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Development of the Optimal Quality Management System Model Based on the Implementation of the “Lean Six Sigma - ISO 9001” Based Quality Management Systems for Spectra Group Ltd.

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Abstract

Quality Management System (QMS) is an essential component that shows that a company is able to consistently produce products demanded by customers and indicates that a company is quality-driven and ready for systematic improvements. Spectra Group Limited is one of the worldwide suppliers of liquid material for 3D printing. They had an effort to implement the ISO 9001 but did not succeed in it. In order to develop the optimal quality management system the study developed four objectives that were based on the detailed understanding of the current situation at the company, identification of the best quality principles and tools, documenting information and data, finding the potential issues and areas for improvements and proposing the developed model. Since the quality documentation was not properly developed at the company there was an issue with obtaining the data for the project and most of the data for the study was retrieved from the interviews with employees and management of the company. One of the most important factors influenced the production process was the temperature of the environment. Therefore, the study completed research on the effect of the control of the environment temperature and its effect on the production line. The results indicated that the production cycle times will be reduced for all production lines and comfortable temperature will affect the increasing human productivity. Moreover, the study provides the documentation of the standard operating procedures in the production process and proposes the implementation of control documentation for involved in production line processes.

Keywords: ISO 9001, QMS, SME, Lean Six Sigma

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Chapter I: Introduction

Overview

The purpose of this chapter is to present the importance of the proposed project. The problem, objectives of the study, significance, assumptions, and limitations will be presented below.

Introduction to the Problem

Background. Quality Management System (QMS) is an organizational structure that dictates how the organization should do business and manages the quality in order to satisfy customer requirements through various quality procedures and techniques (Gordon, 2009). This framework demonstrates that the company is able to consistently produce products demanded by customers and indicates that the company is quality-driven and ready for systematic improvements. In the book "Out of Crisis", Deming (1986) states that only organizations which would be able to adapt a modern quality management philosophy will survive in today's constantly growing world economic competition. Therefore, Deming (1986) pointed out that satisfaction of external customers after QMS improvement leads to more efficient and effective internal operations, and, thus, increasing the performance rate of the whole organization. In support of this statement, Feigenbaum and Feingenbaum (2004) in their article claim that all processes are focused on the quality improvement, and this quality is nowadays determined by the same external customer rather than by the company which provides these products.

Yeung and Chan (1998) in their study report that a well-designed QMS with a proper management participation and a training system would lead to beneficial results in internal and external improvements of the whole organization. Moreover, the research concludes about the

possibility to accomplish a rapid QMS process. However, to gain all benefits from the implementation, the organization should understand that QMS is a continuous process, which should be processed gradually with full support of motivated employees and the management. Clapperton and Gamlen (2010) claimed in their work that a successful implementation of QMS depends on the people who use this system, and only encouraged employees may effect on the organizational improvements, cultural change, and provide proper training. Moreover, a successful QMS must be simple and well-designed which would be easy to understand and follow.

QMS is an essential component insuring the productivity and quality of the outputs of the company. It is a widely applied method in large and small enterprises with the expectation of the improvement of production process, quality of the product, and the enhancing of the strength of the relationships with suppliers and customers (Koc, 2007). Application of various quality techniques in order to meet customer requirements or improve overall production leads the company to the QMS culture (Ilkay and Aslan, 2012). ISO 9001, “Lean”, and “Six Sigma” are the most popular in this category of quality methods applied all over the world (Chinvigai et al., 2010). ISO 9001 standard based QMS are aimed to ensure that all phases and aspects of the company processes are focused on the achievement of organizational targets, with the most important being the customer satisfaction. The philosophy of Lean focuses on the identification of value-added and non-value-added activities and elimination of all waste in all areas of the production process, while the Six Sigma strategy is improving the overall performance by applying statistical methods in the processes (Pepper and Spedding, 2010). Increasing the

features of quality techniques became one of the targets of researchers and practitioners nowadays.

Customer satisfaction today is the primary factor for any organization to increase the profitability and productivity, and, thereby, to maintain a long-term competitiveness in the global market. The ability to produce a high quality product at the lowest cost is in the core of this development, which cannot be achieved only by applying control and repair techniques. A complete managerial model that covers the entire production process from the initial design process should be built (Taghizadegan, 2006). During the past few decades, researchers and practitioners have been working on the development of such management systems to improve or maintain market competitiveness. Among some developed systems, Lean Six Sigma (LSS) methodology was employed as an efficient management system for deploying a continuous improvement. This system represents an integration model of the two methods mentioned earlier in this text: Lean manufacturing and Six Sigma. Literature reviews show, significantly successful applications of this integrated approach in many companies (Thomas et al., 2008; Pepper and Spedding, 2010; Atmaca and Girenes, 2013; Timans et al., 2012). In addition, to ensure that all phases and aspects of the company processes are focused on the achievement of organizational targets ISO 9000 standard based QMS has appeared. In recent years, the ISO 9000 QMS has been broadly adapted and established as a standard that helps to build effective quality systems. The ISO 9000 documentation is one of the most important factors for organizations that demonstrates the ability of supply organizations to compete on the global market by being able to improve their quality and productivity (Koc, 2007). Generally, ISO 9000 represents the central techniques and structure for an effective, basic quality management system. It supplies the

standardized forms to properly document operation procedures and illustrates the way how operations should be done to produce the quality of customer's needs.

In 2011, a unified QMS model was proposed by Karthi et al. (2011) as an integration of the LSS and the ISO 9000-2008 standard, named as L6QMS-2008, which is used as the basic guideline for the proposed project. The proposed study considers a hypothetical model that consists of 20 steps. This model was successfully implemented and reviewed in two enterprises. An investigation on this process was reported recently by Karthi et al. (2014), indicating its significantly positive effects on the organizational performance.

Spectra Group Ltd., Inc (Spectra). 3- Dimensional or 3D printing is becoming the revolutionary change in the design field. By adding a layer upon layer the 3D printers can successively build anything from very precise intricate parts to the whole house from a digital model (Schubert et al., 2014). Applications of 3D printing in medicine, NASA, military, food, entertainment, and fashion give a clear understanding of the importance of this innovation. Based on the characteristics and features of the demanded products, such as accuracy, precision, colors, flexibility, strength, cost, etc., different types of 3D technologies with various kinds of raw materials might be chosen. Recent studies demonstrate the priority of the stereo lithographic (SL) technology over the plastic extrusion printers, which is based on the higher-resolution, professional print quality of the objects, and a lower costs. The SL technology is based on the photopolymer-based processes where high precision technologies control lasers directed to the tray filled with a liquid photopolymer resin and cause its solidification (Bartolo, 2011).

One of the worldwide suppliers of this liquid resin for 3D printing is Spectra Group Ltd., which is located in Ohio, United States of America. The company was founded in 1991 by

renowned photochemist Dr. Douglas C. Neckers and had an initial order on creation of 3D models for surgical planning based on Computerized tomography (CT) or Magnetic resonance imaging (MRI) scan images, which was developed by Neckers in the laboratories of the Center for Photochemical Sciences at Bowling Green State University. In present days, the company focuses on the photo polymerization, light based color change, and organic and synthetic chemistry produces products (Anderson, 2013). Photochemistry and photopolymers experts employed by Spectra provide development and creative solutions for a large variety of products demanded by customers. Many of the staff are Ph. D. graduates from Bowling Green State University. Availability of their own equipment and collaboration with University of Toledo allow Spectra to provide a wider list of services and products with high level of quality inspection. Recently the company started to extend the variety of their services by producing a larger variety of products (Kuebeck, 2013).

With the interest in 3D printing growing rapidly, the company faces the possibility of a tougher competition on the market. Nowadays, 3D printing is everywhere; in schools, homes, industries, design companies, manufacturing, and research laboratories. Roberts and Mckrell (2015) report about new invented material that allows printing of electro conductive objects, and, moreover, about new process of formation 3D objects in a liquid. Liquid resin is one of such new products for 3D machines that Spectra produces. The production process is not automated since the company does not supply the products in the amounts that would require any type of automation. However, recent data shows an increasing demand on the product and reveals growing interest from the customers. Based on the research by the company management, Spectra purchased a new mixing equipment to increase the productivity, which substantially

improved the overall process. However, increasing the production volume of the liquid resin leads to another issue of the bottling and packaging processes. To resolve this issue, Spectra management has ordered a semi-automatic equipment for the bottling and packaging processes. The semi-automated packaging equipment is expected to dramatically increase the productivity, keeping the same level of the involved labor. The scale-up processes which happen currently in Spectra present an interesting case of study from the point of view of the quality analysis. In this project, the production process of the liquid resin for 3D printing developed by Spectra specialists will be examined using the integrated QMS framework discussed above.

Statement of the Problem

The problem for this study is to develop an optimum QMS for Spectra Group Limited.

Objectives for the Study

Four objectives are necessary to accomplish the study as follows:

1. Analyze the current quality system documentation at Spectra Group Limited.
2. Identify relevant quality principles and tools for a Spectra QMS model.
3. Develop improvements necessary to account for the new changes in the business model of Spectra.
4. Propose a new Spectra QMS model.

Significance of the Study

Small companies have many barriers to overcome in the battle for the place in the global market. Providing better products to its customers nowadays is not enough to survive. In the development of the products, competitive costs and higher quality should also be considered. QMS system is one of the ways to address those issues. Recently it was established that the

number of certified small and medium enterprises (SME) has dramatically increased and many studies have been conducted to examine if the ISO 9000 has effect on the SMEs performance (Ilkay and Aslan, 2012; Bhuiyan and Alam, 2005). Besides, most of the examples of LSS application come from large companies. There is still limited number of literature on implementation of LSS in SMEs (Timans et al.,2012). Thus, current research will demonstrate such application and possibly will be used in the future as a guide for the LSS application in SMEs. Moreover, eliminating waste and reduction of variability and errors would be a big step toward continuous improvement for Spectra.

According to the data from the article written by Williams (2005), the QMS improves the quality of decisions and increases the possibility of producing better goods. QMS is the key factor for companies in the continuous improvement, which may increase many profitable factors of the company; for example, completion of the study may increase the consistence of delivering the service and products in time. Moreover, documented procedures and manuals are a valuable data source for the further research and development since it is a beneficial guidance for researchers to establish data records. Evaluation and analysis of these data is an essential tool to guide the process to the continuous improvements. As company grows and reaches a certain size, it is necessary to have additional managerial employees and a properly prepared process of documentation to succeed in the continuous growing of the company. Moreover, the existence of documented standard operating procedures can increase the value of a company as a quality driven company which cares about its suppliers and customers. Also, quality documentation is used in training procedures for employees, because the work instruction and documentation help to understand the production process. Therefore, quality analytical and descriptive tools may

indicate about process limitations, possible defects, and recommended actions, which should be included in the proposed "optimum" Spectra Model. This model may be a good step for the ongoing and future improvements for the company. Therefore, successful development of Spectra Model can be an essential indicator for other organizations to see how QMS impacts firm performance.

Limitations of the Study

A successful development of the QMS model for the Spectra may not reflect the same outcomes for other small companies due to two reasons. Firstly, this study cannot provide sufficient evidence of its positive adaption by other small organizations. The other reason is related to the culture of the organization. Spectra is a chemical company and all the management and employees are trained chemists, which has its implications on the organizational culture that may not be applicable to other companies producing different products/services.

Another limitation is the lack of literature found on the implementation of the proposed model of L6QMS-2008 to conclude that implementation brings positive results. Moreover, the review of literature shows that different articles refer to SMEs as organizations with different number of employees. For example, some studies indicate that SMEs are companies with less than 500 people. Thus, it is possible that some studies published about companies with 100-500 employees are not appropriate to our study since the Spectra has only twelve employees.

Two limitations appeared during the project implementation:

1. The study do not provide estimation of reduced cycle times for production line 2 and 3 due to limited data collected during the project.

2. The project used simulated data based on the data gathered from interviews with employees of the company.
3. The study does not consider that fact that in summer period the temperature in the building reaches the temperature more than optimal temperature selected for the study. Thus, the viscosity of the materials is lower and the cycle time at those days is lower than calculated improved process cycle time.

Assumptions of the Study

Several assumptions during the project might be applied. These are:

1. The information retrieved from the Spectra employees is truthful.
2. Existing documentation was up to date.

Definition of Acronyms

QMS (Quality Management System): QMS is an organizational structure that dictates how the organization should do business and manage quality in order to satisfy customer requirements through a various quality procedures and techniques (Gordon, 2009).

ISO 9000: ISO9000 is an international quality systems standard originated by International Organization for Standardization (ISO). Based on external needs and as a guide to build own quality management system, the ISO 9000 is used as standards for the quality management and quality assurance (Aggelogiannopoulos et al., 2007). Generally, ISO 9000 represents the central techniques and structure for an effective, basic quality management system (Koc, 2007).

LSS (Lean Six Sigma): LSS is a concept that combines two philosophies: Lean and Six Sigma, where Lean focuses on eliminating non-value added activities and waste and Six Sigma

illustrates a statistical tools and techniques to maintain defect rate by variation reduction (Pepper and Spedding, 2010).

SL (stereo lithographic technology): SL is a technology that processes the curing or solidification of a liquid photopolymer through the use of light power (Bartolo, 2011).

CT (Computerized (or computed) tomography): CT is a cross sectional view of the body that is generated by a combination of many X-ray beams (Stöppler, 2014).

MRI (Magnetic resonance imaging): MRI is a medical imaging technique that uses a magnetic field and reflection pulses of radio waves to make pictures of organs and structures inside the body (Magnetic Resonance Imaging, 2014).

Chapter Summary

The purpose of the chapter one was to discuss the importance of the proposed project for quality control of the Spectra Group Ltd. and for other small companies. The purpose of the study, objectives of the study, significance, assumptions, and limitations were presented along with the general terminology of this project.

