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Elements of organizational culture influencing the maintenance of ISO 9001:2015: A theoretical framework

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ABSTRACT: *ISO 9001 is a quality management system that was employed worldwide by manufacturing and government entities. There were a massive number of ISO 9001 certifications that had been issued to organizations which successfully implemented ISO 9001. ISO 9001 certified organization should maintain its certification effectively because it can help organizations improve their performance. Despite the massive number of ISO 9001 certifications, the guideline or framework for ISO 9001 maintenance is yet to be developed. At the same time, a most previous study in regard to ISO 9001 focuses only on the technical facet. Apparently, the cultural facet of ISO 9001 has been neglected. This paper elaborates the framework of the elements of organizational culture which influences the maintenance of ISO 9001. The model not merely elaborates the need for technical requirements, but also the need of cultural requirements in ISO 9001 maintenance. The model could be employed as a guideline for managers in certified ISO 9001 organizations in their endeavour to maintain ISO 9001 certification effectively.*
KEY WORDS: *ISO 9001 maintenance, ISO 9001 requirements, organizational performance, organizational culture.*

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I. INTRODUCTION

ISO 9000 is a series of quality system standards (ISO, 2015) and these have been in place for a considerable time. They were developed from the military standard, the Allied Quality Assurance Publications (AQAPs) and ISO 9000 was first published in 1987. The standards have been reviewed in 1994, 2000, 2008 and 2015 (Van et al., 2005; ISO, 2009). Upon strong criticism to ISO 9001:1994, a major revision to ISO 9000 standards had been made in 2000. The revision involves major changes in which focus has been given to process approach, effective quality management, continual quality improvement, customer satisfaction and senior management commitment (Bhuiyan and Alam, 2005; Hoyle, 2001; Kartha, 2004; Tsim et al., 2002). The ISO 9001:2000 version consists of 5 requirements namely; quality management system, resource management, management responsibility, product realization and measurement, analysis and improvement (Biazzo and Benardi, 2003; Seaver, 2001; Tsim et al., 2003). In 2008, the ISO 9000 standards were revised but it only involves minor changes. ISO 9001: 2008 does not change the aim of the ISO 9001:2000 and does not introduce new requirements. It's only to initiate clarifications to the existing ISO 9001:2001 requirements. ISO 9001:2008 also introduces changes that are intended to improve compatibility with ISO 14001:2004 (ISO, 2009).

Researchers have studied to what extent ISO 9000 certification has helped organizations to improve their performance. The growth of ISO 9000 certification suggests that there is widespread belief in the business and organizational benefits of ISO 9000 certification. However, many researchers found that ISO 9000 certification helps to improve organizational performance (Chelsom, 1997; Terziovski et al., 1997; Jeng, 1998; Dick, 2000; Singles et al., 2001; Aarts and Vos, 2001; Douglas et al., 2003; Tsiotras et al., 2006, Martinez-Costa and Martinez- Lorente, 2007; Dick et al., 2008). According to Magd et al. (2003), failure to realise organizational performance could have a negative impact on the credibility of the standard. In order to avoid such failure, it is helpful to develop a framework that guides the maintenance of ISO 9001 certification. The aim of this paper is to develop a theoretical framework that describes the influence of the elements of organizational culture on the maintenance of ISO 9001.

II. ISO 9001 MAINTENANCE

Once the initial registration is achieved, the same system must be followed and the controls must be routinely implemented. If the system is practical and beneficial, the surveillance process can be done without much difficulty. If the difficulties are not worth the benefit, it shows that the system needs corrective action (Seaver, 2001). The ISO 9000:2000 adaptations emphasized customer satisfaction and the continuous improvement of the Quality Management System (QMS). Continuous improvement refers to the process of

increasing the effectiveness of the organization to fulfil the quality policy and quality objectives. Thus, ISO 9000 requires the managers to manage the process necessary for the QMS (ISO, 2008).

As registration is dependent on periodic follow-up audits, a company should always maintain its quality system compliance to ISO standards if it wishes to remain registered (Abraham et al., 2000). The maintenance phase is imperative as it involves mechanism necessary to facilitate continuous improvement of the quality management system in order to make it sustainable (Wahid and Corner, 2009). Hoyle (2003) defines maintenance as meaning the action of retaining something in a serviceable or proper condition.

Low and Omar (1997) pointed out that a QMS must constantly be dynamic to improve the quality of both the company's internal and external services. In line with this, they called for proper maintenance which includes constant monitoring, controlling, assessing and improving through both the technical and non-technical (behavioural) approaches. In the same vein, Wahid and Corner (2009) said that human/social-cultural aspects and technical aspects as two of the most important factors for ISO 9001 maintenance.

