A QUALITY MANAGEMENT SYSTEM IMPLEMENTATION FRAMEWORK FOR SMALL-SIZED COMPANIES

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ABSTRACT

A detailed framework is essential to facilitate quality system implementation. In this study, we have offered a cost effective do-it-yourself approach to quality management. We have proposed a quality system implementation framework for small-medium sized organizations to enable their transition from a no-quality system to an ISO 9001 quality management system. The proposed framework is validated using a case study of a small door manufacturing company. The findings reveal several setbacks experienced during quality system implementation and suggests means to overcome them using a proposed seven step framework. This study also advises an effective maintenance tool to facilitate continuous improvement in organizations after implementing a quality management system. The study results will be useful for quality practitioners, managers, consultants and engineers, especially in small companies and discloses several benefits that can be achieved by employing the proposed framework in any organization irrespective of its size and nature.

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DEDICATION

This thesis is dedicated to my heavenly father, my mother, sister and my beloved uncle. I would not have achieved this feat without you. I love you all!

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CHAPTER 1. INTRODUCTION

1.1. Background of Quality Management

In today's world, there is an increasing demand of high quality products and services from the customers. Thus, the biggest challenge faced by organizations is to fulfill or exceed customer requirements. The other objective of providing high quality products and services is to retain current customer as customer retention is another major challenge faced by organizations worldwide. Henceforth, there is a need for a system that assures desired levels of quality of both products and services to the customers through effective planning and management. Numerous industries around the world have adopted different practices to ensure improve customer satisfaction and achieve competitive advantage.

The American Society of Quality defines quality management as the application of a quality management practices and methods in managing a process to maximize customer satisfaction with lesser resources while continuing to improve the process. Quality of products and services desired by customers can only be provided by maintaining and improving the quality performances of the processes that create them. Customer satisfaction can be achieved my implementing a Quality Management System (QMS) within the organizations to facilitate quality control and improvement. However, not all organizations, whether small or large, have successfully QMS implemented for various reasons.

Most of the literature about quality management is based on the experiences of large organizations. However, the key findings, conclusions and lessons learned from these experiences are equally applicable to small-medium sized organizations (Boon and Ram, 1998). There are different QMS frameworks adopted that specify various requirements an organization must fulfil to implement the QMS at their facilities. The applicability of these requirements depends on

current situations in the companies depending on whether they are already in place or needed. Nevertheless, the needs and availability of resources required for QMS implementation will vary from organization to organization. Thus, it is important to design and develop the QMS framework that fits into the needs of a specific organization. The lack of literature on QMS experiences in small companies, compared to large companies, calls for more exploration of research studies to help small-medium sized organization to come up with better implementation strategies.

1.2. Quality Management System Methods

There are different quality management approaches adopted by organizations all over the world. Some of the most widely used are ISO 9000 standards (Tummala and Tang, 1996; Kim et al., 2011), Total Quality Management, Six Sigma (Tummala and Tang, 1996; Amar and Davis, 2008) and Lean methodologies (Jasti and Kodali, 2015), Malcom Baldridge model (Tummala and Tang, 1996) and European Quality Award model (Tummala and Tang, 1996). Malcom Baldridge National Quality Award Model (MBNQA) was released by US national congress in 1987 for organizations in the USA to achieve performance excellence. ISO 9000 standards, launched in 1987, are process based requirements that can be used by any type of organization irrespective of their size. In 1994, the requirements of ISO 9000 were used as the base to develop QS 9000 with additional requirements for automotive industry. Despite having different approach, the quality management themes, principles and tools used by these standards and models are same (Evans & Lindsay, 2013). However, over the recent years, ISO 9000 have grown more popular than other quality management practices due it generic nature. Another reason for its popularity was that it is much more aligned with TQM philosophy compared to other management systems (Evans & Lindsay, 2013).

International Organization for Standardization (ISO), even offers a certification program for organizations that satisfy a set certification criterion. The latest survey conducted by ISO in 2016 revealed 1,519,952 certifications worldwide, a 3% increase than previous year. This implies highest acceptance level for ISO 9000 standards in comparison to other QMS methodologies. Yet, researchers have found different motivation factors among companies regarding QMS implementation and acquiring certifications (Anderson, Daly & Johnson, 1999; Singels et al., 2001; Gotzamani & Tsiotras, 2002; Kim et al., 2011). Studies have also revealed cases of failure of QMS in some companies due to various reasons. Thus, researchers have advised consideration of critical success factors while deciding to implement a QMS in an organization.

1.3. Research Motivation

Many researchers, based on their expertise and experiences, have proposed several conceptual frameworks that can be used by organizations for implementing QMS. However, very few conceptual frameworks have been tested and or implemented practically. Many survey analysis have been conducted to study the impact and success of QMS implementation. Such studies provide lessons learned from organizational experiences that can be used by other organizations for planning and implementing QMS more effectively. Nonetheless, some have already initiated implementation of quality systems while others are unsure about implementation. Very few studies have reported entire efforts of quality management projects from initial planning to implementation. This is especially limited in case of small-medium sized companies that are growing fast along with their population. No perfect framework or QMS practice exists due to constant evolutions and changes happening in today's world. Having said that, we strongly believe that smaller organizations wishing to implement QMS can learn and implement by using findings from previous cases of implementation and benchmarking them to implement a QMS successfully.

This study is focused on one such aspect. Usually small businesses have limitations like lack of direction and expertise in quality management due to scarcity of resources in the form of knowledge, time, money, man power and infrastructure. Thus, small companies need a way to facilitate their transition from a 'no quality system' state to an established quality management system state by overcoming these limitations.

1.4. Research Objective

The objective of this theses study is to propose a QMS framework that can be implemented by any organization with very limited resources. We have discussed several aspects that can be considered by organizations seeking implementation of quality management in their companies. These aspects can be used by any organization to effectively transit from a no quality management system company to an ISO 9001 certified quality management system company, without the need for outside experts and hasty implementation program. The do-it-yourself framework proposed in this study will enable organizations to effectively achieve internal benefits without the need for official certification. This framework is applied and discussed as a journey of a small door manufacturing company from no-quality systems to ISO 9001 QMS.

This thesis is divided in seven chapters. We have discussed introduction to this topic in Chapter 1. Literature review presented in Chapter 2 details the comparison of QMS implementation frameworks and lessons learned from survey analysis and implementation case studies from the literature. Chapter 3 explains the methodology used to counter the thesis statement and details about understanding of the QMS requirements. Chapter 4 outlines our proposed detailed framework for QMS implementation. Chapter 5 discusses the applicability this framework as a case study problem. Conclusions and lessons learned are summarized in the last Chapter no.

6 and followed for a list of literature references. Additional material related to this study is provided in Appendix A, B and C at the end of this document.

CHAPTER 2. LITERATURE REVIEW

2.1. Comparison of QMS Frameworks

Several studies related to QMS implementation have been reported in the literature by quality gurus, quality practitioners, consultants and international organizations. Many survey analysis studies have reported experiences of organizations after QMS has been implemented. Some studies have also reported QMS implementation experiences in the form of case studies while others have only proposed conceptual frameworks. However, most of these studies are only related to large organizations and have limited applicability for small-medium companies (Yusof and Aspinwall, 2000). Our exhaustive study of proposed quality management frameworks and their impacts on organizations performance is summarized in table 1 of Appendix A. A screenshot of this comparison to fit the size of page is shown in table 1 below.

One of the first conceptual frameworks for TQM implementation was developed by Hakes (1991). The author focused on continuous improvement aspect by proposing a series of questions an organization needs to ask itself. These questions were: what are the short term and long term objectives? How to measure performance? How to communicate opportunities for improvement? However, it failed to provide knowledge about quality tools and resource management (Yusof and Aspinwall, 2000). Another quality improvement framework focused on TQM philosophies was proposed by Dale (1995). But, he stressed its limited application to only larger organizations with prior quality systems or quality oriented culture already in place.

A quality management model for larger organizations was proposed by Berry (1991). However, it failed to consider a need for early quality related training in his inner most model required for providing necessary improvement (Yusof and Aspinwall, 2000). Early training is

necessary to educate the employees within the organization and especially the top management, about QMS, its purpose, and efforts an organization must dedicate to initiate the change in culture.

Conversely, there have been very few studies that focused on studying quality systems in small and medium sized industries. Although, some researchers have proposed the use of MBNQA and EQA for QMS implementation, particularly in small companies. However, these provide only QMS requirements and lack the information required to understand how these requirements should be fulfilled (Ghobadian and Gallear, 1997). Hewitt (1997) also argued that these models are more suitable for larger organizations who have already have a quality system in place. Another framework titled as a modified pyramid model was prescribed by Kanji (1996). However, it assumes an organization to already have implemented a data collection system. But, many smaller business lack expertise in order establish a fact-based decision making systems required to use Kanji's model. Thus, applicability of these conceptual frameworks to small or medium business is a very limited due to above discussed prerequisites necessary to implement them successfully.

Majority of these frameworks are too complex for small businesses that do not possess fundamentals like a quality oriented culture, availability of data acquisition processes and knowledge of basic quality tools & techniques (Yusof and Aspinwall, 2000). They also concluded that QMS frameworks for smaller companies should be easily understood with a simple structure and provide a direction on 'how to' implement it successfully, unlike frameworks proposed by Hakes (1991), Berry (1991), Dale (1995), Kanji (1996) and Hewitt (1997).

Interestingly, literature does not provide with any industrial implementation studies that focused on the applicability of these QMS frameworks discussed above.

Table 1: Comparison of Quality Management System Implementation Framework

Sr. No.	QMS Literature	Quality System Considered	Type of Study	Organization Applicability	Implementation Motivation	Impact of QMS	Driving Force
1	Bialy and Maruszewska (2015)	ISO 9001	Case study	Large	Internal or external	QMS outputs	Insufficient information
2	Garza-Reyes et al., (2015)	ISO 9001	Conceptual framework	Small-large	Internal or external	Insufficient information	Insufficient information
3	Valentina Biasini (2012)	ISO 9001	Case study	Small	External	QMS outputs	Outside expert
4	Milan Hutyra (2010)	ISO 9001	Case study	Large	Internal and external	QMS outputs	Outside expert
5	Kim et. Al (2011)	ISO 9001	Conceptual framework	Small-large	Internal or external	Insufficient information	Insufficient information
6	D. Aggelogiannopoulos et al., (2007)	ISO 9001	Case study	Small	Internal and external	Insufficient information	Insufficient information
7	Bhuiyan and Alam (2006)	ISO 9001	Case study	Small	Internal and external	QMS outputs	Outside expert
8	Aldowaisan and Youssef (2006)	ISO 9001	Conceptual framework	Small	Internal or external	Insufficient information	Insufficient information
9	S. Aniyan (2002)	ISO 9000	Case Study	Large	Internal and external	QMS outputs	Outside expert
10	Hermann et al., (2000)	TQM and ISO 9000	Case study	Small-large	Internal	QMS assets	Insufficient information

In one of the recent research works, Kim et al. (2011) compared a few QMS frameworks on the criteria of consideration of critical factors, motivational factors and clarification of links among QMS impacts. The authors also suggested that QMS implementation studies can be evaluated based on the type of impact on organizations. Having said that, authors also proposed that organizations can be classified to have 'zero impact' or impact with 'QMS assets' or impact by achieving 'improved QMS outputs' (Kim et al., 2011). However, they did not provide comparison using this criterion. We also believe that an ineffective QMS might have some impact on the organization. Hence, we refer to such impact as 'negative impact' rather than 'zero impact' in this study.

In our research, we have utilized this idea and compared some of the frameworks in table 1, as stated earlier. Thus, QMS implementation will have 'negative impact' on organizations performance at any level if QMS is ineffective due to reasons like incorrect implementation methods and based only on external motivations. However, 'QMS assets' can be derived from an effective implementation of any quality system (Kim et al., 2011). Such 'QMS assets' have been achieved in the form of improved quality systems (Yahya and Goh, 2001; Magd, 2008; Poksinska et al., 2006; Williams, 2004), Standardized process (Williams, 2004; Yahya and Goh, 2001; Zeng et al., 2007; Jones et al., 1997), sustainable environment (Yahya and Goh, 2001; Zhang, 2000; Zeng et al., 2007) etc. Similarly, QMS outputs have also been achieved by efficient management of QMS assets, that facilitate improved operational performance in the form of cost reductions related to waste and nonconformance's, timely deliveries of products and services, enhanced customer satisfaction levels of both internal and external customers, increased productivity through-out product realization processes (from raw material receiving to product or service

delivery), reliable and controlled processes, shorter cycle times, etc. (Mezher et al., 2005; Jang and Lin, 2008; Han et al., 2007).

Yet, it is to be remembered that studies listed in table 1 above is not an extensive list but a representative sample summarized from the literature for this study only. Having said that, we also acknowledge other studies we might have missed to consider during this review. Also, note that table 1 is the screenshot taken to fit the size of the page. Full list is provided in the Appendix A.

A 24 step QMS development program proposed by S. Aniyan (2002) was used to implement QMS at a large manufacturing company. The implementation was aimed at achieving both organizational benefits as well as ISO certification. The case study concluded that organization achieved several benefits from successful implementation of QMS. The highlight of this study was the strong commitment from the top management of the company to provide necessary resources for successful implementation that was eventually achieved. However, the author does not comment if this framework can be utilized by smaller business. Certification was achieved in mere 16 months by hiring outside experts, not many small organizations would be able to afford.

Lee and Lam (1997) presented a QMS implementation framework for an Asian railway company in six different phases that was based on ISO 9001 standards. Implementation started with the training all staff levels of the organization to ensure total commitment to quality followed by development of QMS documentation phase. This was followed by implementation, internal audits, preliminary assessment & QMS review, dry run and formal assessment. However, the case study failed to explain the basis of development of QMS and related documentation which can be achieved by using self-assessment techniques like ‘Gap Analysis’. Despite the TQM and quality control circles (QCC) program already established at the company, motivation for the

implementation of QMS was not well explained. So also, apart from the initial training, the framework does not include any specific training program for new procedures and work instructions that were affected due to changes. The procedures were also made without understanding the needs of internal customers.

A step by step implementation approach proposed by Ashok Sarkar (1998) was implemented at a large textile mill. In an important step, continuous review of documentation was carried out internal customers for correctness and compliance. Outside experts were used to complete the documentation of entire organization in just 8 months. However, the case study does not provide any information on how to perform initial assessment of the system and steps required to be taken after certification is achieved. Smaller organizations need a self-assessment tool to clearly understand its current quality status.

Garza-Reyes et al. (2015) proposed a five-stage conceptual framework for implementing a quality system or improving a quality system. The first step is QMS and business process diagnostic followed by strategic planning, selection of right models, methods & tools, QMS implementation and Evaluation of QMS and business processes. However, we believe that the framework is very complex and assumes the organization to have prior understanding of audits, quality models and quality methods. The approach might be useful for large organization rather than SME's where these limitations persist. The authors have also called for the validation of this framework before adopting it.

Aggelogiannopoulos et al. (2007) proposed a nine step QMS implementation and certification process for small company in their case study. The authors advised to test its QMS for a small trial period before performing certification audits. Study reveals that external consultancy services were utilized to facilitate implementation. However, it does not provide any

information or suggestions for other small companies that have financial limitations to hire outside experts.

2.2. Critical Success Factors and Barriers to Successful QMS Implementation

An organization with a desire to implement QMS must adopt all the necessary requirements specified in the standard (Psomas et al., 2010). However, many research studies have found implementation of QMS to be challenging (Chow-Chua et al., 2003). Organizations might have different motivations for implementing QMS like achieving certifications. Contrary to that, researchers have also revealed several barriers and critical success factors that organizations seeking QMS implementation should consider. Oakland (1993) defined critical success factors as elements that need to be examined and categorized to ensure successful implementation of a system. In this study, we have used previous QMS experiences from the literature discussed in the prior section and list the different types of organizational barriers and critical success factors needed to be considered while implementing a QMS. Thus, we have classified these critical success factors or organizational barriers into two separate categories.

After carrying out detailed literature review, we strongly believe small-medium business will benefit in understanding QMS in two different phases: 'Quality Management System Planning Phase' and 'Implementation of Quality Management System Planned' in the first phase. To complement this classification, we have reviewed the critical success factors or organizational barriers and classified them based on their consideration and presence during QMS planning & initiation and QMS implementation in any industry. Full categorization of critical success factors is provided in the Appendix A, table 2. A screenshot to fit the page is provided in table 2 below. A few studies have focused on understanding the grounds of unsuccessful and ineffective QMS. Magd (2008) and Angelogiannopoulos et al. (2007) also found that many organizations lack the

experience and knowledge of QMS requirements. This leads them to the development and implementation of a QMS that fails to produce expected results. They also found that many companies lack understanding behind the purpose of documentation and thus fail to address problems evident from quality records.

Augustyn and Pheby (2000) highlighted the need for complaint monitoring system, strong commitment and focus on providing effective training in required areas, reliable data collection methods and error prevention system as critical success factors to ensure that implementation of QMS is successful in providing desired results. A complete process of QMS implementation that was studied in small manufacturing company revealed several factors that slowed the implementation process. The key barriers faced were lack of complete understanding of the purpose of QMS requirements, lack of commitment from the top management, lack of belief in what QMS can achieve, inability to provide sufficient resources for training and implementation of QMS and employee resistance to accept change in processes (Bhuiyan and Alam, 2005). Many researchers have suggested lack of top management support and commitment as one of the most common barriers. This is regarded as a major barrier that also leads to poor attitude towards QMS among employees (Magd, 2008).

Zeng et al. (2007) examined companies that adopted QMS in china and found that main barriers to effective implementation of QMS are lack of commitment to maintaining QMS, keeping high expectations from QMS results and tendency of companies to satisfy minimum requirements to achieve certification. A research conducted on QMS performance levels in Korean shipbuilding companies revealed several factors that hindered the success of QMS implementation like lack of understanding of QMS requirements among employees, partial fulfillment of QMS requirements, lack of interest in QMS from other functional areas and Failure to assign proper responsibilities

and authorities related QMS maintenance (Park et al., 2007). The author also highlighted other barrier of deceitful and dishonest audit reports and other quality records. They suggested that organizations should analyze the impacts of organizational change before to boost their chances of implementing QMS successfully.

Jawad and Al-Najjar (2011) studied the QMS implementation barriers faced by companies in Iraq. One of the most important barrier revealed through their research was difficulty in conducting internal quality audits. Their study also revealed common misconceptions regarding QMS. Most important misconceptions that they highlighted was that QMS causes a decrease in production levels and QMS implementation requires high financial resources. Another research conducted by Magd (2008) in Egyptian manufacturing companies discovered that there was a lack of qualified personnel required for successful implementation and maintenance of QMS and inadequate training was provided to tackle quality related problems.

Organizations have often reported several problems during QMS implementation process like the development of QMS related documentation due to poor understanding of requirements, limited resources and time allotted to QMS planning and implementation and lack of top management commitment (Stevenson & Barnes, 2002). These are common barriers existent in small sized companies (Aldowaisan & Youssef, 2006). A QMS implementation experience in a small-sized winery highlighted a barrier in lack of time commitment in carrying out QMS processes and training provided to temporary hires (Aggelogiannopoulos et al., 2007). Moreover, the same study also concluded with several benefits earned by the winery despite facing difficulties. The benefits achieved were improved internal communication, reduced errors and mistakes, better control over non-conformities, fewer complaints, higher quality of wine making and most notably improved customer satisfaction.

Table 2: Critical Success Factors for Successful QMS Implementation

Sr. No.	Critical Factors to Be Considered During QMS Planning	Critical Factors to Be Considered During QMS Implementation
1	Lack of top management support and commitment to QMS (Psomas et al., 2010)	Lack of top management support and commitment to QMS (Psomas et al., 2010)
2	Inability to provide resources needed for QMS (Magd, 2008; Zeng et al., 2008; Kim et al., 2011; Angelogiannopoulos et al., 2007)	Lack of commitment to maintaining QMS (Zeng et al. 2007)
3	Lack of commitment to financial support from the top management before QMS Implementation (Yahya and Goh, 2001; Magd, 2008; Kim et al., 2011)	Employee resistance to change (Bhuiyan and Alam, 2005)
4	Lack of qualified personnel required for successful implementation and maintenance of QMS of (Magd, 2008)	Lack of time and efforts to implement and maintain QMS (Yahya and Goh, 2001; Magd, 2008, Kim et al., 2011)
5	Lack of experience and knowledge of QMS (Angelogiannopoulos et al., 2007)	Lack of understanding related to quality mythologies, practices, tools etc. (Bhuiyan and Alam, 2005)
6	Lack of training necessary for implementing QMS (Yahya and Goh, 2001; Park et al., 2007; Magd, 2008; Chow-Chua et al., 2003; Psomas et al., 2010; Kim et al., 2011)	Poor problem solving training to tackle quality related problems (Magd, 2008)
7	Lack of motivation among management and employees to improve processes (Heras et al., 2008)	Lack of measurement and monitoring of internal and external customer satisfaction (Park et al., 2007; Kim et al., 2011)
8	Lack of control over documentation (Chow-Chua et al., 2003)	Lack of training to perform performance analysis using quality tools (Yahya and Goh, 2001; Park et al., 2007; Magd, 2008, Kim et al., 2011)
9	Meeting internal and external customer needs and expectations (Psomas et al., 2010; Park et al., 2007; Kim et al., 2011)	Partial fulfillment of QMS requirements (Park et al., 2007)
10	Ensure employee involvement and commitment to QMS development and Implementation (Psomas et al., 2010)	Analyze the impacts of organizational change that are necessary to implement QMS successfully (Park et al., 2007)

A study focused on quality practices in small companies emphasized the need to understand the company culture, based on employee's perspective, before initiating any improvement plans (Watson and Gryna, 2001). Authors suggested that the difference between management perspectives and employee perspectives of achieving quality should be taken under consideration by building a positive quality culture through sharing and training of quality management practices and their purpose. Thus, we strongly believe companies intending to implement QMS will benefit more from experiences during development and implementation.

Another study related to SME's (small and medium sized enterprises) revealed that successful implementation of QMS can be achieved my assigning implementation responsibilities to expert personals with necessary qualification and knowledge to carry out QMS activities. To achieve effective QMS implementation, authors of this study also suggested SME's to consider QMS for right reasons, ensuring availability of necessary infrastructure in the form of resources and training methods (Psomos et al., 2010).

Through his recent study, Murphy (2016) encouraged small-medium sized companies to engage in quality management practices to accomplish business improvements despite several barriers. The most crucial factors repeatedly discussed in literature is the commitment from leaders of the company which can achieved by providing knowledge to the top management, strong commitment from to QMS from the employees which can achieved through careful transition from their old practices to new practices by gaining their trust and effective training methods rather than forceful implementation and ensuring resource availability as needed, which can be compensated by working together with business partners, suppliers and vendors through strategic planning and utilization of partner resources. Due to lack of literature studies and understanding of factors that cause reductions in small-medium sized organizations commitment to quality management,

Murphy (2016) also encourages researchers to study more about this subject and present their literature to promote quality management in SME's.

2.3. Benefits of QMS Implementation

Numerous organizations have benefited from QMS implementation. Organizations all over the world are looking to instill quality management principles to enhance customer satisfaction, operational efficiency and their position in a competitive market (Magd, 2008). A textile mill company that implemented ISO 9001 QMS successfully benefited in the form of reduction in waste and unwanted inventory levels. It also reported to have reduced absenteeism among workers (Sarkar, 1998). A study conducted by Lee and Lam (1997) revealed benefits like improved reliability and less maintenance costs. It is critical for small companies to understand the QMS requirements and their purpose to build effective implementation strategies. QMS will fail if it is not implemented properly (McAdam and Fulton, 2002).

The purpose of ISO 9001 standard is to assist companies of various sizes in any sector to implement and operate an effective QMS by enhancing the firm's ability to design, produce and deliver quality products and services (Ab Wahid and Corner, 2009; Sroufe and Curkovic, 2008). According to some other studies, ISO 9000 certified organizations have found to have better organizational performances (Singels et al., 2001; Jang & Lin, 2008). Additionally, Organizations have also benefited from QMS implementation with advantages like increase in quality productivity, reduction in operational costs, increased flexibility, shortened cycle times and increase in employee satisfaction (Mezher et al., 2005; Han et al., 2007; Kim et al., 2011). The same study also revealed that QMS provided organizations with better control over their suppliers and clear roles and responsibilities among employees. Several other benefits achieved by implementing a QMS are also summarized in table 2 provided in Appendix A.

2.4. QMS Implementation Motivation

Many researchers have studied the factors that motivate organizations to implement QMS and ISO certification was found to be one of the key motivation factors (Singels et al., 2001; Gotzamani & Tsiotras, 2001; Boiral & Roy, 2007). In their study, Lee et al. (2009) found that organizations take different efforts in implementation of QMS requirements as they might have different emphasis and motivations. Anderson, Daly & Johnson (1999) studied US manufacturers and found that their motivation to implement QMS was to achieve standardization of organizational processes to improve the quality of products and internal processes that would enhance customer satisfaction levels and reduction in costs associated with quality.

Due to such varying motivation factors, Leung et al. (1999) classified them into internal driven motivation factors and external driven motivation factors, which were also called as non-customer driven and customer driven motivations respectively.

Internally motivated organizations, that implement QMS for achieving internal benefits, achieve higher levels of organizational performance than externally motivated organizations, which seek certification due to external pressure (Singels et al., (2001). This was also proved from the research conducted by Gotzamani & Tsiotras (2002) which concluded that those motivated by internal factors gain more overall benefits from an effective QMS than those motivated by external factors. However, the long-term effectiveness of QMS depends on overall efforts and commitment of people within the organization in achieving quality improvements. Thus, to ensure that QMS is successful and maximum benefits are achieved, an organization must ensure that QMS performance is regularly monitored for making improvements through total commitment of its employees. In an extensive literature study carried out by Kim et al. (2011) motivational factors responsible for QMS implementation were classified as quality related, operations related,

competitiveness related, external pressure related and organizational image related factors. We believe that, all organizations looking to implement QMS must verify if QMS implementation has successfully achieved their motivations for seeking it. This is especially true for small and medium business.

CHAPTER 3. RESEARCH METHODOLOGY

3.1. Research Method

The primary objective of this study is to propose a detailed framework of quality management system implementation for small-medium sized companies with no-quality system experience. This framework facilitates a transition of any organization from a no-quality system environment to an ISO 9001 quality management system environment with very limited resources. The applicability of this framework is described as a case study experience in the chapter 5.

