

Implementing a Functional ISO 9001 Quality Management System in Small and Medium-Sized Enterprises

Andres Sousa-Poza

Department of Engineering Management
and Systems Engineering
Old Dominion University
Norfolk, 23529, USA

asousapo@odu.edu

Mert Altinkilinc

Department of Engineering Management
and Systems Engineering
Old Dominion University
Norfolk, 23529, USA

malti001@odu.edu

Cory Searcy

Department of Mechanical and Industrial
Engineering
Ryerson University
Toronto, M5B 2K3, Canada

cory.searcy@ryerson.ca

Abstract

This conceptual paper provides guidance for the implementation of a functional ISO 9001 quality management system (QMS) in small and medium-sized enterprises (SMEs). To help a SME understand its starting point, four initial states for QMS implementation are defined. Five paths for moving the QMS from the initial state to the desired state are described. To support the transition from the initial to the desired state, some key considerations in implementing a QMS in SMEs are discussed. The paper is based on site visits and implementation assistance the authors have provided to several SMEs. It is anticipated the paper will help managers in SMEs understand the process of implementing ISO 9001 and help them avoid the development of a paper-driven QMS that provides limited value.

Key words: Small and medium sized enterprises, quality management, ISO 9001

1. INTRODUCTION

Small and medium-sized enterprises (SMEs) play a critical role in economies around the world. To remain competitive, SMEs must be capable of delivering high quality products and services on-time at a reasonable cost. In response to these competitive pressures and customer demand, many SMEs have developed ISO 9001 quality management systems (QMS).

ISO 9001 is an international standard that specifies the basic requirements for a QMS. The two primary objectives of the standard are to help an organization demonstrate its ability to meet customer and regulatory requirements and to enhance customer satisfaction. To that end, the standard contains key requirements clauses focusing on (1) the QMS in general, (2) management responsibility, (3) resource management, (4) product realization, and (5) measurement, analysis, and improvement. Originally released in 1987, the standard was updated in 1994, 2000, and

2008. As of December 31, 2007, at least 951,486 certificates had been issued worldwide certifying verified compliance with ISO 9001 [1]. ISO 9001 is supported by a broader family of standards. These include ISO 9000 (QMS fundamentals and vocabulary), ISO 9004 (QMS guidelines for performance improvements), and ISO 19011 (guidelines for quality and/or environmental management systems auditing).

There is general agreement in the literature that SMEs possess unique characteristics that will influence the implementation of a QMS. In one widely-cited representative study, Ghobadian and Gallear [2] compared the common characteristics of SMEs with large organizations on the basis of organizational structure, procedures, behavior, processes, people, and contact. For example, relative to large organizations SMEs tend to have fewer layers of management, informal rules and procedures, a fluid culture, a simple planning and control system, modest human and financial resources, and a limited customer base [2]. While there is no universal definition of a SME, a widely used classification is that they consist of fewer than 500 employees.

Recognizing that there are differences between SMEs and large organizations, several papers have been published focusing on the application of ISO 9001 and broader total quality management (TQM) principles to SMEs. The literature reveals that there are contradictory results on whether or not implementing ISO 9001 helps improve the performance of SMEs. For example, in a study of Australian SMEs, Rahman [3] found that there is no significant difference between SMEs with and without ISO 9001 certification with respect to TQM implementation and organizational performance. However, in a study of Iranian SMEs, Bayati and Taghavi [4] concluded that acquiring ISO 9001 certification improved the performance of the companies studied. Similarly, Koc [5] found that SMEs gain significant benefits by implementing ISO 9000 standards. For further information on ISO 9001 and TQM implementation in SMEs, the interested reader is referred to Lewis *et al.* [6], Poksinska *et al.* [7], and Pinho [8].