2.1 Impact of ISO Maintenance on Organizational Performance

In brief, two main contradictory results can be highlighted in the areas of i) the organizational benefits and ii) the organizational performance. Many researchers conclude that ISO 9000 adoption offers benefits for organizations (Buttle, 1997; Chan et al., 1999; Gotzamani and Tsiotras, 2001; Antoni et al., 2002; Williams, 2004; Bhuiyan and Alam, 2005; Magd, 2008; Martinez-Caro and Martinez- Garcia, 2009; Balague and Saarti, 2009; Helbig et al., 2010; Srivastav, 2010). However, ISO 9000 certification also has its disadvantages for organizations (Seddon, 1997; Najmi and Kehoe, 2000; Singles et al., 2001, Escanciano and Santos, 2002; Douglas et al., 2003; White et al., 2009). Some of the previous research depicts that ISO 9000 certification has helped organizations improve their performance (Haversjo, 2000; Heras et al., 2002, Magd et al.; 2003; Mokhtar et al., 2004; Quazi and Jacobs, 2004; Zaramdini, 2007; Bhayati and Thagavi, 2007; Tari et al., 2009; Wu and Liu, 2010).

2.2 Motivation for ISO 9001 Implementation

Some authors believe that certified organizations did not improve their performance due to their motives in seeking ISO 9001 registration (Lipovatz, 1999; Singles et al., 2001; Gotzamani and Tsiotras, 2002; Fuentes et al., 2000; Williams, 2004). The drive of ISO registration is divided into external and internal motives. The external motive means organizations gain ISO certification out of external pressure, such as pressures from customers and competitors. The internal motives means the organizations want to become certified because they feel the need to do so that is there is the real need of the company for improvement (Singles et al., 2001; Fotopolous et al., 2010). Fuentes et al. (2000) claimed that external motives predominate over external ones. Gotzamani and Tsiotras (2002) claimed that the "true motive" of certification is the possession of the certificate itself, not quality improvement. Consequently, Fuentes et al. (2000) and Williams (2004) argued that senior management and the workforce see that they are forced to implement the standard and therefore are unlikely to be fully committed to the process. This would make implementation difficult as Yeung et al. (2003) stressed that the commitment of senior management would significantly affect the development of a QMS and, subsequently, organizational performance.

Gotzamani and Tsiotras (2002) revealed that those organizations which put emphasis on external reasons have failed to gain benefits due to their narrow focus on the short term advantageous of certification.
In comparison, organizations which focus on the development of the standard to improve quality and increase customer satisfaction, have significantly improved their performance. In association with this, Tari et al. (2010) suggested that quality certification may be important for competitiveness, but it is the way such certification is obtained that makes it possible to derive the benefits expected.

The authors added that when certification is used in daily practice and as a catalyst for change, the organization could achieve a distinct operating advantage from its implementation.

Hence, ISO 9001 should be implemented strategically, in which the emphasis should be on internal motives (Fuentes et al., 2000). Likewise, its implementation should focus on continuous improvement and involve all employees (Williams, 2004).

III. ISO 9001:2015 REQUIREMENTS

The QMS should be adopted strategically in which consideration must be given to varying needs, particular objectives, the products provided, the process employed and the size and structure of the organization (ISO, 2008).

The QMS describes the interaction of all processes in the organization in which the main activity is to identify customer requirements and end with their satisfaction. Specifically, ISO 9001 describes a QMS as the integration of major areas: management responsibility, resource management, product realization and measurement, analysis and improvement (Oakland, 2003).

Here the ISO 9001:2015 standard is broken down to make it easier to understand and put into action. ISO 9001:2015 is the latest revision of the ISO 9001 standard. In it, there are 10 sections (clauses) with supporting subsections (sub clauses). The requirements to be applied to the quality management system (QMS) are covered in sections 4-10. To successfully implement ISO 9001:2015 within the organization, the requirements within clauses 4-10 must be satisfied along with meeting customer and applicable statutory and regulatory requirements..

3.1 Section 4 Context of the Organization

Key Requirements:

- Determine, monitor and review external and internal issues
- Determine, monitor and review relevant interested parties
- Establish the quality management system scope
- Determine processes needed for the QMS as well as their required inputs, expected outputs, sequence and interaction, resource needs, responsibilities, risks, and opportunities

The 9001 standard expects to understand the organization's context in the QMS. The context includes defining influences of various factors on the organization and how they impact the QMS; the culture of the company, objectives, and goals, complexity of products, the flow of processes and information. It also requires a reflection of the size of the organization, its markets, and how they define customers and other interested parties. It also uses the context as a way to detect risks and opportunities and how it affects the QMS.