For every small business starting a quality oriented journey can be daunting task. We discussed several reasons that affect QMS in small companies as barriers or critical success factors. Most widely discussed barriers were lack of top management commitment, lack of resources, lack of expertise and employee resistance. A detailed literature study was carried out to identify different frameworks and implementation strategies related to quality management practices. These frameworks were compared with each other to determine their applicability and impact. We are using the lessons learned from past studies in the literature to propose a detailed framework for small-medium sized companies for achieving successful transition to a quality system oriented environment with a do-it-yourself approach.

Our proposed framework is explained using a case study of a small manufacturing company. The information required for this study was obtained from various sources like formal and informal meetings with the managers & employees of the company, cross functional observation of processes and daily activities, other documents of the company like returns tracking and customer survey documents. We have also utilized information from our literature review analysis. ISO 9001:2008 quality management system requirements, an international standard was used as a reference to understand the design, development and implementation requirements for a

QMS (Cianfrani et al., 2009). These requirements specified in the standard were used to develop a 'gap analysis' report to assess the current standards of quality system already established at the company. The findings of the gap analysis, customer survey and customer returns tracking were carefully addressed to understand the needs of the company.

Basic quality tools and data analysis techniques like pareto charts was used, where possible. A Plan-Do-Check-Act (PDCA) approach was used to develop the QMS implementation framework to address the needs of the company. The implementation and QMS maintenance plan was also developed as a part of this program at the company.

3.2. Quality Management Principles

Quality Management System can be defined a management system used for managing a process to achieve maximum customer satisfaction at the lowest overall cost level to the organization while continuing to improve the process (ASQ). As discussed in the literature, QMS implementation in an organization can be influenced by either external factors like customers and competitiveness or internal factors like organizations motivation to improve the quality of its current processes and culture within the company. ISO 9001 standard states that the foundation of a QMS should be developed based on eight quality principles (ISO 9001, 2005). These principles are described as follows:

1. *Customer Focus*
2. *Leadership*
3. *Involvement of people*
4. *Process approach*
5. *System approach to management*
6. *Continual improvement*

7. *Factual approach to decision making, and*
8. *Mutually beneficial supplier relationships*

These quality principles must be inherited within the organization to achieve its quality improvement goals.

3.3. Process-based Approach

A process approach to QMS is proposed in ISO 9001 standard and defined as the application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome (ISO 9001, 2005). The process-based model is illustrated in figure 1. An organizations QMS adoption should start with identifying various process and activities linked with each other. As shown in figure 1, we can see that QMS begins with customer processes i.e. Customer requirements serve as an input to all the other processes and drives organizations operations. Input in the form of customer requirements are directly fed to the product realization processes i.e. purchasing from raw material, reviving raw material, converting raw material to customer desired specifications and then delivery to the customer.

The data collected during these processes is then used to analyses the performance of entire QMS using measurement, analysis and improvement processes. These requirements for QMS related to all these procedures s discussed in the next section. Results obtained from measurement and analysis procedures is then discussed in the management review meetings where management analyses the situation and takes important decisions related to the provision of resources, if needed. These can be achieved by an establishing a resource management processes. Feedback is obtained from the customers after delivery of products or services and customer satisfaction levels are determined using measurement, analysis and improvement processes. This is also applicable to all

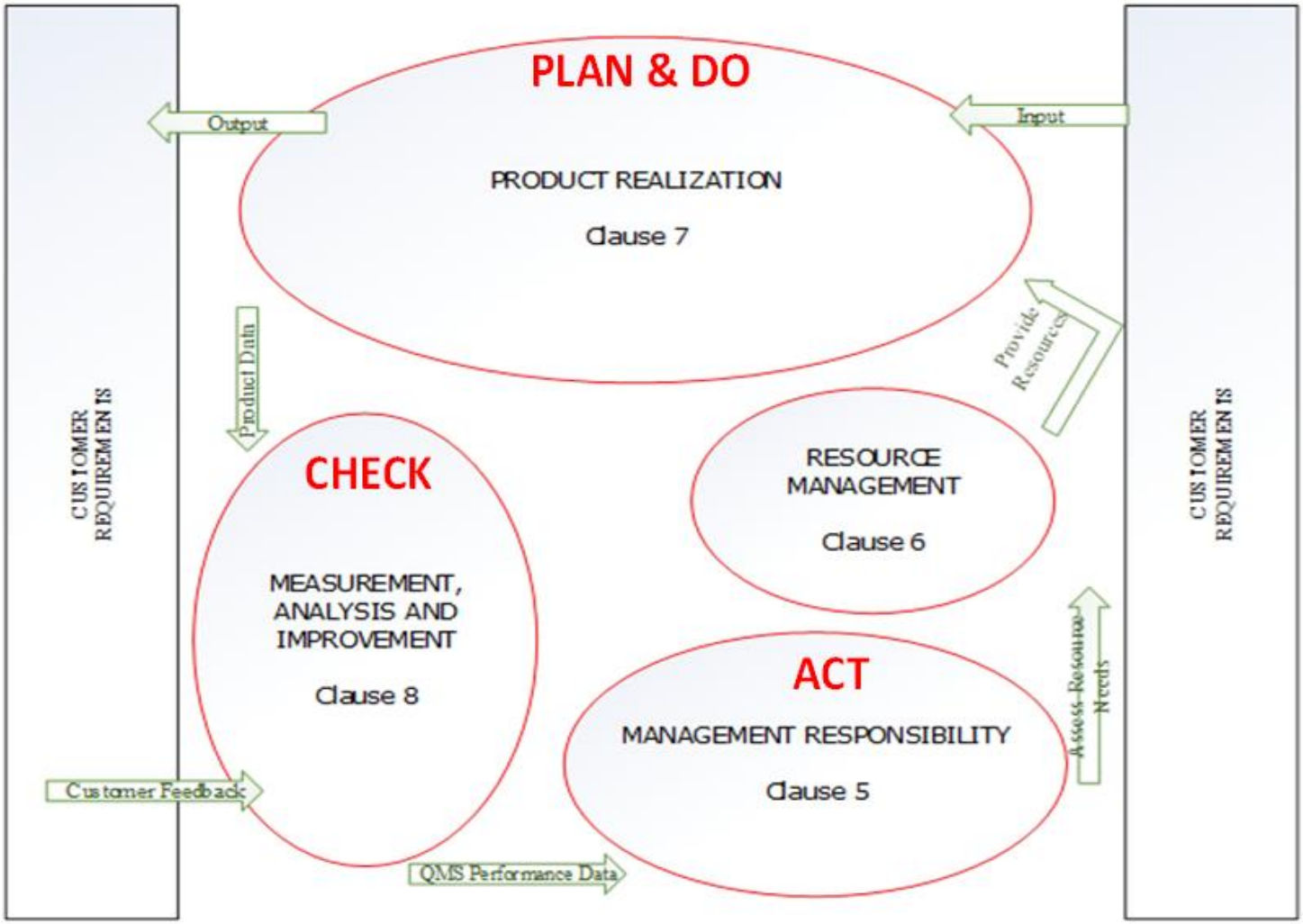

Figure 1: Process-based Approach to Quality Management

the internal customers within the organizations. Thus, an organization should put emphasis on identifying the requirements of both external and internal customer for every process and ensure that desired output is achieved successfully.

3.4. ISO 9001: 2008 Quality Management System Requirements

ISO 9001: 2008 standard facilitates QMS requirements in the form of eight different clauses that can used to develop and implement a QMS. Figure 1 exhibits the process-based approach specified in the standard. Requirements of ISO 9001: 2008 standard are elaborated and provided in the form of gap analysis checklist in Appendix A, table 3.

First three clauses in the standard: Scope, Normative References and Terms and Definitions, provide details and definitions for the rest of the standard. However, the context of these clauses must also be considered. Clause 4 is divided into two different sub-clauses. Clause 4.1 specifies general requirements that every organization must consider. Clause 4.2 specifies documentation requirements that can developed to manage QMS. Clause 4.2 is further divided into clause 4.2.1 that specifies information about general documents in the form of quality manual, quality procedures and quality records. Clause 4.2.2 specifically provides information about quality manual documentation. Similarly, clause 4.2.3 control of documents and clause 4.2.4 control of records defines controls needed to manage quality related documents like procedures, work instructions, manuals, forms, etc.

Clause 5 provides responsibilities of top management of the company and further divided into clause 5.1 management commitment, clause 5.2 customer focus, clause 5.3 quality policy, clause 5.4 planning, clause 5.5 responsibility & authority and clause 5.6 management review. Clause 6 is titled as resource management and provides requirements related to the provision of resources like human resources, infrastructure, and work environment.

Clause 7 is one of the most important clauses that divided into 6 sub-clauses. Clause 7.1 provides requirements related to the planning of product realization, clause 7.2 provides requirements related to customer-related processes, clause 7.3 specifies requirements related to design and development, clause 7.4 provides requirements for purchasing processes, clause 7.5 provides requirements product and service provision and clause 7.6 specifies requirements needed for control of monitoring and measuring equipment's. Clause 8 titled measurement, analysis and improvement is the last clause that is further divided into clause 8.1 general, clause 8.2 providing requirements for monitoring and measurement, clause 8.3 provides requirements needed for the control of nonconforming product, clause 8.4 details about data analysis and clause 8.5 specifically providing instructions for improvement.

A standard documentation structure for any quality system is shown in the figure 2. Quality Manual is described as the highest-level document established by the top management of the company. It included the Quality Policy, Quality Objectives, and most importantly any exclusions from the ISO 9001 requirements. It must be communicated to all the employees in the company. Quality Procedures are standardized procedures established at different organizational levels to ensure that all the employees perform the same tasks, same way and every time without any variations. Quality policy and Quality Procedures are usually used document 'Say what you do' question. It the responsibility of the managers to ensure that employees are doing what is stated in these procedures and hence the phrase 'Do what you say'. This can be achieved by establishing work instructions where necessary. Similarly, Quality Records are used to document the day to day activities related to QMS and prove that desired outcomes are achieved. Where nonconformance's are determined, actions must be taken to correct them and hence improve the QMS.

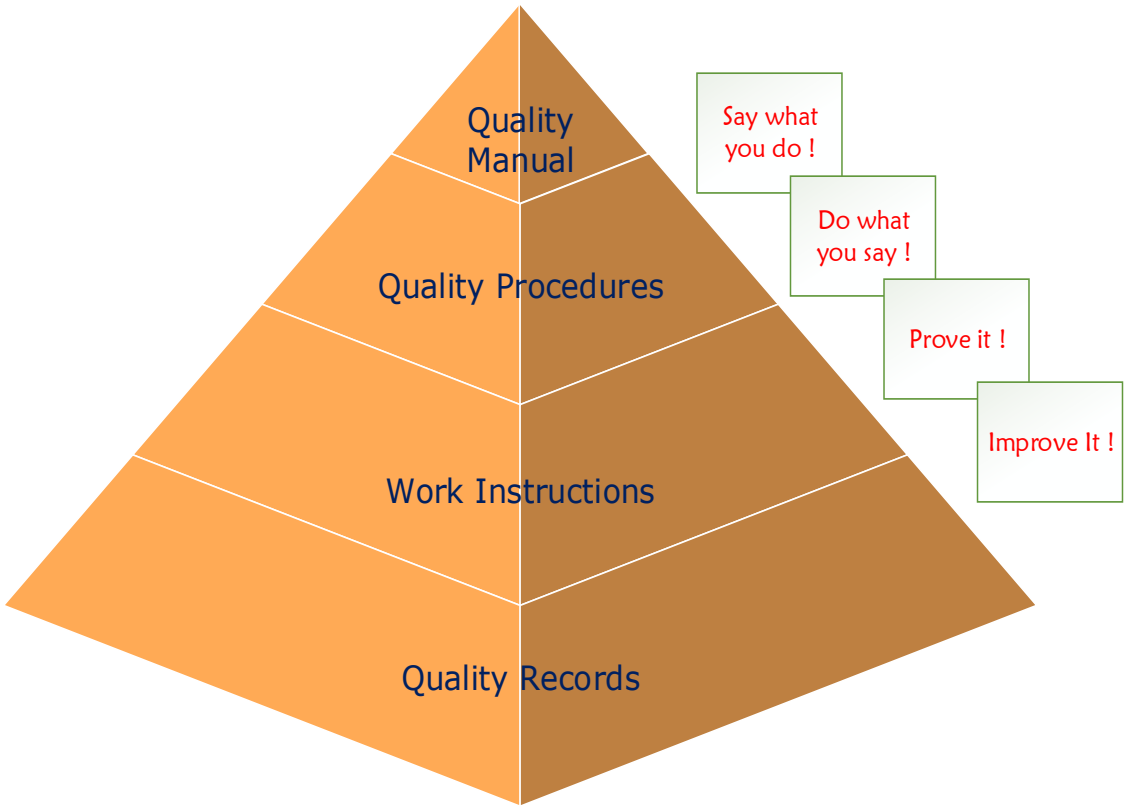

Figure 2: QMS Documentation Structure

CHAPTER 4. PROPOSED FRAMEWORK

4.1. QMS Implementation for Small-Sized Companies

In this section, we have proposed a detailed framework for quality management system implementation for small companies. A step by step framework is proposed to overcome or mitigate the barriers faced during QMS implementation as discussed in the literature review. We have discussed the major obstacles and critical factors to implement a successful QMS in Table 2. We attempt to mitigate the effects of such barriers though our seven-step proposed framework for QMS development and implementation. This is illustrated on figure 3 of this document.

4.1.1. Step 1: Determine Organizational Needs – Do-it-yourself approach (PLAN)

The objective of this step is to identify the needs of an organization with respect to quality systems. For this step an organization should develop a clear understanding of QMS requirements and then compare them using gap analysis tool to determine organizational needs. To overcome the barrier of poor and incorrect understanding of QMS requirements we have provided a clause by clause interpretation of the standard in the form of a gap analysis checklist in the Appendix A, table 3. During this stage an organization can assess the stronger as well as weaker areas within the organization using our comparison checklist. Other methods like SWOT analysis can also performed. If affordable, an organization can also look to hire an external consultant only for developing the basic understanding of QMS by organizing companywide training program. Without assigning external consultants, an organization will need to be patient as it will take time for understanding the QMS requirements. We propose creating a quality improvement team of experienced employees and dividing the responsibilities for quicker start. A management representative (MR) can also be appointed to lead this team and communicate progress with top management regularly.

4.1.2. Step 2: Develop QMS Infrastructure (PLAN)

In this step, we establish the foundation of QMS i.e. mandatory processes required for effective and successful implementation of QMS are defined as QMS infrastructure. Chin et al. (2000) studied QMS implementation in several manufacturing companies and concluded that there are 5 QMS requirements that are very critical to QMS implementation and maintenance. Failure to manage these requirements will eventually lead to failure QMS. These are corrective and preventive actions, management commitment, internal audits, control of documents and records and control of nonconformance. QMS for any company, irrespective of its size and nature, cannot function without QMS infrastructure. We classify QMS documentation under QMS infrastructure as follows:

- Quality Manual and Quality Policy
- Management Review Meetings
- Control of QMS Documents
- Control of QMS Records
- Control of Nonconformance
- Internal Quality Audits
- Corrective and Preventive Actions

At this point, an organization should announce the quality management initiative by establishing a quality policy. A ‘Quality Manual’ is the document specifying the quality management system of an organization. It includes quality policy, quality objectives and other important information in it. ‘Quality policy’ is defined as the top managements overall intentions and direction of an organization related to quality (ISO 9000, 2005). ‘Quality objectives’ are something sought, or aimed for, related to quality (ISO 9000, 2005). ‘Management review

meetings' are activities undertaken to determine the suitability, adequacy and effectiveness of an organizations QMS to achieve established objectives.

A non-fulfillment of a requirement is called as a 'nonconformity' (ISO 9000, 2005). A systematic, independent and documented process for obtaining an audit evidence and evaluating it objectively, to determine the extent to which audit criteria are fulfilled is termed as an 'Internal Audit' (ISO 9000, 2005). 'Corrective actions' are defined as actions implemented to eliminate the cause of a detected nonconformity or another undesirable situation (ISO 9000, 2005). 'Preventive actions' are defined as the actions implemented to eliminate the cause of a potential nonconformity or another undesirable potential situation (ISO 9000, 2005). We suggest establishing quality objectives only for the desired scope for QMS implementation. Thus, objectives can be limited to one process or multiple processes, as suitable.

4.1.3. Step 3: Develop QMS for Critically Important Process (PLAN)

The objective of this stage is to identify the critically important process within the organization i.e. the process or functional area that possesses highest risk in nonfulfillment of customer requirements. This can be achieved by performing risk assessment on all the nonconforming findings in the gap analysis report. An organizational process or functional area possessing highest risk can be termed as critically important for the company. During this step, an organization must look to comply with all the nonconformance's identified in the gap analysis. The decision of the scope of implementation is decided on the basis on risk assessment performed on the gap analysis findings. Using risk assessment, determine the impact of the gap findings and set a priority level to each one of them. Depending on the priority of reaction, initiate QMS only for a process or functional area with the highest priority level. Ultimately, nonconformance's that

possess highest risks should be set on high priority. Establish measurable quality objectives and develop QMS documentation necessary to prove and achieve these objectives.

4.1.4. Step 4: Implement QMS for small a scope, determined in step 3 (DO)

The objective of this step is to implement the QMS designed in the prior stage. This implementation must be limited to the boundaries determined in step 3. Organizational changes occur during this stage. Process owner must ensure that process performers are trained on required changes and use of documentation. It is the responsibility of the management of the company to ensure availability of the required resources, as needed, prior to initiating the implementation. Keeping the process interactions in mind, training must be provided to process performers that will be affected due to the changes made. We also recommend that process owner and top management should document the lessons learned during QMS implementation phase as a feedback and valuable information to improve the implementation methods during the expansion of QMS scope.

4.1.5. Step 5: Maintain and improve the QMS (CHECK & ACT)

Once the implementation program has been achieved, QMS must be maintained to reap benefits. Organizations must devise a plan to successfully maintain the QMS. Regular customer satisfaction levels must be measured for both internal and external customers. QMS can be also be maintained using corrective and preventive action procedures, internal audits and management review meetings. Every nonconformance identified during maintenance of QMS must be corrected before planning for QMS expansion to other company processes. Lessons learned during this stage should also be documented as a reference for future expansion.

4.1.6. Step 6: Expand the QMS Scope

After ensuring successful implementation of QMS for prior scope, QMS can be expanded to other areas, as needed. At this stage, risk assessment should be performed again to determine

the most critical process and then develop procedures to satisfy QMS requirements. Lessons learned during the prior stages must be utilized to effectively expand the scope to improve implementation measures for the QMS expansion.

4.1.7. Step 7: Maintain and Improve the QMS

This step shares the same objective as step 5. The difference being that, every time the scope of QMS is maintained, responsibilities for QMS maintenance also increase. Thus, organizations must react to the lessons learned during QMS implementation phase for prior scopes and use it as a feedback and valuable information to improve the implementation methods during the expansion of QMS scope.

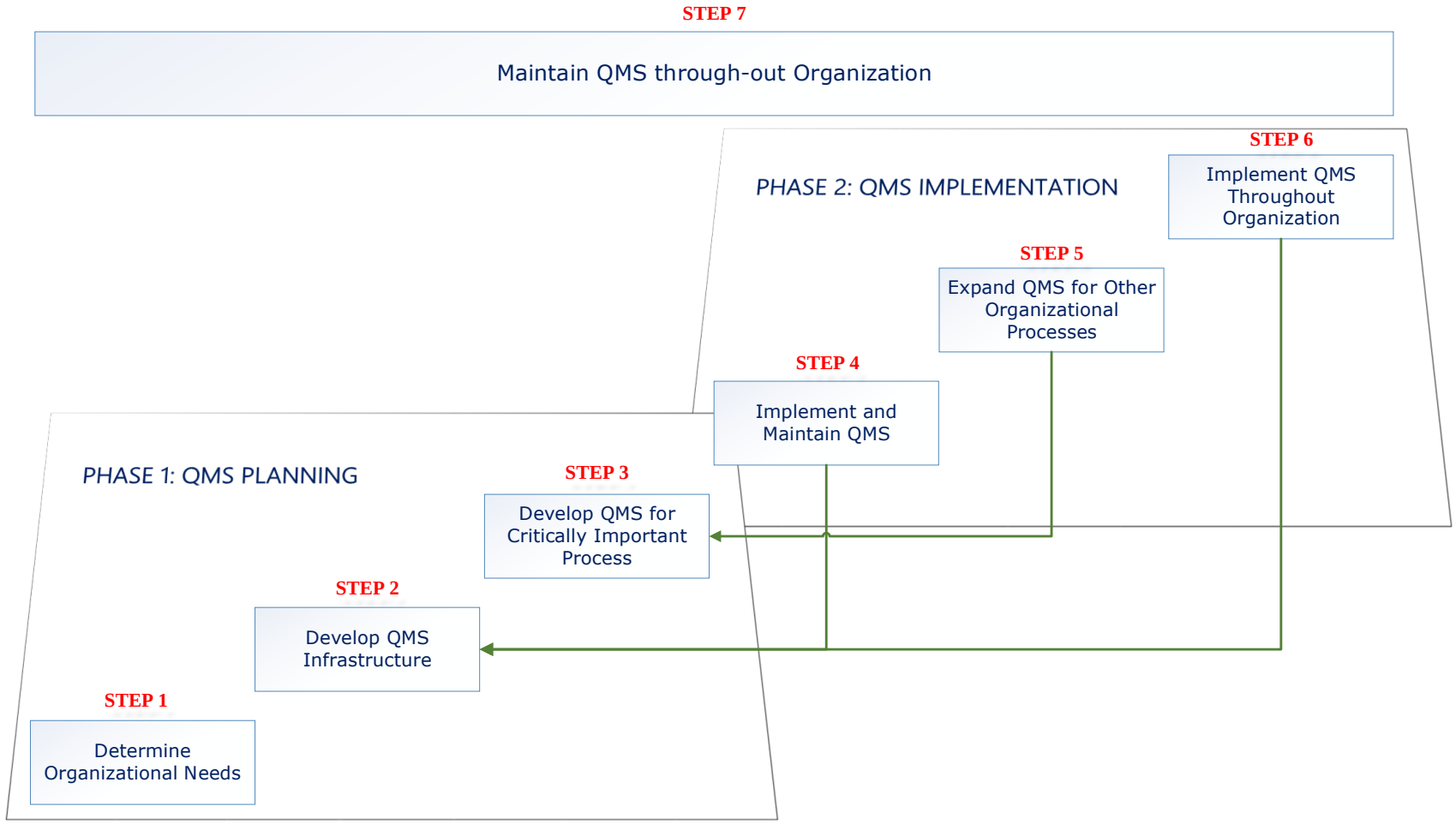

Figure 3: Proposed Framework for QMS Implementation

CHAPTER 5. CASE STUDY EXAMPLE

5.1. Quality Management System Implementation for a Door Manufacturing Company

In this section, we will discuss the implementation of the proposed framework in a small door manufacturing company. The applicability of this framework is not limited to only small business. The framework proposed in the prior section can be adopted by any organization irrespective of its size and nature. The ultimate motivation for this study, however, was to provide guidance to businesses that want to transit to a QMS environment with limited resources.

5.1.1. About the company

The framework proposed in chapter 4 was implemented in a small manufacturing company named D&M Industries (referred to as D&M for following sections), located in Moorhead, MN. This implementation program also facilitated validation of our proposed model. D&M has been providing doors and more for commercial and residential building projects since 1982. The main products of the company are interior pre-hung doors, millworks and exterior doors. It has supplied materials to hotels, motels, apartments and multi-family housing, etc. The company is growing fast and gaining a reputation among its customers due to its willingness and ability to provide doors adjusting to its customer's demands. Majority of items are purchased from its vendors and machined to match customer's requirements. The raw material required for the doors is machined to the specifications and assembled into doors. Majority of the inventory related to the production of doors is received from its vendors and stored at a separate warehouse (named warehouse 2, W2). Material is moved to the main warehouse (named warehouse 1, W1) for production processes, as specified on the production tickets. Material is transferred between W1 and W2, separated only by a few blocks, using transfer trucks owned by the company.

Doors are composed of four main components - door slab, hinge jamb, strike jamb and head. Hinge jamb, strike jamb and head are assembled to make a door frame. A door slab is hinged on to the frame using hinges. Doors stops are stitched on the jambs and head to limit the movement of door slabs. If hinges are attached to a jamb it is called as a hinge jamb and if a strike plate is attached on the jamb it is called as a strike jamb. Interior doors are produced on two production lines with different machines. Exterior doors are produced on the exterior door production line which is comprised of one machine. Production processes at D&M are simple and not very complicated. Items moved from W2 to W1 are received at a designated area. Depending on the customer requirements and material availability, items are then moved to either 'specials process' or 'prep process' before moving to production and assembly lines. As the name suggests special operations are done during specials process like making a hardware prep, undercuts, bevels, etc. Hinge jambs; strike jambs and heads are produced during the prep process. The material is then moved to the production lines to machine and assemble into doors. Sometimes products are directly shipped to the customer from vendors. Doors that need finishing are sent to external providers.

Surprisingly though, the company does not have any date collection system established and relies solely on the experience and knowledge of its employees to facilitate the supply of quality products and services to its customers. Thus, quality levels and efficiency of its current processes cannot be assessed. Lately, the company has experienced higher rate of product returns and customer complaints. Replacements were provided to the customers without any quality analysis of the returns. This was mainly due to the lack of quality personnel in the company. However, D&M was determined to react to decrease the rate of returns and realized a need for external

assistance. This need facilitated the development of this project and coordination between the company and North Dakota State University.

5.2. Analysis of Customer Complaints and Customer Returns

This project started in May 2015 and was completed in September 2016. The initial objective was to find the cause behind high rate of returns. Due to the lack of any quality related data, a simple returns tracking system was established to collect some data to study the customer returns. Important information captured in the returns tracking was type of product, return details or cause of return and returns code. Due to the lack of time commitment and employees, returns tracking responsibility was divided between customer service personnel and inventory specialist. Process flow maps were developed to better understand the working of organizational processes. After a decent amount of data was collected, pareto charts were used to study the data collected. Figure 4 depicts the classification of customer returns based on product category distribution.