Chapter II: Review of Literature

Overview

The focus of this chapter is to introduce the model for the implementation of Lean Six Sigma (LSS) technique using the ISO 9001-2008 standard based quality management systems. The literature review will present a historical overview, background, and practices of ISO9000QMS and LSS. Additionally, the chapter provides a brief discussion on possible quality techniques and tools identified as the best applicable for Spectra.

LSS QMS model

8th International Conference of Modeling and Simulation in 2010 (Chinvigai et al., 2010) reported about a proposal to integrate LSS and ISO 9001 into CMMI-DEV for performance improvement. The proposed model integrated ISO 9000, CMMI-DEV, Lean manufacturing, Six Sigma, and Kaizen techniques. Nevertheless, In 2011 Karthi indicated in his research that there is no published studies on the integration of LSS with ISO9001-2008 QMS. Since Karthi's articles are the only resource on this topic, the study explores the background and the implementation of Lean Six Sigma and QMS methodologies. Karthi's model is the only identified model of LSS implementation using the ISO 9001:2008 standard, which is exactly the purpose of the proposed study. The roadmap (figure 1) to implement LSS through ISO 9001-2008 was demonstrated by Karthi et al. (2011).

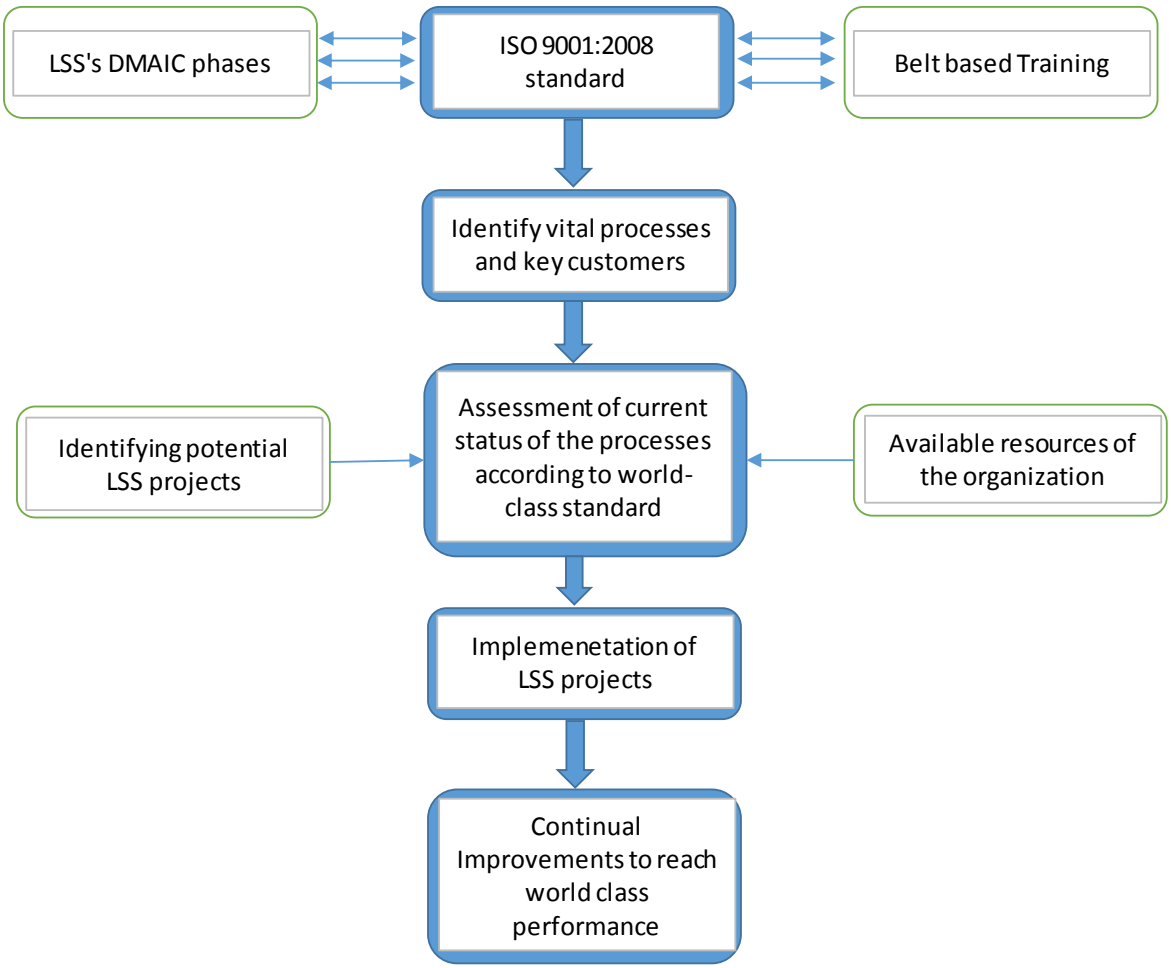

Figure 1: The guide to implement LSS through ISO 9001-2008.

Karthi et al. (2011) have developed LSS ISO 9001-2008 QMS model that consists of eight phases incorporated in integration of DMAIC methodology of Six Sigma, Belt-based training infrastructure, LSS tools and techniques, and ISO9001-2008 standard based QMS. Proposed structure for the implementation of LSS ISO9001-2008 QMS for any organizations

was presented in 20 hypothetical steps. These steps represent the guidelines for the coordinator to implement a proposed methodology. Particularly, the hypothetical model listed necessary meeting, trainings, preparations and implementation identified projects, its documentation, and evaluation of implemented L6QMS-2008 model.

A recently published article (Karthi et al., 2013) indicates about a successful application of the proposed earlier model of L6QMS-2008 in a textile mill. The author states that there were no difficulties during this process, and the 20 steps listed above clearly informed the team members about the purpose and technique of the integrated model. In another paper, Karthi (2014) indicates results from the implementation of the proposed model in two enterprises.

Although no other studies were found on the same topic, Thomas et al. (2008) work demonstrated an LSS model that was successfully implemented in a small engineering company, and may be used as a guide for our project since the Spectra is a small company as well. The LSS model was developed based on the integration of Lean techniques with the Six Sigma model, which was implemented successfully in a number of small and medium size organizations. The model accurately shows each stage up to the solving problem and thereby pushing the system toward continuous improvement (appendix B). The integrated LSS model was based on implementation DMAIC methodology and application of Lean tools.

ISO 9000 QMS

Background. Defined as the QMS standard (Ilkay & Aslan, 2012), ISO 9000 is applicable to any type of manufacturing or service organization and all company sizes. The original standards for the American military were transformed to the manufacturing field in 1987 with the purpose to provide the international framework with the quality assurance and also as

guidance for any organizations to design their own quality systems. It is aimed to manage and improve the quality culture of organizations to be able to follow customers' requirements. The initial version of ISO 9000 consisted of five parts: ISO 9000, 9001, 9002, 9003, and 8402 (Aggelogiannopoulos et al., 2007). ISO 9000 standard is the most popular standard from its launch with a rapidly increasing adoption rate in the world (Bergman, 1994). The first corrections of "quality assurance via preventive actions" to the standard were applied and released in 1994. The next changes were made in version 2000 where three standards ISO 9001, 9002, and 9003 were introduced as one single standard ISO 9001:2000. Every year, ISO conducts surveys to identify a number of ISO certificates given to around the world (ISO, 2014). The latest amendments were released in 2014 under the ISO 9001:2008. The linear increase of ISO application still demonstrates its worldwide popularity (figure 2).

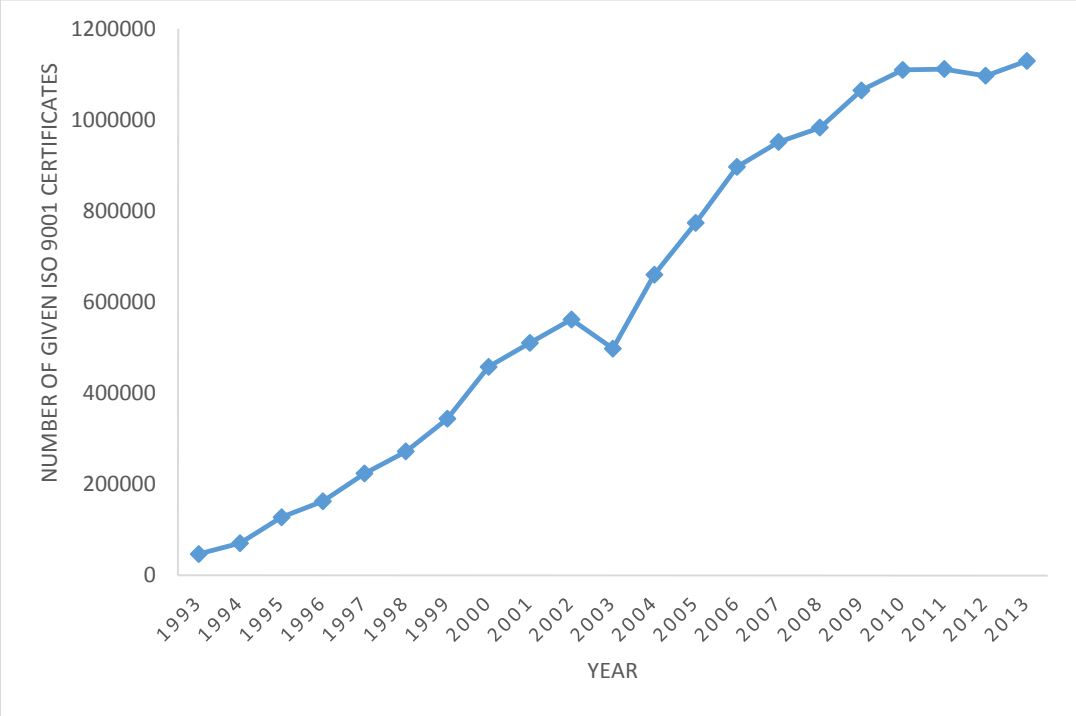

Figure 2: ISO 9000 worldwide statistic.

Application of ISO 9000 QMS in SMEs. Many studies examined application of ISO 9000 QMS in the small and large companies. However, most of the studies examined small companies (Anderson and Sohal, 1998) since small organizations meet more difficulties in the implementation ISO 9000 QMS (Taylor, 1995). Taylor pointed out that small companies are indicated to have specific issues related to understanding the purpose of ISO 9000, techniques of measuring its business effect, and learning of where the potential advantages may lie. Poksinska et al. (2006) revealed from the literature review that there are three major factors that influence the successful implementation of ISO standards. The first factor is the understanding of people of what is the quality and quality systems. The second factor is the missing knowledge about ISO 9000. The third factor is the inappropriate motivation for certification such as customer requirements, which leads to a lesser commitment from the management. The final important factor is the lack of resources since the certification is an expensive process for small companies. However, McAdam and McKeown (1999) concluded from the literature review that the benefits from implementing the ISO 9000 standards can by far outweigh the costs of the certification process.

A variety of literature is available about the benefits and the impact of the ISO certification for SMEs on the performance. While some studies indicate that there are no benefits or no effect on the firm performance, others show that there is a significant effect on performance and other benefits. Bhuyan and Alam (2005) explored the findings in their study in a small manufacturing firm. They indicated that even though the implementation met many obstacles, the outcome of the ISO was beneficial for the organization. Examination of eight small companies in the study by McTeer and Dale (1994) indicates the positive implementation of ISO

9000 QMS, concluding that benefits prevail over negative results. Koc (2007) studied the effect of the ISO 9001 certification on the small and medium firm performance. He examined 106 organizations in Turkey. Conducting survey which consisted of four parts (availability of ISO 9000 certification, firm performance, manufacturing parameters, and competitive priorities) and ANOVA analysis, the study resulted that there is a great positive impact of ISO certification on the firm performance.

On the other hand, Ilkay and Aslan (2012) also did the same research on the SMEs in Turkey. They examined in total 255 of certified and non-certified small and medium-size companies. Motivation and quality practices were the main factors for the study. Their survey consisted of three parts (level of quality application, firm performance, and information about company). Using statistical tools to analyze data collected by the surveys, they identified that there is no significant difference in firm performances between certified and non-certified. However, additional data analysis determined that internally motivated companies demonstrated higher performance over externally motivated. Poksinska et al. (2006) concluded that the obtaining of certification was the only visible benefit from the ISO implementation; thereby, demonstrating no significant effects on the performance.

ISO 9001:2008. Since its publication, the ISO standard was revised several times: in 1994, 2000, and in 2008. Requirements of the ISO 9001:2008 that can be applied to any type of organizations or industry can be seen in appendix B. Eleven aspects are listed with detail description which reflects the following (see appendix A):

1. General format and process of documenting QMS

2. Management commitment
3. Availability of resources for QMS implementation
4. Planning on production and realization processes based on customer requirements
5. Planning and control of the projects processes
6. Control for purchasing process
7. Standardized control of the products or services throughout their use
8. Measurement and analysis of the systems for continuous improvement
9. Control for elimination defect products from delivery to the customer
10. Analysis of the effectiveness QMS
11. Improvement of the QMS

Lean Six Sigma

The Lean Six Sigma is a concept that integrated two philosophies: Lean and Six Sigma. Both methodologies aim to improve organizational performance by increasing the efficiency and speed of the operations with the lowest level of defects. The ideas of Lean have their roots sometime after the World War II, initiated by Taiichi Ohno in implementation in Toyota Motor Company (Pepper and Spedding, 2010). Lean manufacturing focuses on the systematic elimination of wastes by identifying the losses in processes and reducing the complexity (Yang et al., 2011). Moreover, it helps to direct all resources on value adding operations. Later, Six Sigma was developed at Motorola in the USA in the 1980s and became popular after it was identified as the main quality improvement program at General Electric (Timans et al., 2012). Six Sigma model applies statistical techniques to reduce variation in the process ranging within acceptable limits in order to achieve three main objectives: customer satisfaction, cycle time, and

defect rate. It follows the five stage cycle of DMAIC (define, measure, analyze, improve, and control) which is standard approach or model to problem solving. In order to maintain this model the system has a number of tools and techniques such as statistical process control, design of experiments, and response surface methodology. Pepper and Spedding (2010) mentioned value stream mapping (VSM) as the first step in the Lean process and 5S, that will be discussed below, as the most broadly applied lean tool. Timans (2012) also indicates the popularity of 5S tool among the Lean manufacturing tools. However, the feedback on the usage and usefulness of Six Sigma tools is diverse since some of the tools and techniques are not known, or application depends on the type of manufacturing of the organization.