Section 4.1: Understanding the Organization and Its Context

Organizations are to assess both internal and external influences in formulating and implementing a quality management system. In addition to traditional customer, economic and competitive factors, it notes that these influences can include how laws, technical developments and even political/cultural/social changes might impact the mission of the organization.

Section 4.2: Understanding the Needs and Expectations of Interested Parties

This requirement addresses the desires and demands of all those who may have interest in the organization and could impact its mission and who, in turn, would influence its quality management system. It asks those seeking ISO 9001:2015 certification to have an ongoing system for determining these interested parties and their requirements.

Section 4.3: Determining the Scope of the Quality Management System

Because of the above more wide-ranging franchise, the standard requires the scope of the QMS to potentially be widened to include how the needs of those relevant groups noted above can be addressed within the QMS as it delivers its products and services.

The scope of the QMS must be documented and centered around the organization's supplied services and products.

Section 4.4: Quality Management System and Its Processes

Because the ISO 9001:2015 standard maintains the process approach from previous revisions (including the need for stated and verified inputs, outputs and constant improvement of the delivery process in between), it requires understanding and control of the order of each phase in the QMS processes and how one element affects another including:

- Measures used to gage effectiveness
- How those measurements will be taken
- What criteria will be used to indicate success
- How to analyze the process so that it can be continuously optimized to better achieve its goals

A process is needed for determining what capabilities, support and investment will be needed and what by what means this will be provided including:

- Who will be assigned to execute each phase and how these people will be empowered
- Determine both what may threaten execution of the process, and what benefits may come from proper process execution
- Documenting and updating the process, if necessary, and making it available to all involved

3.2 Section 5 Leadership

Key Requirements:

- Top management must manage, not delegate, quality
- Leadership has defined responsibilities for ensuring quality execution

- Emphasis on customer focus with specific applications ranging from support for customer regulatory requirements, risks, and enhancing customer satisfaction
- Management's responsibilities include quality policy establishment, communication and organization-wide responsibility and authority

Section 5.1: Leadership and Commitment

The 2015 standard is similar to 2008 concerning management commitment and responsibility with four exceptions.

1. Quality management can no longer be delegated. The Organization's leaders are responsible for the QMS being implemented and effective.
2. The established quality policy and quality objectives must be compatible with the context and strategic direction of the organization.
3. Leadership must ensure integration of the QMS into the organization's business processes.
4. Leadership must assign the responsibilities and authorities for ensuring that processes are delivering their intended outputs.

Expanding upon this, this section requires organization leadership to:

- Implement the process approach and risk-based thinking
- Provide the necessary support to fully implement and sustain the QMS
- Communicating to the organization the importance of conforming to QMS requirements
- Ensuring the QMS meets its goals
- Engage, direct, and support individuals contributing to the QMS (i.e. Provide employees with training, get employees invovled)
- Create a culture of continuous improvement

An important distinction made by this section now broadens the idea of a "business" to virtually any type of organization that wishes to use ISO 9001 as its quality management system including non-profit and government entities.

Leadership must demonstrate their commitment to customer focus, particularly by fully understanding and monitoring customer requirements and satisfaction. The requirements for Leadership regarding customer focus include:

- Determine, understand and consistently meet customer and applicable statutory and regulatory requirements
- Determine and address risks and opportunities around product and service conformity and enhancing customer satisfaction
- Maintain focus on enhancing customer satisfaction

Section 5.2: Policy

Leadership is to establish, communicate and enforce a quality policy that accomplishes the following:

- Is in line with the purpose, context, and strategic direction of the organization
- Provides a framework for quality objectives
- Includes a commitment to satisfy applicable requirements
- Includes a commitment to continual improvement

Section 5.3: Organizational Roles, Responsibilities and Authorities

Responsibilities and authorities for relevant roles must be assigned, communicated and understood within the organization. Specifically, roles that impact the organization's ability to meet the requirements of 9001:2015, ensure processes are delivering their intended outputs, report QMS performance and improvement, plan and implement changes to the QMS, and promote customer focus.

3.3 Section 6 Planning

Key Requirements:

- Adding risk-based thinking and management to planning
- establishing quality objectives and how they will be achieved
- Planning actions when changes to the QMS are made
- Updating the QMS based on measuring ongoing effectiveness and any newly discovered risks or opportunities

Section 6.1: Actions to Address Risks and Opportunities

A separate section named planning is new for the 2015 update of ISO 9001 (though planning is addressed in the ISO 9001:2008 standard in sections such as 8.5.3, 5.4.2 and 7.1), emphasizing planning as a key dictate in achieving and maintaining ISO 9001:2015 registration.

Building upon the need to include the influence of the wider elements of the organization (See Section 4: Context of the Organization), planning now fully embraces the risk and opportunity management concept. This is to be implemented as a key activity to achieve quality goals on a continual basis, including an evaluation of the risk management process and a priority/scaling of when, how, where and to what level it should be applied.