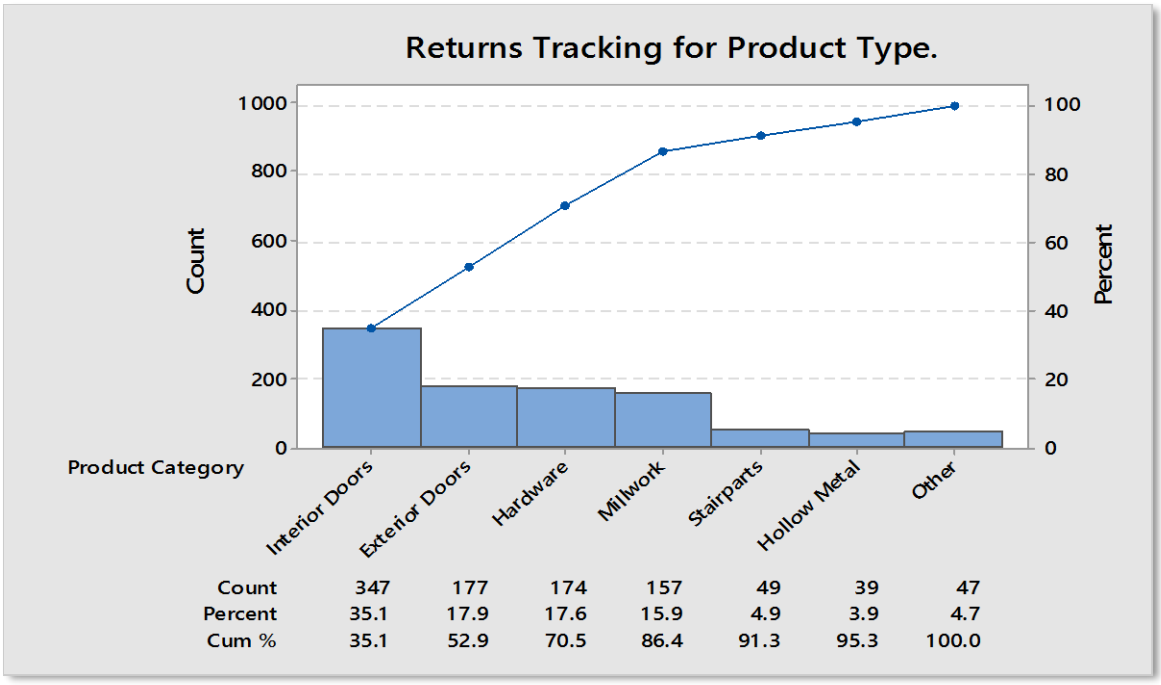

Figure 4: Pareto Analysis for Product Type Using Returns Tracking

Most of the returns, over 50%, were related to either internal doors or exterior doors both of which are machined and assembled at D&M facility. However, D&M does not engage in any major production related activities of hardware, millwork and other product categories and only acts as a distributor. Customer returns were initiated by the sales representatives or project managers due to their direct relationship with the customers. However, one major obstacle was that customer complaints or returns was not officially documented and hence the cause of returns needed to be derived when the return was received back at company's facility. Lack of employees in the customer service department also made it impossible to call the customer and confirm the reason behind their return. Nevertheless, employees responsible for returns tracking tried to keep optimum level of consistency while documenting returns. Figure 5 and 6 summarizes the analysis for returns code using a pareto chart.

Almost 28% of total returns were made due to defective product. Other major reasons were sales errors, shop errors and customer errors. This called for further analysis of defective products. Sales errors and shop errors was a cause for concern as this was the case of lack of efficient internal communication process. The study of details related to defective products was carried out as shown in figure 6. There were inconsistent and incomplete details of returns found in some cases. However, majority of the defectives were found to be manufacturing related vendor defects. Most frequent defectives were due to warping of the doors or jambs, delaminating of veneer, excessive use of glue and bubble in the veneer. As D&M does not manufacture doors, manufacturing related problems were directed to the vendors. Major purchasing errors found were due to wrong purchases made being or incorrect information provided to the vendor. Similarly, wrongly written productions tickets by sales rep was also found to be a major problem. We believed that purchasing

errors and shop errors were mainly due to lack of training and poor attitude which could be controlled immediately.

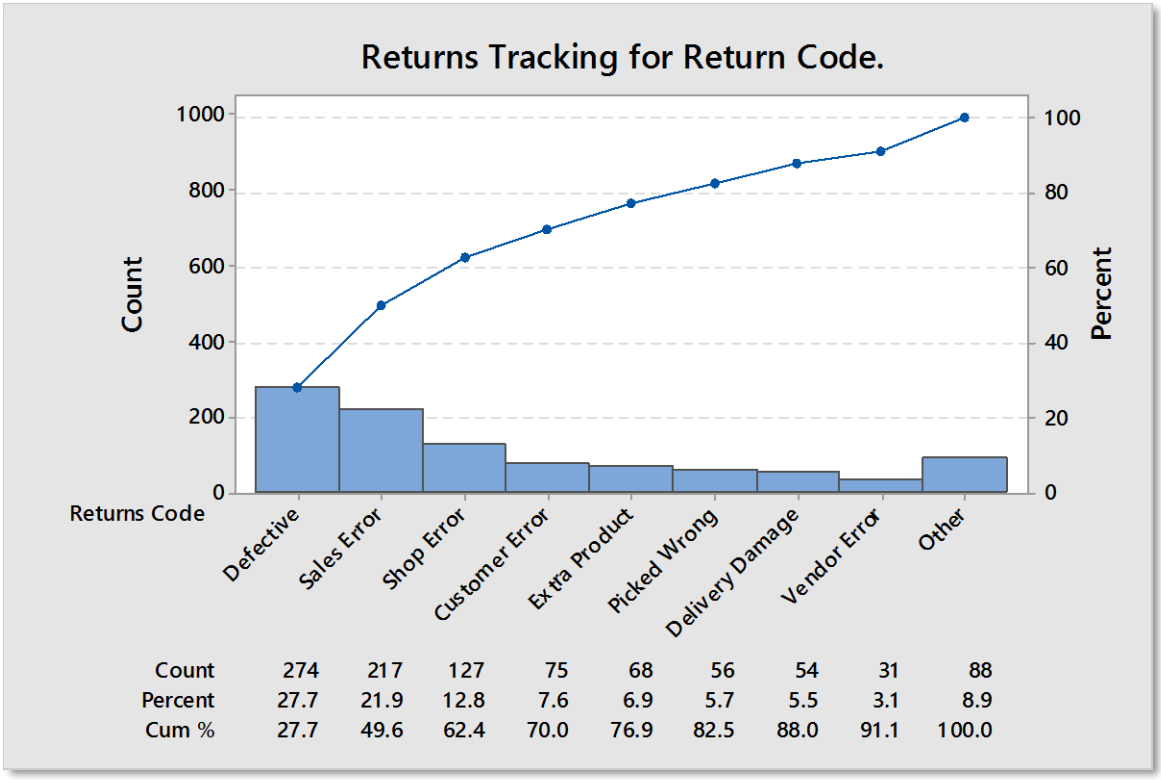

Figure 5: Pareto Analysis for Return Codes Using Returns Tracking

During this period, a short customer satisfaction survey was also conducted by the company. Some of the key findings from the survey are discussed below.

1. Improvement of D&M delivery service as incomplete delivery orders are shipped.
2. Improve packaging to avoid delivery damages.
3. Delivery timing can be improved.
4. Products not machined to specifications. (machining errors are compensated by providing onsite service).

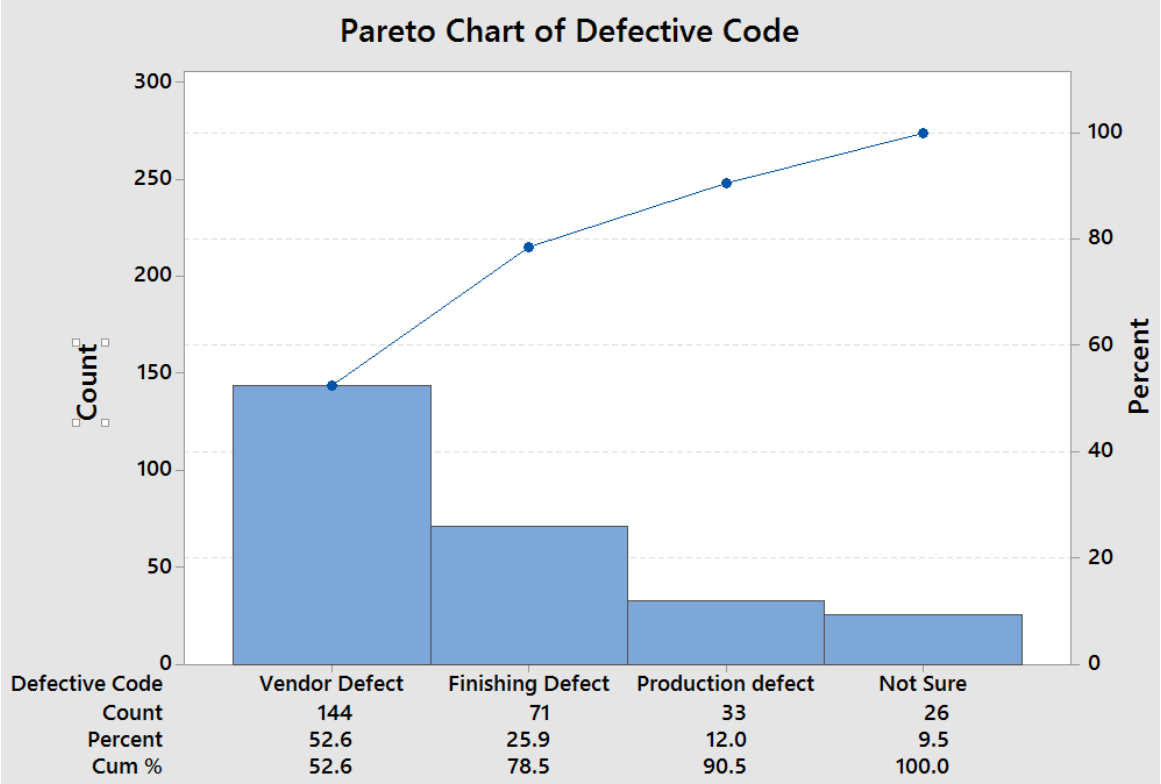

Figure 6: Pareto Analysis for Defective Codes Using Returns Tracking

5.3. Need for Quality Management at D&M Industries

Analysis of the customer returns data revealed that in most cases returns were made due to manufacturing defects or operational error. If purchasing errors, sales errors and other errors can be controlled, the rate returns should be decreased. Similarly, due to the lack of inspection activities especially for receiving material vendor defectives such as warping, veneer peeling and damages were not detected during production processes. Hence, D&M Industries needs an effective management system that will not only identify root causes behind increased number of customer returns but also control current processes, and improve them to facilitate increased customer satisfaction. The company surprisingly lacks in standardized documentation and monitoring activities required to identify, control and correct problems before reaching to the customer. At the

same time, there is a lack of quality oriented culture in the company evident from the absence of any quality related policy.

Information acquired through the returns tracking has helped D&M realize several quality related issues within the company. Poor quality of raw material is one of the major reason for product returns. Such manufacturing related problems need to be recognized when the material is being received at W2. Thus, company needs a system that will organize its process, control its operations, document major findings and facilitate evidenced based decision making. The company needs proper documentation to enhance internal communication to avoid operational errors within the company. Similarly, D&M also needs an effective training program to improve quality awareness and increase competency levels on the production lines to ensure that manufacturing defects are identified and controlled. Top management of the company believe that establishment of a QMS will facilitate the change in culture and drive quality improvement within the company.

5.4. Planning for Quality Management at D&M Industries

In this section, we will discuss how planning for quality system implementation was conducted at D&M industries. First step in any quality system implementation is an assessment of the current system with respect to the requirements of QMS. It is important to determine the gap between QMS requirements and organizations current system to assess the exact needs of an organization. If there are any requirements already established, they need to be verified for correctness & completeness and if they are still fit for the purpose. Identification of organizations real needs is intended to avoid waste in documentation and process development required for QMS implementation. This also avoids duplicity and over implementation of the QMS requirements and with over implementation program. Gap analysis was used as the self-assessment tool to identify

the genuine needs of the company. Gap analysis checklist was used to compare the requirements of QMS and current processes in the company. This idea of gap analysis tool is described in figure 7.

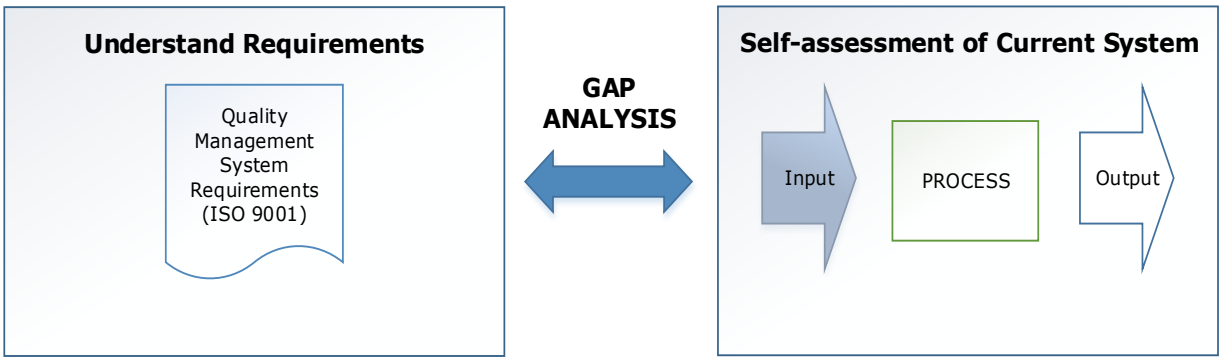

Figure 7: Gap Analysis with ISO 9001

The detailed gap analysis report is presented in the Appendix A, table 3. The gap analysis findings were categorized as conforming, nonconforming or opportunity for improvement. QMS requirements completely established at the company are called as conforming requirements. QMS requirements that are not yet established within the company are called as nonconforming requirements. Similarly, partially established requirements that need further considerations to comply fully with QMS requirements are called as opportunities for improvement. Conforming requirements were designated as Y (Yes), nonconforming requirements were designated as N (No) and opportunity of improvement as O.

From the above literature studies, we categorized the organizational barriers into ‘barriers while QMS planning’ and ‘barriers while QMS implementation’. The gap analysis report and returns tracking data was used together to develop a strategic implementation plan for QMS implementation at D&M industries Based on the information acquired from the returns tracking and literature review findings, we found many important gaps during the assessment of current system at D&M industries. These findings also explained the lack of quality culture in the

company. Gap analysis revealed D&M to have a no-quality system in its company, lack of documentation, lack of standardized processes, poor internal communication etc.

The analysis of the returns tracking data and gap analysis successfully identified the needs of D&M Industries. However, it was important to get top managements support and commitment to proceed with the implementation plan. The organization believed in QMS compliance. But, it feared the change in company's culture will be accepted by everyone. The company also ran on a tight budget and couldn't guarantee availability of resources that might be needed. Thus, it was decided to develop QMS and implement within small scopes that possessed higher risks of noncompliance.

5.5. Quality Management System Development for D&M Industries

In this section, we will discuss the QMS development and implementation plan for D&M Industries. QMS for D&M is developed around the actual needs of the company. These needs were determined by assessing the current quality system in the company using gap analysis and returns tracking data. The analysis of returns tracking data collected at the company provided with an insight about current problems at the company and cause for customer dissatisfaction. Thus, QMS developed for D&M is intended to bridge the findings of the gap analysis. Having said that, the approach adopted to design and develop QMS will overcome or mitigate the negative findings found in the literature. During this stage, we considered all the critical factors during the phase 1 i.e. QMS planning phase, as described in table 2. First steps taken to overcome barriers are discussed below:

1. **Lack of leadership -** Operations manager was given the responsibility of a Management Representative (MR), to be the main coordinator and leader to drive QMS. The development and implementation plans were communicated to the management through MR. Process

owners were appointed as in charge of documentation related to their functions. A Process owner hierarchy chart, figure 7, was developed for the company.

2. **Lack of understanding of QMS -** QMS requirements were explained in the gap analysis to ensure it is available to all the employees. Presentations were conducted to familiarize management with QMS and its requirements. Formal and informal meetings were also conducted with the managers to work together and develop QMS documentation for the current processes. This provided the managers a good understanding or QMS and its purpose.
3. **Employee resistance to change -** QMS documentations were approved by process performers before making them official.
4. **Lack of control over documentation -** It was important to avoid waste in the form of unnecessary documents. Hence QMS documentation was only developed for the needs of the company. These needs were highlighted in the prior section. Documents were also developed and approved by the MR to ensure that it is fir for its purpose and adds value to the organization.
5. **Inability to provide resources -** This barrier was tackled by targeting QMS implementation only for a small scope that possessed most risks. At the same, QMS was integrated within the current process with minimal change. There was a fear that documentation and change might not be readily accepted by the employees despite seeing its benefits. Hence, the top management was not willing to change its current processes for all the functional areas despite nonconformance's found in the gap analysis. It was decided that QMS will be implemented to small scope as a pilot project and ensure that it is successful. The lessons learned and benefits achieved with time shall set a bench mark within the company and serve as a great example for other process owners and process performers to accept QMS.

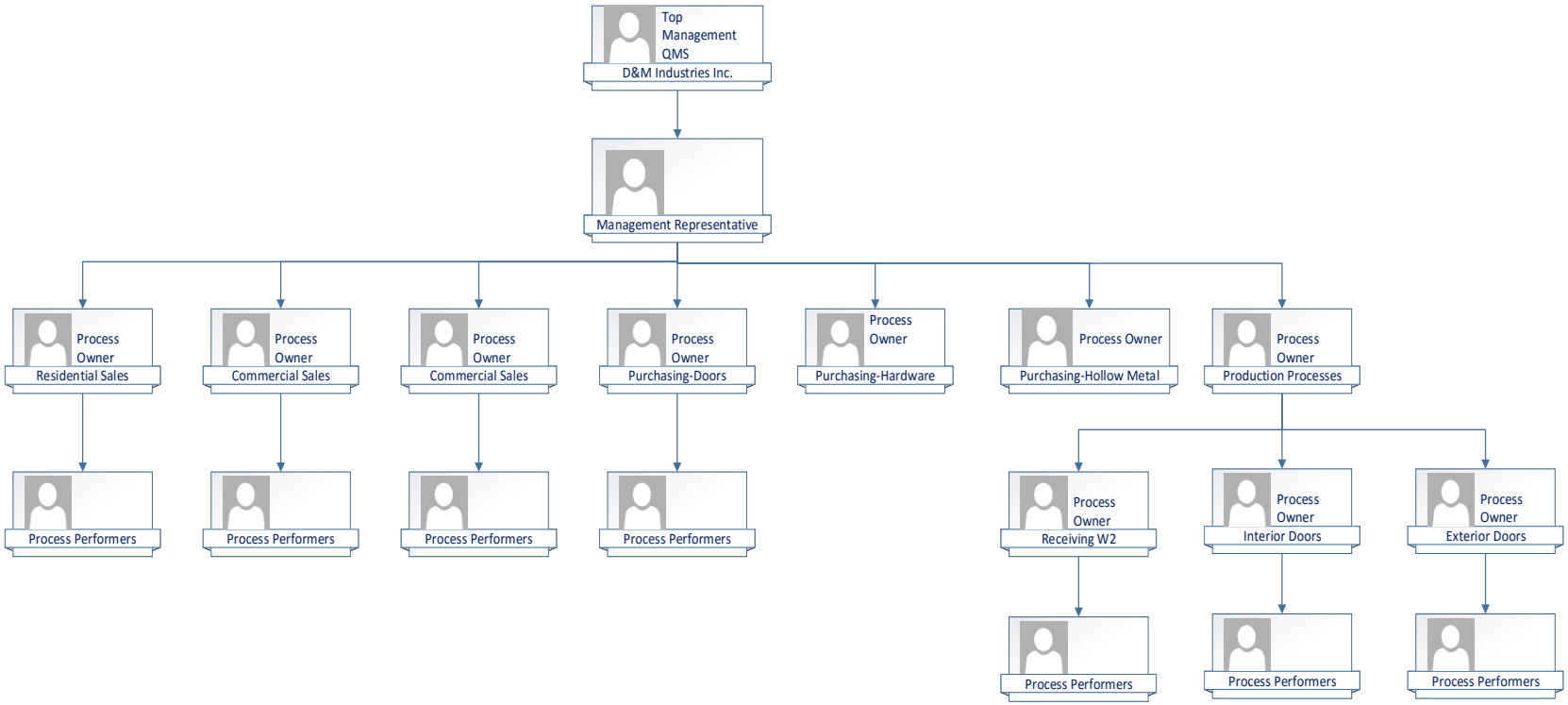

Figure 8: Quality Management System Hierarchy Chart

Now, we discuss QMS for D&M Industries in detail below. Phase 1 of QMS planning for D&M is explained from steps 1-3. Phase 2 QMS implementation is explained from steps 4-7.

5.5.1. Step 1: Identification of real organizational needs

As per our proposed framework, the first stage was to determine the needs of D&M Industries. Thus, we assessed the current quality system status of the company using gap analysis tool and compared them using QMS requirements specified in ISO 9001 standards. The returns tracking also facilitated the necessary information required to determine the needs of the company. These needs are listed below.

- Documented processes for standardized work
- Monitoring and Measurement of product realization processes to identify and control nonconforming products
- Establishment of data collection system to determine process performance and facilitate measurable quality levels
- Acceptance criteria for every process
- Receiving inspection plan for purchased products
- Organizational processes identified for the company are listed as follows:
- Sales contract review process
- Customer communication process
- Purchasing process
- Vendor evaluation process
- Receiving process at warehouse 1 (W1)
- Production control and product release process
- Preventive Maintenance and calibrations

- Packaging and delivery
- Returns
- Control of customer property
- Monitoring, measurement and analysis

These processes were documented using process flow maps, documented procedures or records, as needed. The interaction of these processes is documented using a 'process interaction matrix' as shown in the figure 7.

5.5.2. Step 2: Develop QMS Infrastructure

QMS in any organization cannot be successfully implemented without QMS infrastructure. Consistent with the findings made by Chin et al. (2000) we developed QMS infrastructure based on 5 critical and mandatory QMS requirements. Failure to manage these requirements will eventually lead to failure QMS. These are corrective and preventive actions, management commitment, internal audits, control of documents and records and control of nonconformance. We also believe that these are the most critical requirements and QMS cannot function without these irrespective of its scope. These processes are used to control and maintain the entire QMS system. QMS implementation at D&M Industries was started by establishing a quality policy draft for the company. Thus, D&M created a quality policy draft for the company as described below:

"D&M Industries Inc. is committed to exceeding our customer's expectations through the quality of our products and services achieved by, continuous improvement in all areas, on time and accurate deliveries of our products, investment in our employee owners and our infrastructure and being accountable for our actions and results".

Documents developed for QMS infrastructure were Quality Manual, Quality Policy, Control of Documents and Records, Control of Nonconformance, Corrective and Preventive

Actions, Management Review Meetings and Internal Quality Audits. The 2-page quality manual was developed for the company. It consisted of Quality policy and quality objectives established for QMS. It also contains the process interactions and QMS hierarchy chart.

Control of Documents: This procedure describes the process of controlling documents and changes made to documents that are a part of the Quality Management System at D&M Industries. The requirements specified in this document are:

- Approve documents for adequacy prior to issue,
- Review and update as necessary and re-approve documents,
- Ensure that changes and the current revision status of documents are identified,
- Ensure that relevant versions of applicable documents are available at points of use,
- Ensure that documents remain legible and readily identifiable,
- Ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the QMS, are identified and their distribution controlled,
- Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

*A **Quality Record** associated with the control of documents procedure is titled as 'master document index' and its generic form is described in the Appendix B.*

Control of Records**:** This procedure defines the controls needed for the identification, storage, protection, retrieval, retention and disposition of records. Records are generated and analyzed to determine;

- If the given process has achieved its key performance indicators within acceptable limits
- If the given process has achieved its quality objective
- If the given process is meeting its process criteria

- If specific non-conformances or a non-conformance trend need corrective action

*A **Quality Record** associated with this procedure is titled as 'master quality record index' and its generic form is described in the Appendix B.*

Control of Nonconformance: This procedure defines the requirements for identification, elimination, and disposition of non-conforming products. Products which do not conform to product requirements are identified and controlled to prevent their unintended use or delivery.

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- If the given process has achieved its key performance indicators within acceptable limits
- If the given process has achieved its quality objective
- If the given process is meeting its process criteria
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Control of Nonconformance: This procedure defines the requirements for identification, elimination, and disposition of non-conforming products. Products which do not conform to product requirements are identified and controlled to prevent their unintended use or delivery.

*A **Quality Record** associated with this procedure is titled as 'control of nonconforming product' report and its generic form is described in the Appendix B.*

Internal Quality Audits Procedure: The purpose of this procedure is to provide a planned and documented method for carrying out internal quality audits to ensure that the QMS at D&M Industries Inc. conform to the requirements of the International Organization for Standardization 9001:2008. This procedure also provides requirements to verify whether the quality activities established at D&M Industries comply with planned arrangements.

*There are four different **Quality Records** associated with this procedure and their generic versions are described in the Appendix B. They are titled as:*

- *Internal Quality Audit Schedule*
- *Internal Quality Audit Report*
- *Internal Quality Audit Feedback*

Additional document is developed for this procedure which is titled as 'Internal Auditors Manual'. The purpose of this manual is to provide detailed information to the internal auditors of company for developing and carrying out internal quality audits.

Corrective and Preventive Action (CAPA) Procedure: This procedure is used to establish and outline the process for initiating, documenting, analyzing, and implementing corrective and preventive actions.

*There are two **Quality Records** associated with this procedure and they are titled as 'corrective and preventive action' form and 'verification of effectiveness of CAPA' form. Generic versions of the both the forms are described in the Appendix B. This procedure is also consisting of two **Work Instruction** titled as 'filling out the CAR form' and 'effectiveness verification of CAPA implemented'. Generic versions of these work instructions are also described in the Appendix B.*

		Type of Processes	Quality System Processes										Organizational Processes																	
		Process No.	1		2		3		4		5		6				7		8		9		10		11		12		13		14		15		16	
Type of Processes	Process No.	Interaction of QMS and Organizational Processess.	Control of Documents		Control of Records		Internal Quality Audits		Control of Non-conformance		Corrective and Preventive Action		Management Review Meetings		Customer Communication (Requirements)		Sales Contract Review		Purchasing		Vendor Performance Evaluation		Receiving W1		Production Control and Product Release		Preventive Maintenance and Calibration		Packaging and Delivery		Returns		Control of Customer Property		Monitoring, Measurement and Analysis	
Quality System Processes	1	Control of Documents			>		>	<	>		>	<	>	<	>		>		>		>		>		>		>		>		>		>	<
	2	Control of Records					>	<	>	<	>	<	>	<	<		>		>		>		>		>		>		>		>		>		>	<
	3	Internal Quality Audits								<	>	<	>	<		<		<		<		<		<		<		<		<		<		<	>	<
	4	Control of Non-conformance									>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<
	5	Corrective Action and Preventive Action											>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<
	6	Management Review Meetings													>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<
Organizational Processes	7	Customer Communication (Requirements)															>	<	>	<		<		<		<						<		<	>	<
	8	Sales Contract Review																	>	<		<				<						<		<	>	<
	9	Purchasing Process																			>	<	>	<		<						<		<	>	<
	10	Vendor Performance Evaluation																					>	<	>	<						<		<	>	<
	11	Receiving W1																							>	<				<		<		<	>	<
	12	Production Control and Product Release																									>	<	>	<		<		<	>	<
	13	Preventive Maintenance and Calibration																														<		<	>	<
	14	Packaging and Delivery																														<		<	>	<
	15	Returns																															>		>	<
	16	Control of Customer Property																																	>	<
	17	Monitoring, Measurement and Analysis																																		

	Process C		Process D	
Process A	>		>	
Process B			<	
Process C			>	<

Process Interaction Matrix.