The literature search on the implementation of LSS in SMEs indicates a limited number of studies; however, they demonstrate significant improvements of the organizational performance after processing this powerful hybrid of two techniques: Lean management and Six Sigma. Pepper and Spedding (2010) revised literature on the interaction and integration of Lean and Six Sigma and concluded that there is no standardized model for LSS implementation. Atmaca and Girenes (2013) studied the reflection of LSS on the process improvement in the implementation in Turkey manufacturing company. Their work stated that the combination of Lean and Six Sigma brings more effective results together rather than separately. They indicate that this combination is a positive evolution for companies since these two techniques significantly fulfill each other. Lean methodology can be applied in all fields to increase company performance. Six Sigma provides all techniques and tools to maintain this improved performance. Particularly, while identifying the non-value adding activities through Lean process, Six Sigma makes each step of the process more effective. Moreover, major factors of

successful implementation of Six Sigma (leadership involvement, DMAIC tool, and belt based training) directly influence the effective implementation of Lean methodology. Surveys of leading academics and practitioners from five different countries (Antony, 2011) brought many opinions about these two techniques. However, all gaps of Lean manufacturing were fulfilled by Six Sigma features and the other way around too. After research on similarities and differences between the Lean and six Sigma approaches, he concluded his work with the statement that integrated approach would bring beneficial long lasting outcomes. The similarities of Lean and Six Sigma also has been studied in work written by Bendell (2006). This author has emphasized that, in the majority of the companies that implemented Lean Six Sigma, the Lean tools were included as a part of the Six Sigma training program.

Kumar et al. (2006) implemented Lean principles with the DMAIC technique of Six Sigma in an Indian SMEs. The process has used quality tools such as Charts, brainstorming, and 5S. The study highlights that the integration of these two methodologies as an effective and strong tool for improvement of firm performance. Timans et al. (2012) have conducted research on identifying critical success factors (CSF) on implementation LSS in SMEs in the Netherlands. Separating and highlighting the highest and strongest ranked factors, the research concluded that SMEs in Netherlands have mixed all tools and techniques from Lean and Six Sigma, which, eventually, demonstrated that there is no distinction for SMEs between Lean, Six Sigma, and LSS methodologies. Important improvements were achieved by implementing the LSS model in a small engineering company (Thomas et al., 2008). The paper shows a simple, but highly effective approach, which is based on the Six Sigma model that was successfully implemented in a number of organizations. Overall, analysis based on the literature review indicated that

development and application of LSS models have significantly positive effects on the cost, quality, and time of process performance.

VSM

Value Stream Mapping (VSM) is a graphical illustration of the production process representing material and information flow (Singh et al., 2011). It collects all activities in the process including value-added and non-value-added activities starting from the raw material up to the delivery to the customer. Elimination or reduction of the impact of the identified non-value-added activities is the purpose of this Lean tools. Patel et al. (2015) demonstrate the list of symbols commonly used in VSM (Figure 3).

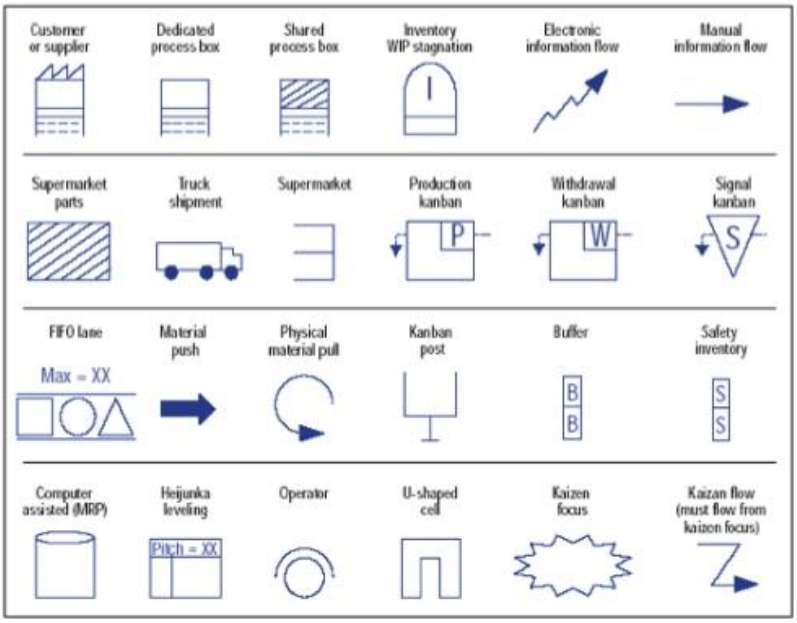

Figure 3: Typically used VSM symbols.

Data collection process for VSM starts with a review of the Operations Manuals and the Standard Operating Procedures (SOP) (Rahani and Al-Ashraf, 2012). Processing time

intervals are measured as important data related to the process flow in VSM. The VSM analysis consists of three steps: creating of the current value stream map; generating the future value stream map; and the development of the implementation plan.

5S

5S is widely popular as the first tool that was applied in Lean manufacturing methodology (Al-Aomar, R., 2011). Visualization is an efficient method that was used to reduce waste, clean workplace, and increase labor efficiency. The 5S is a Japanese technique that stands for seiri, seiton, seiso, seiketsu, and shitsuke, which were translated and transformed in English as sort, set in order, shine, standardize, and sustain (Bayo-Moriones et al., 2010). These five phases are explored as: Sort: Eliminating of waste or thing that is not related to current operation; Set in Order: identifying the best place for items and labeling them; Shine: cleaning of workplace; Standardize: Documentation the structure of improved work area; Sustain: control for implementation of the defined model for work area. The implementation of 5S broadly demonstrates reduction in materials and work floor area for the operation.

OPCP

Ongoing Process Control Plan (OPCP) is the documentation that represents the processing information of the ongoing production. OPCP documentations are the essential communication tools for current customers and for doing business in the future .This tool collects all general information about the processing and its procedural issues of the production. Aimed to provide better understanding of the process, the OPCP illustrates the key methods, techniques, tools, and other product parameters and characteristics. Moreover, the OPCP includes information about the product specifications required by customers, inspection method,

possible correction methods, and other information that is significant for process improvement. Thus, all the information combined in the OPCP might be collected from suppliers, customers, governing regulations, standards in industry, and so on. It is also very vital to understand that OPCP is a dynamic system that changes over time accepting process improvements, applying corrective and preventive actions.

Saux (2006) in his work demonstrated the typical process control plan layout where the information was documented as follows:

1. Process Operation: list of operations of the production process
2. Machine, Tool, or Device: equipment that is used for indicated operation
3. Control Characteristic: list of process parameters that is being controlled in the operation and equipment
4. Method: operation or technique that controls the control characteristic
5. Frequency: frequency of the process control
6. Control method: how the control is documented
7. Reaction Plan: corrective actions if failure happens
8. Performance Measurement: standard that indicate the success of the process control

SOP

Standard Operating Procedures (SOPs) are defined as a set of procedures that represent operations or activities aimed to manage the maximum production effectiveness. They are the basement of the Quality Systems (Yoswick, 2007), and can assist in monitoring of the performance, training supports, and as a starting point in the quality improvement process

(Chaneski, 1998). Although the origins of the SOPs are unclear, as was indicated in the Encyclopedia Britannica that the term initially came into use around the mid-1900s. Currently, SOPs are widely used ranging from military operations to business routines, and from manufacturing processes to medical activities (Chaneski, 1998). The experience of using SOPS clearly shows that a proper documentation of the production procedures is a very important practice, which became one of the requirements for the conformance to the products quality standards.

In the manufacturing process where the smallest failure can jeopardize the quality of the final product and affect the production cost, SOPs are important instructions to follow in order to avoid such failures. Quality specialists must utilize checklists in several stages to guarantee that products are matching the standards set by quality regulations, and that the general production process itself follows the required norms for conveyance to the general population. Numerous organizations design checklists to assess whether their SOPs conform to establish regulations of the quality control standards and whether they will in the end create an acceptable product. These checklists have turned into the most critical piece of the modern SOPs.

FMEA

Background. Failure Modes and Effects Analysis (FMEA) is a tool broadly applied to eliminate potential high - risk failures, analyzing their potential causes and effects. The FMEA was initially presented in the airspace field in the 1960s. Friendly introduced by people who had restricted specialized training, FMEA was widely adapted across companies and industries, mostly in the automotive industry, with the main objective to reduce risks and error rates (Chiozza and Ponzetti , 2009). Paparella (2007) reported in the paper that based on the 40 years'

of experience in FMEA application, no matter how knowledgeable the management is, there always will be a possibility of errors and risks, which are assumed to be "preventable and predictable". FMEA is a simple tool that unites the best personalities in your field to look deliberately at issues that are hazardous before they really bring unwanted consequences.

Teoh and Case (2004) in their study, where they used an object - oriented approach to build the FMEA model, indicated that FMEA may be classified into two types:

1. Design FMEA related to the design activities, and defined as a process of identification of the potential failure modes, causes, their effect on the production, level of risks, and current control of each sub-component of the product.

2. Process FMEA caused in the manufacturing process; particularly, conducted the same analysis process for each step that was identified from the process flow.

Teoh and Case (2004) indicated that the team for FMEA implementation is usually formed of specialists from various departments on the planning stage of the new product. Rhee and Ishii (2003) highlighted in their work that determination of 'root cause' and 'end-effects' of processed failures in the subsystem or component are usually in the design engineers responsibilities.

Chiozza and Ponzetti (2009) showed that even though the FMEA application might be very efficient and productive, it may also lead to consumption of other resources. However, well trained quality personal can greatly reduce these factors.

RPN. Failure modes identified in FMEA are assessed by a numeric score that represents the Risk Priority Numbers (RPN). Any improvements in the FMEA process would be indicated by this index (Teoh and Case, 2004). These scores are computed by three factors, each of which

are scaled from 1 to 10. The first is the estimation of the probability that the failure and the cause will occur, where the value of 10 represents the highest probability or failure of every other part and 1 represents one failure in million parts. The second is the detection index, which indicates the possibility of detecting a failure, where 10 correspond to the failure that is almost impossible to identify and 1 is the opposite. The third factor is the severity of the effect of the failure on a person or on the equipment (Rhee and Ishii, 2003). The multiplication of all three factors identifies the RPN factor, which is calculated for each defined failure mode. Consequently, the RPNs range from 1 to 1000. Evaluating the occurrence, detection, and severity is the responsibility of the cross-functional group, and it is very important to have a group familiar with the process that required the FMEA analysis. If the conflicts happen due to various scores, the average technique is applied to compute the factor's scores. RPNs that have a score of 125 or more are considered as required corrective actions; however, the first always reviewed the highest scored RPNs (Rath, 2008).

Improvement of the process starts from reducing the RPN scores. The severity is the first index that decreases when the recommended action is identified. Implementation of the corrective actions reduces the detection and occurrence indexes. Thus, the result of the multiplication of these factors that indicate the RPN score demonstrates the improving control system of the process due to reducing the failure level. In contrast, Rhee and Ishii (2003) indicate in their article about limitations of RPN score estimation and claim that the RPN, as a product of multiplication severity, detection, and occurrence, is not significant. The decision is based on confusion in understanding of the meaning of detection factor; specifically, detection might be related to the level of the company's control system or to the chance of the customer to

identify the failure, or “Are we trying to measure how easy it is to detect where a failure has occurred or when it has occurred? On the other hand, are we trying to measure how easy or difficult it is to prevent failures?”. Moreover, they claimed that conventional FMEA sheets provide limited space to explore the failure and its causes which constraining the understanding of the real problem and require additional resources on the problem.

Although Rhee and Ishii (2003) pointed out significant shortages of RPN factor in FMEA application, Leeuwen et al. (2009) demonstrated a successful application of the method to Near-Infrared (NIR) analytical procedure used for screening drugs on authenticity. The team of four people from different expertise was chosen for the FMEA analysis. During the process, 31 failure modes were identified and recommended actions implemented. The highest RPN scored failure modes were fixed. As a result they reported that the most failures are caused by human errors and concluded that FMEA is a useful method where there is a high probability of a human error.

Chapter Summary

The focus of the chapter two was to introduce the Lean Six Sigma model based quality management system ISO 9001 standard, historical overview, background, and practices of ISO9000QMS and LSS. Additionally, the chapter provided a brief discussion of possible quality techniques and tools identified as the best applicable for Spectra.

Chapter III: Methodology

Overview

This chapter provides an explanation of methods and procedures to develop an optimum model production system based on a Quality Management System. The chapter is composed of restatement of the purpose of the study, objectives for the study and procedures to achieve the objectives.

Restatement of the purpose of the study

The purpose for this study is to develop an optimum model production system based on a Quality Management System.

Objectives for the Study

Several objectives were necessary to accomplish the study, all based at Spectra Group Limited. The objectives of the project proposed as follows:

1. To identify the current quality system documentation at Spectra Group Limited.
2. To identify relevant quality principles and tools for a Spectra QMS model.
3. To continue developing documentation at Spectra as a new QMS model.
4. To propose a Spectra QMS model.

Each objective is restated and the steps required to address the objective are explained below.

Objective 1: To identify the current quality system documentation at Spectra Group Limited. Objective 1 requires two key steps to be fulfilled as follows.