Section 6.2: Quality Objectives and Planning to Achieve Them

This subsection builds upon an accurate definition and plan to achieve specific quality objectives including:

- Being directly driven by the quality policy itself
- More accurate measuring, monitoring and updating
- Being applied to ensure product and service consistency and customer satisfaction
- Having a sufficiently wide scope to ensure quality performance success
- Specific quality objective documentation

There is to be a conscious approach to changing the QMS itself, using a controlled process that constantly considers the reason and impacts of the considered change, as well as how it may affect the level and allocation of resources and assignments

The standard requires taking the general concepts of planning into the operations realm by defining the needs associated with service or product provision, creating supportive processes, determining customer acceptance criteria and the needed assets to ensure compliance with quality standards.

Section 6.3: Planning of Changes

When changes to the QMS are needed, they must be carried out in a planned manner. Examples of QMS changes include plans to transition from ISO 9001:2008 to 9001:2015 or make improvements to the existing QMS. Risks, resources needed, re-assignment of employee responsibility and the integrity of the QMS all need to be considered with developing plans for implementing changes.

3.4 Section 7 Support

Key Requirements:

- Providing necessary monetary and physical assets, resources and systems (such as personnel, plant/office, logistics, working conditions, etc.)
- Providing and maintaining monitoring and measuring resources (i.e. calibrated equipment)
- Determining and maintaining organizational knowledge
- Ensuring personnel competency and providing additional training to achieve competency
- Communicating the quality policy, relevant quality objectives, and each employees contribution to the QMS
- Documenting information necessary for the operation of QMS processes and conformance to ISO 9001:2015

Section 7.1: Resources

This section takes a broad view of items needed to realize the requirements of ISO 9001:2015, specifically calling for support in these critical areas:

- What resources on hand vs. what needs to be procured including:
  - labor/skills
  - plant or office facilities/utilities
  - information technology/communications
  - transportation/logistics
  - equipment
- working conditions/environment (including physical and interpersonnel emotional, intellectual, and motivational issues)
- Measuring the type, level, scope, continuity and suitability of resources including ongoing justification of their need.
- Calibrating or verifying monitoring and measuring resources that affect the conformity of products and services.

- Determining and maintaining organizational knowledge such as backing up electronic documents, records, or systems and documenting essential tribal knowledge.

Section 7.2: Competence
The aptitude of those who execute QMS processes need to be assessed against the requirements for the tasks, and any deficiencies be addressed through personnel training, exposure, outsourcing or reassignment.
Section 7.3: Awareness
The standard requires that everyone, not just those who administer the QMS, become familiar with its policies and objectives and know what they must do to achieve its goals, including what happens if they don't adequately meet these requirements.

Section 7.4: Communication
A formal plan and activities for informing the organization about the QMS needs to include:
- Who needs to know about each specific QMS element
- How and when that communication will take place
- And who is responsible for the information being transmitted

Section 7.5: Documented Information

The nature of documentation has been expanded in order to both meet that which is required by the standard, but also what is needed by the organization itself to practically implement the QMS. For example, the documented procedure is not needed for every process, but may be required for more complex processes. The extensiveness of that documentation will vary based on a variety of factors (i.e. size, mission, products, services, sophistication, etc.). It does provide these specific documentation criteria:
- It must include a means for proper description including its source, purpose, change history, review/approvals and the method of communicating (text, audio, video, pictorial, multimedia, interactive, etc.)
- A means must be provided to formally manage the documentation, balancing the need for access versus security
- Going further, there must be a plan and approach governing documentation dissemination (what, when, and where documentation can be accessed and by whom), integrity/validation, revision, approval, storage and destruction (if applicable)

Much of these criteria can be met using document control software which helps to manage all the documented information. Some ERP or MRP systems include document control capabilities. The most basic method used for document control is maintaining on a shared network with restricted editing functionality and updates managed manually. Many organizations will assign document control responsibilities to a designated Document Controller.

3.5 Section 8 Operation
Key Requirements:
- Plan, implement and control processes need to meet requirements for products and services
- Ensure requirements for products and services are defined and claims for products and services offered are met
- Establish, implement and maintain an appropriate design and development process
- Ensure externally provided processes, products and services conform to requirements
- Production and service provision must be under controlled conditions (identification, verification and validation)
- Products and services are not to be released until planned arrangements are completed
- Nonconforming outputs are to be identified and controlled.