Process 'A' provides i/p to Process 'C' and Process 'D'.

Process 'D' provides i/p to Process 'B' OR Process 'B' receives i/p from Process 'D'.

Process 'C ' may provides i/p to Process 'D'.

Process 'D' may provides i/p to Process 'C' OR Process 'C' may receive i/p from Process 'D'.

Figure 9: Identification and Interaction of processes

Management Review Meetings: This procedure defines the process and methods for conducting Management Review Meetings, at planned intervals, of the Quality Management System implemented at D&M Industries Inc. to ensure its continued suitability, adequacy and effectiveness.

*A **Quality Record** associated with this procedure is titled as 'management review meeting' form report and its generic form is described in the Appendix B.*

5.5.3. Step 3: Develop QMS for Critically Important Process

The objective of this step was to determine the most important process or functional area within the company that has the most negative influence on D&M's ability to provide quality products and services to the customers, due to high risks of nonconformance associated with it. This was determined using the gap analysis report and performing risk assessment for each nonconformance identified in the gap analysis findings. Each nonconformance was careful analyzed on potential impact and action priority required. Information from the customer survey analysis report and returns tracking was also considered while determining the potential impact of the identified risk i.e. gap finding. Following risk assessment options were used:

Table 3: Risk Assessment Category

Potential Impact of Risk	Action Priority for the Risk
Minimal Impact	*No Action required*
Moderate Impact	*Low Priority*
High Impact	*Medium Priority*
Severe Impact	*High Priority*

Based on the risk assessment performed, purchasing department was found to be the most important functional area. The full report is summarized in the Appendix A. Table 4 shows the findings related to the most critical process. As seen from the table 4, D&M does not have any fixed criteria to select vendors while purchasing raw material. Similarly, the company does not have any vendor evaluation criteria in place. Vendor are selected based on low price and quality of products supplied. However, the company do not have any system establish to verify the quality of purchased products and then facilitate evidence based decisions. This is a very important step in the production realization process of the company as raw material is directly supplied to the production or stored as inventory without any inspection activities. Thus, there was a need for monitoring activities to identify the defective products supplied by vendors and eliminate them before production processes. This is also important as the gap finding also revealed that the company lacks control over its production processes.

There were no criteria for verifying the output of the prior process before accepting to the next process. Thus, nonconforming material, if any, went unchecked through the production process and delivered to the product without final inspection. This was one of the key reasons for high rate of customer returns as discussed in the prior section. So also, due to the lack of data collection system, product quality is cannot be measured at any level of the production process. Thus, quality level of product cannot be assessed. Hence, quality objectives and KPIs are established for organizational processes. Screen shot the risk assessment is described in the following table. The full report is attached in the Appendix A, table 3.

As evident from the table 4, all the nonconformities associated with purchasing would have a severe risk in providing quality products to the customers. Nonconformities identified for the purchasing department and product realization processes were also evident from the return

tracking data analysis that highlighted maximum number of defects due to vendor problems. Thus, purchasing process was documented with a defined criterion for vendor selection and evaluation of vendor performance, to qualify into an approved vendor list by monitoring receiving shipments at the company through receiving inspection plan. Purchasing department was thus considered as the first small scope for QMS implementation. Processes related to purchasing were documented as follows:

Purchasing Process: The purpose of this process is to describe the requirements for effective purchasing process for D&M Industries. This process is applied to all the vendors, unless an exception is sanctioned by the management representative or the operations manager. This process describes requirements for selection & control of vendors, purchasing process & purchasing information and verification of purchased product. The evaluation of vendor performance is described in a separate procedure titled '*vendor performance evaluation procedure'*.

Vendor performance Evaluation Procedure: This procedure describes in detail the selection criteria for purchasing raw material from a vendor. It also describes the process for performance evaluation of the vendor and its qualification criteria for approved vendors list. All the vendors were also evaluated using a '*vendor quality questionnaire*' that includes questions required to be answered by the vendor regarding its commitment to quality. Shipments are inspected using a *'receiving inspection plan'*.

Vendor Performance Log: Information from the receiving inspection sheet is transferred to the vendor performance log to calculate the Total Score Earned by the vendor that determines the evaluation of vendors into the AVL. Based on the performance, vendors are assigned one of these quality status: (A*) Approved, Preferred, (A) Approved, (N) Non-Approved, or (P) Provisional.

Table 4: D&M Industries Risk Assessment and Gap Analysis

Sr. No.	ISO 9001 2008 Quality Management System Requirements Clause 7.4. Purchasing Process	Gap Finding	Risk Impact	Action Priority
1	D&M has established criteria to select and evaluate suppliers?	N	Severe	High Priority
2	D&M has established procedures to evaluate its suppliers/vendor's ability to supply products that meet D&M's requirements.	N	Severe	High Priority
3	D&M ensures that supplier/vendor evaluations records are kept and discussed.	N	Severe	High Priority
4	D&M also ensures that all purchased products meet specified purchase requirements?	N	Severe	High Priority
5	D&M ensures that purchasing requirements are adequately specified before discussing them with suppliers/vendors.	N	Severe	High Priority
6	D&M has established product verification or inspection methods to ensure that purchased products meet purchase requirements.	N	Severe	High Priority

Approved Vendors List (AVL): AVL is the list of vendors that fulfil D&M's quality expectations and fit into vendor selection criteria. Vendor quality performance is regularly monitored by inspecting every shipment of raw materials received at D&M. Any non-conformances identified are documented on the '*receiving inspection sheet*' and controlled using the nonconformance procedure.

Vendor Quality Manual: The expectations of D&M Industries and vendor evaluation criteria are established in the vendor quality manual.

Overall, the purchasing department was documented using two procedures titled as 'purchasing processes and 'vendor performance evaluation and qualities to AVL'. A vendor quality manual was produced and distributed to vendors as an instructions manual that specified the expectations of the company. Every vendor was also evaluated using vendor quality questionnaire and analysis of receiving inspection data at the end of every month to update the ranking of vendors in the AVL. So also, a 'vendor corrective action request (VCAR)' was issued to the vendors whose shipments are rejected. Generic versions of all these documents is provided in the Appendix C.

Following vendor selection criteria (VSC) was approved by the Purchasing Manager (PM) and Operations Manager (OM) established at D&M industries:

- On-time Delivery: Whether the shipment is received on the expected time of arrivals (ETA) as specified on the purchase order.
- Quantity Accuracy: Quantity ordered vs Quantity received.
- Quality of shipment (Product & Packaging Quality): Whether quality levels are acceptable or not for the condition of pallets, strapped, sturdy and wrapped packaging (secure packaging).

We used Likert's scale as reference to quantitively evaluate vendor's quality performance. Vendor selection criteria was used key performance indicators. Vendor's performance will be determined using Total score earned. Based on the Likert's Scale VSC will be given following ratings during receiving inspection.

- Rating Of 1 = 0% – 39% (Unacceptable)
- Rating Of 2 = 40% – 59% (Needs Further Analysis)
- Rating Of 3 = 60%-79% (Average)
- Rating Of 4 = 80% – 89% (Acceptable with Some Problems)
- Rating Of 5 = 90% - 100% (Acceptable Without Any Problems)

Total score earned =

Score of (Quality of Shipment) + Score (Quantity Accuracy) + Score (On-time delivery)

Total scores for VCS will be calculated using weight factors. Amongst the VSC, quality was the most important focus area and hence it was assigned more points than other areas. Hence, we decided that quality of shipment will be assigned total points of 40. Similarly, Quantity accuracy and on time delivery were assigned 30 points each so that total possible score a vendor would get for each shipment will be equal to 100. We used the rating from 1-5 with the total weighting of 20 points each for easier calculations. We used highest rating (5) to find out total weight factor of each focus area (i.e. VSC). Hence the total weight factors for each criterion were calculated as follows.

- Weight factor (Quality of Shipment): Importance / Highest Rating = 40/5 = 8
- Weight factor (Quantity Accuracy): Importance / Highest Rating = 30/5 = 6
- Weight factor (On-time delivery): Importance / Highest Rating = 30/5 = 6

These weight factors will be used to find total scores for each vendor selection criteria as shown in figure 10. Based on the vendor performance evaluations, we categorized vendors as 'Approved, Preferred', 'Approved', 'Non-Approved' and 'Provisional' Vendors.

Vendor Evaluation Through Receiving Inspection

Key Performance Indicator *Vendor Selection Criteria*	**Performance Rating (PR)**	**KPI Weight Factor (WF)**	**Score Earned (%) (PR × WF)**
Quality of Shipment		**8**	
Quantity Accuracy		**6**	
On-time Delivery		**6**	
Total Score Earned			

Performance Rating:
1 = Unacceptable shipment
2 = Needs further analysis
3 = Average
4 = Acceptable with some problems
5 = Acceptable without problems

Figure 10: Vendor Evaluation Criteria

Vendors are identified as 'Approved, Preferred' vendors if they have continually delivered products in a way that meets and exceeds all of D&M's VSC. One of the following conditions must be true:

- *D&M receives a copy of the vendor's ISO 9001:2008 or ISO 9001:2015 certificate*
- *After (6) six successive acceptable lots, each meeting the Total Score Earned of 70% or higher*
- *Their Total Score Earned from the last qualification is higher than 90%*
- *A passing on-site audit, meeting or exceeding D&M's OM and PM expectations*
- *OM or PM override this procedure*

Vendors are identified as 'Approved' vendors if any of the following conditions are true:

- *After (3) three successive acceptable lots, each meeting the Total Score Earned of 70% or higher*

- *If their average Total Score Earned from the last qualification is between 70% and 90%*
- *An on-site audit, meeting minimal requirements set by D&M's OM and PM*
- *OM or PM override this procedure*

Vendors are identified as 'Non-Approved' vendors if any of the following conditions are true:

- *After (3) three successive lots, each below 70% VSC Total Score Earned*
- *If their average Total Score Earned from the last qualification is below 70%*
- *A failed on-site audit by D&M's OM and PM*
- *Failure to respond to (1) one or more VCARs within 30 days*
- *A Management Review Meeting decision*
- *OM or PM override this procedure*

Vendors are identified as 'Provisional' vendors if any of the following conditions are true:

- *No previous history of doing business with D&M*
- *No business done with D&M for more than (2) two years*
- *Vendor hasn't completed the 'Vendor Quality Questionnaire' and 'Vendor Quality Manual'*
- *OM or PM override this procedure*

Other documents developed for Purchasing are Vendor Quality Questionnaire, Vendor Corrective Action Request (VCAR) and Receiving Inspection Sheet (RIS) and are attached in the Appendix C. Figure 10 depicts vendor quality questionnaire. Figure 11 depicts a VCAR. Figure 12 depicts a receiving inspection sheet.

Vendor Quality Questionnaire Rev.

Vendor:	**Contact Name:**
Address:	
Telephone No:	**Postcode:** **Email:**
Other Trading Names or Name of Group:	
Goods/ products Supplied:	

1. Have you nominated a person responsible for the Quality Management function? If yes, what is their name, title and contact number? **YES/NO**
2. Are you registered to ISO 9001:2008 or ISO 9001:2015? If yes, please attach a copy of your current Certificate, sign this form and return to the address below. **YES/NO**
3. Are you contemplating or currently applying for ISO 9001:2015? **YES/NO**
4. Do you maintain up-to-date technical data of your products / services? **YES/NO**
5. Is proper equipment and methods used to prevent product damage or loss in all phases of the material handling process? **YES/NO**
6. Are production samples inspected and provided to customers upon request? **YES/NO**
7. Do you operate a supplier or vendor quality assessment system? **YES/NO**
8. Would you allow an on-site assessment of your quality system if requested? **YES/NO**
9. Please provide name, contact and telephone no. of two references for credit check purposes:

i)

ii)

Signed: **Date:**

Position:

PLEASE RETURN BY EMAIL OR MAIL IN ORDER THAT YOUR COMPANY CAN BE CONSIDERED FOR INCLUSION ON OUR LIST OF APPROVED VENDORS. THANK YOU.

OFFICE USE

Vendor Reference No:	
Performance Rating:	Signed:

Figure 11: Vendor Quality Questionnaire

Vendor Corrective Action Request (VCAR)

Rev.

** Section 1: Completed by D&M Industries*

Vendor :

Date Sent:

Phone #:

D&M PO #:

Description of Nonconformance:

If the nonconformance is parts-related, complete the following:

Report #:

Part #:

Part Description

Quantity Affected:

Sent by:

RESPONSE TO THIS ISSUE MUST BE RECEIVED WITHIN 30 DAYS OF RECEIPT; FAILURE TO DO SO MAY RESULT IN REMOVAL OF YOUR COMPANY FROM FUTURE PURCHASING CONSIDERATION.

** Section 2: Completed by Vendor*

Root Cause of Nonconformance: *(Provide the details of cause of the problem; answer as many why steps as possible to get the actual root cause).*

1. Why -
2. Why -
3. Why -
4. Why -
5. Why -

Corrective Action Taken or Planned: *(Provide the actions taken to correct the specific nonconformance described above).*

Signature of responsible manager: **Date:**

Print Name and Title:

** Section 3: Completed by D&M Industries*

Response Accepted? *If not already, attach additional sheets with explanation and follow-up.*

Purchasing Signature: **Date:**

Figure 12: Vendor Corrective Action Request

RECEIVING INSPECTION SHEET
(Form)

Vendor Name:	Shipment Arrival Date:	Sheet #: (yy/mm/dd/hh/mm)
Type of Carrier: ☐ Vendor ☐ D&M ☐ LTL: _____ ☐ Finisher: _____		

PO #:	Missing/Extra Qty:	Wrong/Incorrect Qty:	Damaged Qty:

Final Comment: Vendor Evaluation

	Evaluation Criteria	*Performance Rating*
	Quality of Shipment	
	Quantity Accuracy	
	On-time Delivery	

Issue #	Problem Type / NC Code	Problem Description - Include any and all Part #s affected
Example	*Missing Info / Vendor Error*	*Packing Slip Incomplete / Missing 2 x SOD1#256487*
1		
2		

Inspector's Signature:	Forman's Signature:

Vendor Performance Rating

1 = Unacceptable shipment	2= Needs further analysis	3= Average	4 = Acceptable with some problems	5= Acceptable without problems

Non-conformance Code

Defective	*Vendor Error*	*Finishing Issue*	*Freight Damage*	*Extra Product*

Figure 13: Receiving Inspection Sheet

5.5.4. Step 4: Implement and Maintain QMS

In this section, we will discuss the implementation aspect of the QMS. Due to the limitations in time, the QMS implementation was not implemented completely in this company. However, the implementation plan adopted is discussed here. Prior to initiating the actual implementation of the documented process, all the documentation was approved by process performers, the management representative and the purchasing manager. Several iterations and revisions were performed to document the process that is best fit for the organization's needs. Following tasks were performed to initiate the implementation plan.

1. Establish clear roles and responsibilities related to QMS documentation

Purchasing manager was chosen to be the owner of all the documents related to the purchasing department. Purchasing manager was also responsible for regularly analyzing the receiving inspection data and updating the AVL. Receiving inspector was appointed among the employees. It was decided that VCAR only PM and OM are authorized to issue a VCAR to the vendors.

2. Provide necessary training to the process performers

Purchasing agents and receiving inspectors were trained on changes in their daily tasks, new roles and use of documentation like filling out the VCAR, vendor performance log and receiving inspection sheet.

3. Establish quality objectives for the purchasing department

The objective was to establish measurable quality objectives. Thus, SMART (specific, measurable, achievable, realistic and Timely) quality objectives were established for the purchasing department. These were zero purchasing errors and 90% acceptance of incoming shipments.

To ensure QMS was maintained, first trial internal audit was scheduled to be carried out after 3 months of full implementation of QMS in the purchasing department.

5.5.5. Step 5 & 6: Expand QMS for other organizational processes

As the implementation was not fully implemented, QMS expansion to other process cannot be discussed. However, an expansion plan is discussed in this section to facilitate the expansion and eventual implementation of QMS throughout D&M industries. After successful implementation of the QMS in purchasing department, D&M must expand the scope to the most critical process currently within the organization. At this stage, step 3 must be repeated by using gap analysis and risk assessment. Lessons learned during the prior stages must be utilized to effectively expand the scope to improve implementation measures for the QMS expansion. Figure 14 shows the complete interaction of all QMS process considering full scope of implementation of QMS at D&M Industries.

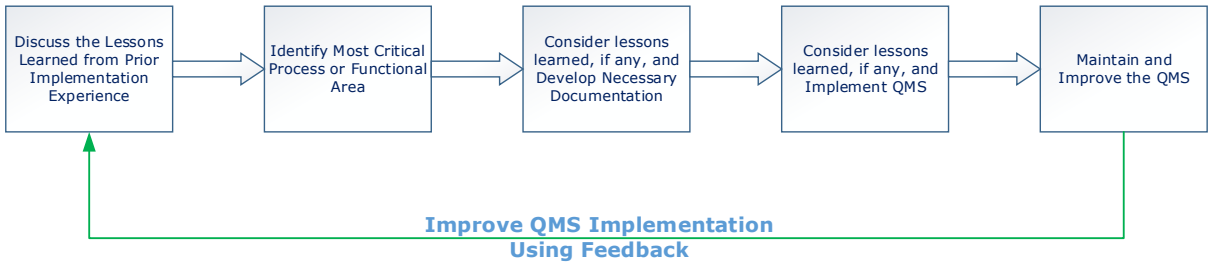

Figure 14: QMS Expansion Plan

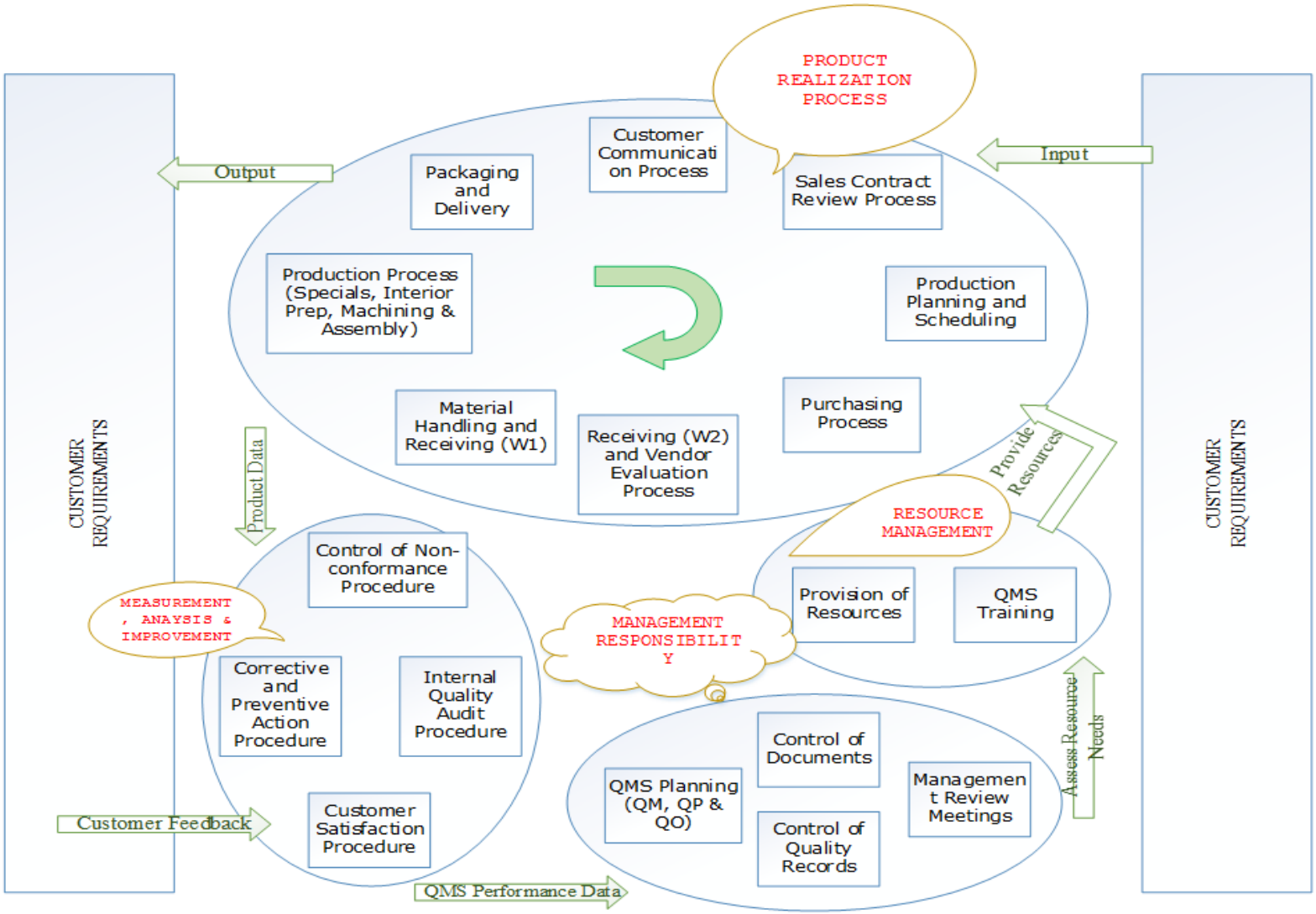

Figure 15: Process Interaction and Process-based Approach to QMS for D&M Industries

5.5.6. Step 7: Maintain and Improve QMS implementation

To ensure that D&M reaps maximum internal benefits, it is important to ensure that the QMS is maintained to drive continuous improvement. D&M must react to the lessons learned during QMS implementation phase for prior scopes and use it as a feedback and valuable information to improve the implementation methods during the expansion of QMS scope. Purchasing manager must ensure that the performance of purchasing process tracked every month and AVL is updated without failure to select vendors based on evidence data. Operations manager must ensure that the Control of nonconformance procedure and Corrective and preventive action procedure are always followed within the company. Internal audits are conducted using internal audit schedule. Process performances must be discussed the management review meetings where the top management of the company can take decisions to improve the QMS implemented. Having said that, we propose an effective continuous improvement Plan (maintenance plan) for QMS using a 'Process Health Tracker' (PHT) which tracks the quality status and importance of the processes at regular basis.

The purpose of this tracker is to monitor the health of the QMS processes with respect quality objectives & KPIs and alert the management representative and managers about poor performances when the expected results are not achieved. The PHT is illustrated in figure 16. We use the process performance as the measure in this tracker. We classify the Process status of each performance based on the following criteria:

a. **Low (1):** the process is stable. All performance indicators, metrics, objectives, complaints, audit results, etc. consistently achieve planned targets.
b. **Medium (2):** Minor problems exist in the process that might need minor process or product changes.

c. **High (3):** Unstable Process with poor performance. Thus, might need to have new process, product(s) or major changes. May or may not have significant findings in past audits.

d. **Critical (4):** Unstable Process with consistent poor performance. Hence, it is expected to have significant audit finding in last 6 months and need for process/product change. Might result in safety or regulatory compliance issues.

Similarly, we have classified the process importance based on the following criteria.

a. **Low (1):** Failure in process potentially has little to no risk of adversely affecting customer satisfaction, resulting product quality, delivery, or profitability of the company.

b. **Medium (2):** Failure in process might have an adverse effect on customer satisfaction, resulting product quality, delivery, or profitability.

c. **High (3):** Failure in process will most likely have a significant adverse effect on customer satisfaction, product quality, delivery, or profitability.

d. **Critical (4):** Failure in process will most likely cause safety or regulatory compliance issues.

Number of customer complaints and internal corrective actions associated with processes are also considered to validate out tracker. As the tracker is the measure of quality performances, it is important to consider the customer dissatisfaction root cause and the associated process. Similarly, Corrective actions taken also implies that the process is prone to nonconformities in the past. If the corrective actions were not effective, the same problems might occur again. The criteria for scoring customer complaints and corrective actions is explained below.

Criteria for customer complaints: Number of customer complaints * 3

We have set high importance and priority level and it is the responsibility of an organization to study and consider customer complain seriously as a feedback to QMS performance. Thus, number of complaints will be multiplied by 3 to get the total score for customer complaints.

Criteria for corrective action requests: Number of CAR's * 3

PHT will be monitored by top management. Based on the health of the process, the internal audits can be conducted against the audit schedule, if needed, to find the nonconformities in the QMS and initiate corrective actions for improvement. Following audit criteria is proposed.

Total Score:

Total score = Process performance score + Customer complaints score + Internal CAR score.

Depending on the total score, internal audits should be conducted to identify the root cause of the problems. A color scheme is also used and explained as follows:

Table 5: Internal Audit Criteria for QMS Improvement & Maintenance

Total Score	Internal Audit Criteria based on PHT
< 5	Internal Audit should be scheduled at least once per year.
6 to 12	The audit should be scheduled within 6 months and review periodically, as necessary
> 12	Internal audit should be scheduled every month until process performance is improved and reviewed every quarter, as necessary.

We strongly believe that process and importance tracker will increase the engagement of top management in QMS and continuous improvement.

Quality Management Process List (Process Health Tracker)			Process Performance			Corrective Action Requests		Customer Complaints (External)		Total Score
			Process Status × Process Importance			Internal CARs×3		Received Complaints×3		Internal + Internal CAR + External Score
Sr. No.	ID.	Title	Status	Importance	Internal Score	Number of CARs	Total Internal CAR Score	Number of Complaints	External Score	Ranking
1	QP001	Control of Documents								0
2	QP002	Control of Records								0
3	QP003	Internal Quality Audits								0
4	QP004	Control of Non-conformance								0
5	QP005	Corrective Action and Preventive Action								0
6	QP006	Management Review Meetings								0
Operational Processes			Status	Importance	Internal Score		Total Internal CAR Score		External Score	Ranking
Sr. No.	ID.	Title								0
1	OP001	Customer Communication (Requirements)								0
2	OP002	Sales Contract Review								0
3	OP003	Purchasing Process								0
4	OP004	Vendor Performance Evaluation								0
5	OP005	Receiving								0
6	OP006	Production Control and Product Release								0
7	OP007	Preventive Maintenance and Calibration								0
8	OP008	Packaging and Delivery								0
9	OP009	Returns								0
10	OP0010	Control of Customer Property								0

Figure 16: Process Health Tracker for Continuous Improvement & Maintenance of QMS

CHAPTER 6. CONCLUSION

With the help of this study, we have proposed a quality management system implementation framework for small sized companies that want to transit from a no-quality system to an ISO 9001 QMS environment. Our framework was built on assessing the of needs of the organizations and integrating QMS with operational processes. Our framework is specifically applicable to small-medium sized business that want to achieve continuous improvement using QMS. We have proposed a do-it-yourself approach that will significantly decrease costs associated with outside experts and consultants. However, this framework is applicable only if an organization wants to adopt incremental approach to continuous improvement. One major limitation is the longer time that will required to develop and implement QMS on smaller scopes and eventually expanding to organizational needs. This is also the first case study conducted for a door manufacturing company. Hence, it also signifies the applicability of QMS in door and window industry.

