DEFINITION AND DEPLOYMENT OF A QUALITY SYSTEM FOR A SMALL FIRM — THE MODEL FACTORY OF THE MAYAGÜEZ CAMPUS

by

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ABSTRACT

This work presents the methodology and results of the deployment of a quality system in a small business environment. This quality system was implemented at the Model Factory of the University of Puerto Rico, Mayagüez Campus, a small business which represents a manufacturing activity in academia. The activity at the Model Factory is run by engineering students under the guidance of faculty. The Model Factory, as most small businesses, has a limited number of resources, both in terms of personnel as well as funding.

The small business requirements for quality systems have been documented by regulatory agencies and are available in the literature. However, there is a limited number of technical papers on implementation experiences accessible to small business management. The Quality System Regulation (QSR), developed by the Food and Drug Administration (FDA), has served as reference for defining the quality management system for the Model Factory.

The implementation of the quality management methodology defined in this project contemplates a mid–long term impact that includes: (1) improved customer satisfaction by reducing customer complaints, (2) increased productivity, (3) less rework activities and (4) improved business organization. An immediate academic benefit of the project has been to allow students working in the Model Factory to be exposed and become familiar with FDA manufacturing regulations.

RESUMEN

En este trabajo se presenta la metodología y los resultados del despliegue de un sistema de calidad en una empresa pequeña. Este sistema de calidad se ha implementado en la Fábrica Modelo de la Universidad de Puerto Rico, Recinto Universitario de Mayagüez. Esta fábrica representa una empresa pequeña de manufactura en un ambiente académico. La actividad es operada y realizada por estudiantes de ingeniería tutelados por miembros de la facultad. La Fábrica Modelo, como la inmensa mayoría de los negocios pequeños, tiene recursos limitados, tanto en términos de personal como de fondos.

Los requisitos de sistemas de calidad para pequeñas empresas se han documentado ampliamente por las agencias reguladoras y están disponibles en la literatura. Sin embargo, existe un número limitado de artículos técnicos en experiencias de implantación disponibles a la gerencia de las pequeñas empresas. Para este trabajo, a la hora de definir el sistema de gestión de calidad para la Fábrica Modelo, se ha utilizado como referencia la Reglamentación del Sistema de Calidad (QSR por sus siglas en inglés) desarrollado por la Administración de Drogas y Alimentos (FDA).

La implementación de la metodología del sistema de calidad definido en este proyecto contempla un impacto a mediano y largo plazo que incluye: (1) mejora de la satisfacción del cliente reduciendo las quejas, (2) aumento de la productividad, (3) reducción de las actividades de re-trabajo y (4) mejora en la organización empresarial. Un beneficio académico inmediato del proyecto es que ha permitido que los estudiantes asignados a la Fábrica Modelo se expongan y familiaricen con las reglamentaciones del FDA para la manufactura.

DEDICATION

Dedicated to the one I love

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CGMP – Current Good Manufacturing Practices

CPE – Criteria for Performance Excellence

DMR – Device Master Record

EBI – Electro Biology Inc.

FDA – Food and Drug Administration

GMP – Good Manufacturing Practices

MBNQA – Malcolm Baldrige National Quality Award

PCB – Printed Circuit Board

QA – Quality Assurance

QMS – Quality Management System

QSR – Quality System Regulation

SBA – Small Business Association

SMT – Surface Mount Technology

TQM – Total Quality Management

UPRM – University of Puerto Rico Mayagüez

1 Introduction

1.1 Preface

The Industrial Engineering Department, at the Mayagüez Campus of the University of Puerto Rico, has developed a for-profit business activity since 2004. This is a manufacturing activity that has been labeled the Model Factory. It seems to be the first known for-profit manufacturing activity in an academic environment run primarily by students under the guidance of university faculty. Currently the Model Factory is equipped with an automated line for printed circuit boards (PCBs) assembly based on surface mount technology (SMT).

The main customer of the Model Factory is Electro-Biology, Inc. (EBI), a medical device manufacturing company located in Guaynabo, Puerto Rico. The Model Factory assembles three types of SMT boards for EBI which are used in a magnetic bone-healing system. This medical device is prescribed by orthopedic physicians to accelerate the mending of bone fractures at extremities. Given that this product is a medical device, EBI has to comply with the Quality System Regulation (QSR) being enforced by the United States Food and Drug Administration (US-FDA). The Model Factory, as a subcontractor for EBI, in principle must comply also with the regulation. Notwithstanding this fact, this project will approach the quality systems literature with an open mind to define the method that best suits the Model Factory as the small firm selected for the deployment of this project.

The definition and implementation of a quality management system in the Model Factory has the potential to improve internal effectiveness, as well as customer satisfaction. A well defined quality system becomes a crucial decision factor when a prospective client is selecting outsourcing companies to make their products. Having a quality system in place assures products and service quality. In the case of the Model Factory, having the quality system in place is seen as a facilitator for attacting new business.

1.2 Categorizing a firm as small

There are various ways used by researchers to categorize small firms. Robinson and Pearce (1984) found that firms were typically defined as small on the basis of either annual sales or number of employees. They reviewed 50 studies that define a small business as having anywhere from one to 2000 employees. Keats and Bracker (1988) found that on the variable of annual sales, researchers place small business size in a range from “under $150,000” to “less than $150 million.”

The U.S. Small Business Administration defines a small business as “one that is independently owned and operated, and which is not dominant in its field of operation.”

A more detailed employment breakdown also used is: less than 20 employees, very small; 20-99, small; 100-499, medium sized; and more than 500, large. These size breaks are consistent with standard business employment, asset and receipt-size classes established in 1982 by the Office of Management and Budget for use by all federal agencies when publishing business data (Hodgetts et al., 1999). Many government agencies, including the Department of Commerce, use 500-employees as the threshold between smaller firms and larger firms. In its three and a half years of manufacturing activity, the Model Factory has had between ten and 18 students working, for which it falls in the very small category.

The number of employees and the annual revenues of a firm are only two quantitative characteristics that differentiate small firms from large ones. Shuman and Seeger (1986) state that "smaller businesses are not smaller versions of big businesses ... smaller businesses deal with unique size-related issues as well, and they behave differently in their analysis of, and interaction with, their environment."

The 1971 Bolton report explicitly highlighted the "fervently guarded sense of independence" which is seen to be a prime motivator for many small business owner-managers. Contrary to popular belief, and a great deal of economic theory, money and the pursuit of a personal financial fortune are not as significant as the desire for personal involvement, responsibility and the independent quality and style of life which many small business owner/managers strive to achieve. Equally, many surviving small businesses are seen, in terms of rational theory, to operate at sub-optimal levels of performance. These characteristics can be destructive to the small firm. The actual root

cause of small firm failures seems to lie with the apparently non-rational behavior and decision-making of the entrepreneur and/or owner-manager who does not obey the "rules" of classical management theory (Jennings and Beaver, 1993). The desire for owners to do things their way, labeled as “independence”, in the face of proven methods, contributes to the owner/managers points of view with respect to performance frameworks such as Total Quality Management (TQM) and the Criteria for Performance Excellence (CPE) embedded in Baldrige.

Presenting this discussion at the outset is important. It cannot be assumed that all small business research uses the same criteria when deciding which firms to include in the small firm category. Therefore, it must be clear which parameters are used here to categorize small firms. For this project, the scope of the literature review has been limited to include firms that employ between 50 to 500 employees or less. Small firms in this category are mature, established, viable and their size has little variation.

Churchill and Lewis (1983) have established that small firms develop through five stages; namely, (i) existence, (ii) survival, (iii) success, (iv) take-off, and (v) resource maturity. In sub-stage (iii-d), success disengagement, the company has attained economic health, has sufficient size, and earns average profits. The company can stay at this stage indefinitely, provided environmental change does not destroy its market or ineffective management and lack of a quality system in place reduces its competitive abilities.

1.3 Objectives

The main objective of this project is to define and implement a Quality System (QS) for a small business, using the Model Factory as a case study and complying with the following guidelines and constraints:

a) The Quality System must be easy to manage; i.e., it must comply with requirements using a limited number of resources.

b) The Quality System must be easy to communicate and internalize given the lack of exposure and skills of most employees.

c) The Quality System must be highly visible so that factory personnel have easy access and can internalize the specifics on the shopfloor.

d) The Quality System must comply or exceed the expectations of the customers.

1.4 Contribution

The main contribution of this project, outside the intended objective of defining a quality system for the Model Factory, is to provide information and guidelines for local small businesses, manufacturing or service, that wish to include and implement high-performance management practices in their activities. Local small businesses can be motivated to implement a quality management system in an effort to improve customer satisfaction. This is achieved by: (1) improving outgoing quality which should help in decreasing customer complaints; (2) improving in-house quality which should help in decreasing rework activities; and (3) enhancing continuous improvement activities which should help improve product flow and ontime delivery.

In the 1980's, the U.S. government, along with leading commercial organizations, realized the significance of improving the quality of products and services in order to enhance the international competitiveness of companies and the national economy. This realization led to the development of high performance management practices, embodied in the Malcolm Baldrige National Quality Award, with criteria for performance excellence (CPE) that have now spread across all sections of the business community.

Research has determined that implementing high performance management practices can result in positive impacts on firms, allowing them to achieve performance excellence and improve competitiveness in their markets. In principle, small organizations with their limited resources can apply high performance management principles with measurable success, and without undue expense. However, in many instances the quality system frameworks may not be present.

Prior to the execution of the project, it was clear that the definition of high performance management principles to suit the characteristics of small firms was not obvious and work needed to be done to define a suitable quality system framework.

It seems logical that small firms may not be specifically familiar with frameworks such as Baldrige and the Criteria for Performance Excellence, but they may be practicing some or all its principles every day without placing such a label on it. Therefore, small businesses may lack specific knowledge concerning high performance criteria but not the underlying management principles. Dissemination of this research

project will allow small firms to identify quality system options and which specific quality system works best for varying small business scenarios.

2 Literature Review and Hypothesis Development

2.1 Background

Prior to the development and implementation of a Quality System for the Model Factory, the basics of quality and the relevance of high performance criteria to small firms have been reviewed.

There are many definitions for quality (Bauer, Duffy, and Westcott (2002)). For the military, quality is the composite of all the attributes or characteristics including performance of an item or product (MIL – STD – 109B, 1969). The American Society of Quality Control (ASQC) uses a definition where quality relates the features and characteristics of a product or service to the ability of that product or service to satisfy stated or implied needs (ANSI/ ASQC/ A3 -1987). A more recent definition of the ASQC is that quality is a subjective term for which each person has his or her own definition. In technical usage, according to this ASQC definition, quality can have two meanings: a) the characteristics of a product or service that bear on its ability to satisfy stated or implied needs, and b) a product or service free of deficiencies ("The Quality Glossary", ASQC Quality Press, 1993). According to the International Quality Management System standards, quality is the degree to which a set of inherent characteristics fulfills requirements (ANSI, ISO/ ASQ Q9000 – 2000, Quality Management Systems – Fundamentals and Vocabulary, December 2000).

Montgomery (2001), in contrast, defines quality as a multifaceted entity which inclusively has the following eight important dimensions:

a) Performance – will the product work as intended?
b) Reliability – how often does the product fail?
c) Durability – how long does the product last?
d) Serviceability – how easy is to repair?
e) Aesthetics – what does the product look like?
f) Features – what does the product do?
g) Perceived quality – what is the reputation of the company or its product?
h) Conformance to standards – is the product made as the designer intended?

In the early and mid 1950s quality had a huge and revolutionary boom. It was caused by World War II and the poor quality typical of non-military products in the post-war years. During this period, some quality authorities developed theories and practical techniques to improve quality.

The most important of these pioneers are Deming, Juran, Feigenbaum, and Crosby (Montgomery, 2001). Deming is the best known of the early pioneers and is credited with popularizing quality control in Japan in the early 1950s. He is best known for developing an approach for statistical quality control, although his contribution goes substantially beyond those techniques. His philosophy begins with top management, but he maintains that a company must adopt the 14 points of his system in all levels. Deming defines quality as a predictable degree of uniformity and dependability, at low cost and suited to the market. Although it is the worker who ultimately produces quality products, Deming stresses worker pride and satisfaction rather than the establishment of quantifiable goals. His approach focuses on improvement of the process, claiming that the system, rather than the worker, is the cause of variation. Deming's universal 14 points for management are summarized in Appendix A (Deming, 1982).

Juran introduced in his lectures the managerial dimensions of planning, organizing, and controlling. This author focuses on the responsibility of management to achieve quality and the need for setting goals. He defines quality as fitness for use in terms of design, conformance, availability, safety, and field use. Unlike Deming, Juran focuses on top-down management and the technical methods rather than worker pride and satisfaction. Juran's ten steps to quality improvement are summarized in Appendix B (Juran, 1988).

Fiegenbaum used a total quality control approach that may very well be the forerunner of today's TQM. His suggestion is to promote a system for integrating efforts to develop, maintain, and improve quality by all the groups of the organization. He was more concerned with the organizational structure and a systems approach to improving quality over statistical methods. In contrast to the modern view, he suggests that much of the technical capability should be concentrated in a specialized department (Fiegenbaum, 1991).

Crosby, the author of the book “Quality Is Free” (Crosby, 1979), argues that poor quality in the average firm costs about 20 percent of the revenues, most of which can be avoided by adopting good quality practices. He states that quality is free because the small cost of prevention will always be lower that the costs of detection, correction, and failure. Crosby’s “absolutes” of quality are:

a) Quality is defined as conformance to requirements, not “goodness.”
b) The system for achieving quality is prevention, not appraisal.
c) The performance standard is zero defects, not “that’s close enough.”
d) The measurement of quality is the price of non-conformance, not indices.

Like Deming, Crosby has his own 14 points that are summarized in Appendix C (Crosby, 1979). All of these pioneers and authorities believed that management and the system, rather than the workers, are the cause of poor quality. This characteristic has to be taken into account when designing the implementation of a quality system for a small business.

It is also worthwhile to discuss the relation between terms such as quality control, quality assurance and quality system. Quality control relates to the set of procedures intended to ensure that a manufactured product or performed service adheres to a defined set of quality criteria or meets the requirements of the client or customer. A quality assurance system is said to increase customer confidence and a company's credibility, to improve work processes and efficiency, and to enable a company to better compete with others. A quality system relates to the objectives and processes of a company designed to focus the company toward quality and customer satisfaction. The QMS consists of written documents followed by the business, examples of which are ISO 9000 and FDA-QSR, to be discussed later.

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2.2 Relevance of High Performance Criteria to Small Firms

In the mid-1980’s, as introduced above, the U.S. government along with many important commercial organizations realized the significance of improving the quality of products and services in order to enhance the international competitiveness of companies and the national economy (Anonymous, 1999). This realization led to the

development of the Malcolm Baldrige National Quality Award for Performance Excellence Criteria (PEC) that has now spread across all sections of the business community, including large and small enterprises. The Baldrige criteria are an evolutionary framework revised annually to conform to contemporary high performance management practices. The criteria provide a flexible set of practices that firms can adopt to fit their competitive environment.

Case studies and empirical research have determined that implementing the Baldrige criteria can result in positive impacts on firms allowing them to achieve performance excellence and improve competitiveness in their markets (Barclay 1993, Hendricks and Singhal 1996, Mendham et al, 1994). Firms that implement all of the chosen elements of a comprehensive quality management framework are found to have better operational performance, reflected through the quality of their products (DeBaylo 1999, Ahire and Golhar 1996). When specifically identifying small firms that choose to embrace such quality management (QM) principles, Ahire (1996) indicates that there is a consistent statistically significant difference between small QM and non-QM firms.

Additional research suggests that small firms that adopt and follow the CPE are superior performers (Hodgetts et al., 1999). However, only a slight fraction of small firms adopt these criteria. Raymond (2000) has established that for a significant portion of the small business community, awareness of the criteria and its benefits is inadequate. Feedback from Raymond's research indicates that only 28% of the small firms in their survey report meaningful familiarity with the CPE criteria, while 36% report some familiarity with the criteria and another 36% report little or no familiarity, indicating an overall lack of awareness of the CPE and its potential benefits.

It is difficult for a firm to take advantage of a QM framework with which they are not completely familiar or that they do not understand. Wilkes and Dale (1998) argue that "there is a plethora of information and advice on QM and continuous improvement, and it is easy for an organization to become coned by the different emphases and directions highlighted in each initiative." Since very few of the approaches and information are tailored for small firms, there is a tendency for a small business to try and apply them through interpretation of information aimed at large companies. Many methods that succeed within larger companies are often recommended for small firms

despite the many differences that may make such practices unworkable (Rodwell and Shadur, 1997)

Small firms are often under pressure to gain registration to a standard quality management system, such as ISO 9000, and many find the burden of formal quality certification too costly and time consuming (Chittenden et al., 1998; Taylor, 1995; Rayner and Porter, 1991). These pressures and the associated cost burdens alienate small firms that do not understand the underlying principles and advantages of embracing such QM systems. There may be a tendency to reject any packaged “quality system” out of hand. Nevertheless, it has been proven that small organizations with their limited resources can apply the CPE principles with measurable success, and without undue expense (Ghobadian and Gallear, 1996). Andreichuk (1992) argues that smaller companies can be more successful than larger firms at soliciting employee support and involvement because there are fewer management layers and fewer people to convince of the benefits. Yet, others find the frameworks themselves lacking.

According to Wilkes and Dale (1998), the development of the EFQM model (European model based on Baldrige) to suit the characteristics of small firms is needed and more needs to be done to simplify the language, the format of the model and the application process. They state that small firms are generally “aware of the existence of the EFQM model but do not fully understand how they can derive benefits from self-assessment against its criteria. To them, self assessment is perceived to be used only when applying for an award, which is something for large organizations only.”

Notwithstanding these facts, it can be argued that familiarity with a particular theoretical concept or framework and understanding its underlying principles are two different conditions. It seems logical, as discussed for TQM by McTeer and Dale (1994) and Van der Wiele and Brown (1998) that small firms may not be specifically familiar with the Baldrige CPE, but they may practice its principles every day without placing such a label on it. Therefore, there may be a lack of specific knowledge concerning Baldrige, but not the underlying management principles. Ahire (1996) suggests that companies who embrace a QM framework should exhibit a systematic, firm wide acceptance.

2.3 The Importance – Implementation Gap for QS in Small Firms

Figure 1 shows the several streams of thought considered in the process of reviewing the literature prior to defining and implementing a QS in a small firm such as the Model Factory. The literature review takes into account documentation in quality management (QM), quality implementation critical success factors (CSF), high performance criteria for performance excellence (CPE), and small business research. Through the consolidation of these sources, it is possible to enter into the discussion of the importance of high performance practices in the small business population.

The Malcolm Baldrige criteria for performance excellence (CPE) defines a business management framework designed to aid organizations in elevating competitiveness. These criteria help organizations to be more competitive by continuously enhancing the value of the organizations' products and services to customers and by improving organizational performance and capabilities. The CPE is managed, evaluated and improved on an annual basis by the National Institute of Standards and Technology (NIST, http://www.quality.nist.gov). The criteria can act as a foundation for organizational self-assessment and are also the basis for the Malcolm Baldrige National Quality Award (MBNQA).

The MBNQA honors outstanding U.S. businesses that exemplify the core values of the criteria. These values are: a) customer-driven quality, b) leadership, c) continuous improvement and learning, d) employee participation and development, e) fast response, f) design quality and prevention, g) long-range view of the future, h) management by fact, i) partnership development, j) company responsibility and citizenship, and k) a results focus. The questions posed are: 1) How many of these criteria apply and need to be taken into account to define a Quality System for a typically small firm? 2) How do small firms perceive the importance of these criteria and to what extent do they implement the criteria?

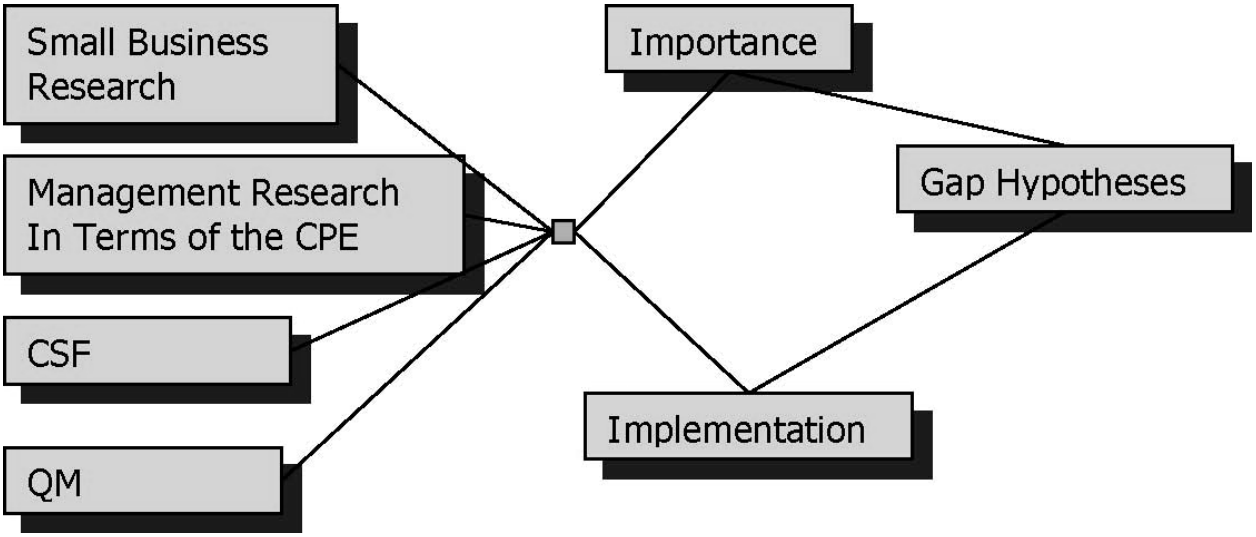

Figure 1 – Elements to Consider in the Implementation of a QMS. Raymond (2000)

Ford and Evans (2000) state that despite a high level of practitioner attention, theoretical and empirical research that focuses on the CPE has not been abundant. Much of the research in quality management implementation has focused on critical success factors (CSF's) to successful implementation (Saraph et al., 1989; Porter and Parker, 1993; Tamimi and Gershon, 1995; Black and Porter, 1996; and Ahire et al., 1996). Yusof and Aspinwall (1999) also developed critical success factors for quality management implementation with focus on small and medium sized organizations. They point out that past research "did not incorporate the perceived importance level for the factors proposed." Yet, one should expect small firm managers to assign overall significantly high importance ratings to the practices described in the CPE. Small firm managers recognize the value in high performance quality systems. The CPE are designed to be generic and flexible enough to apply to many different kinds of organizations. The management of small firms are not to be less concerned with quality management than their larger company counterparts (Van der Wiele and Brown, 1998). Kayis (1998) found that ninety-seven percent of the surveyed population already had a formal written statement of quality, while the other 3% were in the process of developing a quality policy, and they emphasized their commitment to QM implementation. Therefore, it can be stated that small firm managers recognize high performance

management practices and will identify them as important to their firm. Implementing such practices is another matter.