There are a number of challenges that SMEs face in implementing an effective ISO 9001 QMS. Building on the discussion in Ghobadian and Gallear [2], some of the representative challenges SMEs may face include a lack of financial and human resources, inadequate technical knowledge of quality management, a lack of knowledge of formalized systems, and a lack of experience in internal auditing. Although the heterogeneous nature of SMEs makes it difficult to generalize, managers and employees in SMEs are typically well focused on core activities such as production, sales, and customer service. However, they are generally not knowledgeable about QMS requirements or on how to improve processes. As Temtime [9] explains, "...the majority of SMEs understand the importance of both TQM and planning activities for their survival and growth. However, their approach to both is generally unsystematic, non-formal and short-term oriented". An unsystematic approach is likely to exacerbate the problems faced by SMEs when attempting to introduce an ISO 9001 QMS.

The development of a systematic approach to ISO 9001 implementation should help managers in SMEs increase the possibility of a successful implementation. In particular, guidance is required on recognizing the initial state, recognizing the desired state, and defining a path to navigate the transition. This paper presents a conceptual model with those needs in mind. The paper is organized into five sections. Immediately following this introduction, four initial states of a QMS in SMEs are introduced. This provides the basis for the third section focusing on how the QMS can be moved from the initial state to the desired state. In the fourth section some of the key considerations in implementing ISO 9001 in SMEs are highlighted. The paper finishes with a brief summary and conclusions.

2. ESTABLISHING THE INITIAL STATE OF THE QMS

The implementation of an ISO 9001 conformant system must recognize that it is but a step in a long-term development of a continually improving QMS. This is depicted in Figure 1. Unfortunately, it is often the case that ISO 9001 is taken as a means to an end, where the implementation of a QMS is not the primary objective, rather certification is. As a result, SMEs may end up with stacks of documentation waiting to be processed that adds no value, but cost.

According to the requirements of ISO 9001, an organization must develop only six documented procedures: (1) control of documents, (2) control of quality records, (3) internal audits, (4) control of non-conformities, (5) corrective action, and (6) preventative action. A quality manual and several records are also required. The development of other procedures, work instructions, and other documents is largely at the discretion of the organization. From the very beginning of the process, it is therefore essential that SMEs establish a balanced view between a short-term focus (marketing/sales) and a long-term focus (achieving company-wide quality awareness through TQM). ISO documentation should be considered as an enabler along that way and SMEs must guard against the creation of unnecessary documentation.

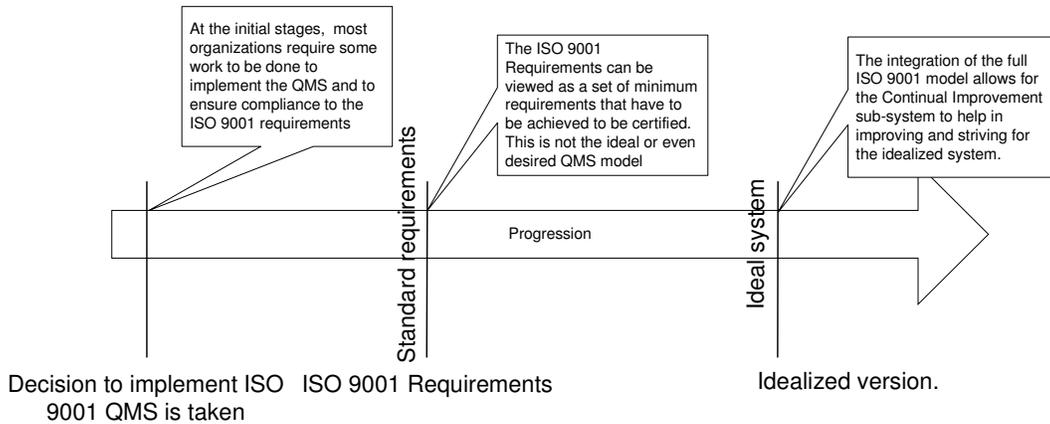


FIGURE 1: The QMS Implementation Continuum

However, even when such a view is adopted, many SMEs struggle to move from their initial state to a fully functional ISO 9001 QMS. Over the last several years, we have been involved in ISO 9001 implementation projects in seven different SMEs. The SMEs have ranged in size from approximately 20 employees to 500 employees. The SMEs have been drawn from a variety of sectors in Virginia, including manufacturing, distribution, and services. Based on our experience, we developed a schematic of initial states of an organization in terms of the *existence* and *functionality* of the QMS as shown in Figure 2. Throughout this paper, existence is equated with the documentation required by the standard while functionality is equated with an effectively operated QMS that leads to increased customer satisfaction and continuous improvement of business results. A successful QMS must be fully functional and appropriately documented. With that in mind, there are four main states in which SMEs can be located in the beginning of the implementation process:

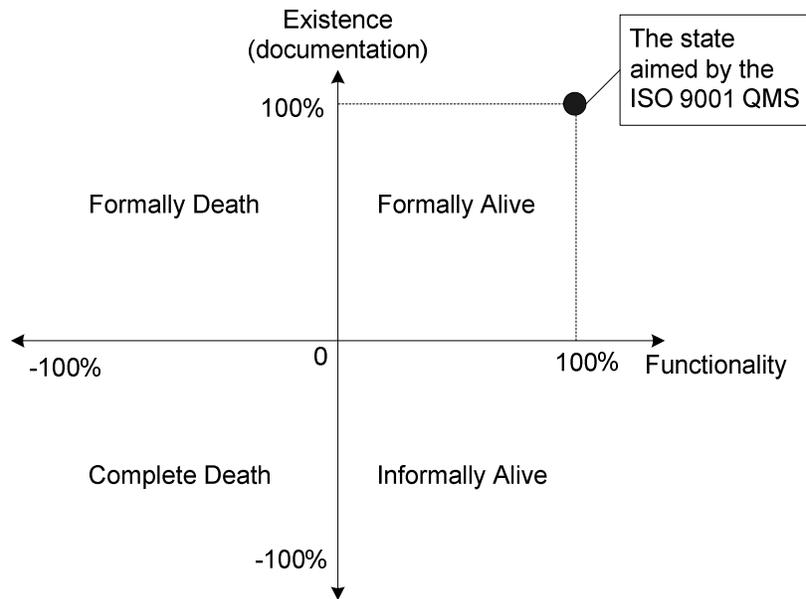


FIGURE 2: Schematic of Initial States in terms of Existence and Functionality of ISO 9001 QMS

1. *Complete Death: No documentation, no functioning.*

This is the state in which there is no indication of the existence and functionality of the QMS. No documentation exists and no processes are in place to help ensure the quality of the product. Relatively few companies will find themselves in this situation.

2. *Informally Alive: No documentation, some level of functioning.*

Many SMEs exhibit an organic structure characterized by an absence of standardization and the prevalence of loose and informal working relationships. SMEs operating in this state are more likely to rely on people rather than a system. In such situations, key personnel may resist documentation for two key reasons “(1) documentation is considered a waste of time and (2) documentation of processes and procedures makes the individual less dependable” [2]. SMEs in this state perform some or all of the processes required by ISO 9001 and the QMS may function fairly well. However, they are not willing and ready to document those processes unless there is a cultural change lead by top management.

3. *Formally Death: Some level of documentation, no functioning.*

SMEs categorized in this state have documented processes and procedures at some degree, however, the documents are generally not followed and do not necessarily reflect the actual manner in which the organization undertakes its operations and management. This situation highlights the fact that the mere existence of documentation does not necessarily lead to a functional QMS. Moreover, such a situation may help perpetuate the view that ISO 9001 is a way for SMEs to market their products and services but that implementation of the standard requires stacks of documents that offer no value.

4. *Formally Alive: Some level of documentation, some level of functioning.*

Each SME considered in this state, achieves a unique combination of the existence and functionality of processes and procedures that may or may not be required by ISO 9001. As illustrated in Figure 2, this situation is closest to the desired state of full functionality (100%) of the ISO 9001 QMS and full documentation (100%) of this functionality.

3. MOVING THE QMS FROM THE INITIAL STATE TO THE DESIRED STATE

The unique characteristics of each SME will affect the implementation process and the constituent elements of each step in different ways. After determining its initial state, the organization must formulate the unique implementation approach that will take it to the ideal state depicted in Figure 3. Building on that premise, Figure 4 shows the different ways that a SME can move from its initial state to the desired state of a 100% “Formally Alive” ISO 9001 QMS. Each of the transitions in Figure 4 is discussed below.