Based on our detailed literature study, we conclude that very few studies have been conducted related to QMS implementation and development for small-medium sized companies. We investigated several conceptual frameworks and compared them based on their applicability and impacts on organizational performance. We found that many of these conceptual frameworks are too complex and hence do not have any implementation studies based on them. These frameworks were classified based on impacts i.e. negative impact, QMS assets and QMS outputs. Failed attempts and ineffective implementation of QMS had negative impacts on organizational performance levels. QMS assets are obtained with some level of effective QMS implementation. Similarly, a successfully implemented QMS will produce QMS outputs. The case study provided a cost-effective quality management model that can adopted by any organization. This study will

be useful for quality engineers, quality managers, quality consultants and other quality practitioners looking to develop and implement QMS.

We found the validation of our proposed model challenging but successful. Our case study revealed several issues for a small manufacturing company. A company without any quality system lacks in data collection system required to facilitate evidence based decision making. This was found true at D&M industries as decisions were taken based on experiences rather than facts. QMS designed for purchasing department facilized selection of vendors based on vendor evaluations. Lack of expertise to initiate quality practices was another reason for small companies to not have any quality systems. This was especially true for D&M that run on a tight budget and lacked resources to hire engineering positions. Due to the lack of a documented quality system, quality of processes and products could not be measured at D&M. The needs were realized only when the rate of customer complaints went beyond the acceptable limits. Without QMS in place, there was lack of control over organizational processes, lack of standardized processes, lack of measurable performance indicators, and lack of problem detection and correction system.

Despite realizing the need for QMS, there were many obstacles faced. All the process in the company needed to be identified, verified and documented. Due to lack of time commitment to the project, top management of the company was not able to formally establish the quality policy. Due to lack of financial resources, the company was not able to hire an inspector necessary to perform inspection of receiving shipments from the vendors. Hence, the responsibilities were divided between employees and hence implementation processes were slower than expected. Operations manager of the company was appointed as the management representative to continuously monitor and facilitate QMS implementation throughout D&M Industries. WMS hierarchy chart was developed to appoint QMS process owners and process performers. Notable

benefits were achieved by D&M Industries from this program. D&M obtained several QMS assets in the form date collection system that facilitates detection, control and correction of Nonconformance's, Standardized operational processes with control of operations, evidence-based decision making using documented processes, improved quality perception and initiation of quality oriented culture. These assets will provide D&M with improved operational performances, reduction of costs due to control of vendor problems and customer returns and improved productivity using acceptance criteria's, inspection check points and work instructions to perform same work, same way and every time.

Based on the benefits achieved by D&M Industries, our proposed framework was successfully validated with the help of this case study implementation. Our risk assessment on gap analysis checklist can be used by any organization to identify critically important processes and real organizational needs. The Process Health Tracker provided in this study can used effective tool for successful maintenance and improvement of any QMS. Thus, we recommend the use of proposed framework for future QMS implementation initiatives in any organization irrespective of its size and nature. We have provided generic versions of QMS documentation that can used by quality practitioners seeking quality improvements in their organizations.

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APPENDIX A. SUPPLEMENTAL TABLES

Table A1: Comparison of Quality Management System Implementation Frameworks

Sr No	QMS Literature	Quality System Considered	Type of Study	Organization Applicability	Implementation Motivation	Impact of QMS	Driving Force	Final Comment
1	Bialy and Maruszewska (2015)	ISO 9001	Case study	Large	Internal or external	QMS outputs	Insufficient information	Benefits: safe production, high quality products, controlled documentation, reduced waste and inventory, less nonconformities
2	Garza-Reyes et al., (2015)	ISO 9001	Conceptual framework	Small-Large	Internal or external	Insufficient information	Insufficient information	Insufficient information
3	Valentina Biasini (2012)	ISO 9001	Case study	Small	External	QMS outputs	Outside expert	Benefits: Clear and well defined roles & responsibilities, enhanced employee morale, better internal communication, reliable data tracking
4	Milan Hutyra (2010)	ISO 9001	Case study	Large	Internal and external	QMS outputs	Outside expert	Benefits: Enhanced process management, clear role and responsibilities, increased customer
5	Kim et. Al (2010)	ISO 9001	Conceptual framework	Small-Large	Internal or external	Insufficient information	Insufficient information	Insufficient information
6	D. Aggelogiannopoulos et al., (2007)	ISO 9001	Case study	Small		Insufficient information	Insufficient information	Insufficient information
7	Aldowaisan and Youssef (2006)	ISO 9001	Conceptual framework	Small	Internal or external	Insufficient information	Insufficient information	Insufficient information

Table A1: Comparison of Quality Management System Implementation Frameworks (continued)

Sr No	QMS Literature	Quality System Considered	Type of Study	Organization Applicability	Implementation Motivation	Impact of QMS	Driving Force	Final Comment
8	Yang (2001)	ISO 9000	Conceptual framework	Small-Large	Internal or external	Insufficient information	Insufficient information	Insufficient information
9	Bhuiyan and Alam (2006)	ISO 9001	Case study	Small	Internal and external	QMS outputs	Outside expert	Benefits: increased control over internal and external problems, enhance safety measures, documented structure
10	S. Aniyan (2002)	ISO 9000	Case Study	Large	Internal and external	QMS outputs	Outside expert	Benefits: Waste reduction, continuous improvement, less rework, better control over processes, employee commitment, enhanced profit and customer satisfaction
11	Hermann et al., (2000)	TQM and ISO 9000	Case study	Small-Large	Internal	QMS assets	Insufficient information	Insufficient information
12	Houston and Rees (1999)	ISO 9000	Case study	Large	Internal	Negative Impact	Insufficient information	Insufficient information
13	Ashok Sarkar (1998)	ISO 9000	Case study	Large	External	QMS outputs	Outside expert	Benefits: Less waste and reduced inventory, reduced power consumption, increased employee involvement.
14	Czuchry et al., (1997)	ISO 9000	Case study	Large	External	Insufficient information	Inside and Outside expert	Insufficient information
15	Kanji (1996)	TQM	Conceptual framework	Large	Internal or external	Insufficient information	Insufficient information	Insufficient information

Table A1: Comparison of Quality Management System Implementation Frameworks (continued)

Sr No	QMS Literature	Quality System Considered	Type of Study	Organization Applicability	Implementation Motivation	Impact of QMS	Driving Force	Final Comment
16	Dale (1995)	TQM	Conceptual framework	Large	Internal or external	Insufficient information	Insufficient information	Insufficient information
17	Lee and Lam (1997)	ISO 9000	Case study	Large	Internal	QMS outputs	Outside expert	Benefits: Significant decrease in maintenance costs, reliable, increased safety and cleanliness, enhances internal and external customer satisfaction
18	Berry (1991)	TQM	Conceptual framework	Large	Internal or external	Insufficient information	Insufficient information	Insufficient information
19	Hakes (1991)	TQM	Conceptual framework	Large	Internal or external	Insufficient information	Insufficient information	Insufficient information

Table A2: Critical Success Factors for QMS Implementation

Sr. No.	Critical Factors to Be Considered During QMS Planning	Critical Factors to Be Considered During QMS Implementation
1	Lack of top management support and commitment to QMS (Psomas et al., 2010)	Lack of top management support and commitment to QMS (Psomas et al., 2010)
2	Inability to provide resources needed for QMS (Magd, 2008; Zeng et al., 2008; Kim et al., 2011; Angelogiannopoulos et al., 2007)	Lack of commitment to maintaining QMS (Zeng et al. 2007)
3	Lack of commitment to financial support from the top management before QMS Implementation (Yahya and Goh, 2001; Magd, 2008; Kim et al., 2011)	Employee resistance to change (Bhuiyan and Alam, 2005)
4	Lack of qualified personnel required for successful implementation and maintenance of QMS of (Magd, 2008)	Lack of time and efforts to implement and maintain QMS (Yahya and Goh, 2001; Magd, 2008, Kim et al., 2011)
5	Lack of experience and knowledge of QMS (Angelogiannopoulos et al., 2007)	Lack of understanding related to quality mythologies, practices, tools etc. (Bhuiyan and Alam, 2005)
6	Lack of training necessary for implementing QMS (Yahya and Goh, 2001; Park et al., 2007; Magd, 2008; Chow-Chua et al., 2003; Psomas et al., 2010; Kim et al., 2011)	Poor problem solving training to tackle quality related problems (Magd, 2008)
7	Lack of motivation among management and employees to improve processes (Heras et al., 2008)	Lack of measurement and monitoring of internal and external customer satisfaction (Park et al., 2007; Kim et al., 2011)
8	Lack of control over documentation (Chow-Chua et al., 2003)	Lack of training to perform performance analysis using quality tools (Yahya and Goh, 2001; Park et al., 2007; Magd, 2008, Kim et al., 2011)
9	Meeting internal and external customer needs and expectations (Psomas et al., 2010; Park et al., 2007; Kim et al., 2011)	Partial fulfillment of QMS requirements (Park et al., 2007)
10	Unclear roles and responsibilities (Yahya and Goh, 2001; Magd, 2008: Kim et al., 2011)	Lack of motivation among management and employees to improve processes (Heras et al., 2008)
11	Over-expectations from standard (Zeng et al. 2007)	Incompetent internal auditors and process owners (Park et al., 2007; Magd, 2008: Kim et al., 2011)

Table A2: Critical Success Factors for QMS Implementation (continued)

Sr. No.	Critical Factors to Be Considered During QMS Planning	Critical Factors to Be Considered During QMS Implementation
12	Ensure employee involvement and commitment to QMS development and Implementation (Psomas et al., 2010)	Analyze the impacts of organizational change that are necessary to implement QMS successfully (Park et al., 2007)
13	Lack of interest in QMS from other functional areas (Park et al., 2007)	Lack of continuous improvement efforts using internal audits (Magd, 2008; Zeng et al., 2008; Kim et al., 2011)
14	Partial fulfillment of QMS requirements (Park et al., 2007)	Deceitful and dishonest audit reports and other quality records (Park et al., 2007)
15	Analyze the impacts of organizational change that are necessary to implement QMS successfully (Park et al., 2007)	Satisfy external auditor requirements to achieve certification (Zeng et al. 2007)

Table A3: Gap Analysis and Risk Assessment Report

(ISO 9001:2008 requirements were specified in Cianfrani et al. (2009) and explained below for this case study implementation.)

Sr. No.	Quality Management Requirement - ISO 9001: 2008	Gap Finding/ Risk (Y, N, O)	Potential Risk Impact	Action Priority
	Clause 4.1. General Requirements			
1	D&M Industries has identified all the organizational processes and resources required to carry out its management activities, measure performance and realize its suite of products and make improvements.	O	High	Medium Priority
2	D&M has established methods, criteria and specific KPIs to ensure that each process is effective?	O	High	Medium Priority
3	Interaction of organizational processes and their control has been documented.	O	High	Medium Priority
4	D&M processes have the appropriate level of resources needed.	O	High	High Priority
5	D&M provides appropriate level of information and instructions required for effective operations and their monitoring.	O	High	High Priority
6	D&M processes are controlled, monitored, measure and analyzed to verify process performance.	N	High	High Priority
	Clause 4.2. Documentation Requirements			
7	D&M has a list of documentation currently in use.	N	Moderate	Medium Priority
8	D&M have developed and established 'Quality Policy' (QP)	N	High	High Priority
9	D&M has identified and established the required documentation and records.	N	Severe	High Priority
10	All the documents established at D&M accurately reflect 'what you do?' and 'how you do it?'.	N	Severe	High Priority
11	D&M has established the interaction and hierarchy of its QMS documentation.	N	High	Medium Priority
12	D&M has developed and distributed a 'Quality Manual' for its QMS.	N	High	Medium Priority
13	Quality Manual established at D&M accurately defines the scope (boundary) of its QMS.	N	High	Medium Priority

Table A3: Gap Analysis and Risk Assessment Report (continued)

Sr. No.	Quality Management Requirement - ISO 9001: 2008	Gap Finding/ Risk (Y, N, O)	Potential Risk Impact	Action Priority
14	Quality Manual justifies all exclusions.	N	High	Medium Priority
15	All D&M procedures are well documented and/or referenced in its Quality Manual.	N	High	Medium Priority
16	Quality Manual describes process interactions.	N	High	Medium Priority
17	Documents are approved prior to their distribution or reviewed and re-approved whenever they are updated or revised.	N	High	High Priority
18	External documents used for D&M activities are also identified and managed and controlled.	O	Moderate	Medium Priority
19	Control of documents at D&M ensures latest versions are used and obsolete documents are prevented from any misuse and accidental use.	N	High	High Priority
20	D&M records are identifiable, legible and retrievable.	O	Moderate	Medium Priority
21	D&M records can be used as evidence and prove that the requirements have been met.	N	High	High Priority
22	**Clause 5.1. Management Responsibility.** Top management of D&M fully supports the development and implementation of its QMS.	O	High	High Priority
23	Top management supports the development and implementation of Quality Policy and Quality Objectives (QO).	Y	-	-
24	Management has communicated within D&M and believes in importance to meet statutory and regulatory requirements, customer requirements and other QMS requirements.	Y	-	-
25	D&M's top management strongly supports the efforts to continually improve the effectiveness of its QMS.	O	High	High Priority
26	D&M's top management strongly supports continual improvement of its processes by conducting adequate number of management review meetings to review the performance of its QMS.	O	High	High Priority

Table A3: Gap Analysis and Risk Assessment Report (continued)

Sr. No.	Quality Management Requirement - ISO 9001: 2008	Gap Finding/ Risk (Y, N, O)	Potential Risk Impact	Action Priority
	Clause 5.2. Customer Focus			
27	D&M has identified its stakeholders and customers.	Y	-	-
28	D&M periodically reviews its customer requirements and satisfaction levels to enhance customer satisfaction.	O	Moderate	Medium Priority
29	D&M periodically conducts customer satisfaction surveys to ensure that customer requirements are met.	Y	-	-
	Clause 5.1. Management Responsibility.			
22	Top management of D&M fully supports the development and implementation of its QMS.	O	High	High Priority
23	Top management supports the development and implementation of Quality Policy and Quality Objectives (QO).	Y	-	-
24	Management has communicated within D&M and believes in importance to meet statutory and regulatory requirements, customer requirements and other QMS requirements.	Y	-	-
25	D&M's top management strongly supports the efforts to continually improve the effectiveness of its QMS.	O	High	High Priority
26	D&M's top management strongly supports continual improvement of its processes by conducting adequate number of management review meetings to review the performance of its QMS.	O	High	High Priority
	Clause 5.2. Customer Focus			
27	D&M has identified its stakeholders and customers.	Y	-	-
28	D&M periodically reviews its customer requirements and satisfaction levels to enhance customer satisfaction.	O	Moderate	Medium Priority
29	D&M periodically conducts customer satisfaction surveys to ensure that customer requirements are met.	Y	-	-

Table A3: Gap Analysis and Risk Assessment Report (continued)

Sr. No.	Quality Management Requirement - ISO 9001: 2008	Gap Finding/ Risk (Y, N, O)	Potential Risk Impact	Action Priority
	Clause 5.3. Quality Policy			
30	Quality policy is fit for its purpose and well communicated, discussed and understood throughout D&M.	N	High	High Priority
31	Quality policy is reviewed periodically for its suitability?	N	High	High Priority
32	D&M's quality policy makes a commitment to continually improve the effectiveness of the QMS by meeting its QO?	N	High	High Priority
	Clause 5.4. Planning			
33	Top management, managers, supervisors and employees support the establishment of Quality Objectives.	Y	-	-
34	D&M has established Quality objectives that are 'SMART' i.e. specific, measurable, achievable/attainable, realistic/relevant and timely.	N	High	High Priority
35	Quality objectives are effective and support the quality policy and other performance measures.	N	High	High Priority
36	D&M has planned for the ongoing maintenance and continual improvement of its QMS.	N	High	High Priority
37	D&M ensures to protect the integrity of your QMS whenever systemic changes are being planned and implemented.	N	High	High Priority
	Clause 5.5. Responsibility, Authority and Communication.			
38	D&M has defined, established and communicated responsibilities and authorities related to its QMS.	O	Moderate	Medium Priority
39	Top management, managers and supervisors ensure that communication processes are established and routinely occur within D&M.	O	Moderate	High Priority
40	Top management ensures that the effectiveness and performance of its QMS is communicated and discussed throughout the organization.	N	High	Medium Priority
	Clause 5.6. Management Review			
41	QMS is reviewed at planned intervals for its suitability, adequacy and effectiveness.	N	High	High Priority

Table A3: Gap Analysis and Risk Assessment Report (continued)

Sr. No.	Quality Management Requirement - ISO 9001: 2008	Gap Finding/ Risk (Y, N, O)	Potential Risk Impact	Action Priority
42	Top management, managers and supervisors evaluate opportunities for improvement on regular basis.	O	Moderate	Medium Priority
43	Top managers keep a record of management reviews	N	High	High Priority
44	D&M examines and discusses previous management reviews and results of internal audits.	N	High	High Priority
45	D&M examines and analyzes the status and effectiveness of preventive & corrective actions and opportunities for improvement.	N	High	High Priority
46	D&M examines and discusses feedback from customers, product conformity data, process performance data and status of previous actions related to continuous improvement.	O	High	High Priority
47	Top management generates decisions and actions to improve suitability and effectiveness of its QMS.	N	High	High Priority
48	Top management generates decisions and actions to improve product and process performance to enhance its ability to meet customer requirements.	O	Moderate	Medium Priority
49	Top management generates decisions and actions to change its quality policy, objectives and performance metrics, when appropriate.	N	High	High Priority
50	Top management generates decisions and actions discuss resource needs.	O	Moderate	Medium Priority
51	D&M has identified resources needed to implement, maintain and improve its QMS.	O	Moderate	Medium Priority
52	D&M has identified the resources needed to ensure the customer's needs are being met and to help enhance customer satisfaction.	O	High	High Priority
53	**Clause 6.2. Human Resources.** D&M has clearly identified the qualifications, skills, knowledge and experience required by all the employees.	Y	-	-
54	D&M ensures that all employees have the appropriate, qualifications, skills, knowledge and experience, as required.	Y	-	-

Table A3: Gap Analysis and Risk Assessment Report (continued)

Sr. No.	Quality Management Requirement - ISO 9001: 2008	Gap Finding/ Risk (Y, N, O)	Potential Risk Impact	Action Priority
55	D&M has identified the competence requirements of personnel within its QMS who perform work that could directly or indirectly affect its ability to meet product requirements.	Y	-	-
56	At D&M, training is provided and other suitable steps are taken to meet its competency requirements.	Y	-	-
57	D&M ensures that all employees are aware of how their activities can affect D&M's ability to meet product requirements and how important their efforts are.	O	Moderate	Medium Priority
58	D&M evaluates the effectiveness of its training and awareness activities.	N	High	High Priority
59	D&M maintains suitable records of competency, education, training, experience and skills of its employees.	O	Moderate	Medium Priority
60	D&M has identified the infrastructure needed to ensure that product requirements are met?	Y	-	-
61	D&M ensures that appropriate support, communication and information is provided, as required, to ensure product requirements are successfully met.	O	Moderate	Medium Priority
62	D&M also ensures that the work environment is properly managed and maintained.	Y	-	-
63	**Clause 7.1. Product Realization.** D&M has identified processes for effective planning and control of its production processes required to realize its products.	O	Moderate	Medium Priority
64	D&M has identified processes to establish objectives and KPI's for its product realization processes.	N	High	High Priority
65	D&M has identified necessary acceptance criteria's, documents and records required to effectively carry out product realization processes.	N	Severe	High Priority
66	D&M has also identified the monitoring, measurement and verification methods required to control product quality throughout its product realization process.	N	Severe	High Priority

Table A3: Gap Analysis and Risk Assessment Report (continued)

Sr. No.	Quality Management Requirement - ISO 9001: 2008	Gap Finding/ Risk (Y, N, O)	Potential Risk Impact	Action Priority
	Clause 7.2. Customer-related Processes			
67	D&M has procedures in place to identify customer's stated and unstated requirements like product specifications, delivery requirements, packaging requirements etc.	Y	-	-
68	D&M has procedures in place to identify any statutory and regulatory requirements related to its customer's stated and unstated requirements.	Y	-	-
69	D&M has procedures in place to ensure that all the customer requirements are considered and reviewed before commitments are made and products are supplied.	O	High	High Priority
70	D&M ensures that any differences in initial quotations and original customer order are resolved before starting its product realization processes.	Y	-	-
71	D&M has established documents and records to reflect changes in customer's product requirements?	O	Minimal	Medium Priority
72	D&M has procedures in place to ensure that all the customer requirements are considered with internal customers to ensure D&M's capability to fulfil customer requirements before making any commitments.	O	High	High Priority
73	D&M ensures that any changes in customer orders are well communicated to relevant employees and functional areas.	O	Moderate	Medium Priority
74	D&M has also established a process to handle customer enquiries, feedback and complaints?	N	High	High Priority
75	D&M ensures that procedures are established to control how product information, contracts and amendments to contracts are provided to its customers.	Y	-	-
	Clause 7.4. Purchasing Process.			
76	D&M has established criteria to select and evaluate suppliers?	N	Severe	High Priority

Table A3: Gap Analysis and Risk Assessment Report (continued)

Sr. No.	Quality Management Requirement - ISO 9001: 2008	Gap Finding/ Risk (Y, N, O)	Potential Risk Impact	Action Priority
77	D&M has established procedures to evaluate its suppliers/vendor's ability to supply products that meet D&M's requirements.	N	Severe	High Priority
78	D&M ensures that supplier/vendor evaluations records are kept and discussed.	N	Severe	High Priority
79	D&M also ensures that all purchased products meet specified purchase requirements?	N	Severe	High Priority
80	D&M ensures that purchasing requirements are adequately specified before discussing them with suppliers/vendors.	N	Severe	High Priority
81	D&M has established product verification or inspection methods to ensure that purchased products meet purchase requirements.	N	Severe	High Priority
82	**Clause 7.5 Production and Service Provision** Production at D&M is carried out under controlled conditions.	N	Severe	High Priority
83	D&M has established a plan for how production and service delivery will be monitored.	O	High	High Priority
84	D&M has planned how operational procedures will be used to monitor production and service delivery.	O	High	High Priority
85	D&M has planned how measurements are used to monitor production and service delivery.	N	Severe	High Priority
86	D&M has a procedure in place to monitor production after post-delivery activities.	N	High	High Priority
87	D&M has established criteria to help verify production processes.	N	Severe	High Priority
88	D&M has documented procedures to verify performance of production	N	Severe	High Priority
89	D&M verifies its production and service provision processes whenever process outputs cannot be measured, monitored, or verified until after the product is in use or the service has been delivered.	N	High	High Priority
90	D&M has established procedures to identify and preserve the unique identity of its products throughout the product realization process.	O	Moderate	Medium Priority

Table A3: Gap Analysis and Risk Assessment Report (continued)

Sr. No.	Quality Management Requirement - ISO 9001: 2008	Gap Finding/ Risk (Y, N, O)	Potential Risk Impact	Action Priority
91	D&M maintains records of the identity of products whenever traceability is a required.	O	Moderate	Low Priority
92	D&M maintains the monitoring and measurement status of your its products throughout the product realization process?	N	Severe	High Priority
93	D&M has established procedures to identify property supplied to it by its customers.	O	Moderate	Medium Priority
94	D&M has established procedures to verify property supplied by customers.	O	Moderate	Medium Priority
95	D&M has established procedures to ensure customer property is protected from any damage.	O	Moderate	Medium Priority
96	D&M uses suitable identification methods to preserve raw materials, products and other components during internal processing and delivery to the intended destination within its organization.	Y	-	-
97	D&M ensures to preserve its products and components during delivery through effective packaging.	Y	-	-
98	**Clause 8.1. Measurement, Analysis and Improvement.** D&M has identified and implemented the monitoring, measurement, and analytical processes needed to be able to demonstrate conformity to QMS requirements and make improvements.	N	Severe	High Priority
99	D&M has identified & implemented monitoring & measurement processes required to be able to continually improve the effectiveness of its QMS.	N	Severe	High Priority
100	D&M has identified & implemented, where necessary, statistical measurement methods required to show that products meet requirements.	N	Severe	High Priority
101	D&M has identified and implemented required analytical processes to ensure that QMS requirements are being met and continually improved.	N	Severe	High Priority
102	D&M has established monitoring processes to continually improve the effectiveness of its QMS.	N	Severe	High Priority

Table A3: Gap Analysis and Risk Assessment Report (continued)

Sr. No.	Quality Management Requirement - ISO 9001: 2008	Gap Finding/ Risk (Y, N, O)	Potential Risk Impact	Action Priority
	Clause 8.2. Monitoring and Measurement			
103	D&M has established and implemented methods that used to monitor and measure customer satisfaction (perception).	O	Moderate	High Priority
104	D&M uses customer satisfaction levels as a measure of its performance.	-	-	-
105	D&M methods are capable of monitoring and measuring if its QMS can meet customer requirements or not.	N	Severe	High Priority
106	D&M has procedures in place to ensure that customer satisfaction information obtained is used as a feedback to its QMS.	N	Severe	High Priority
	Clause 8.2.2. Internal Audit			
107	D&M has established and implemented an internal audit procedure.	N	Severe	High Priority
108	D&M has documented its internal audit procedure.	N	Severe	High Priority
109	D&M has established procedures that define internal audits, its scope and how it should be performed.	N	Severe	High Priority
110	D&M ensures that previous internal audits findings are also considered.	N	Severe	High Priority
111	D&M has defined the scope of internal audits.	N	Severe	High Priority
112	Audits are conducted by independent personnel and records are maintained.	N	Severe	High Priority
113	D&M ensures that corrective action requests are initiated when nonconformities are found during audits.	N	Severe	High Priority
114	Process owners ensure that root causes of nonconformities are identified and corrective actions are implemented successfully without delay.	N	Severe	High Priority
115	Process owners ensure that corrective actions are monitored and followed to verify its effectiveness.	N	Severe	High Priority
116	Process owners ensure that results of verification activities are communicated to the top management.	N	Severe	High Priority