There is to be found a significant gap between the importance rating of the CPE and the extent to which the criteria are currently being implemented. Goh and Ridgway (1994) state that top level management may have a high level of commitment to many of the underlying principles of quality management, but often these ideas are not actively communicated to employees. When these same managers are specifically asked about the implementation of a quality management system, they state that TQM is inappropriate to their company and is applicable to only larger firms. Shin et al. (1998) discuss that while the principles of quality management appear obvious, many organizations have found them very difficult to execute. This is reportedly due to the fact that the implementation is cumbersome, time-consuming, and frequently lacking in focus.

Ahire and Gohar (1996) discuss that many of the characteristics of small firms may adversely affect the implementation of TQM. They argue that (1) the lack of market clout may impact the small firm ability to get suppliers involved in these efforts; (2) small firms may not recognize the importance of human resource management (HRM) strategies (Amba-Rao and Pendse, 1985; McEvoy, 1984) and therefore small firms experience lower levels of employee empowerment, use of employee involvement strategies, and employee quality training; (3) lack of professional management expertise (Siropolis, 1994) and the short term focus of many small firms (Verser, 1987) may be reflected in inadequate allocation of resources to TQM efforts; (4) quality tracking and improvement techniques such as benchmarking and SPC may also be used less frequently and less effectively in small firms (Ebrahimpour and Withers, 1992); (5) through a less effective use of internal quality information, the lack of an information infrastructure can add to the difficulties experienced by small firms in implementing high performance techniques (Ashmore, 1992).

Yusof and Aspinwall (1999) identify one other factor unique to small firms that impacts implementation. The authors discuss that resources had not previously been specifically identified as a critical factor. This becomes one the main arguments for the importance/implementation gap. If all the practices are considered important, then

limited resources have to be spread out over all practices. Van der Wiele and Brown (1998) argue that quality management implementation in small firms is completely a function of organizational change. They point out that change in a small firm is difficult because of many obstacles that have to be overcome. These obstacles are not only related to the implementation of a quality philosophy, but are difficulties encountered in any change the small firm has to go through. Other research finds that the lack of professional management expertise (Siropolis, 1994) and the short- term focus of many small firm managers (Verser, 1987) should result in a low level of commitment to quality management from top leaders that directly leads towards less implementation.

It is important to note, that even though both importance and implementation are rated on the same scale, they are measuring two different aspects of small firm management perceptions of the criteria. It could be argued that if a manager finds a practice to be of high importance, then implementation might be found to be equally high or extensively practiced (Raymond, 2000). However, in each key area of the CPE there is a significant difference between how important small firm managers rate the criteria versus to what extent they are implementing the criteria. In other words, even when a manager rates a practice as being highly important, implementation is not rated as high and is always significantly lower on the same one to five scale. This finding clarifies the situation in small firms with respect to the true nature of the importance–implementation gap. If small firms were avoiding certain parts of the criteria, this would allow them to pool resources to implement the more important practices at higher levels. But since small firms find all of the practices to be important, or at least moderately important, they seem to be unable to implement any one particular item at high levels. No practice is extensively implemented and resources are spread out to address as many of the practices as possible. The literature review supports this conclusion.

2.4 The NIST Criteria for Performance Excellence

The Criteria for Performance Excellence (CPE), as stated earlier, are managed, evaluated and improved on an annual basis by the National Institute of Standards and Technology (NIST, http://www.quality.nist.gov). The criteria are created from seven distinct categories and several items from which the high performance management

practices have evolved. The seven main categories are: 1) Leadership (L). 2) Strategic Planning (S). 3) Customer and Market Focus (CM). 4) Information and Analysis (IA). 5) Human Resource Focus (HR). 6) Process Management (PM). 7) Business Results (BR). Each of the following sub-sections describes the category and discusses briefly how small firms are characterized in terms of these categories. The discussion includes issues that come up from the sub-categories (subsequently referred to as items). Methodological approaches evolve naturally from the discussion.

2.4.1 Leadership

The Leadership category (L) examines the company's leadership system and senior leader's personal leadership. It deals with senior leaders and how the leadership system addresses values, company directions, and performance and other expectations. It consists of two items: L1 – Leadership Systems and L2 – Company Responsibility and Citizenship. A leadership system addresses whether leaders evaluate the needs of all stakeholders when setting company direction (Table 1, Item 1). This includes, besides senior leaders, all employees, customers, suppliers, partners, and shareholders. An inclusive, "stakeholder" approach to leadership runs counter to typical small firm leadership practices. Founders are driven to retain control over organizational concerns (Miller and Simmons, 1992), and so they develop management systems and leadership styles that centralize power and decision making (Mintzberg, 1984; Seymour, 1993).

Similarly, family business CEOs (whether or not they are the founders) also tend to be "authoritarian" (Birley ,1986) and "paternalistic" (Dyer, 1988), and their high need for control is reflected in their management systems (Dyer, 1988) and leadership styles (Longenecker and Schoen, 1978; Lansberg, 1988). However, Specht (1987) argues convincingly that interpersonal contacts are the key in the small and medium sized enterprises and hence supports the basic notion of all stakeholders importance. This suggests that small firm managers value highly their developed set of interpersonal relationships and rely on these when they need guidance. Reliance upon a subset of stakeholders will lead managers to neglect potentially key stakeholders. Thus, given the opportunity, the small firm manager will attempt to develop good personal relationships will all stakeholders. The problem is that single individuals are limited to the number of

close business relationships that they can manage. Therefore, leadership systems consider all relevant stakeholders are important to small firm leaders, but the actual implementation of leadership systems that consider all relevant stakeholders is rarely found at small companies.

Leadership systems also address if the company uses formal and informal methods for selecting managers and developing leadership skills (Table 1, Item 2). In the small firm environment there are very few layers of management. The manager has the opportunity to work with and observe other managers and employees in the daily operation of the firm. From this experience, the company leadership will recognize and groom specific talent that they observe on a first hand basis. Thus, there is little need for a formal system to select managers in the small firm. As for the development of leadership skills, this is normally handled through mentoring and experience. Small firm managers are not professional managers and for the most part lack specific training in leadership. They sharpen their skills through doing and expect the same for employees they are preparing for management. Leaders in a small firm recognize the importance of picking the right people for management positions, but they tend to put few resources into formal systems. If such development is done at all, small firms use informal mentoring processes of which little documented evidence is found. Schwartz (1994) points out that, “What is ironic about the situation is that those small organizations, the very ones who need qualified, experienced people, either can't or won't put their resources into training …or at the very least, encourage opportunities for mentoring.”

Another aspect of a leadership system is that leaders demonstrate their expectations in their behaviors and communicate expectations throughout the entire workforce (Table 1, Item 4). Chapman (1999) points out that small business owners do possess one advantage in that they are more likely to be aware of all of the aspects of their business including its employees. Lee and Oakes (1995) discuss the strengths of small firms relative to larger companies. If top management is convinced of the need for a particular approach, then it is easier for managers to inspire and motivate others in the organization. Because organizational structures and systems are generally simple, the process of implementing improvements can be made visible more easily and defined in a holistic way. The people dimension is easier to tackle on face-to-face relationships,

because of the low number of employees. Decision making processes are simpler in small firms (Axland, 1992). Because of this open system and simple structure, small firm managers place a high value on communicating clear beliefs and company expectations and these managers have the ability to extensively communicate such values to their employees.

The leadership system sub-section item also calls for systems designed to sustain individual development, initiative and organizational learning (Table 1, Item 3). Small firms tend to be lean, agile and flexible in responding to customer needs, opportunities and crisis. Small firm managers know that just one poor decision may seriously threaten their existence (Haveman, 1993; Norburn and Birley, 1988). The rigors of operating under such pressures may lead small firm managers to be more conservative or risk averse in their decisions. Due to the immediacy of management decisions and potential impacts of poor decisions, small firm managers will rely heavily upon themselves for final decisions involving all aspects of the business. This bias towards micro-management contradicts the need to delegate authority, allow leaders throughout the company to take initiative and learn from mistakes. Therefore there is a tendency at small firms for management to discount the design of formal leadership systems conducive to initiative and organizational learning and thus the implementation of such formal systems are difficult to find at small firms.

The leadership system should examine if leaders review firm performance (Table 1, Item 5) and use this process to build consistency in goals and whether the system is periodically evaluated and improved (Table 1, Item 6). Chittenden, Poutziouris, and Mukhtar (1998) establish how small firms tend to be owned and managed by individuals who have close personal involvement in every aspect of their business. They indicate that there is no evidence to suggest that informal quality management, based upon the personal involvement of business owners and with detailed knowledge of customer requirements, is in any way inferior to more formal systems. Even though top managers in small firms avoid formal leadership systems, the management of these firms does periodically consider their informal methods and try to improve them. Thus, small company leadership feels that managing and continuously improving informal, flexible

leadership systems are important but there is little evidence of conscience, well documented continuous improvement of leadership systems for small firms.

Table 1 and the Tables that follow summarize the literature discussion of all aspects of the CPE categories looking at each practice and evaluating how small firms rate each practice. Additionally, the Tables show how each practice is implemented at small firms. The use of high, medium or low to estimate the level of importance and implementation for each practice is arguable. It is very difficult to review the literature and assign a clear index for importance or implementation. Different individuals could interpret the literature and come to different ratings. In some cases the literature strongly suggests high importance or low importance, but in most cases there is room for interpretation. What it is clearly seen is that, as summarized for each item, importance is rated higher than implementation.

Item	Code	Practice	Importante	Implementation
1	L11	Leaders evaluate the needs of all stakeholders when setting company direction	**HIGH:** Small firm leaders value interpersonal contacts and they feel important the feedback from these stake-holders. (Specht, 1987)	**MEDIUM:** Leaders rely upon a manageable sub-set of stake-holders. Some key stake-holders may be overlooked
2	L12	The company uses formal and informal methods for selecting managers and developing leadership skills	**HIGH:** Leaders in small firms recognize the importance of selecting the right people for management positions. They use informal mentoring.	**LOW:** The development of leadership skills is handled through experience with little formal training (Schwartz, 1994)
3	L13	The leadership system is designed to sustain high performance, individual development, initiative, and organizational learning.	**MEDIUM:** Bias towards micromanagement contradicts the need to delegate authority (Birley, 1986; Dyer, 1988). Opportunities for learning are minimized.	**LOW:** There is a tendency at small firms for management to discount the design of formal leadership systems (Lansberg, 1988). Implementation of such systems are rare at small firms
4	L14	Leaders demonstrate their expectations. Leaders communicate their expectations to the entire work force.	**HIGH**: Small firm managers value highly the communication of clear beliefs and company expectations to the work force (Axland, 1992).	**HIGH**: The open system and simple structure of small firms allow managers to commun-icate such values to their employees (Chapman, 1999).
5	L15	Leaders review overall firm performance and use this process to build consistency in goals and allocation of resources.	**MEDIUM:** Such processes are considered important because these key decisions have an immediate impact on the business (Haveman, 1993).	**LOW:** Evidence of formal systematic reviews will not be apparent. Leaders get caught up in day to day operations.
6	L16	The leadership system is periodically and systematically evaluated and improved.	**MEDIUM:** Formal systems are unnecessary. However, informal methodologies are common.	**LOW:** Formal systems do not exist so they are not evaluated. Informal systems are rarely evaluated and improved.

Table 1 — Leadership System - Summary of Item Practices, Importance and Implementation. Source: Raymond (2000)

The second leadership item (L2) in the CPE, Company Responsibility and Citizenship, discusses how the organization addresses its responsibilities to the public and how the organization practices good citizenship (Table 2). The firm should consider the legal and ethical ramifications of their actions (Item 1) when making decisions. Not only should the firm meet all of the regulatory requirements, these should be treated as areas for improvement. Additionally, leaders of the firm should support employee involvement in the local community.

Small firms find the legal, ethical and risk requirements of their products important on two levels. Firstly, small firms feel unduly burdened by legal (government regulation) requirements. Environmental costs and taxes are functions of the local and national government. Safety regulations, workers compensation, and meeting pollution requirements all add additional costs. Some industries are more regulated than others. This impacts firms in different ways but generally affects all firms in a single industry equally.

Secondly, the cost of government regulation is a larger burden for the small firm. These legal requirements can create barriers or drive existing firms from the industry. According to Reiland (1999), for the US small- and medium-sized companies, the cost of complying with regulations consumes a much higher share of sales revenues than in larger enterprises. In manufacturing, for instance, the yearly cost per worker of complying with OSHA is twice as high in companies with 500 employees as in firms with 5,000 employees. On the other hand, small firms employing 50 or fewer employees are often exempt from some regulation. These issues have a significant impact on the operation of the business and the small firm manager considers them very important. The small business manager has to take these issues under consideration when making decisions because the impact could seriously threaten the existence of the business.

Vyakarnam, et al. (1997), in their discussion of small business ethics, note the personal characteristics of the owner-manager, and particularly the extent to which they can detach themselves from the business and its various stakeholders, have an impact on the firms outward social responsibility (Table 2, Item 3). Local image is indeed very important to the smaller firm (Irwin et al. 1997).

The small firm management is conflicted by their legal and ethical commitments. Close connections with their local environment makes them sensitive to such issues but the perceived overburden of federal policies alienates these managers. Therefore, small firm leaders give strong consideration to issues of community involvement and social responsibility, are somewhat involved in their local communities and take moderate steps towards meeting high standards of social responsibility given the limitations of their resources.

Item	Code	Practice	Importante	Implementation
1	L21	The company addresses the current and potential impact of its actions – products, services, and facilities – on society. Legal and ethical ramifications are taken into account in the decision making process.	**HIGH:** These issues have a significant impact on the operation of the business and managers consider them very important. They could seriously threaten the existence of the business (Reiland, 1999).	**HIGH:** Small firms that ignore such issues usually do not survive. Small companies may not systematically address such considerations and do not have the resources to monitor changes
2	L22	The company not only meets all local, state, and federal legal and regulatory requirements, but also treats these as areas for improvement.	**HIGH:** Small firm managers have close connections with their local environment, making them sensitive to legal and ethical issues. But they feel the overburden of federal policies (Vyakarnam et al., 1997)	**MEDIUM:** Small firms will meet the minimum requirements, but they usually do not find competitive advantage through treating these issues as areas for potential improvement.
3	L23	The company and its employees support and strength their communities through personal involvement, which is encouraged, supported, and recognized by senior leadership.	**HIGH:** Small firms are likely to be involved in the concerns of their communities. Managers are likely to have roots in the community in which they operate. The close contact with their employees constitutes also a strong tie to the local community (Irwin, et al., 1997).	**MEDIUM:** Because of their limited resources, small firms usually cannot contribute significantly to communities. Although, they can and do support employee involvement in the community.

Table 2 — Leadership System: Company Responsibility and Citizenship - Summary of Item Practices, Importance and Implementation. Source: Raymond (2000)

2.4.2 Strategic Planning

The Strategic Planning category (S) deals with how the company sets strategic directions. It consists of two items: S1 – Strategy Development Process and S2 – Strategy Implementation in Action Plans. Strategy cannot be discussed without addressing the strategy development process. This process should consider customer expectations, the competitive environment and all risks. This includes examining financial, market, technological, and societal risks. In this process, the firm should assess the markets in which they compete and new markets they might consider entering. The firm must consider its operational capabilities, such as flexibility and responsiveness, and human resources, such as skills and availability (Table 3).

Small firm managers may admit that taking time to think about the future of the firm, and putting some things down on paper, is a good idea (Table 3, Item 1). But there is never time to do so. To one degree or another, small firm managers spend some time thinking about strategy, but for the most part the work is insignificant. Ahire (1996) explains that small firms are characterized by a myopic view of management which focuses on meeting day-to-day survival challenges, partly due to lack of resources and partly due to the inability of the owner-manager to exhibit understanding of the strategic aspects of business. Robinson and Pearce (1984) suggested that small firms lack the necessary staff and time to engage in strategic planning, and they concluded that small firms generally do not plan. Small firms are generally considered more vulnerable to competitive challenges, in part because they spend more time adjusting rather than predicting and controlling the business environment (d'Amboise and Muldowney, 1988).

In the strategy development process, the firm must consider its ability to be responsive to change by examining its operational capabilities, technical resources and supplier and partnering relationships (Table 3, Item 2). Drozdow and Carroll (1997) report how small firms are easily overtaken by the speed of competitive changes in industry and the economy. The small firm environment, which begins as a source of innovation and creativity, “can sustain a profound conservatism.” The structure of the small firm inhibits the development of strategic initiatives. While the small company has a firm handle on its operational capabilities, its structure strictly inhibits changes that might make the firm more responsive or flexible.

The second strategy item in the CPE is the implementation of company strategy (S2). Once developed, strategy is translated into action plans. Action plans should be clearly defined, including measures of effectiveness and resources needed for implementation (Table 3, Item 3). Small company managers will give some priority to translating such ideas into formal plans of action, but they are limited by their resources to the number of ideas that can be converted to action. Brady (1995) argues that small businesses most often use limited resources to initiate strategies that respond to their customer needs, possibly because most cannot afford to make mistakes. Small firms are even less likely to develop action plans based on internal planning, but they will work with their larger customers to implement commonly held action plans (Shan, 1990). The company will follow the plans that do bear fruit, but firm leaders will place little value on systematically tracking the few projects that can be implemented at any one time (Table 3, Item 4). These types of key measures are time and resource consuming and considered unnecessary. Consequently, the tracking of progress towards meeting action plans becomes unlikely for the small firm, unless it is specifically driven by the customer (Table 3, Item 5).

Comprehensive human resource plans should be implemented that address all aspects of Human Resource Development, HRD (Table 3, Item 6). Kerr and McDougall (1999) found that very few small firms adopted a HRD approach that locates training and development strategically in the plans of the company. The authors found that the majority of small businesses do not identify training needs from the business plan before providing training, and few evaluate training effectiveness.

In addition to action plans, firms develop 2-5 year projections of company performance (Table 3, Item 5). Companies must plan for the long term and try to anticipate how short term decisions will impact the long run competitiveness of the firm. For small firms, some thought goes into how such plans help strengthen their performance, but not much is known on how it will help the firm in terms of competitive advantage. As was discussed earlier, small firms tend to get caught up in day-to-day operational concerns and have difficulty planning from year to year. It seems logical that small firms spend even less time doing long term projections.

Item	Code	Practice	Importante	Implementation
1	S11	The firm has a strategy development process that considers customer expectations, the competitive environment, and all risks.	**MEDIUM:** Small firm managers find little need for a formal system of strategic planning, but it still consider the idea of strategy formulation very important (Ahire 1996).	**LOW:** Implementation of formal strategic planning at small firms is low (Robinson and Pearce 1984; Matthews and Scott 1995) but there is a level of informal planning.
2	S12	The strategy development process assesses markets in which to compete, operational capabilities, human resources and supplier relationships.	**HIGH:** Small firms have a good handle on their operational capabilities. Leaders will enter into partnering relationships (Shan 1990) but do not share strategic initiatives.	**MEDIUM:** Small firms often fail to develop true strategic initiatives because they lack the resources to do a complete analysis (Drozdow and Carroll 1997).
3	S21	Strategy is clearly translated into action plans that support achieving critical requirements at the company, process, and work unit/individual job levels.	**HIGH:** Small firm managers give high priority to translating strategic ideas into formal action plans, but are limited by resources to the number of ideas that can be planned (Brady 1995).	**MEDIUM:** Small firms are less likely to translate and develop action plans based on internal planning, but they will work with their customers to implement commonly held action plans (Shan 1990).
4	S22	Progress toward meeting action plans is systematically tracked using key measures of performance.	**MEDIUM:** The plans that do bear fruit will be followed but small firm leaders will place little value on systematically tracking all projects.	**LOW:** Little activity is directed to follow up projects because the impact of every significant change at the small firm is quickly apparent (Brady 1995).
5	S23	Progress toward meeting action plans is systematically tracked using key measures of performance.	**MEDIUM:** Tracking of progress towards meeting action plans is moot point for the small firm manager unless is customer driven	**LOW:** The impact of every significant change at the small firm is immediately apparent. These type of key measures are considered unnecessary.
6	S24	Comprehensive human resource plans are derived from overall company strategy	**MEDIUM:** Education and training of human resources in small firms does not follow from the business plan and few evaluate training effectiveness.	**LOW:** Very little is done to adjust human resource planning to based on overall company strategy.
7	S25	Two to five-year projections are made for key areas and are compared to projected competitor performance.	**MEDIUM:** Small firm managers think informally about long term goals, but they do not make competitor projections. Benchmarking is uncommon.	**LOW:** Small firms are fixed in day-to-day operational concerns and have difficulty planning from year-to-year.