1. Request an existing at Spectra quality documentation. Pre meeting with top management was conducted before the project started. The idea was to identify the current situation at Spectra; particularly, about quality documentation and any quality systems that were implemented or were made efforts to implement, and areas that require improvements. The retrieved from literature review L6QMS model was introduces to the president of Spectra to get approval and cooperation to implement it. Additionally, permission to involve company employees in surveys were needed.

2. Review of existing documentation. Based on the literature review it was identified that QMS has a mandatory set of documentation for organizations required by ISO 9001 which includes quality manuals, quality procedures manual, work instructions manual, and quality records (Aggelogiannopoulos et al., 2007). Thus, the primary attention was to identify the existing of these documents at Spectra. After reviewing the retrieved documentation the meeting will be conducted to introduce the L6-QMS methodology and purpose of its implementation to management.

Objective 2: To identify relevant quality principles and tools for a Spectra QMS model. Objective 2 requires five key steps to be fulfilled as follows.

1. Identify organizational culture based on review of documentation, interviews with employees and management, size of the company, and resources available (Sousa-Poza et al., 2009). After conversation during a pre-meeting with the director of the company it was identified that the organization had some efforts to initiate quality documentation process. The provided PFMEA document and flowchart of the Spectra process indicated about this quality documentation. However, documentation such as work instructions, SOPs, quality manuals, and

other quality papers are missing, and this issue requires more investigation since some documentation might be lost or kept in other archives.

2. Identify the problematic operations at the company based on documentation review and interviews with company employees.

3. Organize and define the L6QMS projects for identified operations and discuss with top management about its implementation.

4. Identify plan for implementation of the projects according to DMAIC methodology.

5. Based on the type of the operation, involved parameters, ISO 9001:2008 requirements, and literature review identify best Lean and Six Sigma tools and techniques applicable for identified issues.

Objective 3. To continue developing documentation at Spectra as a new QMS model. Objective 3 requires three key steps to be fulfilled as follows.

1. Based on conducted research based on Objectives above, 1 and 2, continue documenting identified missing instructions and manuals according to the requirements of ISO9001:2008.

2. As soon as the operations for implementation of L6QMS and quality tools which are best for these processes are identified, the meeting with management is required. Introduction of quality tools and techniques is very important to understand and use as a quality driven process rather than as a requirement from top management.

3. Identified best quality principles and tools for identified operations should be initiated in process to identify non-value added activities and wastes in production.

Objective 4. To propose a Spectra QMS model. Objective 4 requires three key steps to be fulfilled as follows.

1. Based on identified and processed documentation identify potential areas for improvements and generate the improved model for Spectra.
2. Estimate the potential improvements based on simulated expected parameters.
3. Introduce the created model for the process to top management at Spectra.

Established objectives and key steps should be organized in project plan spreadsheet and updated during the project.

Chapter Summary

The purpose of chapter three was to give an explanation of methods and procedures to develop an optimum model production system based on a Quality Management System. The chapter was composed of restatement of the purpose of the study, objectives for the study and steps to achieve the objectives.

Chapter IV: Findings and Analysis

Overview

The purpose of chapter four is to provide findings and data analysis of the study carried out at Spectra, with the goal of making specific methodological conclusions and making recommendations based on the results obtained at Spectra. This chapter is composed of the specific for Spectra restatement of purpose of the study, objectives, analysis of the findings according to each objective, and conclusions and recommendations.

Restatement of the purpose of the study

The purpose for this study is to develop an optimum model production system based on a Quality Management System based on the model of Spectra Group Limited.

Objectives for the Study

Several objectives were necessary to accomplish this project, all based at Spectra Group Limited. The objectives are stated as follows:

1. To identify the current quality system documentation at Spectra Group Limited.
2. To identify relevant quality principles and tools for a Spectra QMS model.
3. To continue developing documentation at Spectra as a new QMS model.
4. To propose a Spectra QMS model.

Findings and Analysis

Objective 1

According to the request to gain the existing quality documentation, the management of the company prepared a file with all documents regarding the existing quality control and quality

assurance at Spectra. Even though the interview with the CEO indicated that no work instructions and procedures were documented, it was identified that the company had an attempt to develop documentation to obtain ISO 9001 certification. Thus, the administration provided a documented control plan, process flowchart, and PFMEA analysis. Moreover, all equipment technical instructions were provided as an additional resource of information about the process.

A review of the retrieved documentation showed that the implementer of the documentation did not have sufficient amount of knowledge about the quality documentation procedures, since files indicated that the information was collected from the perspective of chemists only, and not all operations were included in documentation. Even though the process is chemistry related, it is very important to consider the technical and logistical aspects of the process and all operations. The plan of the project was introduced to the top management of the company to show what kind of information will be requested from all employees and clarify the availability of time for interviews.

Objective 2

Identification of relevant quality principles and tools for the Spectra QMS model was based on the review of literature and documentation, organizational culture, and understanding of the production process. As, it was mentioned above, the company had an attempt to implement the ISO 9001 program, but only in order to respond to a customer request where, provided documents were very helpful to understand the production process.

In this project, the A3 technique was used as the initial step to create VSM of the current and future production processes. Individual interviews with each employee were used to collect

detailed information about the entire process by writing everything on one sheet to let everyone see comments of previously interviewed personnel. Then, based on the gathered data, it was identified that the company has three main production lines, where each line produces several types of product., and VSMs of the current process for each production line was drawn in the Microsoft Excel worksheet (see figures 4, 5, and 6).The timelines for each operation in the VSM were estimated, based on the three runs of the production lines during the company visits.

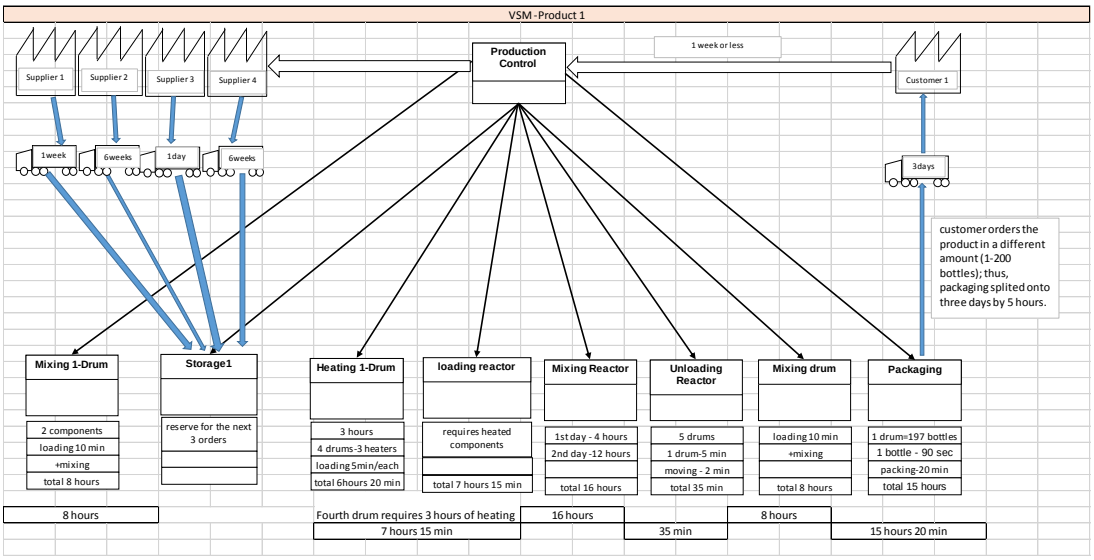

Figure 4: VSM Production line 1

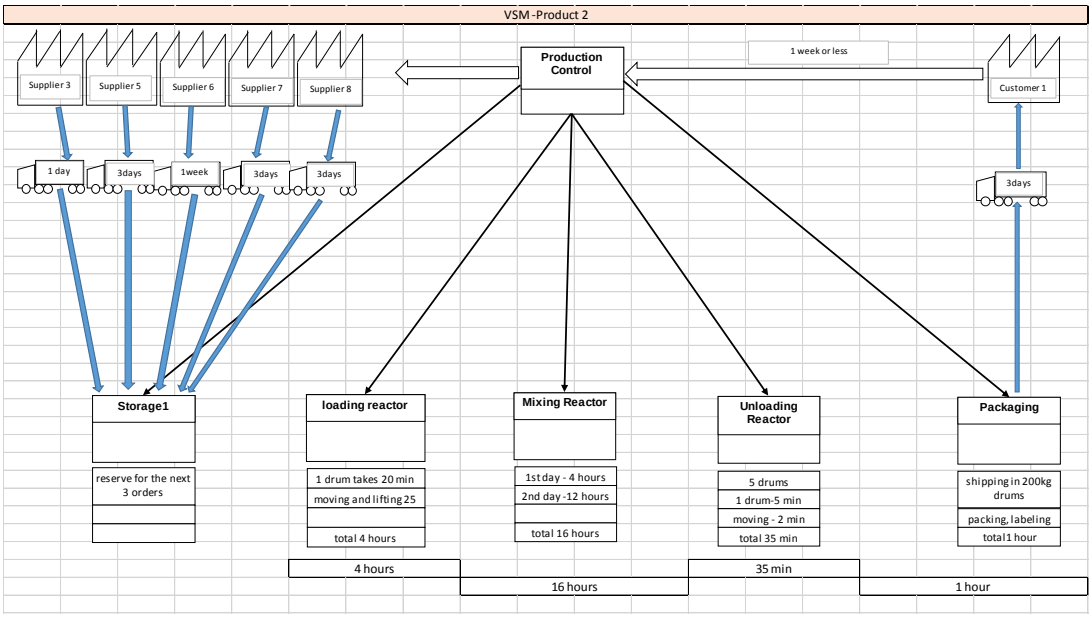

Figure 5: VSM Production line 2

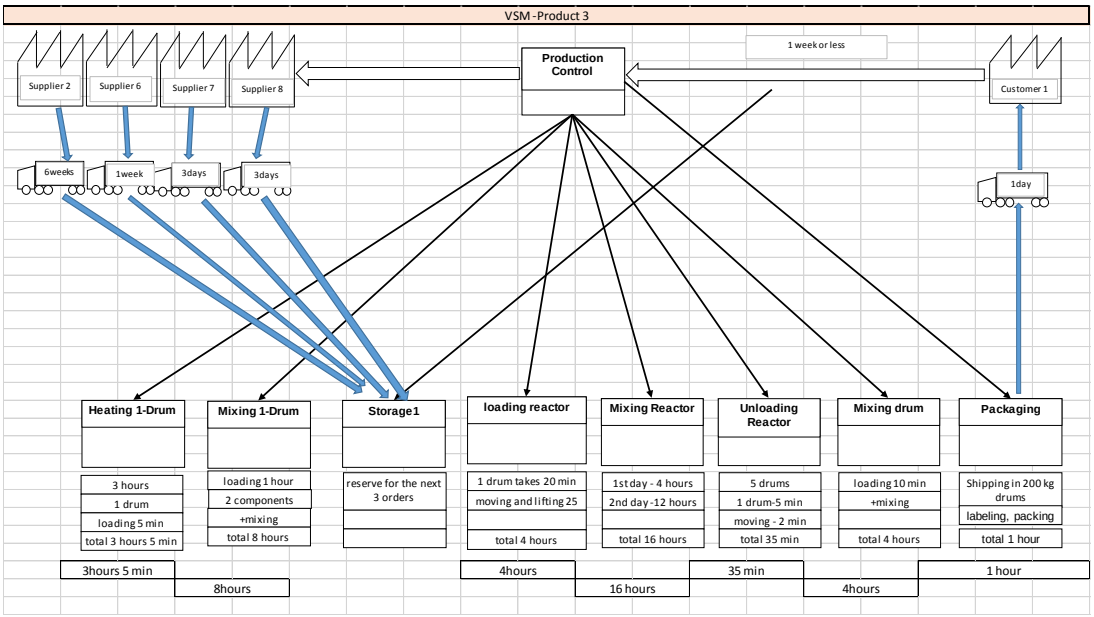

Figure 6: VSM Production line 3

Chiozza and Ponzetti (2009) reported that FMEA is a broadly applied tool used to identify and eliminate potential high - risk failures. According to the reports by Teoh and Case (2004) the study selected and developed PFMEA methodology separating all steps in the production line and identifying potential failures for each operation. However at Spectra, the PFMEA analysis (see appendix F) was not complete due to the lack of control information about the operations and equipment in the production process. Thus, since the PFMEA process failed, it was important to implement required process control documentation into organization.

All gathered data about the production process indicated that the cycle time of the operations relied on appropriate environment conditions, which in this case, represents the temperature in the building. Process engineers described that the temperature affects the viscosity of the materials and thereby directly affected the process of loading and unloading of the material from one reservoir to another. This variation was understood and discussed with top management, where we proposed three different ways to eliminate variation:

- Build a storage room for the drums with the material for the production line
- Build the skirt for the reactors and install heaters inside
- Separate the room of production process and control the temperature in the entire room

The management was interested only in the analysis of the last proposal and asked for the analysis and estimation of the cycle time reduction. Top management requested the quick analysis based on the approximate values of the required parameters. Thus, the study had to use simulated dataset for the project. The plan for the implementation was developed according to the DMAIC principle (see table 1).

Table 1: Project Implementation Plan

Implementation Plan

Phase	Objectives	Start date	Finish date
Define	Identify parameters that are critical in the identified project Design the control documentation form for identified parameters	12/5/2015	12/6/2015
Measure	Identify optimal value for the control parameters Identify approximate values for identified parameters according to the feedback from the employees	12/5/2015	12/8/2015
Analyze	Collect all data and identify the relationships between the identified sets of values Estimate the time reduction according to the collected data	12/6/2015	12/9/2015

	Present the results to the top management of the company	12/8/2015	12/9/2015
Improve	Implement control documentation and conduct training		
	Document gathered data and information for identified operations	12/8/2015	12/12/2015
Control	Identify employees responsible for the control and updating of the implemented documentation	12/12/2015	12/14/2015

The plan for the project was based on brainstorming with the process engineer and the VP of the company on a regular meetings basis. The plan was clearly defined and described with all the required steps of the implementation. Data for the project had to be collected from the interviews with employees and the designed VSM for the current process. Analysis of the data was carried out by using a statistical plot in Microsoft Excel. Calculation of the reduction times carried out using basic mathematical knowledge. Documentation of all information gathered during the implementation was required as SOPs for the operations. Finally, responsibility had to be based on the decision of the top management of the company.