Table A3: Gap Analysis and Risk Assessment Report (continued)

Sr. No.	Quality Management Requirement - ISO 9001: 2008	Gap Finding/ Risk (Y, N, O)	Potential Risk Impact	Action Priority
117	**Clause 8.2.3., 8.2.4. Monitoring & Measurement of Process & Product** D&M has established monitoring and measurement activities to ensure that its QMS is successfully achieving planned results.	N	High	High Priority
118	D&M has implemented procedures in place to ensure that corrective actions are requests and implemented when nonconformities are identified.	N	High	High Priority
119	D&M has implemented monitoring methods to verify that product characteristics have been met.	N	High	High Priority
120	Production records of monitoring activities prove that acceptance criteria are met.	N	High	High Priority
121	D&M ensures that its performs monitoring & measuring activities before products are released to be delivered to its customers.	N	Severe	High Priority
122	**Clause 8.3. Control of Nonconforming Product** D&M has implemented a documented procedure for identification and control of nonconforming products.	O	High	High Priority
123	Nonconforming procedure defines how to prevent unintended delivery or use of nonconforming products.	N	Severe	High Priority
124	Nonconforming procedure also defines a plan on how to address the effects and consequences that result from the delivery or use of nonconforming products?	N	Severe	High Priority
125	D&M has defined and allocated responsibilities related to nonconforming products.	O	High	High Priority
126	Nonconforming procedure also describes how nonconforming product records will be managed and maintained?	N	Severe	High Priority
127	Procedure implemented also describes nonconforming product correction and re-verification methods.	N	Severe	High Priority

Table A3: Gap Analysis and Risk Assessment Report (continued)

Sr. No.	Quality Management Requirement - ISO 9001: 2008	Gap Finding/ Risk (Y, N, O)	Potential Risk Impact	Action Priority
128	D&M ensures that detected nonconformities are eliminated, records are maintained and corrective actions are implemented to tackle nonconforming products.	N	Severe	High Priority
	Clause 8.4. Analysis of Data			
129	D&M ensures that relevant data is collected regularly and analyzed to ensure suitability and adequacy of its QMS.	N	High	High Priority
130	Information and data related to customer processes is analyzed and communicated with the top management.	N	High	High Priority
	Clause 8.5. Improvement			
131	D&M top management ensures that it works towards continually improving the overall effectiveness of its QMS.	N	High	High Priority
132	D&M uses methods like data analysis and objectives to make quality improvements?	N	High	High Priority
133	D&M performs internal audits to make improvements?	N	High	High Priority
134	D&M conducts management reviews to make quality improvements?	N	High	High Priority
135	D&M initiates and implements corrective actions to make quality improvements?	N	High	High Priority
136	D&M initiates and implements preventive actions to make quality improvements?	N	High	High Priority

APPENDIX B. QMS INFRASTRUCTURE

B.1. Control of Documents Procedure

1. **Purpose:** The purpose of this procedure is to describe the process of controlling documents related to Quality Management System (QMS);
    i. To ensure that controls are in place to approve and issue documents prior to its use.
    ii. To review, update, as necessary, and re-approve documents to ensure consistent performance of all activities affecting quality.
    iii. To ensure any changes in document requirements are communicated to those who must implement them.
    iv. To prevent unintended use of obsolete documents to ascertain that up-to-date information is available for use.
2. **Scope:**
    2.1. This procedure is applicable to all the documents generated for processes within the scope of QMS described in the quality manual for D&M Industries.
    2.2. This procedure is applicable to all the documents that ensure effective management and maintenance of QMS within D&M Industries. Different documents under control include the Quality Manual, Quality Procedures (SOP's), Work Instructions, and Forms. (And other external documents, if any).
3. **Glossary:**
    a) OM - Operations Manager
    b) MR - Management Representative
    c) QMS - Quality Management System
    d) ISO - International Organization for Standardization

e) EM – Engineering Manager

4. Definitions:

4.1. Document: A document can be a manual, procedure, work instruction or a form used for performing roles, responsibilities and activities.

4.2. Master Document Index/List: List of all the documents and document owners related to the QMS implemented at D&M Industries.

5. Responsibility:

5.1. MR/ OM: It is the responsibility of the MR/OM to ensure the appropriate implementation of this procedure. The OR/MR is also responsible for the authorization, review, issue and amendment of any documents related to QMS.

5.2. Managers/ Process Owners: have immediate responsibility of the management of records relating to their processes and activities. Process owners should ensure their process performers are using latest versions/ revisions of the documents.

6. Procedure:

6.1.This procedure is consisting of following sections that explain the requirements related to the control of documents specified in ISO 9001: 2008 international standard;

i. Creation of documents.
ii. Documental Review and Re-approval.
iii. Document Identification and Distribution.
iv. External Documents.
v. Obsolete Documents.

(Refer to figure B.6 for master document index form related to control of documents procedure.)

6.2. CREATION OF DOCUMENTS:

6.2.1. Documents in relation to D&M's QMS are created by the process owner or OM/MR.

6.2.2. All the documents related to QMS must be approved by OM/MR through his/ her signature.

6.2.3. Soft files created shall be saved for future reference (MS word, etc.). Each document must include title, reference number, issue date and page number or shall not be approved.

6.3. DOCUMENT REVIEW AND RE-APPROVAL:

6.3.1. Quality experts recommend that all quality system documents should be reviewed at least once annually and during any organizational changes.

6.3.2. If the document is still fit for its purpose no revision needs to be made. Revised documents must also be re-approved by the OM/MR before redistribution and use by employees.

6.3.3. Any amendments, where necessary should be made prior to the release or redistribution and shown in bold or *italic* or highlighting it with a color and/or underlined to give a visual indication from the previous issue. Any deleted paragraph is shown as: *Paragraph 3, Deleted*.

6.3.4. All previous versions are moved to 'Obsolete Documents Folder' for historical purposes if necessary. However, this folder/ or obsolete documents are password protected/unlocked/safe, to protect from any unwanted use or unauthorized editing.

6.4. IDENTIFICATION & DISTRIBUTION OF DOCUMENTS:

6.4.1. A document reference system is used for identifying documents. For example, a document numbered D&M-PUR-PRO-001 could mean it belongs to D&M Purchasing department, Procedure number 001. (It is up to the organization to decide what format the documents should take).

6.4.2. All the controlled documents in use are stored in the 'Quality System Documentation' folder and can be accessed through D&M's intranet.

6.5. EXTERNAL DOCUMENTS:

6.5.1. Other external documents like industry standards and specifications in use or referred are checked annually to ensure that latest versions are being used.

6.5.2. All external documents are controlled in the same way as the quality system documents.

6.6. OBSOLETE DOCUMENTS:

6.6.1. Any obsolete documents, if necessary are retained for lifetime for historical purpose or can be removed from the use or destroyed from the system by the OM/MR.

6.6.2. All Obsolete documents are clearly identified as obsolete and moved to the 'Obsolete Document's Folder'.

B.2. Control of Records Procedure

1. Purpose:

1.1. This procedure explains how D&M Industry's QMS records are to be maintained to provide evidence of conformity to requirements and effective operation of QMS.

1.2. This procedure also defines the requirements for the identification, storage, protection, retrieval, retention time and disposition of controlled quality records.

2. Scope:

2.1. This procedure is applicable to all the records generated through processes within the scope of QMS described in the quality manual.

2.2. This procedure is applicable to all the quality records generated regardless of their form.

2.3. Records outside of this scope do not require any control, but may be controlled at the discretion of D&M management.

3. Glossary:

a) MRL - Master Records List

b) OM - Operations Manager

c) MR - Management Representative

d) QMS - Quality Management System

e) ISO - International Organization for Standardization

f) IE - Industrial Engineer

4. Definition:

4.1. Record: Typically, when a 'Form', either electronic or paper, is filled and completed, it becomes a quality record. Completed forms are controlled documents and are, therefore, part of company's documented control system.

4.2. Records are generated and analyzed to determine;

i. If the process under consideration has achieved its objectives?

ii. If the given process is meeting its process criteria?

iii. If the KPI's are within acceptable limits and up to D&Ms standards.

iv. Defects for correction or if a trend indicates corrective action is needed.

4.3. Record – Anything retained to provide and preserve as a permanent evidence of

conformity.

4.4. MRL – is the complete list of D&M's quality records.

5. Responsibility:

5.1. MR/ OM: It is the responsibility of the MR/OM to ensure the appropriate implementation of this procedure.

5.2. Managers/ Process Owners: have immediate responsibility of the management of records relating to their processes and activities. Process owners should ensure their process performers are using latest revisions of the forms.

6. Procedure:

6.1. IDENTIFICATION:

6.1.1. The control of records form indicates the records being maintained by process, record type, identification, and retention period and storage location. The records are identified in the table below, along with the controls for each record type.

6.1.2. Each department or functional group are responsible for generating and maintaining adequate records.

6.1.3. Where necessary, electronic records should be write protected and access restricted.

6.2. STORAGE:

6.2.1. Storage methods can be stored as electronic files or paper files. Electronic records must be stored on company server and access restricted.

6.2.2. Paper or hardcopy records must be (scanned and converted into electronic records?) stored in places that prevent from damage and deterioration.

6.3. RECORD RETENTION.

6.3.1. Records must be maintained for a minimum period of 3 years.

6.3.2. Training records and other records pertaining to employees must be retained for at least one year or beyond that employee's end of employment.

6.3.3. When archived records are stored offsite or in another location, these shall be stored in a controlled environment that also protects them from damage or deterioration.

6.4. RETRIEVABLE:

6.4.1. Records shall be made available to the process performers and auditors for monitoring, measurement and trend analysis.

6.4.2. Records shall be made available to the customers, if and as stated in the contractual agreements.

6.4.3. Records shall be made available to external auditors, during external audits, as required by ISO.

6.4.4. Archived records should be reasonable retrievable.

6.5. DISPOSITION:

6.5.1. Records that are now discarded and obsolete must be permanently destroyed.

(Refer to figure B.7. for master records index form related to control of records procedure).

B.3. Control of Nonconformance Procedure

1. Purpose:

1.1 This procedure defines the requirements for identification, control and analysis of nonconforming products, to ensure that products/ materials that do not conform to specified requirements are prevented from unintended use or delivery.

2. Scope:

2.1 This procedure is applicable to all the material used to produce doors manufactured at D&M Industries, that are found to be nonconforming during various activities taking place at,

i. Warehouse 2 receiving process
ii. Specials and Interior prep
iii. Interior pre-hung production lines (990 & KVAL)
iv. Exterior prep
v. Exterior production line
vi. Packaging, handling, storage and delivery.

1.2 This procedure is also applicable other material types related to millwork, hollow metal, rediframes and hardware.

2. Glossary:

a) OM: Operations Manager.

b) PM: Production Manager.

c) PM: Purchasing Manager.

3. Definition:

3.1. Nonconforming product is any product, whether raw material or finished product that is found to not conform to specified requirements. These requirements are related to customer requirements, statutory or regulatory requirements or any other requirements.

3.2. Statutory-regulatory requirements: Both statutory requirements and regulatory requirements are those requirements that are required by law. These requirements are non-negotiable and must be complied with. Failure to comply a legal requirement may result in

a fine or penalty and possibly a custodial sentence for the person or persons responsible or organization for such failure.

4. Responsibility:

4.2.1 It is the responsibility of the MR/OM to ensure that this procedure is followed and implemented.

4.2.2 Sales rep are responsible for documenting the details of NC related to customer returns.

4.2.3 Process owners and supervisors shall ensure that every NC identified is documented.

4.2.4 To examine every customer return using FORM# sent by sales reps.

5. Procedure:

5.1. IDENTIFICATION OF NON-CONFORMANCES AT D&M:

5.1.1 Nonconforming products are detected in many ways, by any person, at any time at D&M Industries or by a customer or contractor following delivery of the products.

5.1.2 NC related to product and processes are identified during data analysis, audits or as a part of routine operations where an individual or department might identify a NC through following activities:

i. Complaints (internal or external).

ii. Inspections.

iii. Observations.

iv. Internal audit findings.

v. Third party audit findings.

5.1.3 Use temporary hold tags or REJECTED / DEFECTIVE tag and move the nonconforming product in the nonconforming area/defective parts area to avoid its use and check the NC in detail.

5.2 DOCUMENTING A NONCONFORMANCE:

5.2.1 Every NC identified is documented and communicated to the supervisors without delay.

5.2.2 NC identified at W2 receiving are documented using Receiving Inspection Sheet #_____.

5.2.3 NC identified at Warehouse one are documented using #_____.

5.2.4 NC's are evaluated by process owners and if necessary, Corrective Action can be initiated using Corrective and Preventive Action Procedure #____.

5.2.5 Vendor Corrective Action Requests, VCAR, is initiated against a vendor by PM when required.

5.2.6 Process owner should determine the seriousness of the problem/severity of NC, based on its effects or potential effects on the products and then rank the NC as follows:

i. HIGH Risk

ii. LOW Risk

iii. NO Risk

5.2.7 Ranking of the NC is essential to recognize the need for detailed evolution for implementing remedial action and permanent solution to eliminate or mitigate the cause of NC's.

5.3 DISPOSITION OF NC:

5.3.1 Disposition of the NC products is decided by immediate supervisors and process owners. Only following personal have disposition rights:

i. W2 supervisor

ii. Production Manager

iii. Operations Manager

iv. Receiving Manager

v. Returns specialist

5.3.2 Identify the product clearly to distinguish it from its product acceptance criteria.

5.3.3 For NC's related to Sales, communicate with the sales rep and sales manager.

5.3.4 For NC's related to vendor delivered items, contact the purchasing manager and operations manager.

5.3.5 For other NC identified at Warehouse 1, contact the production manager.

5.3.6 Disposition action is required to correct the NC. It should distinguish the NC items to avoid its unintended us and delivery.

5.3.7 Following disposition actions can be taken:

i. **Accept as is or Use as is**: When it can be established that the NC item is satisfactory for its intended use with appropriate authorizations including, the customer, when required.

ii. **Repair**: For repairs, which affect customer design, Sales must obtain customer / regulatory waiver and record below and then proceed with the Repair.

iii. **Rework**: item shall be reworked to conform to its original requirements by completion or correction.

iv. **Return to vendor**: Item shall be returned to the vendor.

v. **Scrap**: Item shall be scrapped or put in auction trailer.

5.4 IDENTIFICATION OF NC AFTER DELIVERY TO THE CUSTOMER:

5.4.1 When NC product is detected after delivery by the customer or contractor, sales rep to contact their customer and document the NC as detailed as possible.

5.4.2 After receiving the product back from the customer, to verify the returned products using the details on customer complaint #___ and comment if any additional NC's are detected.

5.4.3 Disposition action to be decided by _____ As discussed above.

5.5 RE-VERIFICATION OF NC:

5.5.1 Sales rep to send the copy of the customer complaint form# ___ to the customer service before printing production tickets.

5.5.2 Customer Service to attach a copy of the customer complaint form to the production ticket.

5.5.3 It is the responsibility of the customer service to communicate the NC details to production manager to avoid the same mistake from happening again.

5.5.4 Inspectors verify the products that are repaired or reworked against customer requirements.

5.5.5 Document any NC detected and repeat the steps described above, as necessary.

(refer to figure B.8 for quality inspection sheet form that depicts control of nonconformance procedure).

B.4. Internal Quality Auditing Procedure

1. Purpose:

1.1 The purpose of this procedure is to provide a planned and documented method for carrying out internal audits to ensure that the Quality Management System at D&M Industries conforms to the requirements of ISO 9001 International Standard.

1.2 Provide requirements to verify whether the quality activities established at D&M Industries comply with planned arrangements.

2. Scope:

2.1 This procedure is applicable to all the departments and functional areas of D&M where the quality management system requirements have been established.

3. Glossary:

a) AS - Audit Schedule

b) MR - Management Representative

c) QMS- Quality Management System

d) NC - Nonconformity

e) OBS- Observations

f) QA - Quality Auditor

g) LA - Lead Auditor.

h) MRT - Management Review Team

i) IE – Industrial Engineer

4. Definitions:

4.1 Internal Audits:

Systematic, periodic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which requirements are fulfilled. Internal audits are conducted by, or on behalf of, the organization itself for management review and other internal purposes for the verification of activities, records, processes and performance.

4.2 Objective Evidence: Information that can be proven true, based on facts obtained through observation, measurement, test or other means

4.3 Internal Audit: Process used by D&M Industries to audit themselves. Internal audits findings are used as inputs to the management review process.

4.4 Internal Audit Criteria: Internal Audit criteria relates to the QMS policies, objectives, ISO requirements, customer requirements, industry standards, QMS documentation etc.

4.5 Internal Audit Methods: Methods used by internal auditors to gather objective evidence related to non-conformance. For example: conducting interviews, review of documents and records, observation of processes and activities etc.

4.6 Auditee: Department or functional area of an organization being audited. An 'Auditee' can express their views and opinions anytime during audits.

4.7 Audit Finding: Results from internal audits process that evaluates audit evidence and compares it to audit criteria.

5. Roles and Responsibilities:

5.1 Management Representative

MR schedules audits and maintains the audit system.

MR is responsible for implementing and maintaining the internal audit program at D&M Industries.

5.2 Quality Auditor: Internal Quality Auditor performs audits and documents the audit findings on audit reports.

5.3 Management Review Team

MRT will review the effectiveness of internal audit program within D&M Industries using audit findings and take decisions based on the findings, as required.

6. Procedure:

6.1 Internal audit procedure describes the requirements for the following sections.

i. Internal Audit Planning and Scheduling

ii. Internal Audit Execution & Reporting

iii. Follow-up

6.2 AUDIT PLANNING:

6.2.1 Internal quality audits within the D&M Industries are planned based on the Audit Schedule (AS) approved by the Operations Manager.

6.2.2 Internal audits must be scheduled for all sections within the scope of QMS, mentioned in the quality manual. For example, refer to figure B.1.

6.2.3 OM must ensure that all sections of the QMS are audited at least once per year.

6.2.4 More important activities or areas with identified problems, evident from the 'Status and Importance Tracker', are audited as often as required, but with OM's consent.

6.2.5 QAs are trained and independent auditors are appointed by the Lead Auditor to conduct audits.

6.2.6 QA must ensure that the AS is updated following an internal audit to show the latest audit status and to provide information for future planning.

6.2.7 The QAs will decide with the relevant personnel to confirm the day of the audit and availability prior to the conducting an audit.

6.3 EXECUTION of INTERNAL AUDITS & REPORTING:

6.3.1 Internal audits are carried out using internal audit report form # _____.

6.3.2 QA must put accurate information like audit date, scope, objective and name of auditees in the 'Step 1' of the internal audit report as shown in figure B.2.

6.3.3 QA must also identify and list the applicable documents in 'Step 2' of the audit report.

6.3.4 Quality auditor must review the last completed audit report before auditing the area of interest, to check any areas of concern noted at the previous internal audits. Based on the review, QA must put the required information in 'Step 2' of the audit report.

6.3.5 Then, the audit should be conducted by clearly recording all the audit findings and observations on the internal audit report.

6.3.6 Audit findings must describe the process and records audited and people interviewed. The findings should be clear and unambiguous to anyone reading the report.

6.3.7 Auditor can randomly sample records, enough to provide information about the process performance, while performing audits.

6.3.8 QA's to fill in the required information related to the audit findings in 'Step 3' and 'Step 4' of the audit report.

6.3.9 QA's to document the audit findings and describe the status of findings as one of the following:

OP – *Opportunity,* the findings are not incorrect but give cause for concern or could be improved;

NC - *Nonconformity,* the findings indicate a procedure has not been followed or the procedure does not meet the requirements of the QMS;

✓ - ***Passed,*** the findings and answers are satisfactory and comply with the procedure

6.3.10 When a NC is identified, each negative finding must include the following:

Indication of the requirement – Document, requirement or clause which is thought to have been violated.

Objective evidence – Traceable-indication of the evidence found which supports the claim of NC identified, with sufficient details to ensure it can be found out later, if necessary.

6.3.11 Where applicable, all the NC's identified must be controlled using the control of non-conformance procedure #_____.

6.3.12 QA must evaluate risks associated with the identified NC to list the Major NC in the report for considering corrective action requests.

6.3.13 The appropriate section of the report must be signed by the auditee. Areas where more than one auditee is audited, audit findings must be communicated to all.

6.3.14 QA must ensure that a copy of audit report, whether good or bad, is sent to the LA

and auditees for review.

6.3.15 LA will review the reports for completeness and send back any incomplete reports to the internal auditor for completion. LA to summarize is review in ‘Step 5’ of the audit report.

6.3.16 LA will send complete audit reports to the MR.

6.4 FOLLOW UP AFTER AUDITS:

6.4.1 MR to call up a closing meeting with process owner and other auditees, if required, to discuss the audit findings and need for corrective actions. MR to fill the details of this closing meeting in ‘Step 5’ of the report.

6.4.2 MR / EM to initiate discussions with the process owner or relevant employees to come up with actions necessary to bridge the gap between current situation and the requirements needed to fulfil.

6.4.3 CAR’s should be initiated using CAR form # and CAPA procedure #.

6.4.4 All such actions must be documented and clearly detail what is to be done, who is responsible and the times scale for completion to ensure that the issues are resolved and the recurrence of a similar problem is prevented.

4.3.5 The audit results and effectiveness of actions taken are reviewed at the Management Review meeting and, if considered necessary, additional corrective and preventive actions are decided to be implemented.

INTERNAL QUALITY AUDITS SCHEDULE

(Record)

Year: 2016

Department or Function	Description	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Sales	Customer Communication (Requirements)												
	Sales Contract Review												
Purchasing	Purchasing Process												
	Vendor Performance Evaluation												
Product Realization: Operations	Receiving W2												
	Receiving W1												
Product Realization: Production	Production Control and Product Release												
	Preventive Maintenance and Calibration												
	Packaging and Delivery												
Product Realization: Operations	Returns												
	Control of Customer Property												
Management Responsibility	Monitoring, Measurement and Analysis												

Internal Audit Planned

Internal Audit complete and Corrective Action Request Initiated/Implemented

Internal Audit completed and Corrective Actions Successfully implemented

Plan your audits depending on the status and the importance of the processes and the areas to be audited, as well as the results of previous audits.

1st Quarter *(January-March)*	2nd Quarter *(April-June)*	3rd Quarter *(July-September)*	4th Quarter *(October-December)*
Quality Auditor # 1	**Quality Auditor # 2**	**Quality Auditor # 3**	**Quality Auditor # 4**
Customer Communication. (Requirements)	Purchasing process	Receiving W1	Returns
Sales Contract Review.	Vendor Evaluation	Production Control and Product Release	Control of Customer Property
	Receiving W2	Preventive Maintenance and Calibration	Monitoring, Measurement and Analysis
		Packaging and Delivery	

LIST OF D&M QUALITY AUDITORS

Sr. No	Auditor Name	Position	Audit Responsibility
1		Industrial Engineering	Lead Auditor
2		Production Manager	Internal Auditor
3		Inventory Specialist	Internal Auditor

Figure B.1: Internal Audit Schedule and Audit Team

Step 1: Internal Audit Planning **Rev:**

Audit Number:			**Audit Date:**	
Audit Type:	☐ Quality Policy	☐ Procedure	☐ Process	☐ Special Purpose
Audit Scope:	☐ Sales ☐ Purchasing ☐ W2 Receiving ☐ Delivery ☐ Interior Doors ☐ Exterior Doors ☐ Returns ☐ Other: _____.			
Audit Objectives:	☐ To meet the QMS requirements as specified in the ISO Standard. ☐ To verify conformance with statutory, regulatory and contractual requirement. ☐ To obtain and maintain confidence in the capability of a vendor. ☐ To identify areas for potential improvement or opportunities for improvement. ☐ To provide assurance that customer requirements are being met. ☐ To review organizational risks within D&M Industries. ☐ To continually improve QMS effectiveness, efficiency and thereby eliminating waste. ☐ Other:			
Name, Lead Auditor:				
Auditor 1:			**Auditor 3:**	
Auditor 2:			**Auditor 4:**	
Name, Process Owner (Auditee):				
Name, Interviewee 1:			**Position:**	
Name, Interviewee 2:			**Position:**	
Name, Interviewee 3:			**Position:**	
Name, Interviewee 3:			**Position:**	

Figure B.2: Internal Quality Audit Report

Step 2: Applicable Documents

Primary Document Title:		
Document Number:	Current Rev No:	Revision Date:
List Other Relevant Documents		
Doc/ Record No:	*Procedure or Record Title:*	*Current Rev No:*

Previous Audit No.: _____

Previous Audit Findings			
Key Audit Findings	Process owner Response	Corrective Action # (if any)	Findings Addressed?

Figure B.2: Internal Quality Audit Report (continued)

Step 3: Comparing Actual Practice VS Requirements specified by Standard

Note: For Audit Findings, OP = Opportunity for improvement, NC – Nonconformity, P = Passed.

Evaluate the Risks associated to identify Major NC's.

Compare the requirements of QMS & operational procedures against what employees are doing in everyday practice.			
#	**Question / Requirement**	**Audit Finding**	**✓Major NC.**
1	The documented process is clearly identified and well defined (i/p, o/p, and deliverables)?		
2	Do we review and fulfil - Any customer requirements applicable to this process?		
3	Do we review and fulfil - Statutory or regulatory requirements?		
4	Process is well communicated & understood by process performers?		
5	Process (documented/ undocumented) is implemented and maintained?		
6	Process (documented/ undocumented) controls are effective?		
7	Is the process effective in achieving the desired results?		
8	Process measurable, KPI's are regularly monitored by the process owner?		
Provide objective evidence below. *Also, provide any suggestions for improvement related to the documentation.*			

#	**QMS Requirement or Question: Clause 7.4.1**	**Audit finding**	**✓Major NC.**
1	Is there an 'Approved Vendor' (AVL) list? Is it maintained?		
2	How does the vendor get on AVL?		
3	How does the vendor stay/dropped from the AVL?		
4	Is vendor performance evaluated every month to update AVL?		
5	Criteria for vendor selection and performance evaluation is established and followed?		
6	Vendor performance evaluation methods are established and documented as records?		
7	Type and extent of control on the vendor is dependent on the effects of purchased products on quality of final product.		
Provide objective evidence below. *Also, provide any suggestions for improvement.*			

Figure B.2: Internal Quality Audit Report (continued)

Step 4: To Verify the effectiveness of the process. Study and Analyse the records related.