Table 3 — Strategic Planning: Strategy Development Process (S1) and Company Strategy (S2)- Summary of Item Practices, Importance and Implementation. Source: Raymond (2000)

2.4.3 Customer and Market Focus

The Customer and Market Focus category (CM) consists of two items: CM1 – Customer and Market Knowledge, and CM2 – Customer Satisfaction and Relationship Enhancement. For the first item, firms need to be attuned to their customer base and the markets they serve (Table 4). Management should clearly define the markets in which they compete or plan to compete. This is not as difficult for the small firm as it might be for the large firm. Small companies are more likely to serve a smaller customer base, enter into a limited number of markets and know very well their customers. On the other hand, small firms spend less time investigating how their current capabilities could be used in markets in which they do not already compete (Table 4, Item 1).

Businesses should establish proven methodologies for listening and learning from their customers (Table 4, Item 2). Small company managers are most comfortable with face to face relationships with their customers. The feedback they get from frequent customer encounters provides all of the information they need. The studies investigating market research practices of smaller ventures have found the following: 1) formal market research (use of marketing professionals) and written marketing plans are not perceived as valuable (Hills and Narayana, 1989); 2) formal market research is seldom carried out (Robinson and Pearce, 1984); and 3) the value of formal market research is perceived as limited (McDaniel and Parasuraman, 1985; Spitzer, Hills, and Alpar, 1989).

Regardless of the formal or informal methods used for listening to customers, the company must follow this up by using what it learns from listening to customers (Table 4, Item 3). Small company leaders are highly accessible to their customers and feel it is very important to follow up on customer concerns. Case studies show informal market research practices produce high quality information and tend to be used more often by small businesses (Hills and Narayana, 1989).

Reeves and Hoy (1993) find that the active involvement of the owner-manager and employees in small firms allows them to tailor the firms' offerings to the specific needs of their customers without going through the bureaucratic layers typical in large companies. Therefore, detailed market analysis and formal approaches to implementing customer feedback are not necessary (Table 4, Item 4). Kinra (1995) found that small companies are actively involved in reacting to feedback from their customers.

Item	Code	Practice	Importance	Implementation
1	CM11	Customer groups and or market segments are clearly defined and customer needs are anticipated.	**HIGH:** Small firms serve a small customer base, enter into a small number of markets, and know well their customers.	**MEDIUM:** Small firms spend less time investigating how their capabilities could be used in new markets (Kinra, 1995).
2	CM12	Approaches for listening and learning from customers are established as part of overall business strategy.	**MEDIUM:** Small firms have a good handle on their operational capabilities. Leaders will enter into	**MEDIUM:** Formal approaches are not used. Customer base is small for informal collection of information (Fuller, 1994).
3	CM13	Listening and learning approaches result in key product and service features that customers expect.	**HIGH:** Small firms feel that it is very important to follow up on customer concerns.	**HIGH:** The active involvement of managers and employees in small firms allows tailoring of offerings to customer needs.
4	CM14	The company systematically evaluates and improves its approaches for listening and learning from customers.	**LOW:** Formal methods are not needed but improving informal methodology is still somewhat important.	**LOW:** Once an informal method is established, it does not get evaluated in a systematic fashion.
5	CM21	The company provides easy access for customers when they seek assistance or wish to comment or complain.	**HIGH:** Small firm leaders know customer satisfaction is the key to maintain the firm reputation (Raymond et al., 1998)	**MEDIUM:** The small firm has fewer layers of staff and employees can be reached in a timely manner.
6	CM22	Requirements for direct interaction with customers are well defined and applied by all and are periodically evaluated and improved.	**MEDIUM:** Small firm managers believe that the experience their sales personnel gain in their work is sufficient.	**MEDIUM:** Only 40 % of small firms provide formal training for their employees in contact with customers (Goh and Ridgway, 1994).
7	CM23	A complaint management process exists to resolve complaints, which are analyzed for improvement.	**HIGH:** Small firms know are more vulnerable to the loss of customers. Managers feel the complaint process is important.	**MEDIUM:** Nearly 60% of small firms measure their customer's complaint rate (Guilhon et al., 1998).
8	CM24	The company follows up with customers for feedback and gathers information about customer satisfaction.	**MEDIUM:** Small firms tend to misperceive their customers needs and their opinion about the company and its products.	**LOW:** Small firms tend to over-emphasize intrinsic quality and underestimate quality service (Roper et al., 1997).
9	CM25	Information on customer satisfaction is gathered. Customer satisfaction is used to drive improvement.	**HIGH:** All companies agree on the importance of the customer and try to establish a good relation with their customers (Goh and Ridway, 1994).	**LOW:** Only 7% of the small firms studied (Goh and Ridway, 1994) conduct customer surveys to determine customer needs and expectations.

Table 4 – Customer and Market Knowledge (CM1) and Customer Satisfaction (CM2) – Summary of Item Practices, Importance and Implementation. Source: Raymond (2000)

The second item (CM2) in the Customer and Market Focus of the CPE is Customer Satisfaction and Relationship Enhancement. Small firm managers recognize that customer satisfaction is very important to maintaining the reputation of the firm, which impacts all aspects of the business (Table 4, Item 5). One aspect of customer satisfaction is that the company should provide easy access for customers when they are seeking assistance and/or they wish to complain. Small enterprises have unique advantages, including a proximity to their market, and the loyalty of their customers (Raymond et al., 1998). Small firms have some inherent advantages and disadvantages in terms of their accessibility to customers. On one hand, the small firm has fewer layers of staff and responsible employees can be reached in a timely manner. On the other hand, small firms are less likely to have 24/7 customer support.

Employees who interact directly with customers should be well trained and should be aware of all the requirements to do their jobs properly (Table 4, Item 6). In order to keep such practices current to meet customer needs, these performance requirements should be periodically reviewed and improved. Goh and Ridgway (1994) found that only 40% of the small business population in their study, have provided formalized training for their customer contact employees. Management feels that the experience their sales personnel gain through the course of their work is sufficient. Unfortunately, this is inadvisable because the lessons they learn as a result of on-the-job training might well lose the company customers.

A complaint management process should exist that ensures that concerns are resolved effectively and promptly (Table 4, Item 7). Responsible employees must follow up with customers to receive feedback and improve the process. Complaints received should be aggregated and communicated throughout the firm. Since, small firms have a smaller customer base, are more likely to rely on a few large customers and are more vulnerable to the loss of customers, small firm managers do feel that this process is not only important but it is also very necessary. Guilhon et al. (1998) found that nearly 60% of the small companies studied measure the complaint rate of their customers, however less than half measure failure, availability and incomplete delivery rates. They found that the percentage of incomplete deliveries is only calculated in 25% of cases, even though it is an important indicator of customer dissatisfaction.

Information on customer satisfaction is collected to improve internal and external processes (Table 4, Item 8). Additionally, the firm should examine satisfaction feedback in relation to their competition. Small firms tend to perceive incorrectly, not only the customer opinions on the company and products, but their own customer's needs. Roper et al. (1997) found general disparities between the small firm perception of needed quality and the perception of their customers. In particular, small firms tend to over-emphasize the importance of intrinsic quality attributes, while underestimating the importance to their customers of extrinsic quality attributes. Any assessment made by small firms about their relative quality is likely to be highly misleading.

Firms can capture information about customer satisfaction, but they need to use this information to motivate improvements in the company and aid managers in understanding the factors that drive markets (Table 4, Item 9). Determining customer satisfaction levels is important to small firm managers. However, Goh and Ridgway (1994) have found that only 7% of the small firms studied conduct customer surveys to determine customer expectations of the company and the future needs of the customers. Additionally, they found that small firms do not conduct surveys to determine customer satisfaction with company products. Nevertheless, all small companies acknowledge the importance of the customer and have concentrated efforts in establishing good customer relationships.

2.4.4 Information and Analysis

The Information and Analysis category (IA) consists of three items: IA1 – Selection and Use of Information and Data, IA2 – Selection and Use of Comparative Information and Data, and IA3 – Analysis and Review of Company Performance.

High performance practices of the CPE require that key financial and non-financial company data needs are clearly linked to company processes and goals and systematically gathered. It has long been recognized that performance measures can be used to influence behavior and, thus, affect the implementation of strategy (Skinner, 1971). Data needs should be linked to company processes and goals and this information is used to track and improve performance. However, small firms tend to focus their selection and use of data on internal operational process issues. (Neely et al., 1994) This focus on the support of key processes allows the small firm to improve

performance, but attention to only a few key processes consumes resources that are not available to small firms (Table 5, Item 1)

Stakeholders who need data to effectively perform their work should have convenient access to all necessary information. However, the small firm focus on collecting a limited amount of data related to mainly internal processes makes this information of a very limited value to most stakeholders. In small firms, the unplanned and informal nature of information gathering is in direct contrast to other areas of management and manufacturing systems that are strongly systematized (White, 1986; White and Wilson, 1988). Pearson and Ellram (1995) found that the lack of a formalized evaluation process might not necessarily indicate a lack of management sophistication on the part of small firms. In many cases small firms may have developed personalized informal relationships with stakeholders. These informal relationships are sometimes as effective as formal/objective measures of conducting business and can provide the data and information needed by stakeholders (Table 5, Item 2).

The effectiveness of data collection, as well as its usage, needs to be periodically evaluated, improved and kept current (Table 5, Item 3). Pineda et al. (1998) suggests that the more important the decision and the more the manager perceives to be effective in making a particular type of decision, the greater the intensity of the information search, and the greater the use of external information sources during decision-making. Brush (1992) cites five studies that have researched environmental scanning activities of small businesses. Results show that time spent in scanning or assessing outside opportunities is often limited (Kinsey, 1987) and more frequent scanning (frequency of contacts) is related to better performance (Dollinger, 1985). Information sources were more often personal than impersonal (Smeltzer, Fann, and Nikoliasen, 1988) and competitors as a source or subject of investigation were ranked lower than customer, suppliers, and other sources (Fann and Smeltzer, 1989). Beal (2000) has found that CEOs of small manufacturing firms, constrained by their involvement in their firms' daily operations, may not have time for frequent scanning of their external environments.

Item	Code	Practice	Importance	Implementation
1	IA11	Financial and non-financial data needs are clearly linked to key company processes and action plans. Data is gathered systematically.	**HIGH:** Performance measures can be used to influence behavior and, thus, affect the implementation of strategy. (Skinner 1971).	**MEDIUM:** Small firms tend to focus their selection and use of data on internal operational process issues (Neely et al. 1994).
2	IA12	Stakeholders who need data to perform their work have convenient access to all necessary information.	**HIGH:** Small firms prefer to use informal methods but know it is important to provide the best data available (White 1986).	**MEDIUM:** Small firms collect limited amounts of data and are related mainly to internal processes (Brush, 1992).
3	IA13	The data the firm collects, its usage and effectiveness, are periodically evaluated, improved, and kept current.	**MEDIUM:** Data collection in small firms is informal and does not need systematic evaluation.	**LOW:** Because of the informal nature of data collection, small firms do little in this regard.
4	IA21	The firm systematically evaluates its needs for comparative information and has established criteria.	**MEDIUM:** Small firms tend to look inward not realizing the importance of benchmarking and its advantages.	**LOW:** Small firms may value benchmarking competitors but do little to collect data (Fam and Smeltzer, 1989).
5	IA22	Comparative information is used to set goals and to encourage performance in critical areas.	**MEDIUM:** Small firms are content as long as they perform better than their neighbors (Goh and Ridway 1994).	**LOW:** Direct rivals are small firms also and it is difficult to collect private information (Hewitt-Dundas et al. 1997).
6	IA23	Methods to gather and use comparative information is are periodically evaluated and kept current.	**MEDIUM:** Since in small firms information methodology is so limited, it is hard to consider alternatives and improvements.	**LOW:** The main source of information on competitors is how do they interact with the environment (Beal 2000).
7	IA31	Inclusive performance data is integrated and analyzed to assess overall performance. This is used to understand cause-effect connections.	**HIGH:** Performance assessment relative to set plans and goals is rated high but small firms tend to not develop formal plans (Robinson and Pearce 1984).	**MEDIUM:** Small firms have goals in mind but rarely have the time nor the resources to collect data to analyze overall performance.
8	IA32	Company performance and capabilities are reviewed systematically to assess progress relative to goals, plans, and changing needs.	**MEDIUM:** Without guidelines that produce good measures on which to base assessment, any efforts to analyze and review performance are worthless.	**LOW:** Small firm managers wish to assess performance aspects and relate them to goals, but they do little implementation.
9	IA33	Performance reviews are used to set improvement priorities. Reviews translate into improvement actions throughout the company.	**LOW:** Collection and analysis of performance data is of low priority. Small firms do not have the resources to do the work. (Wiarda and Luria 1998).	**LOW:** New technologies enable small firms to better measure, analyze and share data (Starr, 1988). But little is done with limited resources.

Table 5 — Information and Analysis: Selection and Use of Information (IA1), Comparative Information (IA2), and Performance (IA3) – Summary of Item Importance and Implementation. Source: Raymond (2000)

The second item in the information and analysis category of the CPE is the selection and use of competitive information and data (IA2). High performance practices of the CPE require the company to evaluate its needs for comparative information and establish criteria for seeking sources of such data (Table 5, Item 4). This information should be used to set goals (Item 5). How this information is gathered should be periodically evaluated and improved (Item 6). Fann and Smeltzer (1989) suggest that although firms may appreciate the potential strategic value of competitor information, they generally make little systematic attempt to collect or maintain such data (Item 4). In many cases, the direct rival of a small firm is another small firm and research has shown that it is difficult to collect competitive information held internal to the company (such as profit margin) because the majority of these firms are privately held and information is not easily obtained (Item 5, Hewitt-Dundas et al., 1997). However, other research has found that small firms are able to collect information on how competitors interact with the external environment. This becomes the primary source of information about competitors for the small firm (Item 6, Beal, 2000). Goh and Ridgway (1994) found that the majority of the companies either conduct only limited comparisons with their competitors or just monitor trends within their own company. The companies tend to be very inward-looking and are content so long as they are performing better than their neighboring competitors. They have not realized the importance of benchmarking and the advantages it holds for their company (Item 4).

The third item in the information and analysis category of the CPE is the analysis and review of company performance (IA3). Assessing company performance relative to plans and goals may be an arguable point for many small firms since these firms tend to not develop formal strategy and plans. In general, small firms may have certain financial goals in mind, but they rarely have the time or resources to collect data to analyze the overall performance of the company (Table 5, Item 7).

Small firms will review the performance of key process measures but formal goals are not set for these processes (Item 8). Wiarda and Luria (1998) argue that standard benchmarking how-to's are poorly suited to small manufacturers. They conclude that in order to assess overall company performance, small firms need to have an idea of what best practices exist. With little prior knowledge of how they compare,

they are unsure in which areas they should focus their benchmarking efforts. Without proper guidelines that produce good measures on which to base assessment, any effort to analyze and review performance is not worthwhile. Small firm managers may wish to analyze and review some performance aspects of their company, comparing them to goals but actually do little to implement such efforts.

Information based technologies have transformed the nature of manufacturing products, processes, companies and industries. These technologies are especially beneficial to small firms because they lower entry costs, reduce the minimum efficient size of production runs, and lower setup costs. (Starr, 1988) Additionally, they give small firms access to larger markets, more accurate demand information and offer another source for competitive research (Table 5, Item 9). Wiarda and Luria (1998) indicate that the collection and analysis of performance data is of low priority to small firms which have few resources to do in-depth work in this area.

2.4.5 Human Resource Focus

The high performance criteria of the CPE require a company to focus on its Human Resources (HR). This category consists of three items: HR1 – Work Systems Practice, HR2 Employee Education, Training, and Development, and HR3 Employee Well-Being, and Satisfaction.

The CPE require that jobs should be designed to provide opportunities for individuals to take initiative and responsibility for their own decisions (Table 6, Item 1). When the characteristics of leaders in small firms were considered previously (*vide supra*), it was found that there is tendency for these leaders to be autocratic and micro-managers. This runs counter to flexible job design and limits the scope of final decision making, but it does not inhibit the employee from making suggestions and innovations in the job itself. In most small firms, one should expect relatively low levels of employee empowerment, use of employee involvement strategies, and employee quality training. However, Andreichuk (1992) counters this argument finding that smaller companies can be even more successful at soliciting employee support and involvement because there are fewer management layers to permeate and fewer people to convince of the benefits

Item	Code	Practice	Importance	Implementation
1	HR11	Job management and design provide for individual initiative and responsibility.	**HIGH:** Job responsibilities in small firms are very broad and require employee initiative and self motivation.	**MEDIUM:** Jobs may not be well designed in small firms since have to conform to individuals filling a broad position.
2	HR12	Job design ensures effective communication and skill sharing across the firm.	**HIGH:** Few employees handle a broad set of responsibilities, thus good communication and skill sharing is essential.	**MEDIUM:** Jobs are well designed for this purpose but high turnover rates hamper this effort.
3	HR13	Programs for compensation and recognition reinforce performance and learning.	**MEDIUM:** Small firms cannot focus on compensation as a reinforcement tool and rely on recognition.	**MEDIUM:** In small firms employee compensation in terms of salary and benefits is smaller than in large firms.
4	HR21	Education and training activities are structured to address the knowledge and skills employees need.	**MEDIUM:** Formal programs are resource intensive. Training is important but small firms have to be creative (Axland, 1992).	**LOW:** Small firms put little emphasis on training and development of staff at any level (Vicker,s 1990).
5	HR22	Employees and managers have important input in the design of education and training activities.	**MEDIUM:** Management relies on employees and managers to develop education and training activities.	**LOW:** Management puts little effort in designing training programs and employees do most of the design work.
6	HR23	Delivery of education and training activities supports the achievement of key company objectives.	**HIGH:** In small firms training is done on site, it is applicable to the job and supports company objectives (Penzer, 1991)	**MEDIUM:** There may be a disconnection between operational abilities and strategic intentions.
7	HR24	Knowledge and skills are reinforced on the job and education activities are evaluated and improved.	**MEDIUM:** Small firm managers would like to spend more time on improving such activities (Amba-Rao and Pendse, 1985).	**LOW:** In small firms formal programs are not emphasized and little time is allocated for evaluation and improvement.
8	HR31	The company sets goals for health, safety, and ergonomics.	**MEDIUM:** Management tends to fall back on minimum health and safety requirements.	**MEDIUM:** Small firms are unlikely to have on-site staff for these activities.
9	HR32	Services for employee well-being and motivation are available and are evaluated.	**MEDIUM:** Small firms do what they can and understand the impact of employee well-being.	**LOW:** Small firms rely on limited packages that satisfy minimum health requirements.
10	HR33	Adequate methods are used to determine employee well-being and satisfaction.	**HIGH:** Small firm managers strive to reduce turnover and track employee satisfaction.	**LOW:** Small firm managers do not obtain feedback from employees on these issues.
11	HR34	Results related to employee well-being are evaluated relative to business results.	**MEDIUM:** Small firm managers would like to spend more time on this issue but do as they can.	**LOW:** Measures of employee well-being are not available, so this is not done.

Table 6 – Human Resource Focus (HR): Work System (HR1), Employee Education (HR2), and Well-Being and Satisfaction (HR3) - Importance and Implementation. Source: Raymond (2000)

Job design should allow for effective communication and the translation of skills among employees (Table 6, Item 2). Job descriptions are generally much broader at small firms. Fewer employees handle a variety of tasks across functional areas. Compared to the large firm, where you can find very narrowly defined job descriptions with limited responsibilities, at the small firm, the employee is asked to do more and the opportunities exist to get much practical experience in a broad variety of jobs and tasks. The problem is that these expectations come with a price. Fewer resources and less compensation lead to higher turnover. Research indicates that recruiting, motivating and retaining employees is one of the biggest problems for small firms (Hornsby and Kuratko, 1990; Mathis and Jackson, 1991; Verser, 1987; Ghobadian and Gallear, 1996). Higher turnover rates take a toll on learning and experience. This hinders both communication and learning transfer.

It is common knowledge that working in smaller firms means that compensation in terms of salary and benefits do not usually compare with larger firms (Lichtenstein, 1998). This compensation gap is even found at the highest levels of the company (Anonymous, 1995). Furthermore, small business managers do not perceive incentives to be critical to improving productivity (Amba-Rao and Pendse, 1985). Small firms cannot rely on compensation to help reinforce performance and teamwork. These firms have to use other recognition programs to do so. In conclusion, any firm can put together a well thought out recognition program even with limited resources (Table 6, Item 3).

The second item in the Human Resource (HR) management category of the CPE focuses in the employee training and development. The CPE require that at the firm education and training activities should be structured to address the skills employees need to meet their work and personal development objectives (Table 6, Item 4). Employees and their managers should be allowed to give feedback in designing education and training activities (Item 5). These activities should also be designed with company objectives in mind (Item 6). Most importantly, the training should translate back to the job. Such activities should be critically evaluated by employees and managers and periodically improved (Item 7).

Training and learning in small firms is often ad hoc, occurring in the course of normal routines (Hendry et al., 1991). Researchers report that managers of small firms lack training in formal personnel management practices and they do not consider the use of generally accepted HRM practices as essential for improving productivity (Amba-Rao and Pendse, 1985, McEvoy, 1984). In general, small companies have been found to under invest in worker training. Goh and Ridgway (1994) found that 47% of the companies surveyed have at most only 20% of their workforce trained in quality awareness or any other quality practices relevant to the company's operations. Management in these companies feels that their workforce is sufficiently skilled to perform their jobs and, since they have done fine to date, there is no pressing need for any training programs to be implemented. Vickers (1990) suggests that smaller firms, no matter what business sector they operate in, put little emphasis on training and development of staff at any level and that these firms experience a high turnover rate of key personnel.

