation
7.5	Production and service provision	The requirements have to be stated in e.g. QM process instructions, work instructions, process descriptions, workflows, and shop floor papers.
7.6	Control of monitoring and measuring devices	Calibrate and register all test equipment used
8.0	Measurement analysis and improvement	
8.1	General	Definitions of procedures to ensure product conformity
8.2	Monitoring and measurement	On the basis of data, facts and information analyses have to be made
8.2.1	Customer satisfaction	Obtain information on customer satisfaction
8.2.2	Internal audits	Plan and ensure internal audits are done
8.2.3	Monitoring and measurement of process	Basis of improvement of processes is controlling and measuring them
8.2.4	Monitoring and measurement of product	Documented tests serve as a proof that your product has left your factory flawless
8.3	Control of non conforming product	Defective products must not be processed further or delivered
8.4	Analysis of data	Decisions should be made based on data, analysis and information
8.5 8.5.1 8.5.2	Improvement Corrective action Preventive action	Analysis of the results of internal audits, data analyses, preventive and corrective measures as well as management assessments help to improve your system.