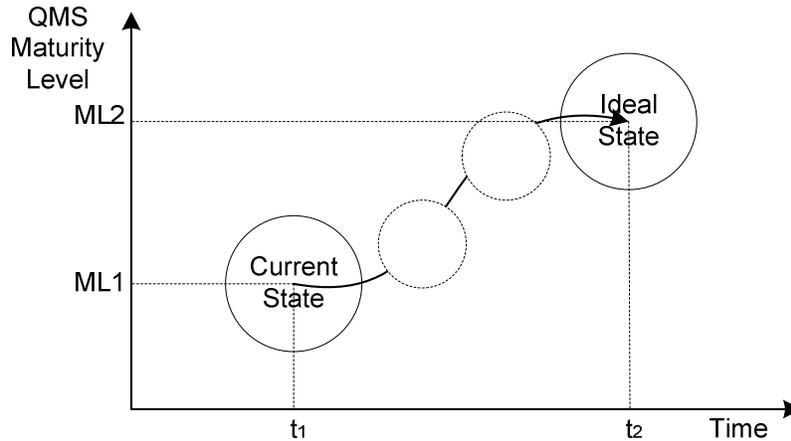


Figure 3: Transition from Initial State to Ideal State

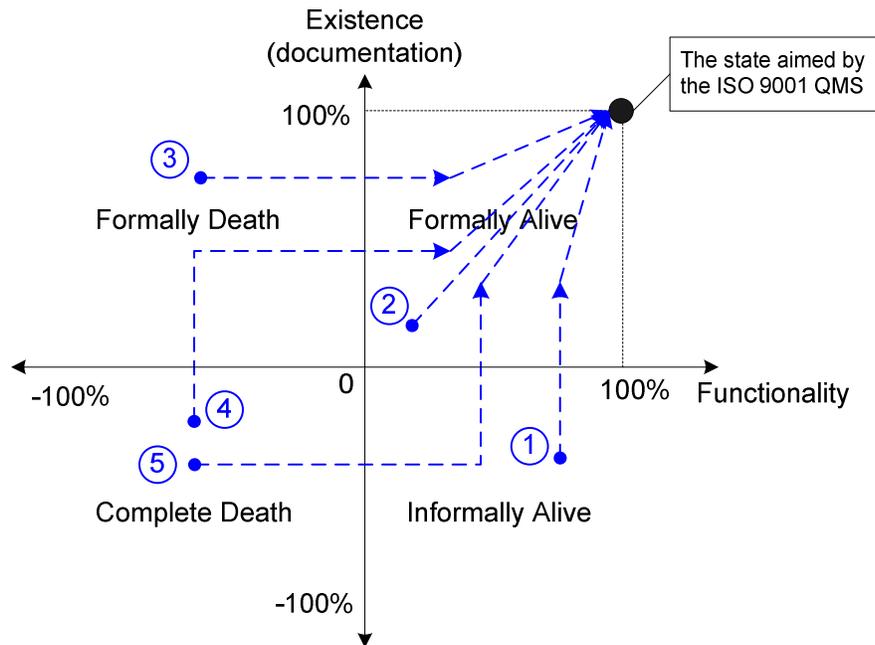


Figure 4: Directions to Formulate an Implementation Approach

1. Informally Alive → 100% Formally Alive:

One advantage of being a SME in today’s global economy is flexibility and agility in the face of changing conditions. The need to react quickly may help create a culture in some SMEs that is against establishing clear processes and procedures. Processes and procedures in this case are initially informal and in the minds of individuals. The first thing that needs to be done in this

situation is to help top management understand the importance of having a fully functional and documented QMS and the organizational changes that are required to achieve it. Once that is accomplished, training must be provided to increase the organization-wide awareness of the QMS and to facilitate the development of the required documentation. The selection of a competent management representative to communicate and continually reinforce the vision to the whole organization is particularly critical.

2. Formally Alive → 100% Formally Alive:

For SMEs that achieve some degree of functionality and documentation in the management of their quality system, the transition to a fully functional and documented QMS will be less dramatic than in the other cases. The SMEs in this state are likely to have a strong base to build on, including an organizational culture influenced by a committed top management that is supportive of the needed education and training. Considerations to begin the transition to a 100% Formally Alive QMS, such as documenting the current processes that are informally done or initiating the realization of processes that have not been previously performed, will depend on the maturity level of the organization.