On the other hand, training at small firms tends to be done on the job and using informal methods. Two methods common at small firms are: partnering experienced employees with newer ones and adapting outside training resources to internal programs. This allows small firms to adapt their limited resources to training. Small firms are also flexible in allowing employees to seek out development and finance it on their own with limited financial support from the firm. The company will allow employees to design more flexible work hours to meet these self-development goals. Since such programs are self-designed, there may be a disconnection between operational activities and the strategic goals of the firm. Employees will sometimes acquire skills not directly connected to the activities of the firm.

Small firms can create the kind of atmosphere that fosters personal growth and encourages people to improve their jobs. (Penzer, 1991) Small firms have a natural tendency for cross-functional training because they have fewer layers of management and staff (Axland, 1992). However, formal training to introduce new learning is less likely since it is normally cost prohibitive. Lean staffing in small firms makes the empowering of people very natural.

The third item in the human resource management category of the CPE focuses in the employee well-being and satisfaction. McEvoy (1984) found HRM practices to be the leading cause of small firm failures (Table 6, Items 8 – 11). These findings were substantiated by Hess (1987), who reported that small firms ranked personnel management as the second most important management activity. However, in practice, other functional areas such as finance, production, and marketing usually get preference over personnel management (McEvoy, 1984).

The company should set goals for health, safety, and ergonomics (Table 6, Item 8). Small firms understand the impact of worker well being on the company. However, the management at these firms does what it can, given the resource base to address such issues. Formal, costly programs that offer well-being and motivational services are rarely found at small firms. They tend to rely on limited packages that satisfy minimum health and safety requirements. Small firms do not seem to be able to innovate in this area. They are unlikely to have on-site staff that has specialized knowledge in this area and are unlikely to turn to outside consulting for help (Mathis and Jackson, 1991).

Small firms do not formally solicit feedback from employees on well-being issues. There are informal opportunities for employees to discuss these issues. Unfortunately, management does not get a good idea of the overall environment of employee satisfaction from such methods. Lack of knowledge of HRM issues and their importance in the operation of a successful business has impacted many small firms. Inadequate and inefficient management of HR in firms have often resulted in low productivity, and high dissatisfaction and turnover among the employees.

2.4.6 Process Management

The Process Management category (PM) of the CPE examines the key aspects of process management, including customer focus design, product and service delivery, support, and supplier and partnering processes involving all work units. This category deals with how key processes are designed, implemented, managed, and improved to achieve better performance. The PM category consists of three items: PM1 – Management of Product and Service Processes, PM2 – Management of Support Processes, and PM3 – Management of Supplier and Partnering Processes (Table 7).

Item	Code	Practice	Importance	Implementation
1	PM11	The product and service processes are designed systematically incorporating all stakeholders.	**HIGH:** Small firms tend to focus on operations and operations are the embodiment of the process management category.	**HIGH:** Manufacturing activities In small firms are strongly systemized (White and Wilson, 1988).
2	PM12	The design of production-delivery processes incorporates quality and operational performance.	**HIGH:** Firm managers are highly concerned with controlling quality and operational performance parameters.	**MEDIUM:** Small firm lack of well trained personnel is countered by their simpler processes and management.
3	PM13	Design and service processes are coordinated to ensure trouble-free delivery of products.	**HIGH:** Small firm owners-managers are focused on meeting delivery schedules due to cash-flow considerations.	**HIGH:** The lean nature of the small firm favors coordination of design and service processes and its managed improvement.
4	PM14	The firm defines clearly product and service processes and ensures they meet all requirements.	**MEDIUM:** Processes are clearly defined but corrective action and in-process measurements may yield to other activities.	**MEDIUM:** The lean nature of small firms allows quick action, but managers may emphasize delivery over inspection.
5	PM15	Product and service processes are evaluated to increase performance.	**MEDIUM:** Process evaluation and improvement is important but small firms adapt slowly.	**MEDIUM:** More emphasis is placed on creating efficiencies, reducing waste and set-ups.
6	PM16	Results of the evaluation of product and service processes are shared.	**HIGH:** Managers think it is very important to share results from operational performance.	**HIGH:** The lean structure of the small firm allows easy share of evaluation and improvements.
7	PM21	Support processes are clearly defined, measured and managed.	**HIGH:** Processes that support products or service are essential to the firm.	**HIGH:** Support processes allow the firm to meet the customer needs (Moreno-Luzon 1993) f
8	PM22	Key support processes are evaluated and improved to increase performance.	**HIGH:** Small firms consider support processes an essential area to maintain advantage.	**MEDIUM:** Small firms lack the resources to systematically evaluate processes.
9	PM31	Important performance requirements are carefully defined and used to select suppliers and partners.	**HIGH:** Management of important suppliers and partners is important for the small firm.	**MEDIUM:** Cash flow problems make many small firms to tend to source to low cost bidders with easier credit terms.
10	PM32	The firm ensures that supplier and partner requirements are met by requiring feedback.	**HIGH:** The success of many small firms is due to effective networking with suppliers and partners.	**MEDIUM:** Formal annual review of suppliers is used by only 33% of small firms (Pearson and Ellrams 1995).
11	PM33	Supplier and partnering processes are periodically evaluated and improved.	**MEDIUM:** For small firms**,** evaluation of relationships with other firms is important.	**LOW:** Lack of formal review processes shows purchasing is not part of the firm's strategy.

Table 7— Process Management (PM): Product and Service Processes (PM1), Support Processes (PM2), and Supplier and Partners (PM3) – Summary of Item Importance and Implementation. Source: Raymond (2000)

The high performance criteria of the CPE require that the design of product and service processes should be addressed systematically, incorporating all stakeholders and accounting for the changing environment (Table 7, Item 1). Ideally, design and service processes are clearly defined, in-process measurements are taken, and a corrective action approach is established to ensure that products and services meet company requirements (Item 4). Because of the lean structure of the small firm, design and service processes can be coordinated among fewer employees to enable error free introduction and delivery of products (Item 2). Small firm management is focused on introduction of new products and processes and the status of deliveries (Item 3). However, cash flow at small firms has to be managed closely. Operational processes are costly and delivery of a quality product in a timely manner ensures the flow of revenues into the firm. This indicates a potential problem for small firms. Because of cash flow concerns, on time delivery make take precedence over in-process inspection and corrective action (Item 4), leading to product quality problems.

Small firms tend to be operationally focused and operations are the embodiment of the process management category. White and Wilson (1988) concluded in their small business study that manufacturing activities were “strongly systemized” at small firms. Most problems are immediate and stem from operational sources: production, scheduling, inventory management, finding qualified labor, labor turnover, and dealing with government regulation. Norgett (1991) found in his study on the use of design and design management by small firms that such companies display little knowledge of design management and systematically over-rate the extent of their design awareness compared to available good practices. Much of the firms' design capability is found to depend on the personality and abilities of the owner/manager. A fairly commonplace technological innovation at a large company can be viewed as a huge step at a smaller firm. However, innovation of course can be a much easier achievement at the smaller firm than the larger one. The inertia of past actions, stifling bureaucracy, and the inflexibility of the collective whole at larger firms are the impediments of innovation. The lean structure of the small firm and naturally empowering environment allow experienced employees to translate ideas into action. However, in small firms, resource paucity becomes the main inhibitor of innovation.

Research has shown that small firms are slower than their larger counterparts in adopting new technologies (Rees, Briggs, and Oakley, 1984; Schroeder, Gopinath, and Congden, 1989). Additionally, small firms lag in the use of manufacturing practices such as design for manufacturability and the use of continuous improvement teams (Industrial Technology Institute, 1987). Scott et al. (1996) report that overall a greater proportion of the manufacturing process is devolved from larger companies to small firms. Therefore, as large firms outsource critical processing capabilities, the adoption of high performance manufacturing practices becomes more important for the small firm.

The design of production processes should incorporate quality and operational performance requirements (Item 2). These processes should be evaluated and improved to achieve better performance (Item 5). Although a lack of highly trained personnel and a general lack of technical resources hamper smaller firms, their processes tend to simpler because of this and thus easier to manage and improve.

Additionally, evaluations and improvements are easily shared throughout the firm because of its inherent lean structure (Table 7, Item 6). Scott et al. (1996) found that there are many small firms making traditional products with lower technological content. Here, the incremental improvements in products and processes that could be made tend to be hampered by the historically low caliber of technology management skills in these firms. Engineering staffs in small firms are less likely to have capabilities and resources to design and maintain specialized equipment. More emphasis is put on creating efficiencies, reducing waste and setups. Flows are easier to manage because of the smaller size of facilities.

The second item in the process management category of the CPE focuses in the management of support processes. Processes that support operations should be clearly defined. These support processes should incorporate important internal customer requirements (Table 7, Item 7). Support processes can be viewed as the capability of the firm to be flexible in it operations in order to support the management of key product and service processes. Small firms are more willing to change their output so they are more volume and mix flexible (Fiegenbaum and Karnani, 1991). In other words, small firms are less likely to be tied to large orders and specialized equipment so they are more adaptable to changes in demand. This also allows the small firm to be more

capable of quick customization to meet customer needs. On the other hand, these same firms have fewer resources to expand capacity. Being more operationally flexible also focuses the small firm attention on process management. Small firms are more likely to employ standardized equipment and processes are more labor intensive. Generally, small firms lack the economies of scale enjoyed by large organizations. (Moreno-Luzon, 1993) Operations are less likely to run unattended and more potential problems exist in the production or service process than anywhere else in the organization. Therefore, the focus of the manager quite often is pulled to this area (Table 7, Item 7).

Inventory management supports both product and shipping processes (Table 7, Item 8). It is useful to note that several studies (Finch, 1986; Golhar, Stam, and Smith, 1990; Lee, 1996, Manoocheri, 1988; Sohal and Naylor, 1992) suggest that some aspects actually present advantages for just-in-time inventory management (JIT) in small firms. The simplicity and relatively low capital investment required to initiate JIT make this technology very accessible to small manufacturers. In fact, many small firms all over the world have already implemented JIT (Manoocheri, 1988; Sohal and Naylor, 1992; Sonfield, 1984). Just in time inventory techniques are very important to small manufacturing firms. Because cash flows are often volatile in these organizations, wrapping up a lot of capital in inventory is very disruptive. Therefore, inventory management becomes another critical area of concern for the firm.

The third item in the process management category of the CPE deals with the management of supplier and partnering processes. In the selection of suppliers and partners, firms must carefully define performance requirements (Table 7, Item 9). Communication is vital in the supplier development and partnering process. Feedback must be a two way street, back and forth between suppliers and partners on performance towards meeting requirements (Item 10). This system should be periodically evaluated and improved (Item 11). Pearson and Ellram (1995) confirm previous research that supports the importance of the quality criterion in the selection and evaluation of suppliers. The study finds a relatively small number of significant differences between large and small firms among the selection and evaluation criteria. They state that this indicates that the nature of the industry and its competitive environment may have a greater influence on selection criteria than does the size of the

firm (Item 9). The study indicated that a formal yearly review of suppliers was used by 33.3% of the small firms and by 57.7% of the larger firms. Despite the difference in degree of formality, the criteria used are very similar.

Research has found that a great deal of the success of small firms can be linked to the effective networking of their production systems. A cooperative network (supply chain) links various specialized and standard processes, thereby creating a production system of high flexibility and capability (Chen, 1999). Small firms generally lack bargaining power in supply chain management. However, small firms have the ability to establish good long-term relationships with customers and suppliers. Cash flow problems with smaller companies can readily hurt relationships with suppliers. Therefore, many small firms still tend to source to low cost bidders with easier credit terms. Managers may not consider supplier and partnering efforts to be of great importance.

2.4.7 Business Results

The Business Results category (BR) of the CPE examines the company's performance and improvement in key business areas: customer satisfaction (Table 8, Item 1), financial and market place performance (Item 2), human resources results (Item 3), supplier and partner performance (Item 4), and operational performance (Items 5-7). This category examines also the firm's operational performance levels relative to competitors.

Firms should capture performance data on each of these areas, look for trends over time and conduct other appropriate analysis. The category is clear in that performance results should be compared against suitable benchmarks. However, small firm managers may not see the necessity of collecting data from each of these areas. Nevertheless, certain results would be of importance to the small business leader. These managers would focus first on financial results since these are the results that impact the company foremost, ultimately deciding the fate of the firm. Additionally, operational performance is tied to cash flow. Capturing and analyzing data concerned with product quality, service performance and productivity may be very important, but small firm managers are more likely to capture, trend and analyze financial data.

Item	Code	Practice	Importance	Implementation
1	BR11	The firm captures, trends, and analyzes key measures of customer satisfaction– such as retention, gains, and losses.	**MEDIUM:** Small firms tend to misperceive the customers opinions about their products and customer needs.	**LOW:** Given limited time and resources, small firm managers spend little time on trending and analyzing this information.
2	BR12	The firm captures, trends, and analyzes key measures of financial and market performance, and compares them against best-in-class benchmarks.	**HIGH:** Small firm managers will focus on collecting financial information. Thus, this information will be considered the most important business result to analyze.	**MEDIUM:** Small firms are most likely to capture, trend and analyze financial data, and are unlikely to have the ability to benchmark such information because many small firms are privately held.
3	BR13	The firm captures, trends, and analyzes key measures of employee well-being, and compares them against best-in-class benchmarks.	**LOW:** Small firm managers lack training in formal personnel management practices, and they do not consider the use of good HRM as essential as improving productivity.	**LOW:** Given limited time and resources, small firm managers spend little time on trending and analyzing this information.
4	BR14	The firm captures, trends, and analyzes key measures of supplier and partner performance, and compares them against best-in-class benchmarks.	**MEDIUM:** Although small firms put some effort into the development of suppliers, firm managers see limited needs for trending and analyzing this information.	**LOW:** Given limited time and resources small firm managers spend little time on trending and analyzing this information.
5	BR15	The firm captures, trends, and analyzes important measures of product quality, and compares them against best-in-class benchmarks.	**HIGH:** Small company leaders tie operational performance to cash flow and consider analyzing this data important.	**LOW:** Given limited time and resources small firm managers spend little time on trending and analyzing this information.
6	BR16	The firm captures, trends, and analyzes important measures of regulatory compliance and compares them against best-in-class benchmarks	**LOW:** Spending time or collecting and analyzing this data is of lowest importance to small firms.	**LOW:** The small firm is unlikely to collect or analyze data in this regard.
7	BR17	The firm captures, trends, and analyzes important measures of other unique effectiveness and efficiency.	**MEDIM:** Small firms are not likely to be familiar with some of these measures but are interested in order accuracy.	**LOW:** Given limited time and resources small firm managers spend little time on trending and analyzing this information.

Table 8 — Business Results (BR): Measures of Customer Satisfaction, Financial and Market Performance, Employee Well-Being and Satisfaction, Supplier and Partner Performance, Product Quality and Productivity, Regulatory Compliance and Environmental Improvements, and Innovation and Order Accuracy (BR1). Source: Raymond (2000)

Other results that small firm managers tend to capture and analyze are customer satisfaction, supplier performance, and efficiency measures. Small firm leaders do not care much about collecting, trending and analyzing data that includes employee well-being and satisfaction, and governmental regulatory compliance. These are issues that small firm managers feel that are out of their control or beyond their scope of expertise.

Most research, even remotely related to small firms and the collection of business results, discusses the impact of the manager on the outcomes of the firm. The linkage between the role of the CEO and firm performance is more easily observed in smaller firms (Alcorn, 1982). Begley and Boyd (1986) measured growth rate, profitability, and return on investment for founder-operated firms. Their results indicate that founders have a significant and positive impact on firm performance. Moreover, most of the articles dealing with business results collection by small firms focus on the characteristics of the manager. According to Keats and Bracker (1988), small firm performance is influenced by multiple constructs which have been labeled as "Entrepreneurial Intensity" (entrepreneurial characteristics and behaviors which differentiate entrepreneurs from other individuals); "Task Motivation" (intensity of entrepreneurial motivation to attain goal achievement); "Perceived Strength of Environmental Influences" (strategic choices and reactions in response to environmental elements); "Behavioral Strategic Sophistication" (acquisition and implementation of strategic management practices); "Cognitive Strategic Sophistication" (comprehension and integration of strategic management practices); and "Task Environment Factors" (structure of the industry in which the organization operates). These six constructs have been proposed as substantial influences of small firm performance outcomes.

There is also research that addresses the small firms' ability or process for assessing the results of the implementation of high performance management practices. In one study, Goh and Ridgway (1994) noted that many small companies are unaware of the need to maintain detailed and accurate cost of quality records. Some are unaware of the factors involved in the calculations of the cost of quality, and that full cost of quality records comprised prevention, internal appraisal, internal failure and external failure costs. Ebrahimpour and Withers (1992) reported that quality tracking

techniques such as benchmarking are also used less frequently and less effectively in small firms. Dollinger (1984) studied managers in 82 small businesses and concluded that owners-managers spend a significant amount of time and effort seeking information from sources outside their organizations and that the search effort is positively related to financial performance. It is clear from the research that managers-owners seem to take responsibility for outcomes and they realize that their actions reflect most apparently on the financial performance of the firm. It can be argued also that given the limited resources of smaller firms, taking time to develop metrics and measure outcomes takes a back seat to the day to day grind of decision making.

2.4.8 Summary of the NIST-CPE Implementation at Small Firms

Table 9 summarizes the detailed analysis of the NIST criteria for performance excellence from the point of view of small firms. The seven main categories of the CPE split into 63 single items identified by their corresponding codes. In average, each category reflects Raymond's gap hypothesis between importance and implementation. The literature review as discussed supports fully the notion that small firm managers view the high importance of the CPE criteria for their firms, but they fail to extend it to the actual implementation of the criteria to their operations.

Raymond (2000) collected and analyzed data from an impressive array of small businesses seeking the identification of those criteria that are considered important by these firms and how endemic these practices are throughout the small company population. The survey also identified the extension of the gap between importance and implementation of the criteria. The analysis also led to the identification of areas that are well understood and followed and other areas needing more attention for small companies. This has led to a well supported view of why small firms embrace certain criteria for performance excellence while ignore others. At least four items are assigned a HIGH importance by small firm managers (L12, CM25, HR33, and BR15), but these items have a LOW or nonexistent implementation. This is the first strong indication that many items may be considered at least of moderate if not high importance, but given the limited resources of small firms, managers have to compromise on the allocation of time and money for implementation.

Code	Importance	Implementation	Code	Importance	Implementation
L11	HIGH	MEDIUM	IA32	MEDIUM	LOW
L12	**HIGH**	**LOW**	IA33	LOW	LOW
L13	MEDIUM	LOW	HR11	HIGH	MEDIUM
L14	HIGH	HIGH	HR12	HIGH	MEDIUM
L15	MEDIUM	LOW	HR13	MEDIUM	MEDIUM
L16	MEDIUM	LOW	HR21	MEDIUM	LOW
L21	HIGH	HIGH	HR22	MEDIUM	LOW
L22	HIGH	MEDIUM	HR23	HIGH	MEDIUM
L23	HIGH	MEDIUM	HR24	MEDIUM	LOW
S11	MEDIUM	LOW	HR31	MEDIUM	MEDIUM
S12	HIGH	MEDIUM	HR32	MEDIUM	LOW
S21	HIGH	MEDIUM	**HR33**	**HIGH**	**LOW**
S22	MEDIUM	LOW	HR34	MEDIUM	LOW
S23	MEDIUM	LOW	PM11	HIGH	HIGH
S24	MEDIUM	LOW	PM12	HIGH	MEDIUM
S25	MEDIUM	LOW	PM13	HIGH	HIGH
CM11	HIGH	MEDIUM	PM14	MEDIUM	MEDIUM
CM12	MEDIUM	MEDIUM	PM15	MEDIUM	MEDIUM
CM13	HIGH	HIGH	PM16	HIGH	HIGH
CM14	LOW	LOW	PM21	HIGH	HIGH
CM21	HIGH	MEDIUM	PM22	HIGH	MEDIUM
CM22	MEDIUM	MEDIUM	PM31	HIGH	MEDIUM
CM23	HIGH	MEDIUM	PM32	HIGH	MEDIUM
CM24	MEDIUM	LOW	PM33	MEDIUM	LOW
CM25	**HIGH**	**LOW**	BR11	MEDIUM	LOW
IA11	HIGH	MEDIUM	BR12	HIGH	MEDIUM
IA12	HIGH	MEDIUM	BR13	LOW	LOW
IA13	MEDIUM	LOW	BR14	MEDIUM	LOW
IA21	MEDIUM	LOW	**BR15**	**HIGH**	**LOW**
IA22	MEDIUM	LOW	BR16	LOW	LOW
IA23	MEDIUM	LOW	BR17	MEDIUM	LOW
IA31	HIGH	MEDIUM			

Table 9 — Summary of Item Importance and Implementation. Source: Raymond (2000)

Raymond's survey is representative of the importance of the CPE criteria for small firms and allows estimating how widespread the criteria are practiced and implemented in the small firm community. The discussion of Raymond's work will be divided into quantifying importance and implementation, and it will end with the importance-implementation gap.

Quantifying Importance — Table 10 shows that one item, S1, is significantly higher than all others (Strategy Development Process) and has rank 1. The next item, L1 (Leadership System) is significantly different from the remaining items and has rank 2. The next two items, IA1 and PM1, are not significantly differently from one another, but they are different from the remaining items and are grouped into rank 3. The next nine items are grouped into rank 4 with three subgroups, 4a-c. The last three items are significantly different from one another and have ranks 5, 6 and 7, respectively.