Objective 3

During the documentation of the SOPs (see appendix L) for the operations in the production line, the interviews reported that the company had issues, which required training tools for employees to overlap another employee responsibilities during vacations and days off. Such limitations led to production delays. To implement the control documentation into the process, the study prepared forms that would be beneficial for further analysis of the proposal to control the temperature of the working area (see appendixes I, J, and K).All forms created were based on the fact that higher temperature decreases viscosity, resulting in faster loading and dissolving time during mixing processes. Moreover, heating processes will be shorter since the initial temperature of the drums will be higher in colder weather conditions. The need and meaning of each column in the forms were explained to the management. A proposal to implement control documentation was accepted, but some employees believed that this was a waste of time.

The task of understanding the production process and the analysis of the VSM of the current process indicated that there are only few operations involved in cycle time of the production line. These are Loading Drums, Mixing in drums, Loading Reactor, Mixing in Reactor, Packaging, and Shipping. Ordering and receiving raw materials were not considered in the production cycle since all materials required for production were always ordered prior to the customer orders and the company always controlled the amount of materials in stock that would be enough to produce the next few batches. Thus, as soon as the customer made an order; the process immediately started by loading the products into the reservoir.

Objective 4

Based on the proposal made to the management to implement the control of the temperature in the building, it was necessary to demonstrate the analysis methodology and potential improvements to the top management of the company. Thus, simulated data was required to accomplish a thorough analysis (see appendixes G and H). To simulate the data, the study conducted an interview of the process engineer and packaging operator, to identify approximate values of required parameters for each operation for the study. Estimation of the time reduction of the production operations and overall process required few steps:

1) Build a chart in Excel with an illustration of the data of the temperature versus time required for each operation, and since the plot demonstrates linear regression; extract the formula for this regression (see figures 7, 8, and 9).

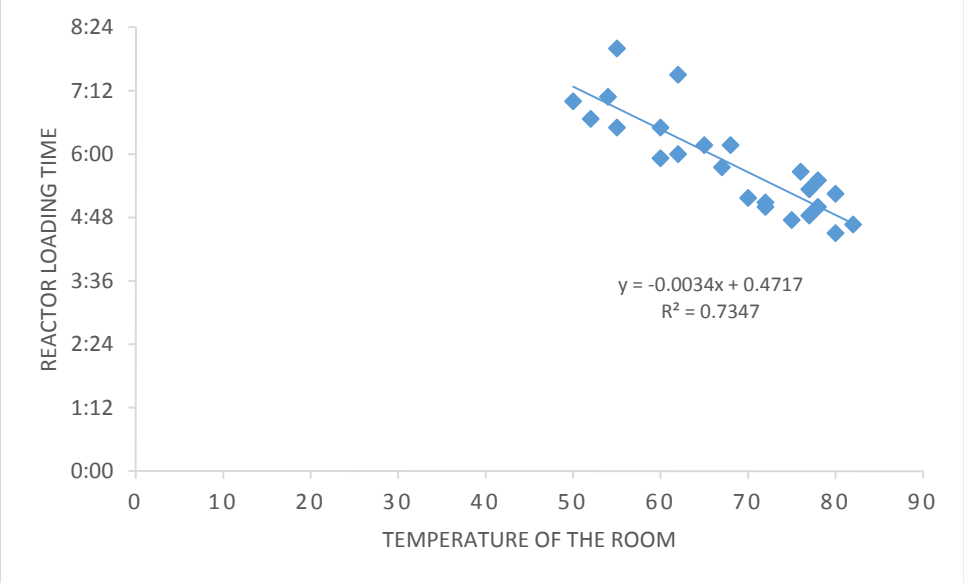

Figure 7: Reactor loading time vs. temperature of the room

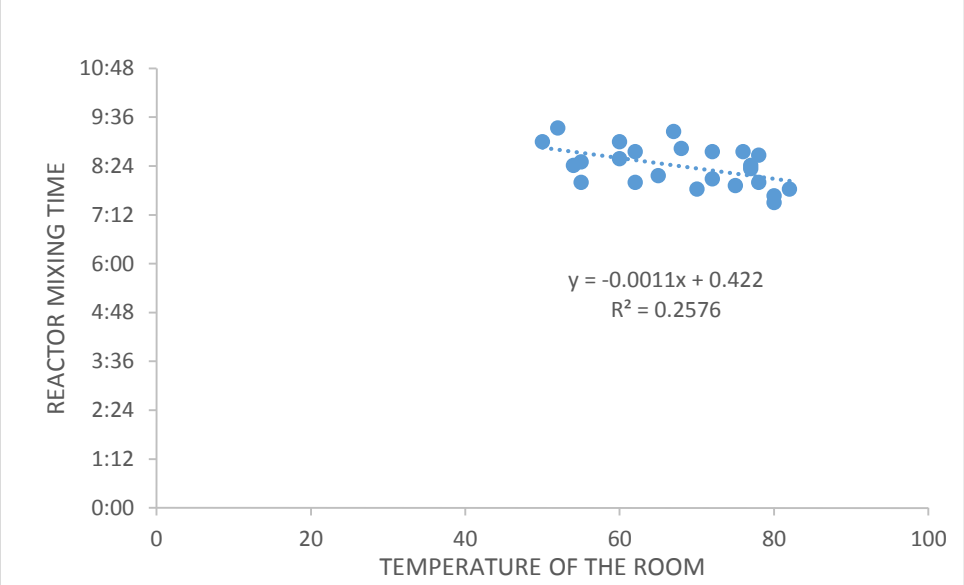

Figure 8: Reactor mixing time vs. temperature of the room

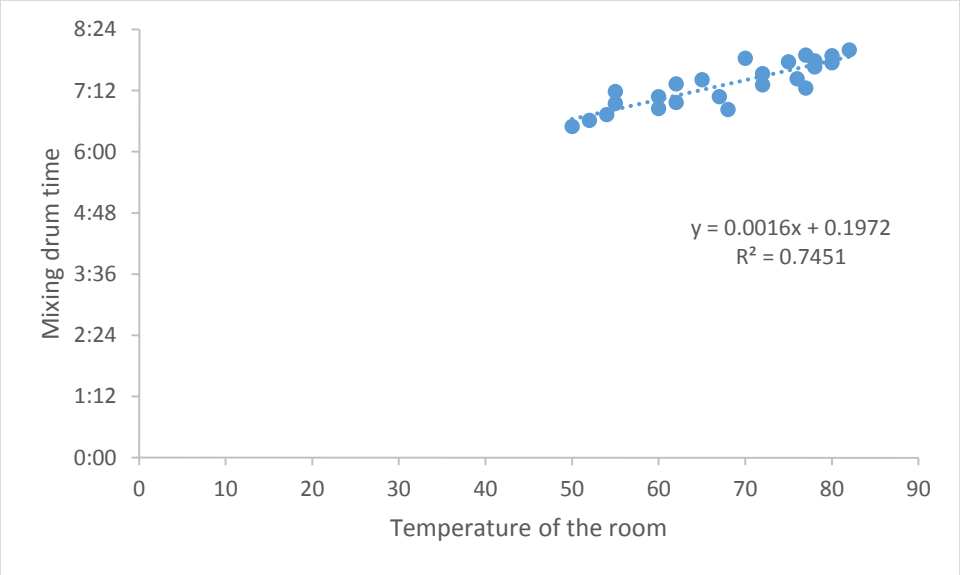

Figure 9: Mixing drum time vs. temperature of the room

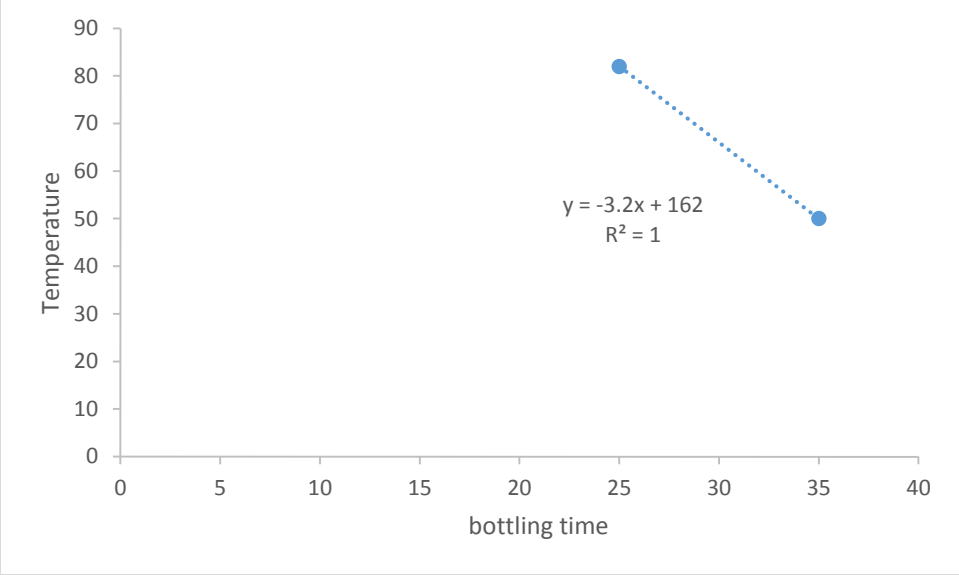

Figure 10: Temperature of the room vs. bottling time

Calculation of mean values for loading process, 5:50, reactor mixing process, 8:23, and mixing drum time, 7:19, was required to show current annual cycle time.

2) According to Chris Adams' (n.d.) research, the best working condition temperature was fluctuating between 66-77 degrees Fahrenheit. Since, the production process requires a higher temperature than cycle time, the study will consider 77 degrees Fahrenheit as an optimal working condition. Using the formulas obtained from linear regression, the time for each operation is calculated for established temperature. These are reactor loading time 5:02, reactor mixing time 8:05, and mixing drum time 7:41.

Bottling process is not a constant process and the operator is a part time employee at the company. The data used to calculate optimal time for 77 degrees Fahrenheit based on the

interview of the operator; claimed that he measured the time in summer time, which is 25 seconds for filling one bottle, and in winter it took 35 seconds.

The study used 50 degrees Fahrenheit as a lowest temperature and 82 degrees Fahrenheit as the highest; moreover, the study considered that temperature and time for bottling represents linear regression. Thus, using Excel worksheet we plotted data and extracted formula for the linear regression (see figure 10). Then we calculated the optimal time for optimal temperature of 77 degrees Fahrenheit, which is 27 seconds. Further analysis based on the calculation of the time reduction of the bottling process for 5 drums of the product, which the study considered 1000 bottles. Calculation of current mean value of bottling time is mean of existing values, which is 30 seconds. Thus, reduction time of bottling process represents difference in time, which is 3 seconds multiplied by 1000 bottles, one batch, which is 50 minutes reduction time. As an initial time for packaging remains the same as was indicated in VSM, 15:20.

Based on our calculations, the sum of mean time values of all operations of the process is equal to 37 hours 27 minutes. The study do not consider shipping time, since Spectra keeps certain amount of the product ready for shipping; thus as soon as customer make an order, Spectra ships the order the same day or in one day. Thus, the study shows the improvement only of the production line.

Finally, based on the estimated time changes noted in the FVSM (see figure 11), calculate the total time related improvement of the processes. Results show total reduced time for production line 1 is equal to 35:53, which represents 1 hours and 26 minutes reduction time, or 3.8% reduction time.

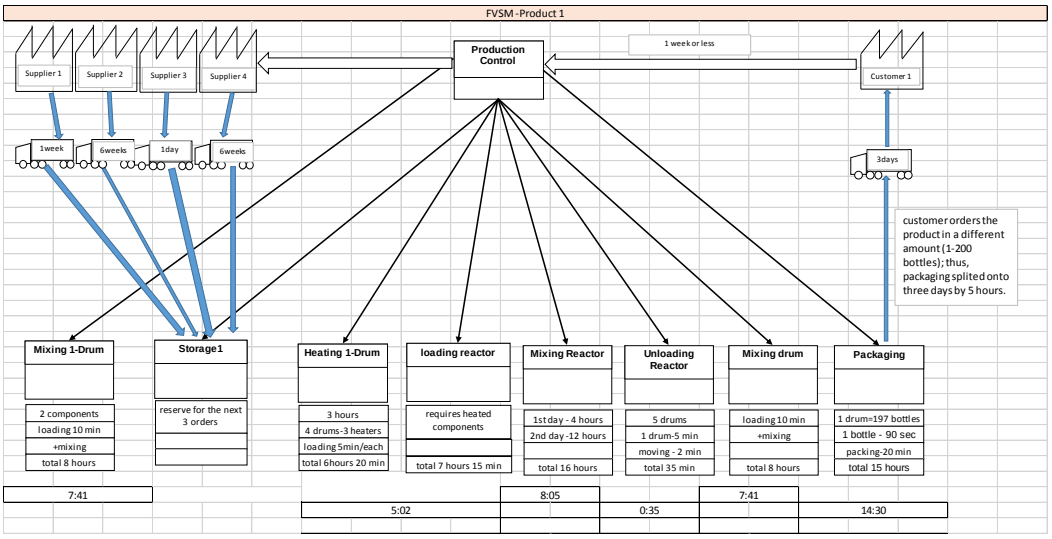

Figure 11: FVSM of the production line 1

Results of the current work were presented to top management of Spectra, reporting all analysis steps.