Section 8.1: Operational planning and control

As with previous versions of the standard, ISO 9001:2015 requires that the quality planning is used in ongoing organizational management. This section on operational management is one of the longest in the standard and requires:
- Documentation of requirements for each of the organization's specific products or services
- An equally specific benchmark for measuring all operational processes and resulting product/service suitability or "acceptance"
- An assessment of required resources to achieve the above
- Meeting product/service prerequisites through all actions

- Proof of resulting product/service consistency
- The result of any quality management process be applicable to all the organization's actions, such that both anticipated and unanticipated changes can be dealt with – whether under direct or indirect organizational control (as when subcontractors or subassembly suppliers are used)

Section 8.2: Requirements for Products and Services

Expanding on the need for specification of product/service needs, the standard breaks down the process of requirement determination into the following:

- Having a system for robust, ongoing customer dialog for general information, order/change orders, measuring performance, complaint/discrepancy handling and use/care of customer-supplied assets – including a plan for dealing with any out-of-bound or unsatisfactory results
- Definition of product/service needs must include requirements based on laws, regulations or even organizational dictates – and that these requirements can be met
- A formal review must be conducted to determine if the above product/service requirements can be met before making any type of supply commitment
- The above review results be documented, especially any customer requirement changes, and that the proper personnel be made aware of any changes in this area.

Section 8.3: Design and Development of Products and Services

If the design and development of the products and services is carried out by the organization, the design and development process is likely the most complex. It is also one of the longest clauses of the ISO 9001:2015 standard. Though a design and development procedure is not required there are many aspects of the design and development process that must be documented. Therefore, it is highly recommend documenting this process in a procedure to close any gaps that may put the ISO 9001:2015 certification at risk.

The ISO 9001 standard requires a development process that addresses:

- The situation, time-frame, intricacy, steps involved, need for review/validation
- Who is responsible both internally and externally for product/service design/development/improvement, and what resources they need
- The level, type, frequency and means of communication and control between those personnel and entities involved in design/development, including customers/users
- What formal requirements result from the initial design specification stages and, at the end of the process, how prove that those specifications have been met by the design/development process

Delving more deeply into how to define a specific product/service design, ISO 9001:2015 creates a process for gathering relevant guidance including:

- How the service is supposed to work (and how well), using information from similar design/development cycles
- Influences on product/service requirements including legal, regulatory and ethical, codes and standards
- Scope and type of outcomes and effects of failing to adhere to product/service performance expectations, as well as a process for resolving any conflicts or contradictions in these stated design/development expectations
- And of course, the need to document and retain the outcomes of the above process

Managing the design/development process is crucial under this standard, so it requires that:

- First, there be a delineation of what the process needs to achieve
- Next, reviews/verification/validation be performed to be sure that design/development expectations and results are aligned including application/use and performance
- And that any deviations that result from these assessments be corrected and all of the above activities are correctly documented

Detailing the results of the design/development planning process (as part of the QMS), the standard dictates that:

- Design/development planning results (i.e. specifications, other outputs) meet the requirement definition phase in a workable way for product/service delivery – including any critical aspects (i.e. for safety, longevity or performance)
- These results are measured against agreed upon expectations and are again documented properly

Special emphasis is accorded to design/development revisions during this process to ensure that:

- These changes don't compromise the original requirements
- This phase be subjected to acceptable documentation practices and rigor to include design/development revisions, formal authorization of design change, design review outcomes and any compensatory actions taken to prevent problems as a result of the change(s)

Section 8.4: Control of Externally-Provided Processes, Products and Services

The ISO 9001 standard requires the same oversight for products, services and supporting methodologies procured outside the organization including:

- Externally purchased products/services must come under QMS control:
  - When they are incorporated (in part or in full) into the organization's own products/services
  - When they are delivered directly to the organization's customers
- There must be a process, determined by the organization, for assessing, choosing, reviewing, improving and replacing these external suppliers against stated expectations.
- These review/adjustment processes must also be documented properly

When engaging in outsourcing, there must be a process to react to problems caused by external suppliers that preclude the organization from delivering upon commitments to its customers including:

- Making sure the organization maintains effective controls over that supplier that are delineated, include a means for accurate evaluation and are tested for effectiveness over time
- The supplier must be made by the organization to understand fully:
  - What it is to provide (including supporting methods, materials and equipment used to produce those products/services)
  - How those products services will be watched and assessed to be acceptable or unacceptable (including on-site assessments)
  - Any special skills, certifications, performance expectations expected of the supplier's personnel
  - How the supplier and organization are to engage one another

Section 8.5: Production and Service Provision

Requiring management and accountability in how a service/product is produced, the standard calls for:

- Clear and documented definitions for product/service specifications, needed activities and results
- Effective step-by-step data collection and measurement to ensure that expectations are being consistently met or, if a process' stages cannot be measured accurately, then ongoing evaluation of the outputs of that process be made
- Acceptable support and surroundings for production, including selection/empowering of skilled, qualified personnel and formal methods to prevent errors caused by those personnel
- Execute actions that ensure quality during and after production/provision of services according to the QMS

With specific emphasis on key performance criteria determination and tracking, the standard requires a method for determining, tracking, tracing and controlling key performance criteria associated with service/product provision.