Even with the extensive literature review, it is not possible to predict these rankings, but it allows explaining the rankings after the survey. These results indicate that small firm managers rank the strategy development process (S1) and the leadership systems (L1) higher than all other items. Small firm managers recognize that they are the driving force behind their organizations and they feel that the leadership and the strategy that they themselves direct are most important to the success of their business.

Next, operational items are ranked high by firm managers. Small firm leaders tend to spend more time dealing with day-to-day operational concerns as compared to leaders of larger organizations. Therefore, small business managers tend to focus on the management of product and service processes (PM1) along with data and information that supports the management of these processes (IA1).

After that, small firm leaders then find customer items (CM1 and CM2) and human resource issues (HR2 and HR3) to be important, but they do not consider as important as issues of leadership, strategy, and operations. Small firm leaders have less control over such issues. They can develop good relationships with their customers and work hard to meet customer requirements, but they tend to be subservient to their customers because of their size.

Rank	Code	Practice Item	Mean Importance
1	S1	Strategy Development Process	4.42
2	L1	Leadership System.	4.34
3	IA1	Selection and Use of Information and Data	4.27
	PM1	Management of Product and Service Process	4.19
4a	IA3	Analysis and Review of Company Performance	4.10
	HR1	Work System	4.09
	L2	Company Responsibility and Citizenship	4.06
4b	CM2	Customer Satisfaction and Relationship Enhancement	4.06
	HR2	Employee Education, Training, and Development	4.03
	S2	Company Strategy	4.00
4c	BR1	Business Results	3.99
	CM1	Customer and Market Knowledge	3.99
	PM3	Management of Supplier and Partnering Process	3.96
5	PM2	Management of Support Processes	3.87
6	HR3	Employee Well-Being and Satisfaction	3.75
7	IA2	Selection and Use of Comparative Information and Data	3.51

Table 10 — Importance means sorted highest to lowest in a five point scale. Source: Raymond (2000)

Additionally, small firms have many difficulties with employee retention, finding qualified workers and providing competitive pay and benefits. These issues concern the small firm leaders, but many times they can do little to improve such problems.

Small firm managers rank items such as supplier and partnering processes (PM3), employee well being and satisfaction (HR3), and the collection and analysis of comparative data (IA2) least important. Small firms tend to have less leverage with suppliers and other business partners because they do not normally represent a major part of their suppliers' business. This is likely why that particular item is ranked lower. Small firms also experience problems with the basic human resource problems such as retention and training. Therefore, the managers at these firms will look to solve these problems while deemphasizing issues of employee well-being and satisfaction. They know that they cannot compete with larger firms in terms of advanced training, reimbursement of educational expenses, pay, and benefits. Small firm leaders rate the collection and analysis of comparative information lowest of all items. Small firms tend to have more competition, the competition tends to be small privately held firms such as themselves, and the cost associated with collecting such information is quite high. Or, the collection of competitive information may be almost impossible.

Quantifying Implementation — Table 11 shows that the first two items are significantly higher than all others (L21 and S11). Leadership System (L11) is reported to rank second in implementation by small firms. The next two items are not significantly different from one another but different from the remaining items and are reported in a third rank group of implementation. The next seven items are not significantly different from one another but different from the remaining categories and are grouped in a fourth rank. The next item (HR31) is significantly different from the rest and is reported in a fifth rank. The next two items (S21 and HR21) are not significantly different from one another but are significantly different from the last category and are reported grouped in a sixth rank. The last item (IA21) is reported in the seventh rank.

Rank	Code	Practice Item	Mean Implementation
1	L21	Company Responsibility and Citizenship	3.66
	S11	Strategy Development Process	3.63
2	L11	Leadership System	3.51
3	IA11	Selection and Use of Information and Data	3.43
	PM11	Management of Product and Service Processes	3.42
4	IA31	Analysis and Review of Company Performance	3.26
	PM31	Management of Supplier and Partnering Processes	3.25
	BR11	Business Results	3.22
	CM21	Customer Satisfaction and Relationship Enhancement	3.22
	PM21	Management of Support Processes	3.21
	CM11	Customer and Market Knowledge	3.16
	HR11	Work Systems	3.15
5	HR31	Employee Well-Being and Satisfaction	3.06
6	S21	Company Strategy	2.97
	HR21	Employee Education, Training, and Development	2.96
7	IA21	Selection and Use of Comparative Information and Data	2.54

Table 11 — Implementation means sorted highest to lowest in a five point scale. Source: Raymond (2000)

The Importance – Implementation Gap — Figure 2 shows the relative ranking of the NIST–CPE criteria between importance and implementation. Raymond (2000) performed a gap analysis between perceived importance and practice for all the criteria by examining whether the variation between importance and practice was greater than the variation within each group.

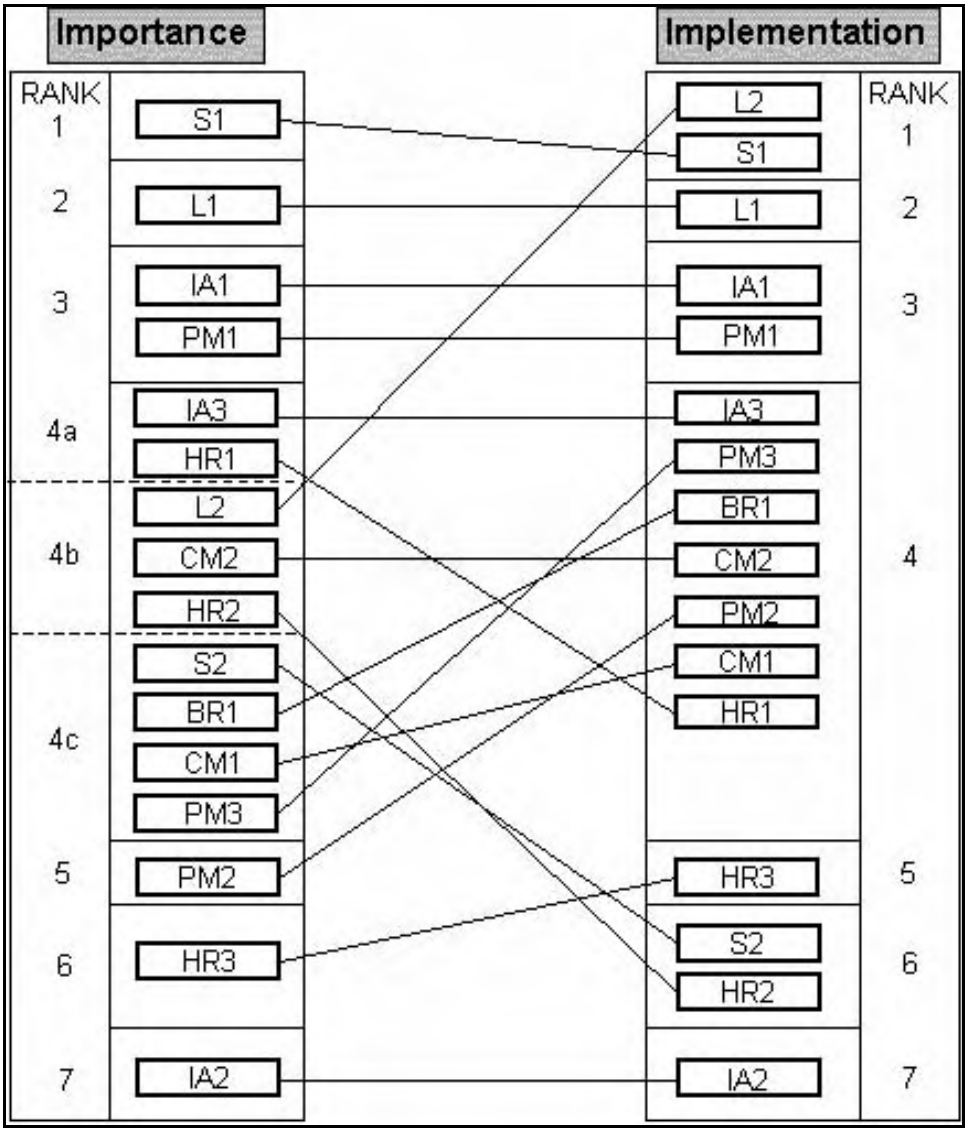

Figure 2 — Relative Ranking of the NIST-CPE Items Between Importance and Implementation According to Raymond (2000)

Since Raymond was checking the significance of difference between two variables that were both provided by the same firms, he selected a paired t-test as the best test of statistical significance. The t-test assumes a normal distribution of the differences and he used the Kolmogorov-Smirnov statistic (Lilliefors, 1967) to test this assumption. In all cases the Lilliefors significance level for testing normality confirmed the underlying assumption. The normality assumption of the response data was also tested by examining the normal probability plot (Q-Q plot). In the normal probability plot, if the sample is from a normal distribution, the cases fall more or less in a straight line. This test also confirmed the underlying assumption.

It is important to note here that in no case do small firms report that implementation meets the level of importance assigned to the practice. The reason for this becomes apparent looking at how small firms rank the importance of the criteria. The lowest mean importance score obtained by Raymond is 3.51, ranging to a high of 4.42. (Table 10) This means that every item is considered at the very least moderately important with many items being considered highly important. Given the limited resources of small firms, managers at these firms have to compromise on the allocation of time and money. Therefore, small firms implement such practices as best they can give their resource paucity.

Given that there are significant gaps for all items, the next question Raymond addressed was whether or not the gap was the same for all items. If all the gaps are the same, then it can be assumed that small firms are trying to spread their resources equally among the practices to implement them as best as they can. All combinations were run to verify the ranking. Four distinct rankings of the gaps were found, with gaps ranging from 0.3992 to 1.0707. The relative ranking of each item showed a somewhat linear relationship where items that were ranked high in terms of importance were also ranked high in terms of implementation. In most cases, items fall in the two categories of extremes: High-High or Low-Low. In a few cases these means cross over into contradiction, High-Low, and these cases (PM3, HR1, and CM2) are in borderline.

Following the performance items from S1 to IA2 indicates that more importance and resources are put into practices such as S1 (Strategy Development) and L1 (Leadership System) and then in the practices HR3 (Employee Well Being and

Satisfaction) and IA2 (Selection and Use of Comparative Information and Data) This indicates that clearly there are some areas that are less important and thus little effort is put into implementation.

Small firm leaders are forced to make choices given their limited resources and this analysis gives a good indication of the choices that are being made. Another way to look at this is by looking as the relative ranks in a side by side comparison. Given the resource paucity argument, we would expect to see items ranked at similar levels in terms of importance and implementation. S1 ranks 1 in importance and 1 in implementation, L1 ranks 2 in both and so on. Even though the gap exists in each case between importance and implementation, for the most part the more important items are implemented at the highest levels with equal rankings. (S1, L1, IA1, P1, and IA3). Therefore, items that are most important also rank highest in terms of implementation. In those cases where the ranking is approximately the same, the gap is nearest to the mean gap.

In conclusion, the literature shows that it is difficult for small firms to implement high performance practices across the board with the depth described in the NIST–CPE criteria. When considering a quality system for small firms, practitioners should account for differences between large and small companies. When using the framework as a self-assessment tool, it should not be as difficult as it was in the past for small firm managers to make adjustments based on the fact that they have limited resources. As discussed in Section 2.4.8, when small firm leaders are asked to examine the underlying principles found in NIST–CPE, they overwhelmingly validate the importance of the entire framework for small firms.

3 Methodological Approach

3.1 Approaches to a High Performance Quality System

The review of the NIST Criteria for Performance Excellence (CPE) from the perspective of small firms gives a strong clue on how the small firm managers understand the CPE criteria and how the criteria can help their organizations. As discussed in Section 2.4.8, most managers understand the basic principles behind the high performance criteria, but they fail in the implementation of these criteria to their operations.

A small firm can take one of three main avenues to define a high performance quality system for its operations: 1) participate in the Malcolm Baldrige National Quality Award (MBNQA), 2) request and obtain ISO 9000 certification, and 3) conform and comply with the Food and Drug Administration (FDA) – Quality System Regulation (QSR). Selecting one of these systems for a particular firm is an important business decision. Defining the set of performance criteria that are relevant to the small firm operations and are likely to be implemented by top managers requires more elaboration and will be the end result of this project.

The Malcolm Baldrige National Quality Award, as stated earlier, is based in the NIST high performance criteria that have now spread across all sections of the business community, including large and small enterprises. All quality systems, including ISO 9000 and the FDA – QSR, are based on or can be related to the NIST – CPE. Thus, irrespective of the quality system to be adopted, the importance – implementation gaps in the CPE categories, as presented in Figure 2, should be taken into account when defining and implementing the system in a small firm.

3.1.1 ISO 9000 Registration for Small Firms

ISO 9000 is a management control procedure that involves documentation of the processes of design, production and distribution to ensure that the quality of products and services consistently conforms to predetermined standards. The elements of the ISO 9000:1994 have been covered by Lamprecht (1993, 1996) in his implementation of

the ISO 9000 series, and his ISO 9000 implementation for small business, respectively, and by Willig (2001) in her plan for total quality control from manufacturer to consumer.

Chittenden et al. (1998) describe ISO 9000 as a series of quality assurance standards that set out requirements and recommendations for the design, and assessment of management systems. The ISO 9000 series consists of five documents: ISO 9000, ISO 9001, ISO 9002, ISO 9003, and ISO 9004. Of the five documents, the ISO 9000 and ISO 9004 are guidelines and are intended to be used only as interpretative reference.

ISO 9001 (ANSI/ASQC Q9001) is to be used when conformance to specified requirements is to be assured by the supplier during several stages which include design and development, production, installation and servicing. The ISO 9002 (ANSI/ASQC Q9002) is to be used when conformance to specified requirements is to be assured by the supplier during production and installation. Finally, the ISO 9003 (ANSI/ASQC Q9003) is to be used when conformance to specified requirements is to be assured by the supplier solely at final inspection and test.

ISO 9000 is largely based on the British Standard BS 5750, which was re-written in 1987 by the International Standards Organization (Switzerland). Since the publication of BS 5750 by the British Standards Institute (BSI) in 1979, the standard has been applied to firms of all sizes and from all business activities (Willig, 2001). Although the compliance is voluntary, some companies have made ISO certification a condition for doing business and can be registered as in compliance with any of the three main standards, ISO 9001, 9002, 9003.

ISO 9000 registration is an excellent choice to improve quality management in any size business; a few years back it became a requirement for doing business in the European Union. As it was discussed in the introduction, small firms may be under pressure to gain registration to a standard quality management system. Therefore, the fact that a company is registered does not guarantee a commitment to quality management. On the other hand, many small firms find the burden of formal quality certification for ISO 9000 too costly and time consuming (Chittenden et al.,1998; Taylor, 1995; Rayner and Porter, 1991).

Nevertheless, if money and time are not serious impediments for a small firm, it can be recommended to take the ISO 9000 avenue. Going through the ISO 9000 registration process could lead a firm to better understand the NIST – CPE framework. This is supported by Guilhon et al. (1998) who conclude convincingly that reactive quality (certification) can lead to a more total quality culture at a firm. The certification may act as a bridge between the traditional management of small firms and a more sophisticated management framework, and could play a catalytic role in the adoption of new management tools. Becoming an ISO 9000 registered company may lead to a more enlightened opinion of high performance quality frameworks such as Baldrige.

In the process of defining a quality system for a small firm, the owner-manager considering ISO 9000 certification should be made aware that the registration process involves independent audit and confirmation that the quality systems are in compliance with the standard. A fee is involved as well as a periodic re-inspection. Once an ISO 9000 certified quality inspector audits the system, a certificate of compliance is provided if compliance is met.

3.1.2 The FDA Quality System Regulation (QSR)

The Food and Drug Administration (FDA) Quality System Regulation (QSR) is a government mandatory quality assurance (QA) system for medical device manufacturers. It emphasizes device, labeling, packaging and process design for all aspects of production; e.g., facilities, equipment, design development, design and production documentation, correct design transfer, production control, production records and feedback. Total quality assurance is a system which emphasizes that “all employees and suppliers are responsible for their activities; design requirements are established and met; process requirements are established and met; all production activities are controlled; finished product specifications are met; and feedback results in appropriate corrections”.

In the introduction of the QSR manual, the FDA states that no matter what the product is or how small the manufacturer, quality should be considered at the earliest stages in every significant area that has an effect on the quality, safety, and effectiveness of the device. The FDA Good Manufacturing Practices (GMP)

requirements are slightly more extensive than ISO 9001 because they include, besides design, production, servicing and corrective/preventive activities, wide coverage of labeling and complaint handling (Lowery, Strojny, and Puleo, 1996).

To Willig (2001) a Quality Management System (QMS) outlines the policies and procedures necessary to improve and control the various processes that will ultimately lead to improved business performance. Neither the FDA – cGMP nor ISO 9000 include measures of effectiveness with respect to the product quality. It is implied that compliance with procedures will improve product quality. He finds that the success of a quality improvement process requires intelligent introduction and application. It must be integrated into the business plan and focused on the achievement of measurable improvements in defined areas. One of the principal purposes is quality control in manufacturing. Although it may seem obvious that quality systems are necessary, many small or start-up companies function, or attempt to function, with only some areas covered due the limited availability of resources (the importance-implementation gap). For small businesses in the medical device manufacturer sector, adoption of the FDA – QSR may be a requirement, but it is full of advantages.

The elements of the FDA – QSR have been detailed by Lowery, Strojny, and Puleo (1996) in their Medical Device Quality Systems Manual. They suggest that an ideal system for quality assurance (QA) is composed of an organization that executes a quality assurance program according to documented policy and specifications in order to achieve the set forth objectives. The recommended system is shown in Figure 3. The written policies and objectives are set by management and are influenced by outside factors such as customer requirements, standards, and regulations. An example given by the FDA is to use the customer requirements and needs to define specifications as quality targets. The objective is to produce safe and effective devices at a profit. It is recommended that the quality system includes everyone in the organization, all fully committed to the quality system program. The tasks to be performed to meet the objective should be described in procedures, work instructions and other documentation.

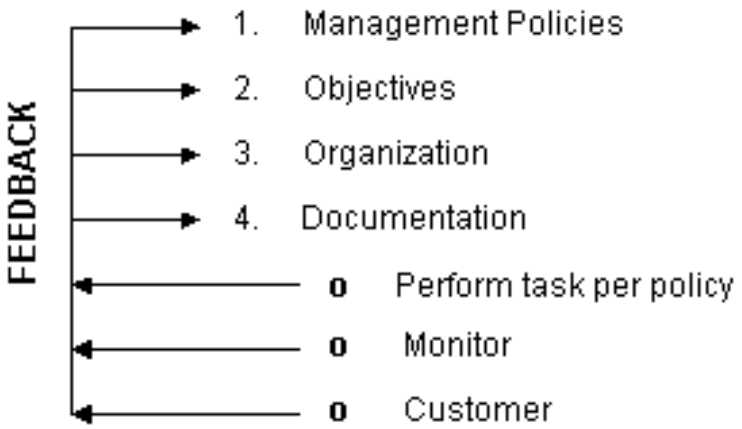

Figure 3 – Quality System Elements Proposed for Medical Device Environments

The authors of the FDA – QSR manual recommend that the documentation for a quality system should be composed of:

a) Product-specific technical documentation such as engineering drawings, component purchase specifications, and procedures for manufacturing processes and testing.
b) General quality system documentation, such as standard operating procedures (SOP's) for employee training, audits, maintenance, management review, etc., applicable to all products.

All activities and product quality have to be monitored; and the deviations found from device (product) and process specifications are fed back into the system where the deviations are corrected by the company policies. Also the complaints and service information are processed and fed back for appropriate corrections. If the required activities are performed, including the feedback, the quality system will be self correcting. Customer surveys can also be used as information that can be included in the feedback.

If the FDA – cGMP is required or adopted, the manufacturer will establish and maintain a quality system that 1) is appropriate for the specific device designed or manufactured, and 2) meets the requirements stated in Subpart A of the system. Compliance is assumed—unless the FDA later in an inspection states otherwise—and no certificate of compliance is provided. Each manufacturer is expected to establish procedures for quality audits and conduct such audits to assure that the quality system

is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

As a result of the research done in this project there were found a few articles on literature related to the implementation of a QMS in small to medium-sized enterprises. The authors are more literate on the ISO 9000 implementation because of its spread in the business world, is the QMS that applies to all types of business small or large companies and whichever type of product. The intention of this project is to give to the manager's of small firms a summary of the available QMS and a way of how to implement the system by them.

One of the sources of literature is in the ISO webpage (http://www.iso.org), an advice from ISO that can help small business's managers in taking the first steps toward implementation of a QMS is to buy the ISO handbook, "ISO 9000 for Small Business". The book explains the standard in plain-language, gives examples, includes the full text of ISO 9001:2000 section by section accompanied by explanations, examples and implementation guidance, and have revised sections on the steps involved in setting up a quality management system. The implementation process is divided in three stages, Development, Implementation, and Maintenance, and there are 9 steps in total for the implementation.

Both ISO 9000 and FDA-QSR identify a list of elements, with policies, procedures, work instructions and forms, that should be implemented to demonstrate compliance. The main motivator for the former (ISO) might be the interest in doing business with ISO-compliant businesses and the European Union market. Adopting FDA-QSR is driven by the interest in medical device manufacturing or the interest in doing business with QSR-compliant businesses (the case of the Model Factory). Cost-wise, ISO seem to be a more expensive approach when compared to FDA-QSR. The Malcolm Baldrige criteria, on the other hand, identifies the concerns that should be demonstrated but is not specific as to how results should be achieved. The motivation for MBNQA pursuit is recognition by the US Department of Commerce, which should have a positive impact on image and competitive position. In conclusion, the motivation for pursuing the three certifications are diverse but all focus on business position.

The chapters that follow deal with the process followed to implement a QMS in the Model factory, including example documentation such as quality audits, SOPs needed to comply with the standards, and the results of implementing the system.