Conclusions and Recommendations

1. Control temperature in the building will reduce the cycle time by approximately 3.8 % of production line 1. Moreover, the control of temperature will also reduce production cycle time of the others two lines since they are located in the same area and they have mostly the same processes. The time will be significantly reduced since production line 2 and 3 have the mixing process which will improved essentially and they do not have bottling process which did not show much improvement for production line 1.

2. Currently there is no certain time for mixing processes and the company tries to overmix than stop mixing when the product is not finished. The same issue relates to the heating

process. Heating the drum is based on the keeping the drum in the heater for 3 hours; however, initial temperature in the summer time is essentially higher and there is no need to heat the material the same time. Thus, it will be beneficial for the company to identify optimal time for mixing and heating operations, to avoid losing time.

3. SOPs (see appendix L) are very useful training tools for new personnel and a beneficial resource for implementation of ISO 9001 program.

4. Due to lack of information about equipment maintenance and repair, the study did not complete PFMEA process. Thus, it is recommended to implement control documentation for these activities. The study suggests implementing a logbook of equipment repairs and maintenance (see appendix K). Prior to implementation, all equipment should be numbered and labeled.

5. The documentation system should be always under control; thus, it is necessary to assign responsibilities for the control of quality documentation at the company.

6. As was indicated from interviews, due to low temperature, some components in mixing drums stage might not dissolve and not pass QC. Reaction action requires 4 hours of heating the drum and 4 hours of additional mixing, which total delay is 8 hours. Controlling the temperature of environment will eliminate this defect in the process.

7. Working at a comfortable temperature would increase productive of employees; thus, control of temperature will also increase human productivity (Adams, n.d.).

Chapter Summary

The purpose of this chapter was to present the findings from a specific research, which was conducted at Spectra Group Limited. The chapter is composed of the restatement of the purpose, objectives for the study, analysis of the findings according to each objective of the study, conclusions, and recommendations. The results and analysis have been summarized and recommendations were presented to the management of the company.

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Appendix A

ISO9001:2008 set of requirements for any organization or industry:

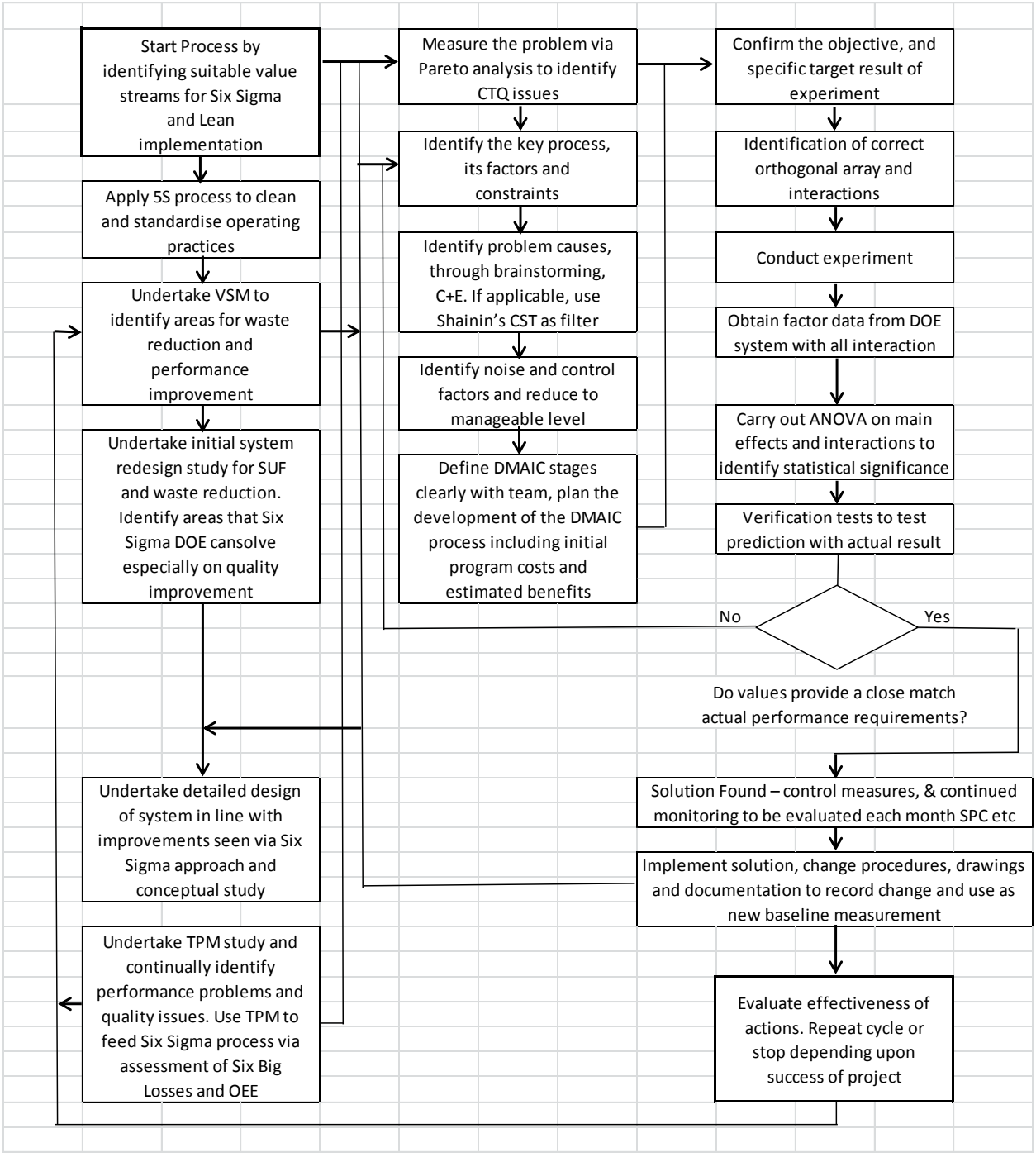
Quality Management System and General Documentation (4.1 – 4.2.4): This section outlines the requirement of creating and documenting a quality management system while ensuring the organization assesses the QMS for opportunities of continuous improvement. The QMS documentation must include a quality manual, quality policy, and quality objectives. "The quality manual must describe the interaction of the processes in the quality management system. The manual must either contain or reference the documented procedures related to the system's processes." Documents required by the QMS must be controlled and a procedure should be established outlining the organization's document control practices.
Management Responsibility (5.1 – 5.6): Management must be committed to the development and implementation of the QMS and continuous improvement. The evidence of this commitment is established with management communication with all levels of the organization, an established quality policy appropriate for the needs of the organization, measurable quality objectives that are in line with the customer needs, quality policy management reviews of the QMS, and assessment the organization's resources for adequacy.
Human Resources and Other Resources (6.1- 6.4): The organization needs to assess resources, including human and facility, to ensure they are adequate to implement a QMS while continuing to assess for opportunities of continuous improvement. The organization must ensure the personnel performing work that would impact the quality of the product or service must be competent with appropriate education, training, skills, and experience.

Planning of Product Realization and Customer-Related Processes (7.1 – 7.2.3): The organization must create processes to ensure consistency in the creation of the product. Prior to releasing the product to the customer, the organization should review all of the requirements associated with the product. Customer20 related process, including customer communication, delivery, and post delivery of the product, must be developed to ensure regulatory and customer specific requirements are met.
Design and Development (7.3 – 7.3.7): The organization should plan and control the design and development of the project to ensure projects are delivered in accordance with pre-determined requirements.
Purchasing (7.4 – 7.4.3): Organizations must have processes in place to ensure purchase products conform to their identified requirements.
Production and Service Provision (7.5 – 7.6): Products and services should be performed in controlled environments, and, when required, products should be identifiable and traceable throughout their use. If customer products are used, they should be controlled in accordance with the products' requirements. Equipment should be measured (e.g., calibrated) with equipment traceable to a standard (e.g., National Institute of Standards and Technology [NIST]), and records should be maintained.
Measurement (8.1 – 8.2.4): The organization must plan and implement processes to measure and analyze systems for continuous improvement. This is done with the use of metrics for select functional areas and customer satisfaction. The organization should implement an internal audit program to conduct audits at planned intervals to assess compliance.

Control of Non-conforming Product (8.3): The organization should have a procedure in place identifying how non-conforming product is segregated to prevent use or delivery to a customer.
Analysis of Data (8.4): The organization must determine the types of data and intervals to collect data for analysis to determine the appropriateness and effectiveness of the QMS. The analysis of data must provide information on customer satisfaction, conformity to product requirements, and characteristics and trends of processes and products, including opportunities for preventative action.
Improvement (8.5 – 8.5.3): The organization must seek opportunities to improve the effectiveness of the QMS. The organization must have a documented procedure for a corrective and preventative action program. The corrective action program procedure should document the steps for reviewing non-conformities, root cause analysis/investigation, corrective action, and, if 21 applicable, preventative actions and evaluation of the effectiveness of those actions.

Appendix B

The integrated LSS model proposed by Thomas et al. (2008).



Appendix C

Grote Industries

POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS
(PROCESS FMEA)

Page 1 of 2

Customer Name/P/N: Grote Industries/ PN 36-0320-02

Item: Flame retardant conformal Coating

Process Responsibility:

Prepared by: Maria Muro-Small

Model Year/vehicles:

Key Date:

Org. Issue Date: 3/28/2014

Rev. Date:

Item Description:

Project Team: Maria Muro-Small, Andrey Ermoshkin, Alex Meljinlski

Item / Function	Potential Failure Mode	Potential Effect(s) of Failure	S e v	C l a s s	Potential Cause(s)/ Mechanism(s) of Failure	O c c u r.	Current Process Controls Prevention	Current Process Controls Detection	D e t e c	R. P. N	Recommended Action(s)	Responsibility & Target Completion Date	Action Results: Actions Taken	S e v	O c c	D e t	R. P. N
Oligomer	Coating does not have the required flex properties. Coating does not flow as expected	Finished product with higher/lower viscosity. Delay in shipment of product	4		1. wrong material sent	1	Visual inspection of material prior production	Measure viscosity of finished product	2	8	discard						
			4		2. contamination	2	Visual inspection of material prior production	Visual inspection of the finished product	2	16	filter and re-inspect						
			4		3. Stabilizer Depleted	2	Inspection. Check for gelation.higher viscosity than expected	Measure viscosity of finished product	2	16	discard						
			4		4. Wrong weight added	1	Verify amount added with batch record sheet	Measure viscosity of finished product	2	8	discard						
Monomer	Coating does not have the required flex properties. Coating does not flow as expected	Finished product with higher/lower viscosity. Delay in shipment of product	4		1. wrong material sent	1	Visual inspection of material prior production	Measure viscosity of finished product	2	8	discard						
			4		2. contamination	2	Visual inspection of material prior production	Visual inspection of the finished product	2	16	filter and re-inspect						
			4		3. Stabilizer Depleted	2	Inspection. Check for gelation.higher viscosity than expected	Measure viscosity of finished product	2	16	discard						
			4		4. Wrong weight added	1	Verify amount added with batch record sheet	Measure viscosity of finished product	2	8	discard						
Photoinitiator Package	Coating does not cure as expected	Tacky coating. Curing only in the surface	4		1. No photoinitiator is added	1		Measure UV-Vis spectrum of finished product. Cure the finish product	2	8	Add photoinitiator and re-mix the coating						
			4		2. Wrong weight added	1	Verify amount added with batch record sheet	Measure UV-Vis spectrum of finished product. Cure the finish product	2	8	discard						
Flame retardant package	Coating lacks flame retardant properties	Coating burns when exposed to a flame	4		1. No flame retardant package is added	1		Perform flame test on finished product (performed by Grote)	2	8	Return material to Spectra. Add flame reatrdant package to the mix and re-mix coating						