3. Formally Death → 100% Formally Alive:

In this state, SMEs already have the documentation required for ISO 9001 certification. However, having the required documentation in place only ensures the “existence” of the QMS. This “Formal Death” of the QMS was relatively common in SMEs certified according to the 1994 version of ISO 9001. To implement a ISO 9001:2008 QMS that will help the organization increase customer satisfaction and continuous improvement, the SME must overcome several critical challenges. These include a short-term perspective of top management, the pressure to gain ISO 9001 certification as soon as possible, over reliance on external consultants, lack of spending on internal training, lack of QMS planning, and a product rather than a process focus.

4. and 5. Complete Death → 100% Formally Alive:

A typical characteristic of SMEs in this state is “underorganization”, a term explained by Yauch and Steudel [10]. In this context, underorganization describes a company that lacks structured systems, policies, and procedures. Organizational members accept this condition as a normal pattern and do not necessarily want a more structured system. “Problems associated with underorganized systems include the dissipation of human energy due to a lack of direction, unavailability of relevant information, and inefficient or undependable task accomplishment” [10]. Therefore, one of the biggest obstacles to the introduction of new processes and procedures in these particular SMEs is management realization and the ability of owner managers to modify their behavior and management style. A key starting point in the resolution of these problems is being explicit and disciplined about goals and objectives, roles and responsibilities, and promoting commitment to the QMS at all levels. The time required for these cultural changes to happen is usually longer than the time “desired” for the organization to be ISO 9001 certified. Figure 4 illustrates that SMEs in this state are therefore at risk of ending up with one of two states in the pursuit of a fully functional and documented QMS (Formally Alive): (1) Formally Death, which is represented along Path 4 or (2) Informally Alive, which is represented along Path 5.

4. KEY CONSIDERATIONS IN IMPLEMENTING ISO 9001 IN SMEs

There are many issues that must be addressed in moving the QMS from the initial state to the desired state. For example, all organizations implementing ISO 9001 will need to consider the unique culture within the organization, its size, and the resources available. Beyond those widely discussed points, three issues that merit particular attention are (1) consideration of the QMS as a parallel function, (2) training, and (3) auditing. Key points associated with these issues are discussed below.

Consideration of QMS as Parallel Function

In the case of all of the transitions depicted in Figure 4, real benefits from the QMS are more likely to be experienced if the QMS is implemented directly into the core structure of the organization. SMEs must be cautious against establishing a QMS that is run separately in

parallel to its other systems. In SMEs, the parallel subsystem most commonly exhibits itself as a separate Quality Assurance, or in some cases, ISO 9001 department. Possible reasons for this may include the existence of rigid departmental boundaries in some SMEs or overemphasis on core activities. As Yauch and Steudel [10] note, SMEs tend to focus their attention on "...necessary routine activities (such as sales, production, shipping, etc.) rather than activities aimed at improving processes or systems." If a SME insists on establishing a separate quality department, its level of effectiveness can be increased by embedding the QMS in widely-used organizational systems where practical. The integration is largely a function of how well the QMS manages to share information with other subsystems and its ability to align with the policies, norms, goals, and values in place throughout the organization.

Training

In SMEs, training and staff development is more likely to be *ad hoc* and small scale because of modest human and financial resources and the absence of a specific training budget. To prevent the problems arising from lack of education and training, two things must be done:

1. Education of Top Management: The centralization of decision-making processes within many SMEs means that the management can either be the main stumbling block to change or the main catalyst for change. Therefore, any approach to ISO 9001 implementation must involve considerable education for the top management of the organization to create awareness and understanding of the implementation process as a change initiative. Implementing a fully functional and documented QMS requires motivation by top management to appreciate, achieve, and implement the necessary measures to meet the standards' criteria.
2. Education and Training of Employees: SMEs are often under pressure to quickly gain ISO 9001 registration. Meeting the requirements of the standard in a short period of time can prove a formidable obstacle for a small company. Since most SMEs do not possess the needed expertise internally, they may be inclined to hire external experts to provide the necessary technical expertise and manpower. However, having a functioning and documented QMS requires more than that. It requires ensuring that all employees in the organization clearly know what is expected of them and how they can contribute to the attainment of their organizations' goals. This will likely require the preparation and implementation of a training plan tailored specifically to the unique characteristics and maturity level of the SME.