4 PROJECT RESULTS

4.1 Selection of a Quality System for the Model Factory

All quality systems, including ISO 9000 and the FDA – QSR, are based on or can be related to Balridge and the NIST – CPE. Table 12 summarizes the correlation between the three quality systems, the FDA – QSR, Malcolm Baldrige, and ISO 9001. The NIST – Citeria for Performance Excellence have been detailed in the literature review and analysis. The FDA – QSR with its subparts, title and sections is listed in Appendix D (Bartoo, 2004) and Appendix F details the complete main elements of the US FDA – QSR (CFR 21 Part 820 cGMP).

The studies found in the literature show that the majority of small firms are not ISO 9000 registered. Chittenden et al. (1998) reported that in their ISO 9000 study of small firms, two-thirds of respondents were unaware of or did not intend to register with the standard. ISO 9000 is not a quality standard per se, but ISO 9000 registration is an excellent choice to improve quality management in any size business. Thus ISO 9000 was initially considered and excellent candidate for the QS to be applied to the Model Factory or to other similar small companies. Registration to ISO 9000 would clearly indicate openness to the NIST – CPE framework. As a small firm with limited resources, the Model Factory would find formal quality certification for ISO 9000 too costly.

ISO 9000	Malcolm Baldrige	FDA – QSR
4.1 Management Responsibility	1.1 Organization Leadership 1.2 Public Leadership	820.1 Scope 820.3 Definitions 820.5 Quality System 820.20 Management Responsibility 820.180 General Requirements 820.181 Device Master Record
4.2 Quality System	2.1 Strategy Development 3.2 Customer Satisfaction 4.1 Measurement and Analysis	820.5 Quality System 820.20 Management Responsibility 820.30 Design Controls 820.181 Device Master Record 820.186 Quality system record
4.3 Contract Review	3.1 Customer Knowledge 6.1 Product and Service Processes	820.160 Distribution
4.4 Design Control	4.1 Measurement and Analysis 4.2 Information Management 6.2 Business Processes 6.3 Support Processes	820.30 Design Controls
4.5 Document and Data Control	4.2 Information Management 6.2 Business Processes	820.40 Document Controls 820.180 General Requirements
4.6 Purchasing	3.1 Customer Knowledge 4.2 Information Management 6.2 Business Processes	820.50 Purchasing Controls
4.7 Control of Customer-Supplied Product	4.2 Information Management 6.2 Business Processes	820.80 Receiving, In- process, and Finished Device Acceptance
4.8 Product Identification and Traceability	6.1 Product and Service Processes 6.2 Business Processes	820.60 Identification 820.65 Traceability
4.9 Process Control	4.1 Measurement and Analysis 6.1 Product and Service Processes 6.2 Business Processes 6.3 Support Processes	820.70 Production and Process Controls 820.75 Process Validation 820.170 Installation
4.10 Inspection and Testing	4.1 Measurement and Analysis 6.1 Product and Service Processes	820.80 Receiving, In-process, and Finished Device Acceptance 820.86 Acceptance Status

Table 12 – Comparison of ISO 9000, Malcolm Baldrige and FDA – QSR

ISO 9000	Malcolm Baldrige	FDA – QSR
4.11 Control of Test Equipment	4.1 Measurement and Analysis 6.1 Product and Service Processes	820.72 Inspection, Measuring, and Test Equipment
4.12 Inspection and Test Status	4.1 Measurement and Analysis 6.1 Product and Service Processes	820.72 Inspection, Measuring, and Test Equipment
4.13 Control of Nonconforming Product	6.1 Product and Service Processes	820.90 Nonconforming product
4.14 Corrective and Preventive Action	4.1 Measurement and Analysis 6.1 Product and Service Processes	820.100 Corrective and Preventive Action 820.198 Complaint files
4.15 Handling, Storage, and Delivery	4.2 Information Management 6.1 Product and Service Processes	820.120 Device Labeling 820.130 Device Packaging 820.140 Handling 820.150 Storage 820.160 Distribution
4.16 Control of Quality Records	4.1 Measurement and Analysis 4.2 Information Management	820.30 Design Controls 820.184 Device history record 820.186 Quality system record
4.17 Internal Quality Audits	---	820.22 Quality audit
4.18 Training	5.2 Employee Training	820.25 Personnel

Table 12 – Comparison of ISO 9000, Malcolm Baldrige and FDA – QSR (Cont.)

It had been anticipated that the fee would be a strong deterrent for the Model Factory given the usual limitations on resources and funding typical of most small firms. Nevertheless, the initial cost of ISO certification was estimated as follows. According to Lamprecht (1996), ISO certification can take six days in average: a) one-half day for document review, b) two days for auditing plus one half-day for report writing, c) one day for first maintenance audit plus half-day for report, and d) one day for second maintenance audit plus a half day for report. A total charge of $1,000 per day is common. The cost of implementing ISO 9000 in the Model Factory would have been $6,000 minimum. Therefore, in spite of all the advantages that might have to become an ISO 9000 registered business, no further consideration was given to the implementation of this quality system standard for the Model Factory.

In consequence, for this project it was decided that the best quality system to implement for the Model Factory was the FDA – QSR. The following points further clarify this decision:

1. The Freedom of Information Act (FOIA) requires the FDA to provide free access to the quality system regulations. The FDA complies with that requirement through their internet webpage. So the basic information needed to define the QS is freely available.
2. The FDA webpage serves as a useful tool when compared to the ISO webpage that offers limited information of their quality systems and the visitor has to purchase the standards documents and the references that will help in the implementation of the quality system.
3. The ISO 9000 registration process requires independent audit and confirmation that the quality system is in compliance with the standard. A fee is involved as well as periodic re-inspections.
4. EBI, the Model Factory‘s current customer, suggested that the quality system appropriate to comply with their requirements was the FDA – QSR.

4.2 Definition of the Implementation Steps

Once the quality system has been selected by the small business management, an implementation plan has to be designed and followed. Arora (1998) recommends a series of steps for the implementation of a QMS that are adequate for a small business. These steps are summarized in Figure 4.

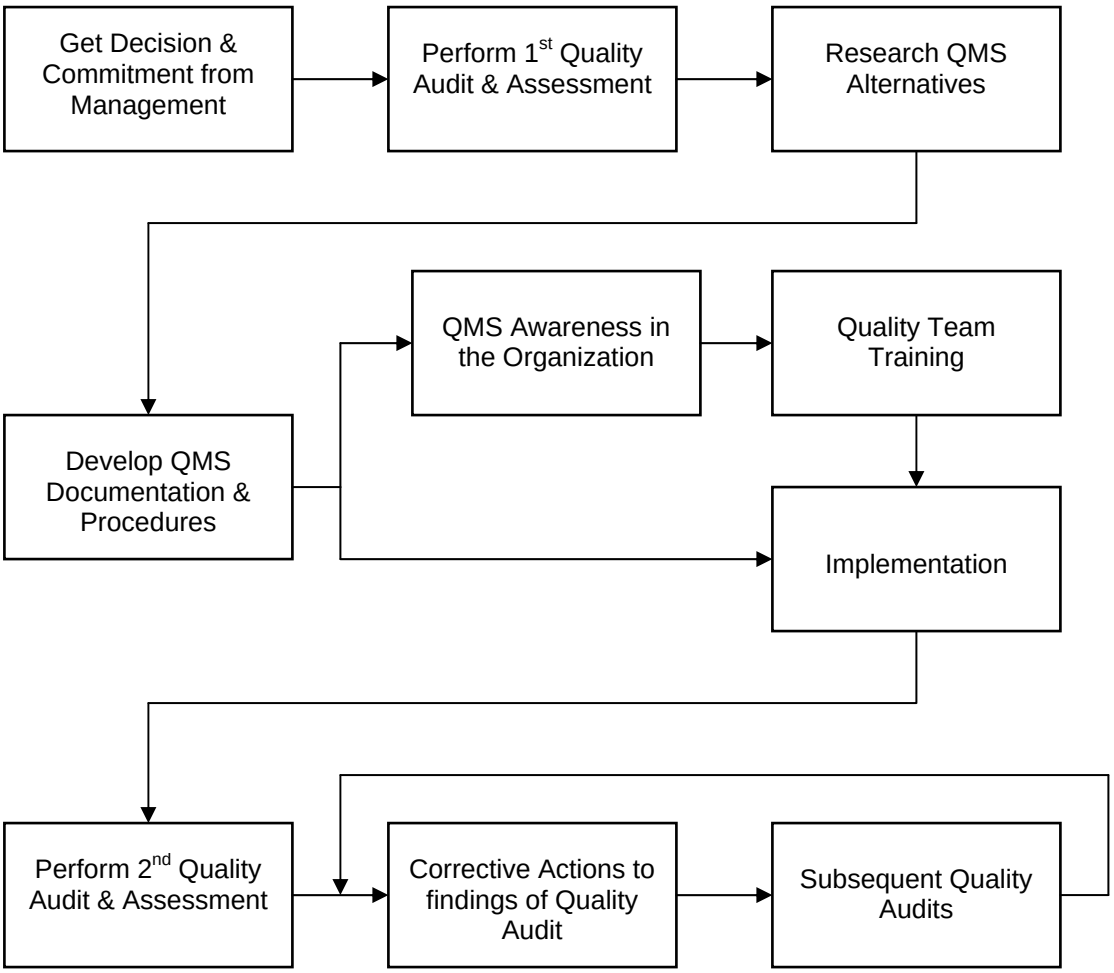

Figure 4 – Implementation Process

4.2.1 Commitment from Management

Management has to be convinced and decide that a quality system is required to improve the quality of the products and processes. It has to be clearly understood that the quality of the products and processes has to be supported by a QMS. Management

has to allocate the needed resources for the implementation effort and assign a management representative to coordinate QS activities. As in other business-wide efforts, it has to be understood that the success of the QMS is dependent on the involvement and commitment of top management.

4.2.2 Quality Audit

A quality audit is an excellent approach to perform a “gap analysis” and measure the QMS status in terms of compliance if there is one in place. Whenever an external auditor or consultant cannot be contracted, one of the client’s quality auditors can be invited to perform the audit. If that option is not available the “gap analysis” spreadsheet presented in Appendix E can be used by an employee from the business, with adequate knowledge on quality systems, to identify the gaps or weaknesses.

4.2.3 Research QMS Alternatives

This step requires studying the pros and cons of each QMS alternative. The decision will depend of the products or services performed by the small business, the customer QMS requirements, and the market being targeted. Another issue already discussed is the cost of certification, training and materials, and re-certification activities.

4.2.4 Development of the Quality System Documentation

This is the most important and time-demanding step during the implementation process. The quality system documentation can be organized in many possible ways. For small companies, the levels of documentation can be presented in just one manual. A list of the documents to be prepared should be drawn up and the responsibility for writing should be assigned to the persons concerned with the activity.

Figure 5 relates to the FDA-QSR elements and illustrates the typical elements found in a quality management system. It is useful to prepare the list of the activities in the organization that need to be documented and to assign responsibilities for each task. The documentation to be prepared need not be onerous; it only has to be adequate to cover the activities in the organization. The number of documents required depends on the size and complexity of the operation and the characteristics of the product. The QS regulation requires the manufacturer to maintain various records such

as device master records, device history records, maintenance schedules and records, complaint files, audit reports, distribution records, and personnel training records.

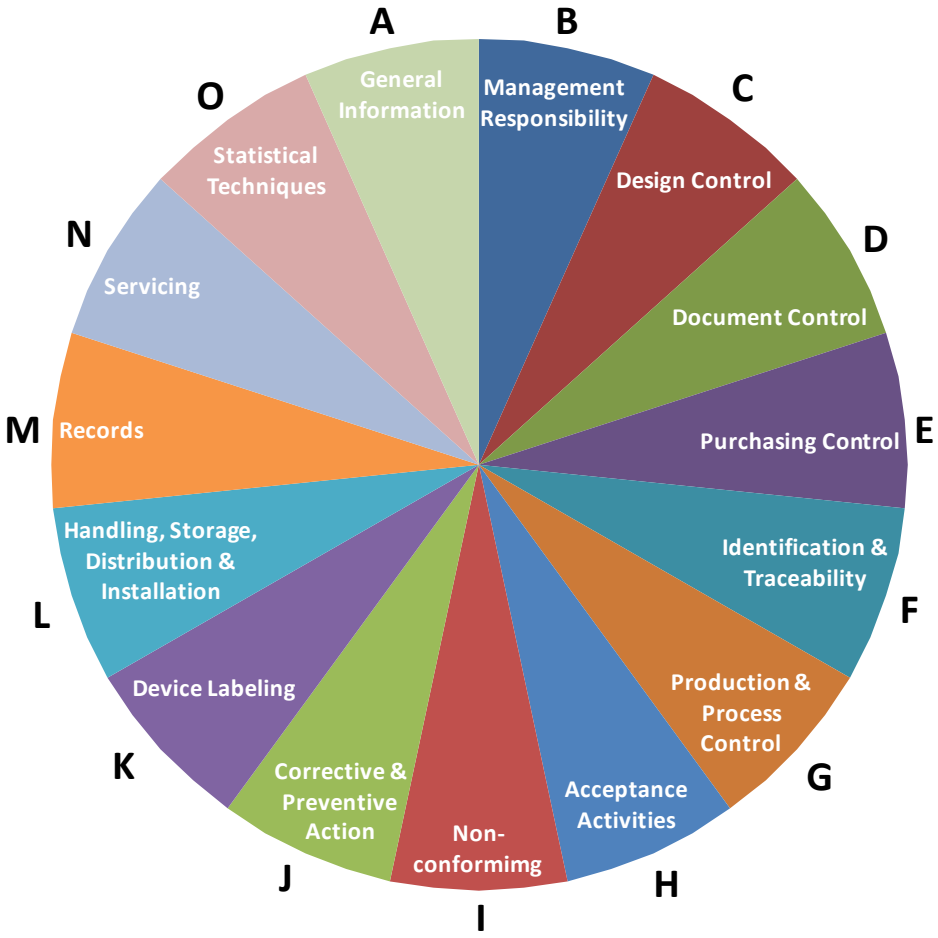

Figure 5 – Quality System Typical Elements

Written procedures need to be in place and industry experience has shown that these should contain the following items: company identification and a procedure title, an identification or control number with a revision level code, an approval signature, and date the procedure becomes effective, the number of pages (e.g., sheet 1 of 4) in the procedure or another means to indicate that the employee has the complete document; and step-by-step instructions for performing the required activities. The main body of the procedure should cover the following items: subject, scope and objectives, who is assigned to perform the task, what task is to be performed, when and where the task is to be performed and how to perform the task, including what tools and materials to use.

4.2.5 Start QMS Awareness in the Organization

The quality system awareness should be conducted to communicate to the employees the aim of the quality system, the advantage it offers, how it works and finally, but not least, their responsibilities within the system. A Quality Committee or Team should be set up. For a small business, it is recommended not to use more than 25 to 30 percent of the employees to make the team effective when tasks have to be sorted. The Quality Team will be responsible for the implementation process, the preparation of documents (manuals, procedures, and work instructions) needed by the system once it is implemented, and for maintaining the system feedback loop. The quality system awareness may cover the basic concepts of quality systems, the overall impact on the goals of the organization, how changed will the processes be, and the work culture implications of the systems.

4.2.6 Training

The Quality Team of the small firm will need to be trained on writing procedures, work instructions, and other necessary documentation. The training should cover also how a QMS is organized and how to make the changes in it when a procedure or process has changed or has been added to the activities in the small firm. The quality team should be aware that there is a lot of preparation and reading involved to be member of the team. Most of the tasks have to be self learned and consultation with experts in the area is highly recommended. Quality System courses and materials should be made available to Quality Team members.

4.2.7 Implementation

It is good practice to implement the procedures shortly after being completed on an element by element fashion. However, in small companies this practice is not typical; the quality systems are often implemented all at once throughout the organization. Shortly after implementation, a quality audit should follow to measure progress and system understanding by users.

4.2.8 Quality Audit

As the system is being installed, its effectiveness should be periodically checked by quality audits. The quality audits are conducted to verify whether the documented

system is actually being followed. The quality audit findings should be fed back to the system. The required changes and recommendations on the findings of the quality audit will be made by the appointed Quality Team.

4.2.9 Management Review

When a documented quality system has been operating for three to six months, a management review should be conducted and the resulting corrective actions will be implemented. Efficacy of these corrective actions should be ensured.

4.2.10 Subsequent Quality Audits

When the system deficiencies are no longer visible, another quality audit may be carried out to ensure that the QMS is well implemented and if necessary make the final changes to correct the deficiencies. The subsequent quality audits should be carried out every six to eight months.

4.2.11 Summary of Implementation Steps for Small Business in General

The flowchart proposed in Figure 4 provides a common sense sequence of activities that were used in the Model Factory, but that could also be followed by any small business interested in selecting and implementing a quality management system. To embark in such an effort, owner(s) must be committed (step 1) and must identify who will lead the activities. If the same owner has the quality system know-how, he or she could serve al leader; if not, an internal or external resource could be put in charge. An initial quality system audit, using available tools such as the one presented in Appendix E, titled “Gap Analysis Checklist”, can be used to identify what is already available and what needs to be developed (step 2).

Three quality systems were considered; namely ISO 9000, FDA-QSR and Malcolm Baldrige (step 3). As presented in the first and third columns of Table 12, ISO and QSR provide a fairly similar list of elements that must be followed to demonstrate compliance for certification. The motivations for selecting between ISO and QSR are fairly clear. ISO should be selected when the small business is interested in doing business with specific regions of the world, particularly the European Union. QSR should be the preferred approach when end products involve medical devices and FDA

compliance is required. Whenever a critical customer requires certification on ISO or QSR, the business owner(s) will decide if the cost and time investments are worthwhile.

The use of the Malcolm Baldrige criteria has a different motivation. MBNQA is a national recognition presented by the US Department of Commmerce. The second column in Table 12 shows the alignment of Malcolm Baldrige with the other more thorough quality systems. The repetition of elements four (measurement, analysis and knowledge management) and six (process management) in the column are evidence that this quality system is not specific on what needs to be done, but emphasizes the need for positive results. For businesses that want to instill the discipline of a quality system, the decision is between ISO and QSR. When the business is mature and is interested in national recognition, MBNQA must be pursued.

The fourth step in the process is the development of the needed documentation. At this stage it is important to refer to the weaknesses identified in the initial audit (step 2), identify which elements of the selected quality system are irrelevant, and which ones are most critical for implementation. Given that the business has a limited number of employees, a small implementation team must be identified. Business owners must communicate the intentions to implement the selected quality system and provide visibility to the members of the team that will perform the tasks (step 5). Owner(s) must emphasize the importance of the quality system for the business and must communicate clearly the quality policy that has been established. The team should ensure that all needed documents will be prepared. This same team will be responsible for the next step, training of all employees in the quality system practices (step 6).

For implementation (step 7), the “big bang approach” (explained later in Section 4.3.7) makes sense for small businesses since it enforces a “new beginning” with respect to the discipline of the quality system; everyone will be well aware that the new practices must be followed throughout the business. A second (step 8) and subsequent quality audits (step 10) could be conducted by quality team members, by the owners, by customer representatives, or by outsiders with quality system expertise. Customer representatives will emphasize business concerns they might have, while other outsiders will provide insight into the general concerns of the business community with respect to quality systems. Corrective actions to findings of quality audits (step 9 in the

process) is a means to show how important the quality system is to the owners; it is also a mechanism to maintain focus on the improvement of the main quality weaknesses. Such results should be a key piece of information for discussion during management reviews.

4.3 Case Study – The Model Factory

The definition and implementation steps described above have been applied to the Model factory as a case study that illustrates how a QMS can be implemented in a small firm. This section describes how the Model Factory has adopted the clauses of CFR 21 Part 820 to comply with the applicable Food and Drug Administration regulation going through the 15 subparts of the QSR. Table 13 summarizes the activities carried out to comply with QSR; out of 27 issues only five (5) were not addressed mainly because these were not relevant. This part continues with the steps followed for the QMS implementation to the Model Factory. The study is structured according to the steps annotated in the methodology. In each step, an explanation of the implementation is provided with an indication of the requirements and actions taken.

During the implementation phase of the project, the following books and guides related to quality management systems and its implementation were amply and are highly recommended. One essential publication is the ISO 9000 Implementation for Small Business (Lamprecht, 1996). This book is geared to the small- and medium-sized companies seeking to obtain ISO registration. It is filled with practical advice and guidance in the preparation of documents to fulfill the requirements. To explain the process of implementation Lamprecht uses two companies as example, a technology firm that manufactures custom electronic power supplies and the other is a laundry business. Using these companies as example, the author stresses his intention to show that all small businesses, whether their processes are complex or not, can implement a QMS like ISO 9000.

A second essential publication is the first edition of the FDA Medical Device Quality Systems Manual: A Small Entity Compliance Guide (Lowery, Strongy, and Puleo, 1996). This new manual, which supersedes the Medical Device Good Manufacturing Practices [GMP] Manual, has been published by the FDA with the

intention to help auditors and quality assurance managers providing guidance in the interpretation of the GMP requirements. The publication also helps manufacturers to complete, maintain, or expand their quality systems. Included are educational materials, aids, and examples, together with detailed explanations, procedures, and control forms.