Form #129
Rev. G 10/18/04

Appendix D

☐ Prototype ☐ Pre-Launch ☐ Production

CONTROL PLAN

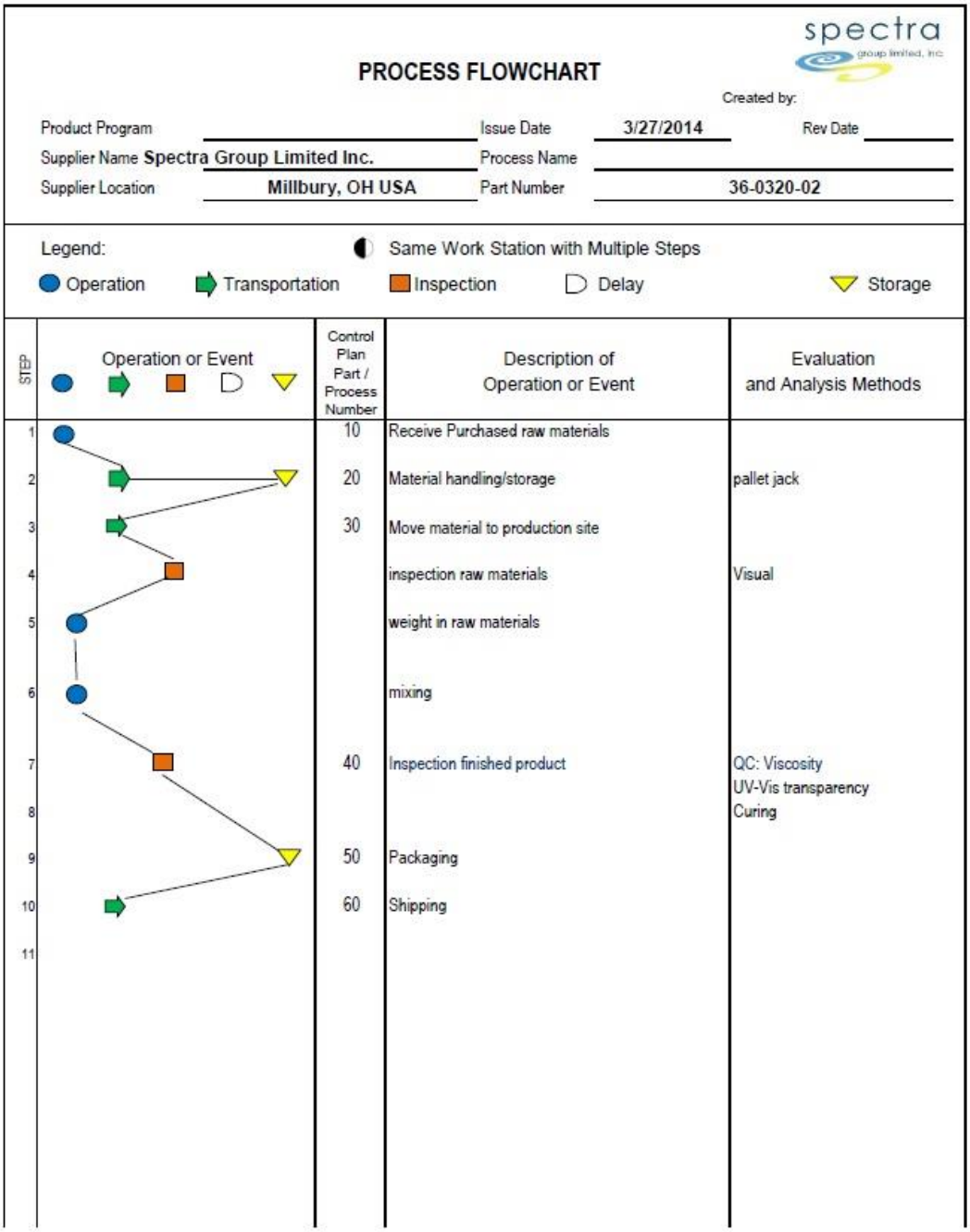
spectra group limited, inc

Part Number 36-02320-02	Key Contact/Phone Maria Muro-Small/ 419-837-9783	Date (Orig.)	Date (Rev.)
Latest Change Level	Core Team Maria Muro-Small, Andrey Ermoshkin, Alex Mejiritski	Customer Engineering Approval/Date (If Req'd.)	
Part Name/Description GRT-7 Flame retardant conformal coating	Organization/Plant Approval/Date Spectra Group Limited/Ohio	Customer Quality Approval/Date (If Req'd.)	
Organization/Plant Madison/Indiana	Organization Code	Other Approval/Date (If Req'd.)	Other Approval/Date (If Req'd.)

PART/ PROCESS NUMBER	PROCESS NAME/ OPERATION DESCRIPTION	MACHINE, DEVICE JIG, TOOLS FOR MFG.	CHARACTERISTICS NO.	CHARACTERISTICS PRODUCT	CHARACTERISTICS PROCESS	SPECIAL CHAR. CLASS	METHODS PRODUCT/PROCESS SPECIFICATION/ TOLERANCE	METHODS EVALUATION/ MEASUREMENT TECHNIQUE	METHODS SAMPLE SIZE	METHODS SAMPLE FREQ.	METHODS CONTROL METHOD	REACTION PLAN
10	Receiving of raw materials	paking list	1	Shipping / Packaging / Supplier Quality Systems	Receiving	minor	PO and packing list match	Visual	1	each container	work instrucion	Note on packing list. Provide documents to office manager
			2	Shipping / Packaging Systems	Receiving	minor	Inspection of container and contents: color & viscosity	Visual	1	each container	work instrucion	Note on packing list. Provide documents to office manager
		Packing List	3	Container Labeling	Receiving	Minor	Container label matches actual contents	Visual	1	Each Container	Work Instruction	Note on packing list. Provide documents to office manager
20	Materials Storage	pallet jack	1	Inventory management	Material Movement	Minor	Materials stored in proper location according to manufacturers specification	Visual	1	Each Container	Work Instruction	Correct issue, contact Materials group or production supervisor for instructions

Form #154
2/17/12

Appendix E



PROCESS FLOWCHART

spectra group limited, inc

Created by:

Product Program		Issue Date	3/27/2014	Rev Date	
Supplier Name	Spectra Group Limited Inc.	Process Name			
Supplier Location	Millbury, OH USA	Part Number	36-0320-02		

Legend: Same Work Station with Multiple Steps

Operation · Transportation · Inspection · Delay · Storage

STEP	Operation or Event	Control Plan Part / Process Number	Description of Operation or Event	Evaluation and Analysis Methods
1		10	Receive Purchased raw materials	
2		20	Material handling/storage	pallet jack
3		30	Move material to production site	
4			inspection raw materials	Visual
5			weight in raw materials	
6			mixing	
7		40	Inspection finished product	QC: Viscosity UV-Vis transparency Curing
8				
9		50	Packaging	
10		60	Shipping	
11				

Form #305
2/17/12

Appendix F

		Potential Failure Mode and Effects Analysis (Process FMEA)								FMEA Number						
Item	Production Line 1									Page	1	of	1			
										Prepared by:	Yun S.					
										FMEA Date:	12/9/2015					
Process Step / Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Potential Cause(s) / Mechanism(s) of Failure	Occurrence	Current Process Control	Detection	R. P. N.	Recommended Action(s)	Responsibility & Target Completion Date	Action Results: Actions Taken & Completion Date	Action Results: Severity	Action Results: Occurrence	Action Results: Detection	Action Results: R. P. N.	
Name, Part Number, or Class Function	Manner in which part could fail: cracked, loosened, deformed, leaking, oxidized, etc.	Consequences on other systems, parts, or people: noise, unstable, inoperative, impaired, etc.		List every potential cause and/or failure mechanism: incorrect material, improper maintenance, fatigue, wear, etc.		List Control activities			Design actions to reduce severity, occurrence and detection ratings. Severity of 9 or 10 requires special attention.	Name of organization or individual and target completion date	Actions and actual completion date					
								0								0
Reactor or Drum Loading	Material overload	Production Delay	3	Broken spigot	7	Visual inspection	8	168								0
			3	human error	7	second operator monitoring	8	168								0
			3	Broken scales	7	regular inspection and calibration	9	189								0
	Spoiled Mixing Material	Total Loss	10	Wrong Material Added	6	Color coated	1	60								0
																0
Reactor Mixing	Material does not pass QC	Production Delay	1	Components are not dissolved		Visual inspection	1	0								0
	Motor Failure	Production Delay	10	Electric Failure		Regular maintenance		0	Buy reserve motor							0
																0
Mixing Drum	Drum Rotator Failure	Production Delay	3	Motor Broken		Regular maintenance	1	0	Buy reserve motor							0
			3	Mechanical parts	7		9	189								
	Drum Cracks	Leak	9	Metal fatigue	6		1	54								0
	Bung cover not tight	Leak	9	Vibrated out	4	Double check	6	216								0
																0
Bottling	Material spilling	Production Delay, Waste	8	Human error		Avoiding distruction		0								0
				Broken Spigot		Visual inspection		0								0
Bagging	Broken heat sealer	Production Delay	9	Blade gets dull	4	Reserve	9	324								0
				Heating element is broken	4	Reserve	9	0								0
								0								0
								0								0
								0								0
								0								0
								0								0
								0								0

Severity of Effect:		Occurrence Rating
No Effect	1. None	1. Very low <.01/1000
	2. Very Minor	2. Low - 1/1000000
Annoyance	3. Minor	3. Low - 1/100000
	4. Very Low	4. Moderate - 1/10000
Loss or degradation	5. Low	5. Moderate - 1/2000
of secondary function	6. Moderate	6. Moderate - 1/500
Loss or degradation	7. High	7. High - 1/100
of primary function	8. Very High	8. High - 1/50
Failure to meet	9. Hazardous with warning	9. Very High 1/20
safety/ regulations	10. Hazardous w/o warning	10. Very High >1/10

Stakeholder	Effects of Failure	Severity
Consumer	Owner Safety Problem	10
(e.g., buyer)	Major Owner Dissatisfaction	8
	Moderate Owner Dissatisfaction	6
	Minor Owner Dissatisfaction	4
Customer	Plant Safety Problem	10
(Manufacturer)	Possible Recall	9
	Line Stoppage	8
	Warranty Costs	7
AIAG PPAP 4th	Scrap	7
	Regulatory Penalty	7
	Moderate Rework (<25%)	5
	Plant Dissatisfaction	4
	Minor Rework (<10%)	3

Appendix G

Reactor Control							
Date	Room Temperature	Start Loading	Finish Loading Time	Stop Reactor (1st day)	Start Reactor (2nd day)	Stop Reactor Time	Names of employees involved
1/1/2016	50	9:00 AM	4:00 PM	5:00 PM	9:00 AM	5:00 PM	Bill
1/16/2016	52	9:00 AM	3:40 PM	5:00 PM	9:00 AM	5:00 PM	Bill
2/1/2016	54	9:00 AM	4:05 PM	5:00 PM	9:00 AM	4:30 PM	James
2/16/2016	60	9:00 AM	3:30 PM	5:00 PM	9:00 AM	4:30 PM	Bill
3/1/2016	62	9:00 AM	3:00 PM	5:00 PM	9:00 AM	3:45 PM	Bill
3/16/2016	67	9:00 AM	2:45 PM	5:00 PM	9:00 AM	4:00 PM	James
4/1/2016	68	9:00 AM	3:10 PM	5:00 PM	9:00 AM	4:00 PM	Bill
4/16/2016	72	9:00 AM	2:00 PM	5:00 PM	9:00 AM	2:45 PM	Bill
5/1/2016	76	9:00 AM	2:40 PM	5:00 PM	9:00 AM	3:25 PM	James
5/16/2016	77	9:00 AM	2:20 PM	5:00 PM	9:00 AM	2:45 PM	Bill
6/1/2016	78	9:00 AM	2:00 PM	5:00 PM	9:00 AM	2:40 PM	Bill
6/16/2016	78	9:00 AM	2:30 PM	5:00 PM	9:00 AM	2:30 PM	James
7/1/2016	77	9:00 AM	1:50 PM	5:00 PM	9:00 AM	2:10 PM	Bill
7/16/2016	80	9:00 AM	2:15 PM	5:00 PM	9:00 AM	1:45 PM	Bill
8/1/2016	82	9:00 AM	1:40 PM	5:00 PM	9:00 AM	1:30 PM	James
8/16/2016	80	9:00 AM	1:30 PM	5:00 PM	9:00 AM	1:10 PM	Bill
9/1/2016	75	9:00 AM	1:45 PM	5:00 PM	9:00 AM	1:40 PM	Bill
9/16/2016	70	9:00 AM	2:10 PM	5:00 PM	9:00 AM	2:00 PM	James
10/1/2016	72	9:00 AM	2:05 PM	5:00 PM	9:00 AM	2:10 PM	Bill
10/16/2016	65	9:00 AM	3:10 PM	5:00 PM	9:00 AM	3:20 PM	Bill
11/1/2016	60	9:00 AM	2:55 PM	5:00 PM	9:00 AM	3:30 PM	James
11/16/2016	55	9:00 AM	3:30 PM	5:00 PM	9:00 AM	4:00 PM	Bill
12/1/2016	62	9:00 AM	16:30	5:00 PM	9:00 AM	4:30 PM	Bill
12/16/2016	55	9:00 AM	5:00 PM	5:00 PM	9:00 AM	5:00 PM	James

Appendix H

Mixing Drum			
Date	temperature of the room	start time	end time
01/01/2016	50	9:00 AM	3:30 PM
01/16/2016	52	9:00 AM	3:37 PM
02/01/2016	54	9:00 AM	3:44 PM
02/16/2016	60	9:00 AM	3:51 PM
03/01/2016	62	9:00 AM	3:58 PM
03/16/2016	67	9:00 AM	4:05 PM
04/01/2016	68	9:00 AM	3:50 PM
04/16/2016	72	9:00 AM	4:19 PM
05/01/2016	76	9:00 AM	4:26 PM
05/16/2016	77	9:00 AM	4:15 PM
06/01/2016	78	9:00 AM	4:40 PM
06/16/2016	78	9:00 AM	4:47 PM
07/01/2016	77	9:00 AM	4:54 PM
07/16/2016	80	9:00 AM	4:45 PM
08/01/2016	82	9:00 AM	5:00 PM
08/16/2016	80	9:00 AM	4:53 PM
09/01/2016	75	9:00 AM	4:46 PM

09/16/2016	70	9:00 AM	4:50 PM
10/01/2016	72	9:00 AM	4:32 PM
10/16/2016	65	9:00 AM	4:25 PM
11/01/2016	60	9:00 AM	4:05 PM
11/16/2016	55	9:00 AM	4:11 PM
12/01/2016	62	9:00 AM	4:20 PM
12/16/2016	55	9:00 AM	3:57 PM

Administration _____

Appendix I

Mixing 1-Drum			
Date	temperature of the room	start time	end time
01/01/2016			
01/16/2016			
02/01/2016			
02/16/2016			
03/01/2016			
03/16/2016			
04/01/2016			
04/16/2016			
05/01/2016			
05/16/2016			
06/01/2016			
06/16/2016			
07/01/2016			
07/16/2016			
08/01/2016			
08/16/2016			
09/01/2016			

09/16/2016			
10/01/2016			
10/16/2016			
11/01/2016			
11/16/2016			
12/01/2016			
12/16/2016			