Review the applicable procedure(s), Quality Objectives, KPI's for this process and answer the questions:			
#	**Questions**	**Audit Finding**	**✓Major NC.**
1	Process is being followed as documented?		
2	Process can achieve intended results regularly?		
3	Does the process meet all the requirements of ISO 9001?		
4	Training records of process performers is maintained?		
5	Are the KPI's or quality objectives met?		
Provide objective evidence below. *Also, provide any suggestions for improvement.*			
Indicate any other problems you uncovered with the process:			
Provide brief details on any areas that you found were well-implemented, particularly effective or worth noting as positive traits of the process.			

FINAL CONCLUSIONS: INTERNAL QUALITY AUDIT REPORT & FINDINGS.

Summarize Findings for CAR: *Evaluate all the NC found in the above sections and List Major NC below.*
Major NC:
Evaluate Associated Risk:
Risk Mitigation Suggestion:
Major NC:
Evaluate Associated Risk:
Risk Mitigation Suggestion:

Figure B.2: Internal Quality Audit Report (continued)

Step 5: Review Audit Report and Submit

Manager/ Process Owner or Process Controller's Response	
☐ Agree	☐ Disagree Reason:
Where deemed necessary, Corrective action request should be initiated using the CAR form and following the corrective and preventive action procedure #	

All internal auditors on the audit team must submit their audit reports for summary and review to the Lead Auditor, _____. Lead Auditor will review the completeness of this report prior to submitting it to the MR/ OM, _____. Be sure your audit findings show objective evidence, that everything is written clearly, and that all checklist questions are answered.

Final Audit Conclusion by Lead Auditor.
Indicate any problems you uncovered with the process below:

Audit Closing Meeting.	
Name of Attendees.	Close Date:
1. 2. 3.	

Figure B.2: Internal Quality Audit Report (continued)

Internal Audit Feedback

Name, Audit Area or Process: _____

Name of the Auditor: _____

Name, Process Owner: _____

List of Auditees: **Feedback Date:**

Sr. No.	Name of Auditee (including process owner)	Audit Date	Who's Providing Feedback
1			☐
2			☐
3			☐

Please find rate our auditors based on your experience during our recent internal audits.

Sr. No.	Criteria	Very Good	Good	Fair	Poor
1	Auditor notified about the audit at least one week before the start of audits.	☐	☐	☐	☐
2	Audit was performed with minimal disruption to your daily activities.	☐	☐	☐	☐
3	Internal auditor was professional.	☐	☐	☐	☐
4	Communication skills.	☐	☐	☐	☐
5	Audit was conducted within the scope.	☐	☐	☐	☐
6	Knowledge about your department and interaction between other organizational process.	☐	☐	☐	☐
7	Level of accuracy of audit findings.	☐	☐	☐	☐
8	Level of recommendations/ consultation provided by the auditor.	☐	☐	☐	☐
9	Received completed audit report on time	☐	☐	☐	☐
10	Audit report was clear, concise and justified audit findings.	☐	☐	☐	☐
11	Recommendations in the final report will improve control of process/ performance of your process.	☐	☐	☐	☐
12	Do you feel this audit added value to your department / organizational process?	☐	☐	☐	☐

This feedback report will be used to improve the IQA process at D&M Industries.

Please take a moment to comment on the following:

13. Detail anything you liked about the audit process and/or auditor.

14. Detail anything you disliked about the audit process and/or auditor.

15. Provide your opinion on how the audit process can be improved.

16. Provide your opinion on how the auditor performance can be improved.

Figure B.3: Internal Quality Audit Feedback Form

B.5. Corrective and Preventive Action Procedure

1. Purpose:

1.1 The purpose of this procedure is to establish and outline the process for initiating, documenting, analyzing, and implementing preventive and corrective actions.

1.2 Corrective actions must be appropriate to the effects of the non-conformities encountered.

2. Scope:

1.1 This procedure applies to detect and potential nonconformities related to both, product and processes, that are identified from scrutiny of processes, work operations, quality records, internal audits and customer complaints.

1.2 This procedure can also applicable for actions taken for continual improvement.

3. Glossary:

a) CAR – Corrective action request

NC – Non-conformity

CAPA – Corrective Action and Preventive Action.

MR- Management Representative, Operations Manager

Compliance Manager

Commercial Sales Manager

Residential Sales Manager

PM- Purchasing Managers

Customer Service

4. Definitions:

4.1. Corrective/Preventive Action Request #

4.1.1 A unique # assigned to a Corrective/Preventive Action for easy identification and tracking purposes.

4.2. Corrective Action

4.2.1 Action taken to eliminate the root cause of a detected nonconformity or other undesirable situation to prevent recurrence.

4.3. Preventive Action

4.3.1 Actions taken to eliminate the cause of a potential nonconformity or another undesirable potential situation.

4.4. Requestor

4.4.1 Person who initiates and / or completes a CAR, Corrective Action Form #

4.5 Nonconformity, NC

4.5.1 Nonconformity is the 'non-fulfillment of a requirement'.

4.6 Root-cause:

4.6.1 Source of a defect such that if it is removed, the defect is removed or decreased.

4.7 Objective Evidence:

4.7.1 Verifiable qualitative or quantitative information that can be proven true, based on facts obtained through observations, records or statements pertaining to the quality of the product, process or system.

5. Roles and Responsibilities:

5.1 OM/MR - It is the responsibility of the OM to allocate necessary resources, as required, to ensure that corrective and preventive actions, where necessary, are

implemented throughout D&M Industries. OM/MR will approve/ reject the CAPA request.

5.2 Process owner or department manager is responsible for ensuring that the corrective actions and preventive actions are identified and implemented.

5.3 Process owners and or managers must ensure corrective action requests are closed after corrective actions have been taken.

5.4 Process owners and or managers must ensure that the results of the corrective actions are recorded to review the effectiveness of the actions implemented.

5.5 Process owners/ mangers should report to the OM about the effectiveness of CAPA implemented.

6. Procedure:

6.1 CORRECTIVE ACTION:

6.1.1 Corrective Actions: Corrective action is initiated when a NC or NC's are detected. Corrective Action Requests must be initiated by using a Corrective Action Request FORM as shown in figure B.5.

6.1.2 All NC's identified must be controlled using 'Control of Non-Conformance' procedure #_____.

6.1.3 CAR's can be initiated only by process owners/ managers, however, all CAR's must be authorized by OM/ MR.

6.1.4 The Requestor must typically, provide the following information on the CAR FORM

- *CAR #*
- *Type of request.*

- *Requestor Name.*
- *Request Date.*
- *Source of Request.*
- *Process where NC was identified.*
- *Problem description.*
- *Documented evidence of the problem or nonconformity identified.*

6.2 PREVENTIVE ACTION:

6.2.1 Study and analyze the data collected to determine areas needing preventive action.

6.2.2 Any employee who identifies a potential problem or nonconformance may request or initiate a Preventive Action Request using the CAR FORM# _____. However, it must be authorized by OM/MR.

6.3 CORRECTIVE / PREVENTIVE ACTION REQUEST REVIEW:

6.3.1 OM/MR ensures that CAPA Requests are reviewed as soon as possible and typically within 3 weeks.

6.3.4 OM/ MR approves or disapproves the CAR request received. If the request is not approved, the reason must be documented on the same form, signed and copy of form sent to the responsible department manager, process owner and requestor.

6.3.5 If approved, OM/MR sends a copy of signed form to the responsible department manager, process owner and requestor.

6.3.6 The manager or Process owner to evaluate the problem or NC based on following:

1. Potential Impact of the problem or nonconformity.
2. Risk to D&M Industries and its customers.
3. Remedial action that may be required to avoid recurrence.

6.3.7 The manager / process owner will initiate an investigation;

1. To determine the root-cause of the nonconformance.
2. To analyze the affected processes or operations.
3. To develop a Remedial Corrective/Preventive Action Plan to eliminate the root cause and prevent its recurrence.

6.3.7 The department manager / process owner must also ensure that they document the results of root cause analysis on the same form.

6.3.8 Assignee to ensure that proposed action plan is submitted within the 'Respond by' deadline, without failure. (2 Weeks to develop an action plan?)

6.4 CORRECTIVE / PREVENTIVE ACTION IMPLEMENTATION:

6.4.1 Process owners/ manager to discuss the action plan with the MR/OM and implement only if approved by OM/MR. As the action might require need for process changes and additional resources, prior approval of the plan is very important.

6.4.2 It is the responsibility of the department manager / process owners to ensure that the action plan is successfully implemented within the projected competition date specified on the form.

6.4.2 If any changes in the procedure and or process are being done, they must be documented and recorded using Document Change Request FORM# and retained as Quality Records.

6.4.3 Any training and or communication required after the implementation of action plan must be performed, documented using FORM# and retained as Quality Records.

6.5 VERIFICATION OF CORRECTIVE / PREVENTIVE ACTION EFFECTIVENESS.

6.5.1 Allow sufficient time to generate and gather objective evidence of effectiveness (at least 4 or 5 weeks?).

6.5.2 After the successful implementation of the corrective or preventive action, department managers must request engineering manager to verify the effectiveness of the action or actions taken. (Effectiveness of actions must be performed by independent individuals or internal auditors.)

6.5.3 All such verifications must be completed prior to management review meetings and internal audits.

6.5.4 The 'verification of effectiveness' reports as shown in figure B.4, must be made available to the MR/OM at least 1 week before the management review meetings and internal audits?

6.5.5 Any Corrective / preventive actions implemented less than 4 weeks before the management review meetings and internal audits must be presented at the management reviews with 'Insufficient data' status?

B.5.1. Filling out a Corrective Action Request from (Work Instructions)

1. **Purpose:**

1.1 The purpose of this document is to guide the process owners and managers to identify, correct, and eliminate reoccurring problems to establish permanent corrective actions to target product and process improvement.

1.2 These work instructions satisfy the requirements of 'International Standards Organization 9001:2008 Clause 8.5 – Improvement'.

2. **Scope:**

2.1 These work instructions are applied to all the corrective and preventive actions to be implemented throughout D&M Industries Inc. irrespective of the process or functional area. Unless the Operations Manager / Management Representative bypasses these instructions.

2.2 These work instructions are implemented in part with the 'Corrective Action Request' form, the 'Corrective Action and Preventative Action' procedure, and the 'Verification of Effectiveness of CAPA Implemented' work instructions.

3. **Definitions:**

3.1 Containment: Immediate action taken to isolate a product with a NC from any internal or external customer. For more information, refer to the 'Control of Non-Conformance' procedure.

3.2 Corrective and Preventive Action Request #: A unique number assigned to a corrective or preventive action for easy identification and tracking purposes.

3.3 Corrective Action: Action taken to eliminate the root cause of a detected non-conformance or another undesirable situation to prevent reoccurrence.

3.4 Preventive Action: Action taken to eliminate the cause of a potential non-conformance or other undesirable potential situation.

3.5 Requestor: Person who initiates and/or completes a CAR.

3.6 Non-Conformance: The non-fulfillment of a requirement. Requirements can originate from the customer, vendor, government body, or D&M itself.

3.7 Root Cause: Source of a defect such that if it is removed, the defect is eliminated or decreased.

3.8 Objective Evidence: Verifiable qualitative or quantitative information that can be proven true through logical arguments. The information is based on facts obtained through observations, records or statements pertaining to the quality of the product, process or system.

3.9 5-Why's?: A root cause analysis approach used to identify the root cause(s) to a problem. How it works is you simply ask the question 'Why?' five times, which by the 5th why, the true root cause(s) have probably been found. *NOTE: This is not a guarantee way of finding the root cause(s) to a problem. Further investigation and analysis may be needed.*

3.10 High Risk: Unacceptable Risk. Might need to review current process controls, update process design, add more controls, etc. Might cause harm to a user of the product (therefore the possibility of a lawsuit), or cause a whole shipment/order to be rejected by the customer.

4. Responsibilities:

4.1 The OM/MR is responsible for;

a) Ensuring that these work instructions are successfully implemented when and where necessary
b) Allocating necessary resources, as required, to ensure that corrective and preventive actions, where necessary, are implemented throughout D&M
c) Being the CAR Administrator, therefore deciding the final approval or rejection of CAR forms
d) Monitoring the progress of all implemented CAPA plans to ensure they are finished before the set deadline
e) Appointing an IP/IA to carry out the CAPA effectiveness verification of the CAPA plans implemented

4.2 The PO/DM is responsible for;

a) Ensuring that the CAPA are identified and implemented using the proper work instructions and related forms
b) The first approval of the CAR form from the Responder, and finish filling out the form by completing a root cause analysis and creating a CAPA plan
c) Revising the information on the CAR if changes are made to the process and/or any related documents
d) Keeping track of the CAR-specific process metrics if the CAPA plan is implemented
e) Ensuring that the results of the corrective or preventative actions are recorded to review the effectiveness of the actions implemented
f) Identifying appropriate methods of communication and required information to avoid non-conformities within the process

5. Work Instructions:

5.1 Having identified the NC or quality issue, the Requestor will first determine the need for containment and correct the nonconforming product or service and prevent its distribution or unintended use.

5.2 The Requestor assesses all risks associated with the identified NC, and if deemed necessary, submits a CAR form to the PO/DM in which the NC falls under.

5.2.1 The Requestor selects the type of action needed, the source of the request, the associated function or process where the NC occurred, writes an explanation of the NC, and finally creates a CAR #.

5.2.2 As part of the explanation, the Requestor will define and describe the NC or problem using the '4W2H' approach, What? Who? Where? When? How? How many?

5.2.3 This is also the section where the Requestor must also indicate if the NC is considered a High Risk.

5.3 The PO/DM shall decide if the CAR is accepted or not. If the CAR is accepted, the OM/MR will assign the responsibility for developing an action plan to the PO/DM. If it's rejected, the OM/MR may request the Requestor to investigate further into the NC.

5.4 The PO/DM shall first properly define the problem by gathering the necessary quantifiable and/or qualitative data. Then they will determine, identify and verify the root cause(s) of the problem or NC detected.

5.4.1 The PO/DM will establish a team of people consisting of all the necessary product and process knowledge, if deemed necessary.

5.4.2 There are multiple methods of root cause analysis, all of which have the same goal of finding the root cause(s) of a problem and not just its symptoms. At D&M, the

Engineering Department has decided that the ‘5 Whys?’ approach will be the default way for root cause analysis.

5.4.3 Use pictures if they would be helpful in explaining the NC in a concise and clear manner.

5.5 Develop an ‘CAPA Plan’ focused on permanently eliminating the root cause(s) of the problem / NC

5.5.1 Ensure to detail the action plan such that the results after implementation can be quantifiably analyzed. This allows for the evaluation of the effectiveness of the action implemented and whether improvements have been made.

5.5.2 Use pictures if they would be helpful in explaining the NC in a concise and clear manner.

5.6 Communicate the proposed CAPA plan, using the CAR form, to the OM/MR for final approval.

5.6.1 If the OM/MR rejects the CAR, the PO/DM will develop another CAPA plan.

5.6.2 If the OM/MR approves the CAR, the PO/DM will implement the CAPA plan before the deadline date specified on the CAR form.

5.7 Once the CAPA plan has been fully implemented, the PO/DM will notify the OM/MR, who will update the CAR form with the CAR completion date.

5.8 The OM/MR will then determine an appropriate time frame for verification of CAPA effectiveness. The following are guidelines to help with just that:

5.8.1 Allow relatively less time after implementing the action plan when there is:

5.8.1.1 Higher opportunity for occurrence and observation

5.8.1.2 Higher probability of detection

NOTE: In these cases, fewer observations are needed for a high degree of confidence.

5.8.2 Allow relatively more time after implementing the solution when there is:

5.8.2.1 Lower opportunity for occurrence and observation

5.8.2.2 Lower probability of detection

NOTE: In these cases, more observations are needed for a high degree of confidence.

5.9 Internal auditor or independent personnel appointed by the OM/MR will then follow the 'Verification of Effectiveness of CAPA Implemented' work instructions.

5.10 All documents and records of verification are maintained by D&M in accordance with the 'Master Document Index', 'Master Quality Record Index', 'Control of Documents' procedure, and 'Control of Records' procedure.

B.5.2. Verification of Effectiveness of CAPA Implemented (Work Instructions)

1. Purpose:

1.1 This document details work instructions related to performing verification of effectiveness of corrective and preventive actions using the 'CAPA Effectiveness Verification Criteria' form.

1.2 These work instructions satisfy the requirements of 'International Standards Organization 9001:2008 Clause 8.5 – Improvement'.

2. Scope:

2.1 These work instructions are applied to verification of all the corrective and preventive actions implemented throughout D&M Industries Inc. irrespective of the process or functional area.

2.2 These work instructions are implemented in part with the 'Corrective Action and Preventive Action' procedure, the 'Corrective Action Request' form, the 'Filling-Out

the CAR Form' work instructions, the 'CAPA Effectiveness Verification Criteria' form, and the 'Internal Auditor Manual' work instructions.

3. Definitions:

3.1 Containment: Immediate action taken to isolate a product with a NC from any internal or external customer. For more information, refer to the 'Control of Non-Conformance' procedure.

3.2 Corrective and Preventive Action Request #: A unique number assigned to a corrective or preventive action for easy identification and tracking purposes.

3.3 Corrective Action: Action taken to eliminate the root cause of a detected non-conformance or another undesirable situation to prevent reoccurrence.

3.4 Preventive Action: Action taken to eliminate the cause of a potential non-conformance or another undesirable potential situation.

3.5 Requestor: Person who initiates and/or completes a CAR.

3.6 Non-Conformance: The non-fulfillment of a requirement. Requirements can originate from the customer, vendor, government body, or D&M itself.

3.7 Root Cause: Source of a defect such that if it is removed, the defect is eliminated or decreased.

3.8 Objective Evidence: Verifiable qualitative or quantitative information that can be proven true through logical arguments. The information is based on facts obtained through observations, records or statements pertaining to the quality of the product, process or system.

4. Responsibilities:

4.1 The OM/MR is responsible for;

a) Ensuring that these work instructions are successfully implemented when and where necessary

b) Allocating necessary resources, as required, to ensure that corrective and preventive actions, where necessary, are implemented throughout D&M

c) Appointing an IP/IA to carry out the CAPA effectiveness verification

4.2 The PO/DM is responsible for;

g) Ensuring that the CAPA are identified and implemented using the proper work instructions and related forms

h) Ensuring that the results of the corrective or preventative actions are recorded to review the effectiveness of the actions implemented

i) Identifying appropriate methods of communication and required information to avoid non-conformities within the process

4.3 The IP/IA is responsible for;

a) Verifying whether the action plan implemented has permanently eliminated or mitigated the cause of the problem or NC

b) Ensuring CARs are closed after corrective actions have been successful and verified for their effectiveness

c) Reporting to the OM/MR about the effectiveness of CAPA implemented

5. Work Instructions:

5.1 IP/IA will first verify if CAPA effectiveness verification can be carried out or not on the date of verification. I.e. is there enough data to do a proper verification of the CAPA plan?

5.2 CAPA effectiveness can be verified through the four following ways:

5.2.1 AUDITING

5.2.1.1 Auditing is used when the CAPA plan involves changes to a system or process and the verification process is confirming that the changes from the plan have been put in place procedurally and are in use behaviorally.

5.2.2 SPOT CHECKING

5.2.2.1 Spot Checking is a set of random observations of a process's performance or reviews of KPIs or quality objective records. Spot checks provide immediate but limited-insightful feedback.

5.2.3 SAMPLING

5.2.3.1 Sampling is observations of variables or attributes of a physical product, as per a defined sampling plan or inspection plan. E.g. sampling received product during a routine receiving inspection, for checking the effectiveness of the CAPA plan changes made to the receiving inspection plan.

5.2.4 TREND ANALYSIS

5.2.4.1 Trend Analysis is the analysis of recorded data of a process's performance. This method looks at the data over a certain time span to verify that the expected results of the CAPA plan were achieved or not. Trend analysis provides good time-based insight but requires more data therefore longer periods of time between analyses. I.e. a sample review of records after the CAPA plan has been implemented, to find any data trends or new NCs.

5.3 IP/IA shall notify the PO/DM of the process at least 3 (three) business days before carrying out CAPA effectiveness verification.

5.4 The day of the verification date, the IP/IA will use the ‘CAPA Effectiveness Verification Criteria’ form to document any verification findings and communicate the effectiveness verification outcome to the OM/MR.

5.4.1 When filling out the ‘CAPA Effectiveness Verification Criteria’ form, the IP/IA shall use the following effectiveness ratings:

5.4.1.1 **Effective (Yes)**

5.4.1.1.1 CAPA are implemented as intended, have addressed the root cause(s) of the issue/NC, will prevent recurrence of the issue/NC, and demonstrates sustainability. No new corrective or preventive actions are recommended or required.

5.4.1.2 **Partially Effective (Partially)**

5.4.1.2.1 CAPA are implemented as intended, and have partially addressed the root cause(s) of the issue/NC, but does not prevent recurrence or demonstrate sustainability. Revised or new corrective or preventive actions are recommended to enhance the effectiveness of the CAPA plan.

5.4.1.3 **Ineffective (No)**

5.4.1.3.1 CAPA were not implemented as intended, does not address the root cause(s) of the issue/NC, does not effectively prevent recurrence of the issue/NC, and/or does not demonstrate sustainability. New corrective or preventive actions are recommended to enhance the effectiveness of the CAPA plan.

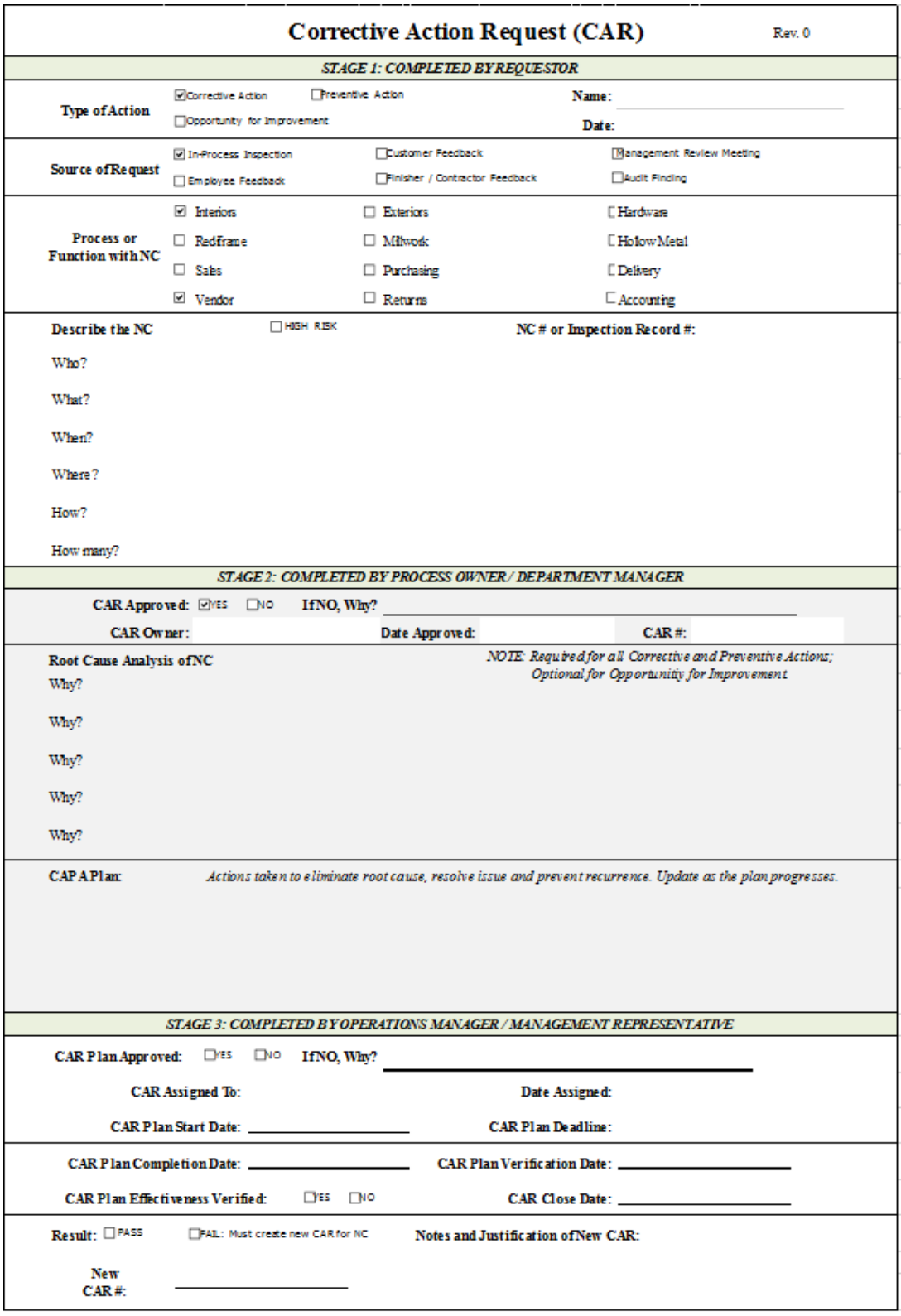
5.5 All documents and records of verification are maintained by D&M in accordance with the ‘Master Document Index’, ‘Master Quality Record Index’, ‘Control of Documents’ procedure, and ‘Control of Records’ procedure.

Verification of Effectiveness of CAPA Implemented (Form)

CAR Verification #:		**Date of Verification:**			
CAR #:		**Date Implemented:**			
Sr. No.	**CAPA Effectiveness Criteria**	**Effective**			**Justification**
		Y	***P***	***N***	
1	Was the action plan implemented on time?				
2	Corrective action was implemented as intended?				
3	Was the action plan communicated to those associated and affected by the process?				
4	Revisions were made to all the documents, where necessary?				
5	Associated employees were trained after changes made?				
6	Everyone is using the latest versions of the documents?				
7	Was the NC/ problem understood by everyone involved in implementing the action plan?				
8	Was the NC/problem correctly documented and verified, before requesting for CAR?				
9	Did the process achieve its new objectives, if any?				
10	Process KPI’s and quality objectives were successfully accomplished?				
11	Same Nonconformity or problem has reoccurred?				
12	New Nonconformity or problems were identified?				
13	Did the action plan, improve the process performance?				
14	Process could deliver outputs successfully?				
15	Process owner or manager took remedial actions to correct the same deficiencies after the action plan was implemented?				
16	Containment action successfully taken?				

Note: Y = Yes P= Partially N = No

Figure B.4: Verification of Effectiveness of CAPA Form



Corrective Action Request (CAR)

Rev. 0

STAGE 1: COMPLETED BY REQUESTOR

Type of Action ☑ Corrective Action ☐ Preventive Action ☐ Opportunity for Improvement

Name:

Date:

Source of Request ☑ In-Process Inspection ☐ Customer Feedback ☑ Management Review Meeting ☐ Employee Feedback ☐ Finisher / Contractor Feedback ☐ Audit Finding

Process or Function with NC

☑ Interiors	☐ Exteriors	☐ Hardware
☐ Redframe	☐ Millwork	☐ Hollow Metal
☐ Sales	☐ Purchasing	☐ Delivery
☑ Vendor	☐ Returns	☐ Accounting

Describe the NC ☐ HIGH RISK **NC # or Inspection Record #:**

Who?