Whether owned by a customer or external supplier, there needs to be a method for taking care of assets (such as materials, components, tools, equipment, facilities, data and intellectual property) when they are under the organization's control, including asset identification, working status/condition, security/protection or location – and provide up to date documentation reflecting this care.

"After sale" operational support (such as warranties, agreed upon performance criteria, repair, recycling, etc.) shall be provided as required legally, by applicable regulation and customer communication in a manner suitable for the product/service application and life cycle, while considering any negative outcomes.

Operational support shall also include periodic evaluation and management of needed service/product offering changes to stay in compliance with customer/regulatory/legal expectations, including a documentation stream as well as change review results and authorizations.

Section 8.6: Release of Products and Services

Before releasing a product or service, there must be a process to ensure that customer expectations have been met at each stage of product/service production, including documentation of formal customer approval that agreed upon product/service needs were met.

Section 8.7: Control of Nonconforming Outputs

There must be a process to detect and correct non-compliant services/products before their delivery or use including a means to correct the problem, separate and return the offending product/service, communicate the issue to customers/users, and by gaining authorization to verify and address the non-conformity.

Non-conformance documentation must include a full description of the problem, corrective actions, any agreed upon compromises/adjustments reached with the customer, and who authorized and accepted the remedies.

3.6 Section 9 Performance Evaluation

Key Requirements:

- Determine what, how, when and by whom results will be measured and evaluated
- Determine the methods for obtaining, monitoring and reviewing customer satisfaction
- Have an objective, planned and effectively implemented internal audit program
- Top management is to review the QMS at planned intervals

Section 9.1: Monitoring, Measurement, Analysis and Evaluation

As noted elsewhere, the standard emphasizes both a process approach, and the need to utilize a review or checking phase (from the Plan>Do>Check>Act approach.) The standard mandates determining what data needs to be collected, how that data is collected and interpreted, and what results should be acted upon from a variety of inputs at various points in the quality management process.

These results must in turn be verified (audited), and they must be subject to management's direct review. This process also must itself be evaluated for effectiveness.

Section 9.1.2: Customer Satisfaction

Data on the degree of customer satisfaction needs to be collected, analyzed and monitored to ensure customer expectations are being met. Data collection methods include surveys, direct customer communication, warranty activity and sales channel reports. The data collected can include measures around on time delivery, product/service quality, or order accuracy.

Section 9.1.3: Analysis and Evaluation

Data that reflects the performance of the QMS must be analyzed and evaluated to determine if improvements need to be made. Examples of data to monitor and measure include customer satisfaction, nonconformities, effectiveness of risk management and external provider performance.

Section 9.2: Internal Audit

In order to confirm that the QMS conforms to the ISO 9001:2015 standard and the organization's standards internal audits must be conducted at planned intervals. A formal internal audit program needs to be established which defines the methods used, scope and frequency as well as assigning responsibility to objective and impartial auditors. The results of internal audits are used to make corrections and improvements to the QMS.

Section 9.3: Management Review

Data collected on QMS performance (i.e. customer input, internal audits, key quality performance indicators) and determination of any support, changes, or improvements must be reviewed and discussed by top management at planned intervals. Actions generated from the review must be recorded and implemented as they will be follow-up on during the next management review.

3.7 Section 10 Improvement

Key Requirements:

- Determine and select opportunities for improvement
- React to nonconformities and take action to eliminate the cause
- Implement corrective actions as appropriate and review their effectiveness
- Keep records of nonconformities and corrective actions
- Continually improve the QMS

Section 10.1 General

Select opportunities for improvements that will enhance customer satisfaction such as improvements to products or services or improving the effectiveness of the QMS.

Section 10.2 Nonconformity and corrective action

When nonconformities occur, react to them appropriately by controlling, correcting, or dealing with the consequences. Determine what the cause is of the nonconformity and take actions to ensure the nonconformity does not recur. After these corrective actions are implemented, review them to ensure they were effective. Corrective actions will often require updating QMS processes and/or risks and opportunities determined during planning. Records describing nonconformities, actions taken, and the results of those actions must be kept.

Section 10.3 Continual improvement

Continually improve the QMS. Consider using internal audits, management reviews, or company performance metrics to help identify opportunities for improvement. Continuous improvement examples include documenting a process, updating a procedure, 5S or implementing as a Six Sigma project.