Admin istratio n

Appendix J

Heating Drum				
ate	temperature of the room	start time	end time	weight

Ad _

ministrati _____

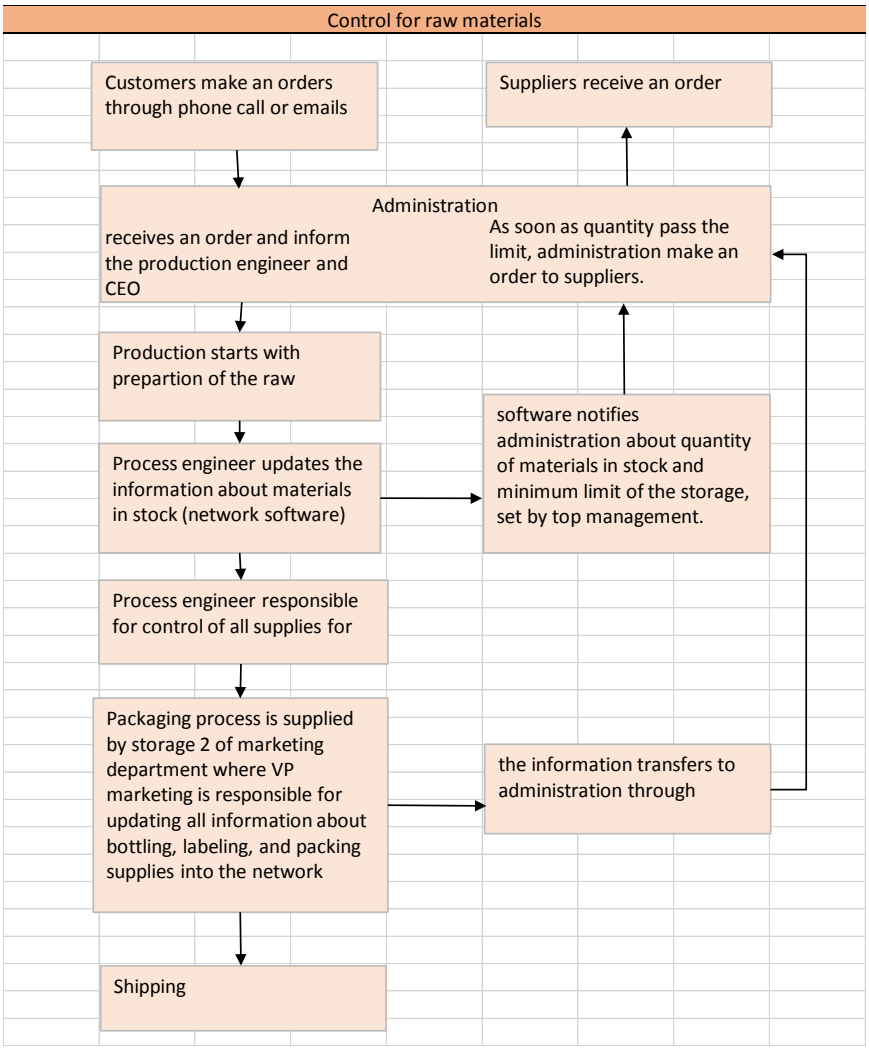
on ___

Appendix K

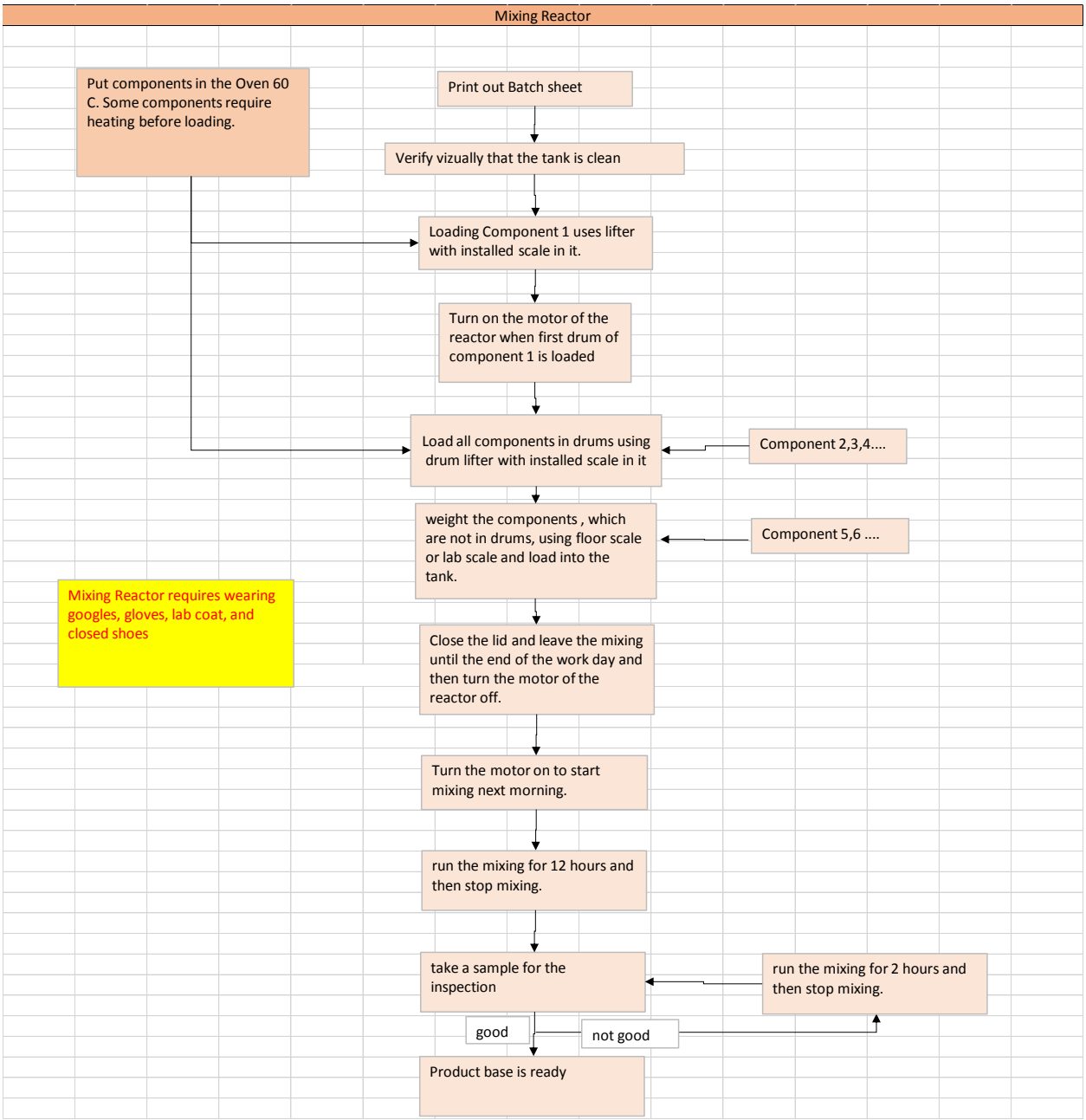
Equipment Maintenance and Repair				
Date	**Time**	**Unit #**	**Work Performed**	**Name**
			Administration	_____

Appendix L: Standard Operating Procedures

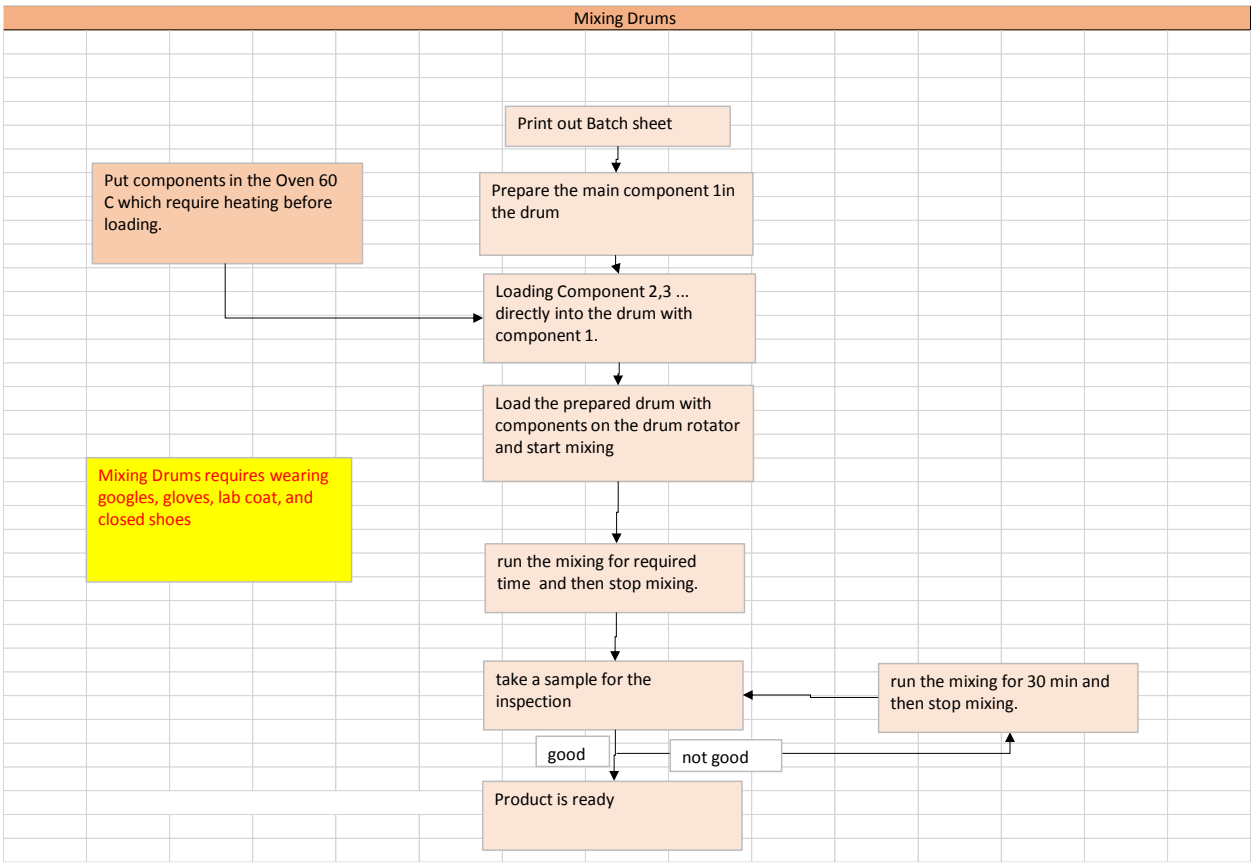
L1: Control for raw materials



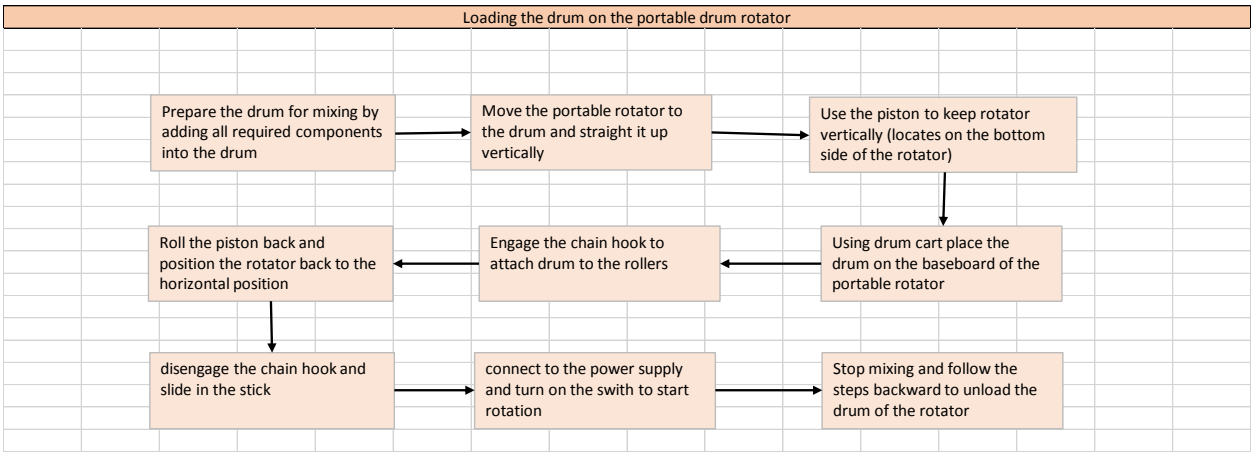
L2: Mixing Reactor



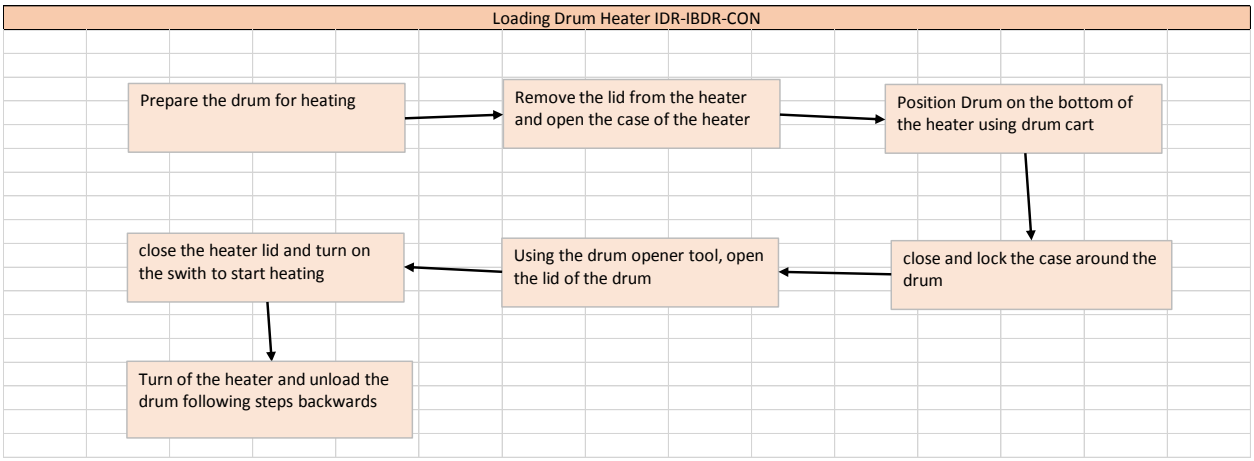
L3: Mixing Drums



L4: Loading Drum on the Portable Drum Rotator



L5: Loading Drum Heater



L6: Usage of drum lifter for reactor loading