Auditing

As emphasized throughout the paper, a QMS is not going to produce the expected results unless it is fully functional. While auditing must therefore verify the existence of the necessary documentation, it must also focus on the functionality of the QMS. The measurement of the functionality and the qualitative and financial impacts of a QMS have been the subject of several studies, including Kaynak [11]. Among the categories used to measure functionality and performance improvement, two are particularly noteworthy for our purposes: management commitment and employee involvement. A QMS cannot be functional in the absence of those two characteristics. Therefore, as a minimum, internal and external auditors should continually verify top management's commitment to increased company-wide quality awareness and improvement in addition to employee involvement in the design, implementation, operation, and improvement of quality related processes and procedures.

5. SUMMARY AND CONCLUSIONS

A wide variety of methodologies and techniques have been used to implement ISO 9001. However, successful implementation of ISO 9001 in SMEs can be elusive. One of the key reasons for this is that many SMEs overlook the complexity of the implementation processes and the organizational changes that are needed to ensure the QMS is fully functional.

A fully functional QMS leads to increased customer satisfaction and continuous improvement of business results. Although the existence of documentation is a key requirement of a functional

ISO 9001 QMS, it is not in itself sufficient. To develop and implement a fully functional ISO 9001 QMS, it is essential that a SME correctly identifies the initial state of its QMS and the path it will follow to achieve the desired state.

This paper uniquely contributed to this challenge by identifying four main initial states and five paths from the initial to the desired state. The explicit identification of the initial states and paths will help managers within SMEs to understand the process of implementing ISO 9001 and the fundamental issues that they must address. This should help SMEs to prevent implementation failures within their organizations. In particular, the paper cautions that ISO 9001 cannot be a documentation-driven system. Although this may indicate the QMS exists, it does not guarantee its functionality.

REFERENCES

1. International Organization for Standardization (ISO). "*The ISO Survey 2007*", International Organization for Standardization, Geneva, 2008.
2. A. Ghobadian, and D. Gallea, "*TQM and organization size*", International Journal of Operations and Production Management, 17(2):121-163, 1997.
3. S. Rahman, "*A comparative study of TQM practice and organizational performance of SMEs with and without ISO 9000 certification*", International Journal of Quality and Reliability Management, 18(1):35-49, 2001.
4. A. Bayati and A. Taghavi, "*The impacts of acquiring ISO 9000 certification on the performance of SMEs in Tehran*", The TQM Magazine, 19(2):140-149, 2007.
5. T. Koc, "*The impact of ISO 9000 quality management systems on manufacturing*", Journal of Materials Processing Technology, 186:207-213, 2007.
6. W.G. Lewis, K.F. Pun, and T.M. Lalla, "*Exploring soft versus hard factors for TQM implementation in small and medium-sized enterprises*", International Journal of Productivity and Performance Management, 55(7):539-554, 2006.
7. B. Poksinska, J.A.E. Eklund, and J.J. Dahlgaard, "*ISO 9001: 2000 in small organizations: lost opportunities, benefits and influencing factors*", International Journal of Quality and Reliability Management, 23(5):490-512, 2006.
8. J.C Pinho. "*TQM and performance in small medium enterprises: the mediating effect of customer orientation and innovation*", International Journal of Quality and Reliability Management, 25(3):256-275, 2008.
9. Z.T. Temtime. "*The moderating impacts of business planning and firm size on total quality management practices*", The TQM Magazine, 15(1):52-60, 2003.
10. C.A. Yauch, and H.J. Steudel, "*Cellular manufacturing for small businesses: key cultural factors that impact the conversion process*", Journal of Operations Management, 20(5):593-617, 2002.
11. H. Kaynak, "*The relationship between total quality management practices and their effects on firm performance*", Journal of Operations Management, 21(4):405-435, 2003.