IV. THE LINKS BETWEEN ISO 9001 MAINTENANCE AND ORGANIZATIONAL CULTURE

Kehoe (1996) suggested that quality development involves systems, techniques and people, and the most critical to develop are the people. This is echoed by Low and Alfelor (2000) who stressed two approaches in ISO 9000; the technical and non-technical (behavioural) approaches. Culture serves as a foundation for an organization's management system; hence, a good idea of management will not work if it does not fit the culture (Schneider and Barsoux, 2000). Lees and Sadri (2001) quoted Goffee and Jones (1996) who stated that for the culture to be effective, it should be consistent with the business environment in which the organization operates. While there is a link between supportive culture and ISO 9001 certification, inappropriate organizational culture would undermine these efforts (Mallak et al., 1997). Several authors (Mallak et al., 1997; Gore, 1999; Maull et al., 2001) have listed the elements of organizational culture required in quality efforts such as customer focus, continuous improvement, employee involvement, advocating challenging work, open communication, trust, empowerment, appropriate leadership, being decisive, and paying attention to detail. Lees and Sadri (2001) have suggested that organizations should assess and categorize their organizational culture and look at how it impacts on employee productivity and morale.

Berggren et al. (2001) suggested that there is less research performed within certified organizations than in those seeking certification. Supporting this, Wahid and Corner (2009) pointed out that not much literature can be found on the maintenance of ISO 9001 and the post certification period. There is an increasing need to understand the critical issues for ISO 9000 maintenance and improvement (Chin et al., 2000). This is echoed by Sharif (2005) who called for doing research to identify the critical issues in certified organizations. Chin et al. (2000) suggest the need for organizational factors such as teamwork, commitment and recognition in ISO 9000 maintenance.

Although an organization might have successfully renewed their ISO 9001 certification, this does not mean that ISO 9000 is maintained effectively. ISO 9001 is effectively maintained if there is quality improvement and enhancement of clients' satisfaction (Low and Omar, 1997). Maull et al. (2001) concluded that culture is the catalyst for effectively maintaining quality management in organizations, however there are authors like Torre et al. (2001), Boon et al. (2003), Sharif (2005) and, Wahid and Corner (2009) who have listed many barriers in ISO 9000 maintenance which can be classified as the elements of organizational culture. These barriers are lack of teamwork, lack of top management commitment, a negative response from managers, ignorance on the part of employees on the quality management system itself, lack of quality awareness, lack of participation from staff, lack of training, lack of reward, lack of motivation programmes, lack of the understanding and misinterpretation of the standard, lack of coordination between departments and lack of communication.

The literature on ISO 9000 mainly focuses on its implementation and ignores cultural issues. Meanwhile, the literature on organizational culture is not often linked to the quality management system ISO 9000. Mallak et al. (1997) contended that most efforts focus on quality improvement without a linkage to culture change. So far, no significant research has been done regarding how organizational culture influences ISO 9000 maintenance. Mallak et al. (1997) have suggested carrying out research on cultures that work towards the maintenance of ISO 9001 certification. According to Sharp et al. (2004), although the soft issues appear to be significant in ISO 9000 process-based management system adoption, much more research is required to conclude these findings as generic.

The literature points to the need for appropriate organizational culture in ISO 9000 programmes and the growing concern about why many certified organizations fail to gain benefits and improve their performance. Hence, understanding the impact of the elements of organizational culture on ISO 9000 maintenance can provide an insight into the ISO 9000 maintenance process.

V. THE ELEMENTS OF ORGANIZATIONAL CULTURE WHICH INFLUENCE ISO 9001 MAINTENANCE

So far, only a few authors have highlighted the elements of organizational culture which are required in ISO 9000 maintenance (Tang and Kam, 1999; Chin et al., 2000; Bhatti and Awan; 2003). The elements are; teamwork, recognition, incentive schemes, top management commitment, staff loyalty and strong motivation for continuous improvement.

In terms of a theoretical perspective, the elements of organizational culture which are required in ISO 9000 maintenance can be extracted from the ISO 9000 requirements; ISO 9000 implementation process, internal audit, certification audit, surveillance, ISO 9000 maintenance and management review. For instance, ISO 9000 emphasises process-based management (Bhuiyan and Alam, 2005), which requires coordination and cooperation between different activities and departments (ISO, 2008). In this way, ISO 9000 maintenance requires teamwork as suggested by Chin et al. (2000) and, Wahid and Corner (2009).

Meanwhile, as the top management has a crucial role in ISO 9000 adoption, they have to embrace some elements of organizational culture which align with it. For example, they have to listen to customer needs and requirements. Their full commitment is also needed to ensure that the organizational quality policy is well communicated, understood, implemented and maintained (Oakland, 2003). The management also needs to frequently participate in the project activities such as meetings, briefings and training (Seaver, 2001).