Subparts		Items	Applicability
A	**General Provisions**	820.1 – Scope 820.3 – Definitions 820.5 – Quality System	Yes. The Model Factory agrees with and is committed to adopt and comply with the QSR requirements to guide their activities.
B	**Quality System Requirements**	820.20 – Management Responsibility	Yes. Quality policy and organizational structure with SOP for management review.
		820.22 – Quality Audit	Yes. Quality Audit conducted by customer representatives.
		820.25 – Personnel	Yes. SOP for training on Quality System elements and task performed in the Model Factory.
C	**Design Control**	820.30 – Design Controls	**No**. The Model Factory does not perform any design activity This item does not apply.
D	**Document Control**	820.40 – Document Controls	Yes. SOP for Document and Change Control made to comply with the requirement.
E	**Purchasing Control**	820.50 – Purchasing Controls	**No.** The materials used at the Model Factory are provided by the customer This item does not apply.
F	**Identification and Traceability**	820.60 – Identification 820.65 – Traceability	Yes. Batch history record in use for daily production.
G	**Production and Process Control**	820.70 – Production and Process Controls	Yes. SOP's and work instructions are available for each operation and maintenance procedure.
		820.72 – Inspection, Measuring, and Test Equipment	Yes. Three-step FDA validation process followed which includes Installation.
		820.75 – Process validation	Yes. Operation and Performance qualification.
H	**Acceptance Activities**	820.80 – Receiving, In-process, and Finished Device Acceptance	Yes. In-process and finished devices are accepted based on IPC-A-610 standard. Received materials are already in acceptance by the customer. The customer performs all incoming inspection of materials.
		820.86 – Acceptance Status	Yes. Device defects data is collected.

Table 13 – CFR 21 Part 820 QSR Application to the Model Factory

Subparts		Items	Applicability
I	**Non Conformance**	820.90 – Nonconforming Product	Yes. SOP for Non-conformance product made to comply with the requirement.
J	**Corrective and Preventive Action**	820.100 – Corrective and Preventive Action	Yes. SOP for CAPA. Includes process to investigation and assignment of the project to resolve quality issues.
K	**Labeling and Packaging Control**	820.120 – Device labeling	**No.** Requirements apply for finished devices. The final product should be labeled with instruction manual and cautions.
		820.130 – Device packaging	**No.** The Model Factory manufactures devices that require further assembly and processing. The final product should include a secured packing.
L	**Handling**	820.140 – Handling	Yes. Anti-static equipments is used to prevent Electro Static Damage (ESD).
	Storage	820.150 – Storage	Yes. ESD-safe containers are used for storage and transportation
	Distribution	820.160 – Distribution	Yes. Devices continue assembly and production at customer's site.
	Installation	820.170 – Installation	**No.** Installation is not required
M	**Records**	820.180 – General requirements 820.181 – Device master record 820.184 – Device history record 820.186 – Quality system record 820.198 – Complaint files	Yes. Product related records are kept in the Device Master Record. Complaint files, setup sheets and product related material are kept.
N	**Servicing**	820.200 – Servicing	**No.** The Model Factory is a manufacturing related business.
O	**Statistical Techniques**	820.250 – Statistical techniques	Quality issues and data of in process devices are collected for analyzing and process improvements opportunities.

Table 13 – CFR 21 Part 820 QSR Application to the Model Factory (Cont.)

4.3.1 Commitment from Management

The Model Factory management along with the customer were convinced that a quality system was required to improve the partnering relationship already established. One of the concerns was that although the quality of the locally manufactured products was excellent, it was not supported by any type of Quality Management System (QMS). The Project Leader decided that an excellent approach to develop a good quality system (QS) for the Model Factory was through the involvement of a graduate student and commissioned the author to document the QS design and its implementation in such a manner that it would serve as a suitable project for a Master Degree in Engineering.

4.3.2 First Quality Audit

A quality audit was carried out by Mr. Carlos Díaz, the QA representative from EBI, the Model Factory customer. This audit identified in which areas to focus for the implementation of the quality system. This quality audit served as a “gap analysis”, but in the Model Factory a “gap analysis” per se was not performed because there was not a previous quality management system to compare the results of the analysis. The Model Factory used the quality auditor as a consultant that helped to have a speedy transfer of knowledge and skills and to provide periodic guidance to keep the quality system on track. Table 14 presents the findings of this first quality audit.

4.3.3 Research QMS Alternatives

Once determined that a quality system was required, a research of the most widely used quality systems in the manufacturing industry was performed. The author evaluated NIST – CPE, ISO 9000, and FDA – QSR considering the size of the organization, the manufactured products, and the quality system in use by the customer. The research focused on finding literature dealing with high performance criteria for QMS, understanding the requirements of the system, and guidance in how to implement the system in a small business organization. Once the research was completed, the customer recommended that FDA – QSR should be the QMS to implement since they could provide support and was the most affordable to implement.

Question	Answer Yes or No	Comments
Does the organization have a Quality Policy?	**Yes**	
Does the organization have a Quality Manual?	**Yes**	
Does the organization have a Documentation Control Procedure?	**No**	There are no procedures or requirements in the facility for the control of documentation use. Approved drawings for the product are not available at the manufacturing process. There is no procedure or requirements for the control of records generated in the facility.
Are personnel performing work-affecting quality competent on the basis of appropriate education, training, skills and experience?	**No**	There is no procedure that defines the training and re-training process. The training records are not directly linked to the SOP used in the manufacturing process.
Has the organization determined, provided and maintained the infrastructure needed to achieve conformity to product requirements?	**Yes**	
Has the organization determined: a) Requirements specified by the customer, including requirements for delivery and post delivery activities? b) Requirements not specified by the customer but necessary for specified or intended use, where known? c) Any additional requirements determined by the organization?	**Yes**	
Has the organization determined and implemented arrangements for communication with customers relating to: a) Product information? b) Enquiries, contracts or order handling, including amendments? c) Customer feedback, including customer complaints? d) Advisory notices?	**Yes**	

Table 14 – Quality System Audit

Question	Answer Yes or No	Comments
Does the organization plan and carry out production and service under controlled conditions including: ▪ Availability of documented procedures, ▪ The use of suitable equipment, ▪ The availability and use of monitoring and measuring devices, ▪ The implementation of monitoring and measuring, ▪ The implementation of defined operations for labeling and packing.	**Yes**	The frequency to perform the temperature profiles of the BTU Oven has not been defined.
Does the organization exercise care with customer property while it is under the organization's control or being used by the organization?	**Yes**	
Does the organization identify, verify, protect and safeguard customer property provided for use or incorporation into the product?	**Yes**	
In the occurrence of any customer property that is lost, damage or otherwise found to be unsuitable for use is this reported to the customer and recorded maintained?	**Yes**	
Has the organization established documented procedures or documented work instructions for preserving the conformity of product during internal processing and delivery to the intended destination?	**No**	Some rejects bare PCBs were found not properly identified.
Does the organization establish a program for maintaining, monitoring and measuring devices and process equipment?	**No**	The preventive maintenance of the equipment is not being properly documented. Preventive Maintenance Manuals are not properly maintained or organized.
Has the organization established a documented procedure for a customer feedback system to provide early warning of quality problems and for input into the corrective and preventive action processes?	**Yes**	Issues are communicated to the customer but no documented in a procedure. See comments in corrective actions requirements.
Does the organization has documented procedure to manage non-conforming product?	**No**	There is no procedure for the control of non conforming product.
Has a documented procedure been establishes and does define the requirements for corrective and preventive actions?	**No**	The process for corrective actions and complaint handling is not formally documented in a procedure.

Table 14 – Quality System Audit #1 (Cont.)

4.3.4 Develop the Quality System Documentation

Considering the QSR elements presented in Figure 5, the only elements not relevant for the Model Factory are: design control, purchasing control, device labeling, and servicing.In the Model Factory all the documentation was developed using as reference the exhibits presented in the “Medical Device Quality Systems Manual: A Small Entity Compliance Guide” and a few SOP’s and forms obtained from EBI The next subsectionpresents a brief description of the QSR’s clauses and the applicability to the Model Factory.

4.3.5 Start QMS Awareness in the Organization

The author conducted a quality system awareness addressed to all the Model factory employees. A quality team was set up involving five (5) members with the recommendation of having a quality leader within the team. The quality team is essential for implementation process. Once the system is implemented, the most important tasks of the quality team are the maintenance of both the system (policy, procedures, work instructions and forms) and the feedback loop described in Figure 3.

4.3.6 Training

Training of the quality team was necessary due to the fact that most of its members had never worked in a QMS environment. In addition, the team had to be informed about how the quality system was structured in the Model Factory. The training involved how to write procedures and work instructions, how the QMS is organized in the device master record (DMR) and how to make the changes in the quality system when there is a change in the activities of the Model Factory. For this purpose, all the references used for the implementation of the QMS, such as the CFR 21 Part 820, a Quality glossary and the “Medical Device Quality Systems Manual: A Small Entity Compliance Guide” were distributed among all members of the quality team.

4.3.7 Implementation

The quality system was implemented all at once throughout the organization by the quality team. This is known as the “big bang approach”. The advantage of this type of implementation is that there is no uncertainty on the start date in specific areas and

the project culminates at an earlier date. All the documentation was approved by the Model Factory management and the management arranged a quality audit to assure that the QMS was in compliance with the regulation.

4.3.8 Second Quality Audit

A second quality audit by a Quality Auditor, Mr. Carlos Díaz, was completed by late December 2007. The results of this audit were compared with the results obtained in the first quality audit and this comparison is presented Table 15, included in Section 4.4.15.

4.3.9 Management Review

A Management Review should be conducted to discuss and decide the corrective actions to the findings of sub sequent quality audits.

4.3.10 Subsequent Quality Audits

` These quality audits should be conducted once the quality system is in operation, with a frequency of every six to eight months.

4.4 Clauses of CFR 21 Part 820, QSR, Applicability to the Model Factory

4.4.1 Application of General Provisions to the Model Factory

Item 820.1(a) (1) states that the regulation does not apply to manufacturers of components or parts of finished devices, but such manufacturers are encouraged to use appropriate provisions of this regulation as guidance. This is the case of the Model Factory; the products manufactured are not -finished products, but components that are later assembled at EBI into the finished device delivered to customers. However, the Model Factory will use the regulation as Quality System to comply with the customer's quality expectations.

Item 820.1(a) (2) states that the QSR is applicable to any finished device as defined in this part, intended for human use that is manufactured, imported, or offered for import in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

Item 820.3 includes wording and definitions used in the whole regulation CFR 21 Part 820 or QSR.

4.4.2 Quality System Application to the Model Factory

Item 820.20(a) establishes that management with executive responsibility shall establish its policy and objectives for quality in addition to ensure that the quality policy is understood, implemented, and maintained at all levels of the organization. The Quality Policy for the Model Factory states the following:

"It is the policy of the UPRM Model Factory to ensure customer satisfaction by providing products and services that conform to all requirements"

Item 820.20(b) requires an organizational structure to ensure responsibility and authority, resources, and management representation. The Model Factory current structure is presented in Figure 6. The structure consists of a top management role in the first row. In the second row are the technical resources and employee leaders that ensure that the manufacturing activities are conducted as expected by the Quality

System. The last row consists of the students that run the operation of the Model Factory.

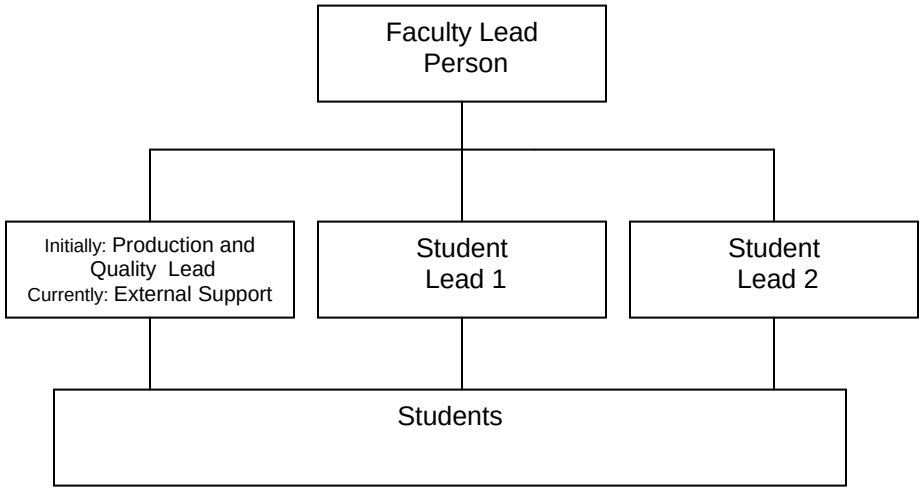

Figure 6 – Current Structure of Model Factory

Item 820.20(c) requires an SOP of Management Review indicating the intervals and frequency in which the Model Factory reviews the effectiveness of the Quality System and pending projects. The results (minutes) of the Management Review are documented. Appendix H presents an SOP indicating the management review details.

Item 820.20(d) requires that the Model Factory establishes a quality plan to ensure that the quality practices, resources, and activities relevant to the devices manufactured are well defined.

Item 820.20(e) requires SOP's and work instructions prepared and available to Model Factory employees.

Item 820.22 establishes procedures for quality audits to assure that the quality system is in compliance. Quality audits are to be conducted by individuals who do not have direct responsibility for the matters being audited. A report of the results of quality audits are to be reviewed by management having responsibility for the matters audited. The dates and results of quality audits must be documented. In the Model Factory the quality audits are to be conducted by customer representatives or external knowledgeable resources; e.g. faculty in charge of quality-related courses.

Item 820.25(a) establishes that the manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all

activities required are correctly performed. Model Factory employees are engineering students and have an approved course, ININ 4050 (titled PCB Assembly), in which they learn about the printed circuit board (PCB) assembly processes and the Model Factory operations. Besides lectures, the course provides significant hands on experience in all processes and includes a team project in which students develop solutions to enhance the Model Factory operations.

Item 820.25(b) establishes procedures for identifying training needs and ensures that all personnel are trained to adequately perform their assigned responsibilities. An SOP for training, training records, and individual training record, presented in Appendix I, is available for the Model Factory and establishes the needs of training and how it will be documented. As explained above, the main source of training is the course (ININ 4050) and related documents (exams and projects) are kept for each student.

4.4.3 Design Control and Its Applicability to the Model Factory

Subpart C does not apply to the Model Factory since it is not involved in design and development activities for medical devices. In the case that it applies, some of the key activities are: determining and meeting the user/patients requirements; meeting regulations and standards; developing specifications for the device; developing, electing and evaluating components and suppliers; developing and approving labels and user instructions; developing packaging; developing specifications for manufacturing processes; verifying safety and performance of prototype and final devices; verifying compatibility with the environment and other devices; developing manufacturing facilities and utilities; developing and validating manufacturing processes; training employees; documenting the details of the device design and processes; and if it applies, developing a service program.

4.4.4 Document Control and its Applicability to the Model Factory

Item 820.40(a) establishes that designated individual(s) will review for adequacy of documents and approval prior to issuance. This approval will include the date and signature of the individual(s) approving the document. In addition, this individual will be responsible for making the documents available at all selected locations and promptly removing all obsolete documents from the points of use.

Item 820.40(b) establishes how to perform the document changes. The SOP indicating how to perform the changes on documents and/or processes for the Model Factory is available in Appendix J. The changes to documentation are flowcharted in Figure 7.

4.4.5 Purchasing Control and its Applicability to the Model Factory

Subpart E does not apply to the Model Factory because the supplier of the materials and components needed to manufacture the products is the customer itself. The customer already performs the supplier evaluation and selection, quality requirements of supplies, and acceptance of supplied parts. This subpart requires that the materials have passed through the process of qualification that includes records and documentation with specific component specifications and supplier qualifications.

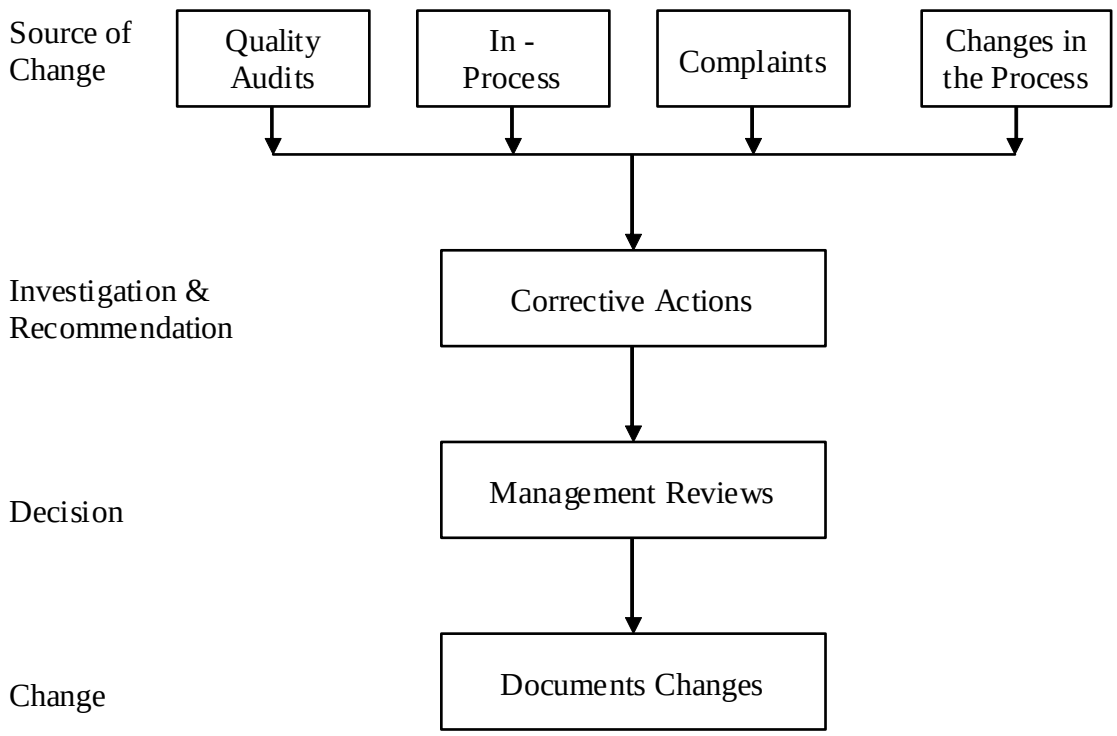

Figure 7 – Flowchart of Document and Change Control SOP

4.4.6 Identification and Traceability and its Applicability to the Model Factory

Item 820.60 establishes that the Model Factory shall have procedures to identify the products in a way to prevent mix-ups. This includes conforming and non–conforming products.

Item 820.65 does not strictly apply to the Model Factory because it is intended for devices that are implanted into the body or for life-sustain devices. With each product container sent to the customer, a Batch History Record is filled out.

Once the subassemblies are on the EBI facilities they complete the Batch History Record and have a traceable way to identify the production lots and give feedback to our process if there is a failure or a quality issue with the subassemblies.

4.4.7 Production and Process Control and its Applicability to the Model Factory

Item 820.70 (a) establishes that the manufacturer controls and monitors production processes to ensure that a device conforms to its specifications with the assistance of SOP's and work instructions and by means of identified and approved representative samples. The Model Factory has a work instructions manual and product samples used during the production process. Appendix P presents the Work Instructions Manual.

Item 820.70 (b) requires that the manufacturer establishes and maintains procedures for changes to a specification, method, process, or procedure. The Model Factory already has a Document and Change Control Procedure in accordance with 820.40 (included in Appendix J).

Item 820.70 (c) establishes that where environmental conditions could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures to adequately control these environmental conditions. In the case of the Model Factory, a clean room environment is not necessary.

Item 820.70 (d) requires that the manufacturer shall establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and product or environment could reasonably be expected to have an adverse effect on product quality. The Model Factory does not allow personnel in the surroundings of equipment or products without appropriate

electro–static discharge (ESD) equipment as established in the work instructions manual.

Item 820.70 (e) requires that the manufacturer shall establish and maintain procedures to prevent contamination of product by substances that could have an adverse effect on product quality. The Model Factory does not use or deals with corrosive substances or materials that could affect product quality.

Item 820.70 (f) establishes that facilities shall be of suitable design and contain sufficient space to perform necessary operations, prevent mix-ups, and assure orderly handling. The Model Factory has a spacious and well prepared facility for manufacturing. In the stations where final product is temporally stored until it is prepared for shipping, the shelves are labeled with each product name to prevent mix-ups. Products are moved to ESD-protected containers as soon as the quantities per container are available.

Item 820.70 (g) states that the manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use. With maintenance schedules, inspection and adjustment procedures including the date and individual(s) performing the maintenance and inspections activities well documented this requirements is complied with. The Model Factory has implemented a Maintenance Procedure to aid the maintenance activity including a Maintenance Schedule for the equipment and a Maintenance Log. Details of this procedure are presented in Appendix K.

Item 820.72 requires that the manufacturer ensures that all inspection, measuring, and test equipment, is suitable for its intended purposes and is capable of producing valid results. The Model Factory does not have inspection, measuring and test equipment in its manufacturing processes that could be routinely calibrated. The fact is that there is no test requirement for the current customer. The Model Factory adds all surface mount components to the printed circuit cards. EBI continues the assembly by adding through-hole components. Afterwards, testing is performed on each bone healing device.

Item 820.75 (a) states that where the results of a process cannot be fully verified by subsequent inspection and test; the process shall be validated and approved according to established procedures. For the PCB's case, process visual inspections satisfy the requirement of process verification and currently the Model Factory operates with two visual inspection stations. This validation activities and results include the date and signature of the individual(s) approving the validation. The Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) activities were done and validated by the EBI's Engineering and Quality Staff. The Process Validation SOP developed to comply with this requirement is presented in Appendix L.

4.4.8 Acceptance Activities and its Applicability to the Model Factory

Item 820.80 (a) establishes that the manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other verification activities. The Model Factory has work instructions that specify how the in-process inspections should be done. In addition, the students are exposed to IPC-A-610, Acceptability of Electronic Assemblies. A Defect Data Collection Form is presented in Appendix L and it is used to record the defects found in the devices to later be tabulated and initiate an investigation to prevent the repetition of the defect.