What?

When?

Where?

How?

How many?

STAGE 2: COMPLETED BY PROCESS OWNER / DEPARTMENT MANAGER

CAR Approved: ☑ YES ☐ NO **If NO, Why?**

CAR Owner: **Date Approved:** **CAR #:**

Root Cause Analysis of NC

NOTE: Required for all Corrective and Preventive Actions; Optional for Opportunity for Improvement

Why?

Why?

Why?

Why?

Why?

CAPA Plan: *Actions taken to eliminate root cause, resolve issue and prevent recurrence. Update as the plan progresses.*

STAGE 3: COMPLETED BY OPERATIONS MANAGER / MANAGEMENT REPRESENTATIVE

CAR Plan Approved: ☐ YES ☐ NO **If NO, Why?**

CAR Assigned To: **Date Assigned:**

CAR Plan Start Date: **CAR Plan Deadline:**

CAR Plan Completion Date: **CAR Plan Verification Date:**

CAR Plan Effectiveness Verified: ☐ YES ☐ NO **CAR Close Date:**

Result: ☐ PASS ☐ FAIL: Must create new CAR for NC **Notes and Justification of New CAR:**

New CAR #:

Figure B.5: Corrective Action Request Form

B.6. Management Review Meetings Procedure

1. Purpose:

1.1 This procedure defines the process and methods for conducting management reviews, at planned intervals, of the quality management system implemented at D&M Industries to ensure its continued suitability, adequacy and effectiveness.

1.2 This procedure also describes the management review meetings inputs and outputs.

2. Scope:

2.1 This procedure is applicable to all the processes, departments and functional areas under the scope of QMS mentioned in the quality manual.

3. Glossary:

a) AS - Audit Schedule

b) MR - Management Representative

c) QMS - Quality Management System

d) NC - Nonconformity

e) OBS - Observations

f) QA - Quality Auditor

g) MRT - Management Review Team

h) EM - Industrial Engineer

4. Roles and Responsibilities:

4.1 Management Representative:

1.1. It is the responsibility of the Management Representative to ensure that management review meetings are conducted at least once annually to ensure continued

working and effectiveness of QMS. MR is responsible for the successful implementation of this procedure at D&M Industries.

5. Procedure:

5.1 CONDUCTING MANAGEMENT REVIEWS:

5.1.1 Top Management of D&M Industries will review its quality management system for suitability, adequacy and effectiveness by conducting formal "Management Review Meeting" held every 3 months? Or quarterly?

5.1.2 QMS can also be reviewed during ongoing management activities, if necessary. The formal "Management Review Meetings are held at a minimum of once per year:

i. To determine effectiveness of QMS to meet customer, regulatory & contractual requirements.

ii. To identify risks, opportunities for improvement.

iii. To correct and prevent NC's.

5.1.3 Top management and other employees in the following list must attend the "Management Review Meetings". Other employees might also be invited, if necessary, to meet the agenda of the meeting.

List of the attendees.

Name	Top Management, Position
	Chairman/President
	Vice-President
	Operations Manager and MR
	HR Manager
	IT Manager

5.1.4 Date for the next management review must be set during the previous management review. It is recommended to have at least 3-month gap between the management reviews meetings. For the first 2 years of QMS implementation, Informal management meetings will also take place after internal audits have been conducted.

5.1.5 All the managers listed above are expected to participate in the meetings. If any attendee is absent, draft minutes will be sent by MR to him/her using management review report to voice his/her opinion.

5.1.6 Management review meetings must be documented as a quality record using "Management Review Agenda" Form #.

5.2 MANAGEMENT REVIEW AGENDA: INPUT TO MANAGEMENT REVIEW MEETINGS

5.2.1 The Management Review Meeting shall include analysis of the following inputs:

Sr. No	**Agenda**	
1	Follow up	Top Management shall start management reviews by a follow-up of all the activities and output from previous management review.
2	Quality Policy	Top Management shall review Quality Policy, QP of D&M Industries for adequacy and to ensure it remains consistent with the needs of customers and industry. Review of QP to ensure it is appropriate to D&M's purpose and provides commitment to comply with the requirements and continually improve the effectiveness of QMS implemented at D&M.

		Is regularly reviewed for suitability, communicated and understood throughout D&M. Provides framework for establishing and reviewing quality objectives.
3	Quality Objectives	Review of Quality Objectives, QO, to ensure that it is fit for the purpose, measurable and consistent with the QP. Top management shall decide if the quality objective will be maintained, is achievable and if new objective shall be set.
4	Process Metrics and KPI's	Review and updating of Process Metrics and KPI's. Top management shall decide if current Metrics and KPI's will be maintained, is achievable and if new Metrics and KPI's shall be set.
5	External and Internal issues	Top Management shall seriously review any external and internal issues of concern.
6	Customer Returns and Customer Feedback	Top Management shall seriously review customer feedback; customer returns and determine the root causes of all returns.
7	Audits	Review the results of internal audits.
8	Corrective Actions	Review status of all CAR's requested and implemented, their effectiveness and related trends. Top management shall also review the effectiveness of all the actions taken to address risks and opportunities.
9	Vendor Performance	Top Management shall also review vendor performance and status and effectiveness of V-CARs.
10	Outsourced Processes	Top Management shall also review performance if outsourced processes (strainers, painters, etc.), including direct shipping.
11	Resources	Review of the adequacy of resources. (Man, material, information, documents etc.)

12	Continual Improvement	Review of recommendations and opportunities for improvement of QMS throughout D&M Industries.

5.3 MANAGEMENT REVIEWS MEETING OUTPUT

5.3.1 Management Representative shall ensure that all the changes that could affect the quality management system are reviewed and documented to ensure only updated versions are available for use.

5.3.2 The Management Review Meeting shall generate following outputs:

1. The date of the next scheduled Management Review Meeting
2. Actual attendance at the meetings,
3. Any changes to the quality policy required,
4. Any new quality objectives,
5. Any Corrective and Preventive Actions recommended,
6. Improvements needed to maintain the effectiveness of the quality management system and its processes,
7. Improvement of product related to customer requirements,
8. Resource needs,
9. Assignments to Top Management for preparing the Management Review meeting inputs for the next meeting, and any additional action items identified during the review.

6.3.3 Management review meetings shall generate Corrective and/or Preventive Action Requests. Initiate corrective actions throughout D&M Industries to improve the quality management system, its products, processes and services.

6.3.4 This includes any decisions and actions related to the improvement of the effectiveness of the quality management system and its processes, improvement of product related to customer requirements, and resource needs.

MASTER DOCUMENT INDEX

DOCUMENT DISTRIBUTION LIST

SR. No.	QMS Document Name	Type of Document	First Release	Storage Location	Operations Manager	Sales	Purchsing	Production Scheduling	Warehouse 2	Production Manager	Packaging and Delivery	Customer Service - Returns
1	Commercial Sales	SOP	Sep-16									
2	Control of Customer Property	QP	Sep-16									
3	Control of Documents	QP	Sep-16									
4	Control of Non-Conformance	QP	Sep-16									
5	Control of Records	QP	Sep-16									
6	Corrective Action and Preventive Action	QP	Sep-16									
7	Customer Satisfaction Survey	F	Sep-16									
8	Customer Service	SOP	Sep-16									
9	D&M Inudstries - Quality Manual	QM	Sep-16									
10	Damaging Product on the Line	WI	Sep-16									
11	Filling-Out the CAR Form	WI	Sep-16									
12	Guide for Writing SOPs	QP	Sep-16									
13	Hospitality Sales	SOP	Sep-16									
14	Internal Audit Report	F	Sep-16									
15	Internal Auditee Feedback	F	Sep-16									
16	Internal Auditor Manual	WI	Sep-16									
17	Internal Quality Audit	QP	Sep-16									
18	ISO 9001:2008 Standard	EXT	Y:2008									
19	Management Review Meeting	QP	Sep-16									
20	Management Review Meeting Minutes	F	Sep-16									
21	Measurement, Analysis, and Improvement	QP	Sep-16									
22	NMHS Internal Audit Checklist	EXT	Sep-16									
23	Order Parts Adjustments/Substitutions Frame Master/Composite Items	SOP	Sep-16									
24	Order Parts Adjustments/Substitutions Inventory Items	SOP	Sep-16									
25	Purchasing Process	SOP	Sep-16									
26	Receiving Inspection Plan	WI	Sep-16									
27	Receiving Inspection Sheet	F	Sep-16									
28	Residential Sales	SOP	Sep-16									
29	Return Inventory Disposition	SOP	Sep-16									
30	Returns – Contract Sales or Residential Replacement	SOP	Sep-16									
31	Returns – Driver – No Form or Service Technician	SOP	Sep-16									
32	Returns – Driver – Scheduled or Service Technician with RA Form	SOP	Sep-16									
33	Returns – Sales Representative – Form Completed	SOP	Sep-16									
34	Returns – Sales Representative – No Form	SOP	Sep-16									
35	Returns – Third Party Shipper	SOP	Sep-16									
36	Returns – Will Call / Walk In	SOP	Sep-16									
37	Risk Management	QP	Sep-16									
38	Sales Contract Review	QP	Sep-16									
39	Vendor Corrective Action Request	F	Sep-16									
40	Vendor Performance Evaluation and Qualification to AVL	QP	Sep-16									
41	Vendor Quality Manual	WI	Sep-16									
42	Vendor Quality Questionnaire	F	Sep-16									
43	Verification of Effectiveness of CAPA Implemented	WI	Sep-16									
44	Employee Performance Evaluation	F	Sep-16									
45	Vendor Corrective Action Request, V-CAR	F	Sep-16									

Key: *QM = Quality Manual, QP = Quality Procedure, SOP = Standard Operating Procedure, WI = Work Instructions, F = Form, EXT = External Document*

Figure B.6: Master Document Index Form

MASTER RECORD INDEX

SR. No.	QMS Record Name	First Release	Last Revision Date	Record Type	Retention Period	Record Owners	Storage Location	Protection
1	Approved Vendors List	Oct-16		Electronic	3 Years	Purchasing Manager, PM		Password Protected
2	Calibration of Machine & Equipment's Log	Oct-16		Electronic	3 Years	Production Manager		Password Protected
3	CAPA Log	Oct-16		Electronic	3 Years	MR/ OM		Password Protected
4	Contract Review Log	Oct-16		Electronic	3 Years	Shared		Password Protected
7	Customer Satisfaction	Oct-16		Electronic	Permanent Record	Sales M, Customer Service		-
10	D&M's Production Ticket	Oct-16		Paper	3 Years	Shared		-
11	Employee Training Status/ Record	Oct-16		Electronic	3 Years	HR, Corporate Trainer		Password Protected
12	Internal Quality Audits Schedule	Oct-16		Paper	3 Years	MR/OM, Internal Auditors		Password Protected
13	Machine Maintenance Log	Oct-16		Electronic	3 Years	Production Manager		Password Protected
14	Management Review Meeting Meetings	Oct-16		Paper	3 Years	MR/ OM		Password Protected
15	Master Document Index	Y:2008		Electronic	Permanent Record	MR/ OM		-
17	Master Quality Record Index	Oct-16		Electronic	Permanent Record	MR/ OM		-
18	Non-Conformance Log	Oct-16		Electronic	3 Years	Shared		-
19	Process Status and Importance Tracker	Oct-16		Paper/ Electronic	3 Years	MR/ OM		Password Protected
21	Returns Tracking	Oct-16		Electronic	Permanent Record	Sales M, Customer Service		-
22	Risk Assessment Register	Oct-16		Paper	3 Years	MR/OM, Internal Auditors		-
23	Vendor Credit Tracking	Oct-16		Electronic	Permanent Record	Inventory Specialist		Password Protected
26	Vendor Performance Log	Oct-16		Electronic	3 Years	Purchasing Manager, PM		Password Protected
27	Vendor Selection Criteria	Oct-16		Paper	Permanent Record	Purchasing Manager, PM		-
28	W1 Receiving Inspection Sheet	Oct-16		Paper/Electronic	3 Years	Production Manager		-
29	W2 Receiving Inspection Sheet	Oct-16		Paper/Electronic	3 Years	W2 Supervisor		-

Figure B.7: Master Record Index Form

QUALITY INSPECTION SHEET

Interior Doors

Ticket #:

NC #:

Date:

NC Identified							
✓	Risk	Disposition		Inspection Stage 1: Warehouse 2 Door Pullers	Lines 1-10	Lines 11-20	Lines 20+
			1	Is the information on the ticket clear and correct?			
			2	Is the material aesthetically acceptable?			
			3	Verify slab information; Core, Material, # of Panels, Size			
			4	Verify slabs are stacked in the correct size and handing sequence			
			5	Is each individual door labeled with a item tag?			
✓	Risk	Disposition		Inspection Stage 2: Production Foreman/ Operator	Lines 1-10	Lines 11-20	Lines 20+
			6	Verify if correct material was received from W2			
			7	Is the material aesthetically acceptable?			
			8	Verify Hinges and Screws; Type and Color			
			9	Verify Jambs; Size, Quantity, Material			
			10	Verify Machine Codes; Slab Size, Bore & Hinge Locations			
✓	Risk	Disposition		Inspection Stage 3: Door Hanger/ Assembler/ Loaders	Lines 1-10	Lines 11-20	Lines 20+
			11	Is the material aesthetically acceptable?			
			12	Verify Jambs; Size, Quantity, Material			
			13	Verify Heads; Size, Quantity, Material			
			14	Verify Stop Alignment on Jambs & Heads; **+/- 1/32"**			
			15	Verify Reveal; Tolerance **+/- 1/32"**			
			16	Verify Bore location; Tolerance +/- **1/32"**			
			17	Verify Hinge Locations; Tolerance **+/- 1/32"**			
			18	Verify Faceplate Depth; Tolerance **+0.025", -0.0"**			
			19	Is the material aesthetically acceptable?			

Note: Document all non-conformances. Use the below NC Codes and Disposition Methods to control the NC material

Disposition Methods		
A = Auction Trailer	**V** = Return to Vendor	**U** = Use as Is
D = Dispose	**S** = Return to Stock	**CW** = Use w/ Customer Waiver
H = Hold	**RP** = Repair	**RW** = Rework

H = High Risk; L = Low Risk; N = No Risk

Note: Identify the NC based on its risk

Figure B.8: Quality Inspection Sheet Form

APPENDIX C: QMS OPERATIONAL PROCESSES

C.1. Purchasing Process

1. **Purpose:**

   1.1 This procedure describes the requirements for an effective purchasing process at D&M Industries Inc.

   1.2 This procedure satisfies the requirements of 'International Standards Organization 9001:2008 Clause 7.4 – Purchasing'.

2. **Scope:**

   1.1 This procedure is applied to all vendors, unless the Operations Manager / Management Representative or Purchasing Manager overrides this procedure.

   1.2 This procedure is implemented in part with the 'Vendor Performance Evaluation and Qualification to AVL' and the 'Receiving Inspection Plan' work instructions.

3. **Glossary:**

   a) D&M - D&M Industries Inc.

   b) ISO - International Standards Organization

   c) OM/MR - Operations Manager / Management Representative

   d) PM - Purchasing Manager

   e) AVL - Approved Vendors List

   f) VSC - Vendor Selection Criteria

   g) RIS - Receiving Inspection Sheet

   h) RIP - Receiving Inspection Plan

4. **Definitions:**

4.1 Vendor Selection Criteria: Criteria used to select vendors to be put onto the AVL. The criterion is based on; On-time Deliveries, Quantity Accuracy, and Product & Packaging Quality.

5. Roles and Responsibilities:

5.1 The OM/MR is responsible for;

a) Ensuring that this procedure is successfully implemented and followed at all D&M facilities

b) Ensuring that the selected vendors comply with D&M's requirements

5.2 The PM is responsible for;

a) Maintaining the AVL and relevant purchasing records

b) Identify appropriate methods of communication and required information to avoid nonconformities in the process

c) Evaluating, organizing, and documenting all vendors

d) Communicating vendor performance to the OM/MR

e) Maintaining, distributing and controlling the AVL

f) Maintaining and verifying vendor performance evaluation and quality records

6. Procedure:

6.1 SELECTION AND CONTROL OF VENDORS:

6.1.1 D&M uses the VSC to select vendors based on their ability to deliver products on-time, and that conform to all the required material and quality specifications.

6.1.2 The VSC controls what vendors are put on the AVL, and the Quality Status, seen below, rates vendors after evaluation. For more information, refer to the 'Vendor Performance Evaluation and Qualification to AVL' procedure.

a) (A*) Approved, Preferred

b) (A) Approved

c) (N) Non-Approved

d) (P) Provisional

6.1.3 All vendors are monitored and evaluated monthly based on their current and past performance.

6.1.4 All new vendors will be requested by D&M to complete the 'Vendor Quality Questionnaire', 'Vendor Quality Manual', and any other documentation deemed necessary by the PM

6.1.5 All records related to inspections and purchasing are made available for the Management Review Meetings.

6.2 PURCHASING PROCESS AND PURCHASING INFORMATION:

6.2.1 All purchases are made only from vendors listed in the AVL. Exceptions can be made only if the PM authorizes the new unlisted vendor.

6.2.2 PM maintains a process that ensures appropriate information is provided to the vendor to enable a request to be quoted.

6.2.3 PM checks the adequacy and accuracy of specified information and requirements prior to sending the quote request to the vendors.

6.3 VERIFICATION OF PURCHASED PRODUCT:

6.3.1 Not all products purchased will be delivered to a D&M facility. However, verification of D&M purchases must be done between the points of receiving from the vendor to just before arriving at the customer. D&M will work with the vendor to decide on a procedure that satisfies this requirement.

6.3.2 PM and OM/MR will make resources available to carry out the verification of every purchase against its PO and any other supporting delivery documentation. If purchases are to be received at a D&M facility, they must be inspected by a D&M employee.

6.3.3 When inspecting, the employee will use the RIS document while following the RIP procedure. Any significant issues with received material that may affect the quality of the finished product (damage, shortages, etc.) are documented by the inspector.

6.3.4 It is up to the inspector to decide the action to take depending on any non-conformances found through the inspection process. If the lot/shipment fails inspection, it could be rejected and then stored until the vendor either replaces, repairs, or personally inspects the rejected lot/shipment. For more information, refer to the disposition methods found in the 'Control of Non-Conformance' procedure.

6.3.5 All documents and records are maintained by D&M in accordance with the 'Master Document Index', 'Master Quality Record Index', 'Control of Documents' procedure, and 'Control of Records' procedure.

C.2. Vendor Performance Evaluation and Qualification to AVL

1. Purpose:

This document defines the 'Vendor Selection Criteria' record and the process on how a vendor will be evaluated and qualified for D&M Industries Inc.'s 'Approved Vendors List' record.

This procedure satisfies the requirements of 'International Organization for Standardization 9001:2008 Clause 7.4 – Purchasing'.

2. Scope:

2.1 This procedure is applied to all vendors, unless the Operations Manager / Management Representative or Purchasing Manager bypasses this procedure.

2.2 This procedure is implemented in part with the 'Purchasing Process' procedure and the 'Receiving Inspection Plan' work instructions.

3. Glossary:

a) VSC - Vendor Selection Criteria

b) D&M - D&M Industries Inc.

c) AVL - Approved Vendors List

d) ISO - International Organization for Standardization

e) OM/MR - Operations Manager / Management Representative

f) PM - Purchasing Manager

g) RIP - Receiving Inspection Plan

h) VCAR - Vendor Corrective Action Request

i) RIS - Receiving Inspection Sheet

j) VPL - Vendor Performance Log

k) NC - Non-Conformance

4. Definitions:

4.1 Approved Vendors List: A list of qualified vendors maintained and used by the Purchasing department and D&M facilities where purchased products are received.

4.2 Vendor Corrective Action Request: An action taken by the vendor to eliminate the cause of a detected nonconformity, problem or any other undesirable situation, therefore preventing reoccurrence.

4.3 Vendor Selection Criteria: Criteria used to select vendors to be put onto the AVL. The

criterion is based on; On-time Deliveries, Quantity Accuracy, and Product & Packaging Quality.

5. Roles and Responsibilities:

5.1 The OM/MR is responsible for;

Ensuring that this procedure is successfully implemented and followed at all D&M facilities.

5.2 The Warehouse Forman is responsible for;

a) Maintaining receiving inspection documentation and tools
b) Deciding when receiving inspection is NOT needed, while still ensuring some form of identification is used and the method of disposition for the items is decided upon
c) Communicating to D&M's Purchasing department concerning any received SO items that need to be re-purchased
d) The final decision maker for accepting or rejecting whole or parts of a delivery
e) Accountable for verifying successfully completed inspections by signing the 'Receiving Inspection Sheet'
f) Communicating any information regarding inspections or vendor performance to the OM/MR and/or PM.

5.3 The PM is responsible for;

a) Requesting corrective actions from a vendor using the VCAR form
b) Evaluating, organizing, and documenting all vendors
c) Communicating vendor performance to the OM/MR and EM
d) Maintaining, distributing and controlling the AVL

e) Maintaining and verifying vendor performance evaluation and quality records

f) Coordinating with the OM/MR to ensure only qualified vendors appear on the AVL

g) Periodic review/audit (at least annually) of the AVL

h) Identify appropriate methods of communication and information required to avoid nonconformities in the process

6. Procedure:

6.1 VENDOR PERFORMANCE EVALUATION:

6.1.1 Performances of all vendors are evaluated every month, based on the VSC. The information that will be evaluated against the criteria will come from the VPL.

6.1.2 For any vendor that Direct Ships (Products that goes directly from Vendor to D&M's customer) will need a more in-depth delivery performance evaluation. Additional methods and tools could be, but not limited to; Vendor's use of D&M's Load Condition Report (LCR) form, detailed audits or on-site meetings performed by D&M personnel, or a D&M assessment of Vendor's current direct ship documentation. Further or different methods and tools can be used, but only if the vendor and D&M agree upon them beforehand.

6.1.3 The VSC compares multiple vendor performance metrics that D&M tracks using the VPL and RIS. The four criteria that make the VSC are summarized below;

a) On-time Deliveries

b) Quantity Accuracy

c) Quality of Shipment

6.1.4 Quantity Accuracy evaluates quantity ordered versus quantity received. So not only does it evaluate whether the vendor missed any items or sent any extra, but it also looks at whether the vendor sent the correct items ordered.

6.1.5 Quality of Product simply counts how many items were received with damage, whether caused by the vendor or the freight company transporting the items.

6.1.6 Quality of Packaging looks at the three of the four Delivery Parameters; Condition of Pallet, Strapped and Sturdy, and Wrapping and Packaging. For more information, refer to the RIP work instructions or the RIS form.

6.1.7 Performance evaluations may result in a VCAR, dependent on the PM's decision and the vendor's Quality Status. Every NC related to the quality of product is analyzed by the PM and the results of the analysis are communicated to the OM/MR within one (1) business week.

6.2 INSPECTION CRITERIA:

6.2.1 All purchase order shipments, other than direct shipments, are inspected by a D&M employee. The D&M employee who is inspecting any received purchased products will verify the items against its corresponding PO. For more information, refer to the RIP work instructions and RIS form.

6.2.2 When the resources for the RIP are limited, the minimum requirements warranting an inspection are as follows:

a) ***Inspect List:*** A list of items that are to be inspected every time

b) ***New Vendor:*** All items received from a new unlisted vendor (any vendor not on the AVL) are always inspected

c) ***Outsourced items:*** All stained or painted items that are received at W2

6.3 INSPECTION FINDINGS:

6.3.1 It is the responsibility of inspector to record the findings of each inspection by filling out the RIS.

6.3.2 Any NC identified during inspection, such as damage, incorrect material, or late delivery, must be recorded and communicated to the appropriate Warehouse Forman, and if applicable, the PM and EM, within (1) one business day. For more information, refer to the disposition methods found in the 'Control of Non-Conformance' procedure.

6.3.3 The PM or a purchasing agent, will enter the data from each RIS into the VPL.

6.4 VENDOR QUALIFICATION TO AVL:

6.4.1 The PM analyzes the data from the VPL every month end, using the VSC, and assigns a Quality Status to each vendor; (A*) Approved, Preferred, (A) Approved, (N) Non-Approved, or (P) Provisional.

6.4.2 The Quality Status is based on the Total Score Earned, generated by the information entered the VPL. The Total Score Earned is represented as a percentage that quantifies the vendor's results against the VSC. The higher the percentage, the better the vendor is performing.

6.4.3 Vendors are identified as 'Approved, Preferred' vendors if they have continually delivered products in a way that meets and exceeds all of D&M's VSC. One of the following conditions must be true:

a) D&M receives a copy of the vendor's ISO 9001:2008 or ISO 9001:2015 certificate

b) After (6) six successive acceptable lots, each meeting the Total Score Earned of 70% or higher

c) Their average of Total Score Earned from the last qualification is higher than 90%

d) A passing on-site audit, meeting or exceeding D&M's OM/MR and PM expectations

e) OM/MR or PM override this procedure

6.4.4 Vendors are identified as 'Approved' vendors if any of the following conditions are true:

a) After (3) three successive acceptable lots, each meeting the Total Score Earned of 70% or higher

b) If their average of Total Score Earned from the last qualification is between 70% and 90%

c) An on-site audit, meeting minimal requirements set by D&M's OM/MR and PM

d) OM/MR or PM override this procedure

6.4.5 Vendors are identified as 'Non-Approved' vendors if any of the following conditions are true:

a) After (3) three successive lots, each below 70% VSC Total Score Earned

b) If their average Total Score Earned from the last qualification is below 70%

c) A failed on-site audit by D&M's OM/MR and PM

d) Failure to respond to (1) one or more VCARs within 30 days

e) A Management Review Meeting decision

f) OM/MR or PM override this procedure

6.4.6 Vendors are identified as 'Provisional' vendors if any of the following conditions are true:

a) No previous history of doing business with D&M

b) No business done with D&M for more than (2) two years

c) Vendor hasn't completed the 'Vendor Quality Questionnaire' and 'Vendor Quality Manual'

d) OM/MR or PM override this procedure

6.5 Vendor evaluations, status of VCARs, and any quality issues are discussed between the OM/MR and PM on a regular basis. This ensures the information discussed during Management Review Meetings is up-to-date.

6.6 All documents and records of vendor evaluations and qualifications are maintained by D&M in accordance with the 'Master Document Index', 'Master Quality Record Index', 'Control of Documents' procedure, and 'Control of Records' procedure.