Personnel whose jobs affect product quality should be competent to deliver their task. They have to have appropriate education, training, skills and experience (ISO, 2008). In addition, Fuentes et al. (2000) and ISO Survey (2004) found that training should be given to top management as well as shop floor personnel. Training for shop floor personnel for instance, is essential to add to their skills and knowledge. This is a prerequisite before the management could assign them with tasks, responsibility and accountability..

The organization should also determine and manage the work environment needed to achieve conformity to product requirements (ISO, 2008). In this way, the organization should develop and maintain good housekeeping (Weallans, 2000). This requirement could be linked to the need for good leadership which has been emphasised in quality management principles. The leader should develop and maintain the internal environment which encourages people to get involved in achieving the organizational objectives. For instance, the leader should create and develop a spirit of trust and innovation in an organization. The employees' involvement and contribution for ISO 9000 adoption should be recognized (ISO, 2008). In line with this, Wahid and Corner (2009) argued that reward system is one of the critical success factors in ISO 9001 maintenance. The authors found that reward that were given to employees in ISO 9001 certified organization is in the form of company bonus, performance bonus, promotion and special increment.

Seaver (2001) suggests that product realization refers to the day-to-day productive business activities. These activities especially need the full involvement of people to identify customer requirements and to communicate with them. In addition, ISO 9000 process-based management encourages the involvement of people and the clarification of their responsibilities. Besides this requirement, people need also to openly discuss problems and issues (ISO, 2008) on ISO 9000 adoption. For instance, they have to listen to suggestions from the management review committee. This is because the job of senior management is to review the QMS performance and to produce suggestions to improve it (Wealleans, 2000).

The principles of quality management which ISO 9000 is based on emphasize that decision making must be based on the analysis of data (ISO, 2008). This could be connected to the measurement, analysis and improvement requirements of ISO 9000. For instance, the organization needs to establish a process of obtaining and monitoring information and data on customer satisfaction. The result of internal audits should be communicated to the area audited, so that the management can take corrective action on the non-conformities recorded (Oakland, 2003). It appears that the decision for corrective action must be made after the facts have been gathered and analyzed. Transparency is also needed to communicate the audit results (ISO, 2008).

The objective of internal audit is to confirm compliance with the ISO 9001 requirements (ISO, 2008). It is also to identify whether the QMS is applicable to the overall objectives of the organizations (Wealleans, 2000). He further urges that the internal auditor embraces a professional approach and becomes familiar with how the organization works and its internal culture. Hence, the organization should recognize their suggestions for improvements.

Meanwhile, in order to gain ISO 9001 certification, a certification audit needs to be conducted by the third party assessor or accreditation body (Tricker and Sherring-Lucas, 2005). Its objective is to see whether the defined systems meet the requirements of ISO 9001 and whether the systems have been implemented effectively. In this way, organizations should listen to external auditors' recommendation to correct major or minor non-compliances (Wealleans, 2000).

The corrective action actually signifies the essential improvement agenda in ISO 9001. The organization needs to establish a process for eliminating the causes of non-conformities and preventing recurrence (Oakland, 2003). In regard to this, Wealleans (2000) argues that the company should avoid blame exercises in managing 'non-compliance' matters. Indeed, he calls for a positive culture to be promoted at all levels.

In order to maintain ISO 9001 certification, it needs to be demonstrated to the certification body that the QMS continuously operates and incorporates appropriate improvements. In other words, it needs continual effort to keep everything together, complete records, track changes and continue the internal audit programme. Maintenance of the certificate means carrying out a regular surveillance audit which normally occurs every six

months. The main difference between the initial audit and a surveillance audit is that, major non-compliance should be re-audited within a shorter time (six weeks), whereas in initial audit, the time given for corrective action is thirteen weeks (Wealleans, 2000).

From the aforementioned discussion, the elements of organizational culture which are required in ISO 9001 maintenance can be identified as follows; teamwork, top management commitment, continuous improvement, coordination, cooperation, competency, training, responsibility, accountability, good housekeeping, leadership, people involvement, communication, listening to the customer, open discussion and effective decision making.

VI. CONCLUSION

The framework categorizes key components of ISO 9001 maintenance under six groups; motive for ISO 9001 registration, the elements of organizational culture, the maintenance process, ISO 9000 requirements, ISO 9001 maintenance and organizational benefits and performance. It provides possible explanations of how the components are linked when maintaining ISO 9001 registration. It also illustrates that organizational culture could have a significant impact on ISO 9000 maintenance. This framework is based on the idea that the ISO 9001 maintenance process is influenced by the continuous dynamic interactions and relationships between its components. The ISO 9001 maintenance process should finally influence organizational benefits and performance from ISO 9001 registration.

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