Item 820.80 (b) establishes that the manufacturer shall establish and maintain procedures for acceptance of incoming product. In the Model Factory case this does not apply because this process is done at the customer facilities as part of the purchase and supplier evaluation requirements.

4.4.9 Non-Conforming Product and its Applicability to the Model Factory

Item 20.90 (a) estates that the manufacturer shall establish and maintain procedures to control products that do not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. An evaluation of nonconformance should be done. The evaluation and any investigation results shall be documented. A Non – Conformance SOP was developed to comply with this requirement and is presented in Appendix M.

4.4.10 Corrective and Preventive Action (CAPA) and its Applicability to the Model Factory

Item 820.100 establishes that the manufacturer will have a procedure to perform the Corrective Action and Preventive Action (CAPA). The Model Factory has a CAPA procedure which indicates how to perform the activity in case that an internal or external customer finds any quality problem(s) in the product or process. The document is provided in Appendix N. The GMP section 820.100 requires an analysis of problem data, returned product, and an investigation of non-conforming product. Section 820.100 refers to analysis of processes, work operations, quality records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming or other quality problems. Section 820.198 also involves reviewing and evaluating complaints to determine whether or not an investigation is necessary. All these activities and their results shall be documented. To document these activities, the Model Factory uses a Project Information Sheet and a Project Improvement Sheet both included in the CAPA Procedure.

4.4.11 Labeling and Packing Control and its Applicability to the Model Factory

Subpart K establishes the requirements of device or product labeling. The FDA defines the term "labeling" as all labels and other written, printed, or graphic matter on the device or any of its containers or wrappers accompanying the device. The term applies any time while the article is in interstate commerce, or being held for sale after shipment or delivery in interstate commerce. Labeling includes equipment labels, control labels, package labels, directions for use, maintenance manuals, etc. The result of this requirement should be a package that protects the device during handling and shipping, and from the environment and microorganisms until the package is opened and the consumer is ready to use this product; the package should be easy to open without compromising the quality of the device. To the Model Factory, subpart K does not apply because before the finished device is shipped to the customer, it requires further processing at the customer facilities, and then the customer is responsible for labeling, packing and distribution of the finish device to consumers.

4.4.12 Handling, Storage, Distribution and Installation and its Applicability to the Model Factory

The regulation requires that the manufacturer handles and stores devices in a way that the quality of the product is not compromised. For the distribution of products, the Quality System requires manufacturers of devices to maintain basic records for: dates of manufacture, the quantity manufactured, quantity released for distribution, acceptance records, primary identification labels and labeling used and any device identification and control number used. When installation is required, the regulation requires that each manufacturer establishes and maintains adequate installation and inspection instructions and, where appropriate, testing procedures. Manufacturers of such devices shall:install the device or have it installed by a qualified representative, inspect and test as appropriate the device after installation to assure the device will perform as intended or provide adequate instructions and procedures for proper installation by another party.

Items 820.140, 820.150, and 820.160 are the titles of Subpart L that apply to the Model Factory. These requirements are covered using ESD–safe containers identified by product and status in the finished product area. In addition finished products are labeled by its manufacturing (Julian) date so that a simple visual check is sufficient to indicate whether the product is acceptable for release and distribution.

4.4.13 Records and its Applicability to the Model Factory

Subpart M discusses how Quality System documentation and records are stored and handled. In the Model Factory, the Quality System documentation is filed in the Device Master Record (DMR) and an index for the DMR by product was prepared identifying all the records and documentation related to each product. A DMR for each type of device shall include or refer to the location of the following information: device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications, production and process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications, quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used, packaging and labeling specifications, including methods and processes used,

and installation, maintenance, and servicing procedures and methods. It should contain device specifications and all the documentation like the SOP's, work instructions and all the records related to manufacturing activity and product manufactured. Related to record retention, the QS regulation in section 820.180(b) requires that all records pertaining to a device shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than two years from the date of release for commercial distribution by the manufacturer.

4.4.14 Servicing and its Applicability to the Model Factory

The intention of this clause of the quality system regulation is to assure that servicing is correctly performed and verified according to company specified requirements such that the serviced device is suitable for the intended use and that service information is collected and analyzed to help correct any quality system problems and device design, manufacturing, labeling, or packaging problems.

The documentation required for servicing should cover: what the device does, theory of operation, operating instructions, safety, device specifications, component specifications, identification and nomenclature, test apparatus, jigs, and special tools, typical failure modes and conditions, how to identify and isolate failures, test points where specific parameters may be measured, removal and replacement of parts, testing and inspecting (verifying) the repaired device, re-installation procedures, if applicable and reporting forms.

The Subpart N does not apply to the Model Factory because the servicing is not defined for the PCA's delivered to the customer. EBI probably has a servicing component since the bone healing systems delivered to customers are returned after use and might be reusable. This activity is out of the scope of the Model Factory.

4.4.15 Statistical Techniques and its Applicability to the Model Factory

The Model Factory captures data at the inspection stations. The Defect Data Collection Form, included in Appendix O, is used to collect data, which is analyzed in order to find the main offenders. This data is analyzed using Pareto diagrams to focus the improvement effort on identified main offenders.

4.4.15.1 Metrics in Place to Monitor Quality System Performance

As part of the implementation process, three metrics were developed to measure the effectiveness of the quality system implemented. These metrics are: audit results, cost of quality, and process defects.

4.4.15.1.1 Quality Audit Success Rate

In the implementation process, step 8 is a second quality audit performed by our customer quality representative. A table comparing the results for the first quality and the second are presented in Table 15. From the results of these quality audits a metric will measure how well the quality system discipline is enforced through time. Equation 1 indicates how this metric is calculated and the results of the two audits already conducted are presented in Figure 8.

$$\text{Quality Audit Success Rate} = \frac{\#\text{ of items in compliance}}{\text{Total }\#\text{ of items audited}} \times 100 \qquad \textbf{(1)}$$

4.4.15.1.2 Quality Costs Related to EBI Attributed to Non-Conforming Materials

Upon arrival of the products to EBI, two types of defects are possible: (1) a mistake in the documents that accompany the products and (2) quality defects in the assembled products. Quality defects might be repaired by EBI personnel, in which case the plant charges the Model Factory for the repair. This charge includes the rate per hour of the direct labor used plus the overhead rate of the plant. Results for this metric are presented in Figure 9. The graph shows a spike in early 2005; the direct labor used was $9.55 per hour plus an overhead of $49.74 per hour, in a repair effort that took 45 hours for a total cost of $2,668. This amount was subtracted from the gross income on February 2006 which totaled $14,475.63; the percentage loss on the invoice due to quality defects was 18.86.

Quality defects could also be returned to the Model Factory for re-inspection and repair, in which case the transportation costs could be the responsibility of the Model Factory. This is the case of the smaller spike of April 2007 on which $125 were charged for transporting three bins of product.

Question	Quality Audit 1	Quality Audit 2
Does the organization have a Quality Policy?	**Yes**	**Yes**
Does the organization have a Quality Manual?	**Yes**	**Yes**
Does the organization have a Documentation Control Procedure?	**No**	**Yes**
Are personnel performing work-affecting quality competent on the basis of appropriate education, training, skills and experience?	**No**	**Yes**
Has the organization determined, provided and maintained the infrastructure needed to achieve conformity to product requirements?	**Yes**	**Yes**
Has the organization determined: a) Requirements specified by the customer, including requirements for delivery and post delivery activities? b) Requirements not specified by the customer but necessary for specified or intended use, where known? c) Any additional requirements determined by the organization?	**Yes**	**Yes**
Has the organization determined and implemented arrangements for communication with customers relating to: a) Product information? b) Enquiries, contracts or order handling, including amendments? c) Customer feedback, including customer complaints? d) Advisory notices?	**Yes**	**Yes**
Does the organization plan and carry out production and service under controlled conditions including: a) Availability of documented procedures, b) The use of suitable equipment, c) The availability and use of monitoring and measuring devices, d) The implementation of monitoring and measuring, e) The implementation of defined operations for labeling and packing.	**Yes**	**Yes**

Table 15 – Quality System Audit Results Comparison

Question	Quality Audit 1	Quality Audit 2
Does the organization exercise care with customer property while it is under the organization's control or being used by the organization?	**Yes**	**Yes**
Does the organization identify, verify, protect and safeguard customer property provided for use or incorporation into the product?	**Yes**	**Yes**
In the occurrence of any customer property that is lost, damage or otherwise found to be unsuitable for use is this reported to the customer and recorded maintained?	**Yes**	**Yes**
Has the organization established documented procedures or documented work instructions for preserving the conformity of product during internal processing and delivery to the intended destination?	**No**	**Yes**
Does the organization establish a program for maintaining, monitoring and measuring devices and process equipment?	**No**	**Yes**
Has the organization established a documented procedure for a customer feedback system to provide early warning of quality problems and for input into the corrective and preventive action processes?	**Yes**	**Yes**
Does the organization has documented procedure to manage non-conforming product?	**No**	**No**
Has a documented procedure been establishes and does define the requirements for corrective and preventive actions?	**No**	**Yes**

Table 15 – Quality System Audit Results Comparison (Cont.)

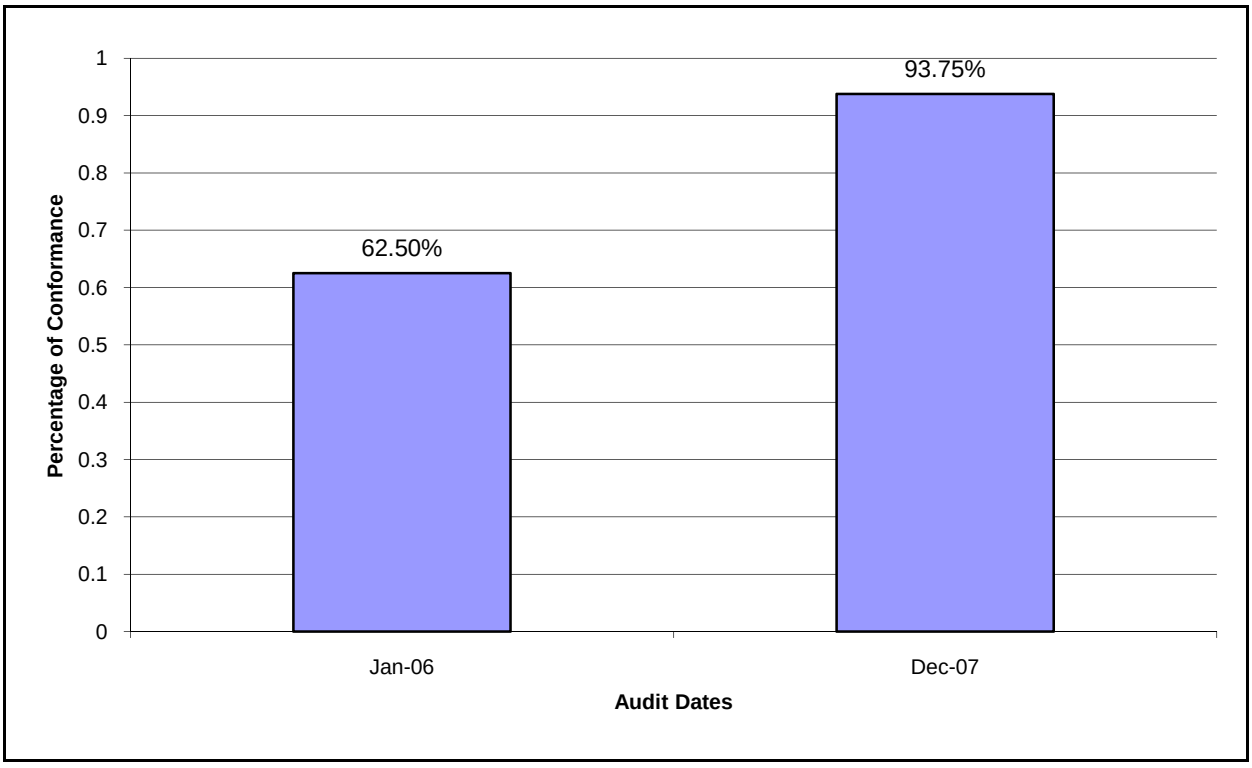

Figure 8 – Results of the Quality Audits

In the case of paperwork mistakes, it typically requires redoing the paperwork and scanning the forms and sending them through e-mail. Anyone of the mistakes always generates a corrective action request. Equation 2 is the selected metric for quality non-conformances captured at EBI. Figure 9 presents the results for the invoices since January 12, 2005, including the two incidents described above related to defective PCA's. The metric highlights the penalty payed by the Model Factory, which is deducted from the invoice prepared for the products delivered to the customer.

$$\textbf{Percent Loss from Quality Incident} = \frac{\textbf{Cost of quality incident}}{\textbf{Gross invoice}} \times \textbf{100} \qquad \textbf{(2)}$$

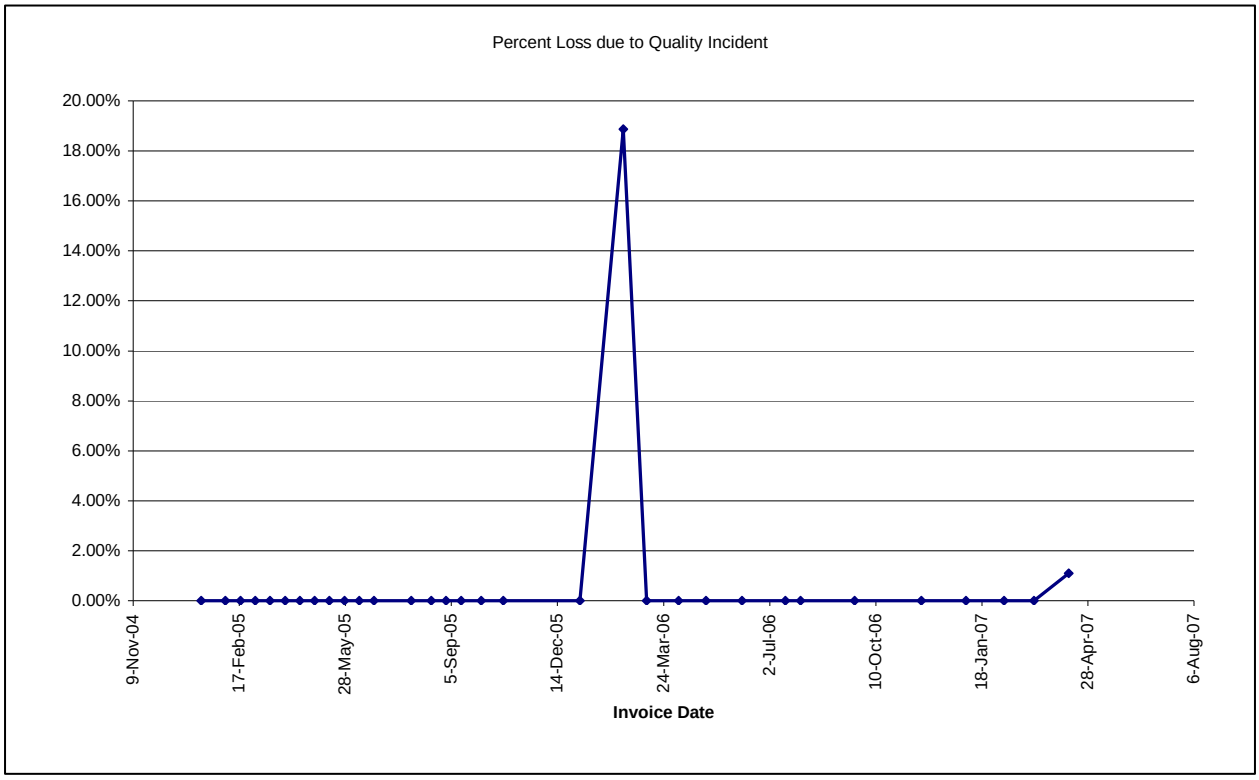

Figure 9 – Percent of Quality Incident versus Gross Invoice

4.4.15.1.3Product Defect Data Analysis

Using the Defect Data Collection form presented in Appendix L and graphing by product, the Model Factory can focus its efforts in making the corrective actions to the process for continuous improvement on product quality. Figure 10 presents the data collected during the first quarter of 2007 in the post-oven inspection station per final assembly product. This graph shows that the main offender during the quarter was skewing (i.e. component slightly rotated) which had a significant incidence in product #2. Capacitors were the components that contributed the most to skewing. A corrective action was worked to solve this top problem.

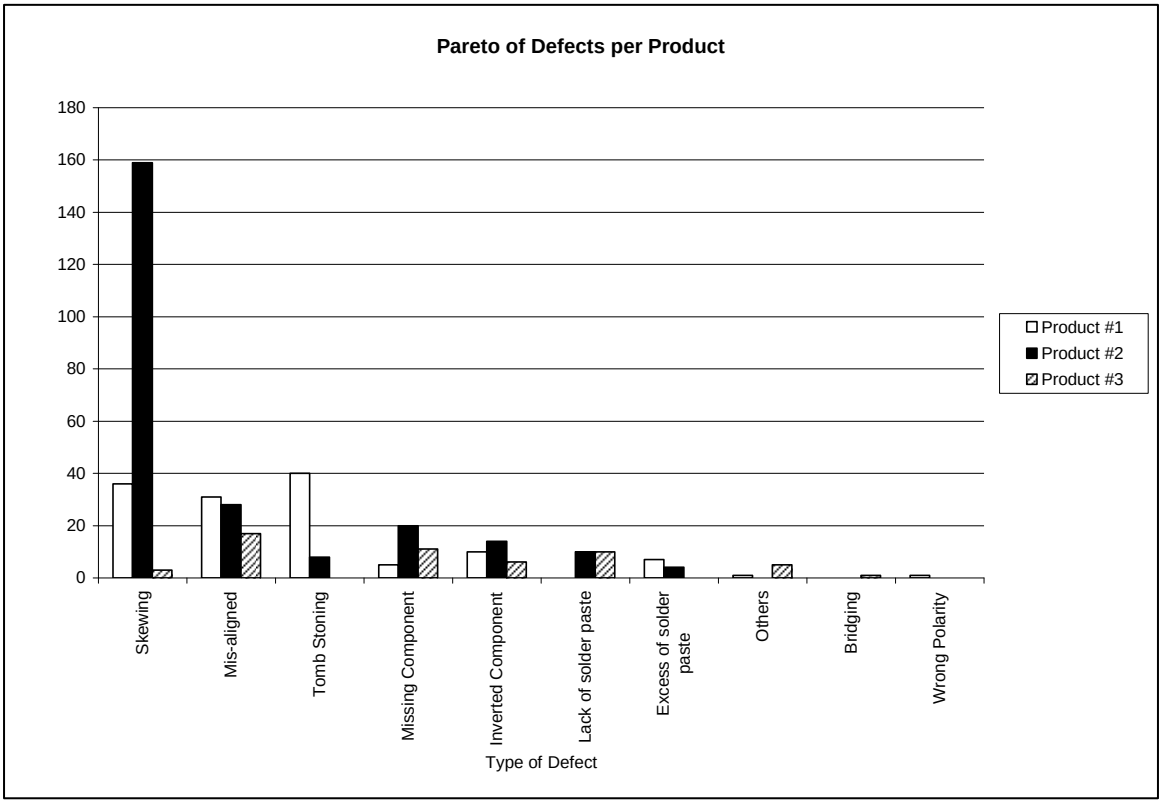

Figure 10 – Occurrence of Defect per Product

5 CONCLUSIONS AND FUTURE WORK

This project is presented as a model to encourage small firm managers to implement a Quality System in their activities. As stated previously, managers understand the importance and the requirements of a quality system and do plan and desire to have one in place. However, at the time of implementation, the items of the quality system are either not correctly implemented or even considered due to financial constrains and lack of time. The project has presented and compared the most popular QMS and the reader can conclude that these QMS are essentially the same.

The project provides examples of the documentation required by the QMS and provided explanations of the requirements that apply to the UPRM – Model Factory. The Model Factory has been operating since December 2004 with the collaboration of faculty from the Industrial Engineering Department of the University of Puerto Rico at Mayagüez. By a requirement of the client and to assure product quality, customer satisfaction and a continuous improvement focus, a Quality System was necessary for the organization. Various quality system models were considered: the NIST – CPE, ISO 9000, and the FDA-QSR. The latter, FDA-QSR, was selected for two key reasons; it was recommended by our customer and it has minimal implementation costs. Implementing any of the ISO quality systems requires a significant periodic investment.

The FDA web page allowed the author to acquire valuable information related to the implementation of a quality system in a small size manufacturing business. Specifically, the FDA publication, “Medical Device Quality Systems Manual: A Small Entity Compliance Guide”, first edition, was a useful guide for understanding and interpreting the GMP – requirements. It provided educational materials, aids, and examples on how to implement elements of a quality system, together with detailed examples of procedures, control forms, and associated data. This manual provides guidance on the interpretation of the GMP requirements, and demonstrates the flexibility of the QS regulation in its application to diverse devices, manufacturing processes, and manufacturers. It encourages that the managers of small firms can rely on industry, national and international consensus standards or guidance to meet GMP requirements in order to comply with FDA requirements if they get a better understanding from them.

This manual was also developed to aid manufacturers in implementing, maintaining, or expanding their quality system. Contents include educational materials, aids, and examples of how to implement elements of a quality system, together with detailed examples of procedures, control forms, and associated data. The examples of typical procedures, drawings, and forms found in this manual were derived from quality systems in the device industry. These materials are not meant to describe universally applicable elements of a quality system that can be used unchanged by any manufacturer. Of course, manufacturers will need to use modify the examples forms or procedures to meet the needs of their devices and operations. To managers of small firms it is important to emphasize that a QMS will work and provide the desired results only if the system is fed back with the correct actions and the system documentation required is followed and updated.

Future work in the quality system of the Model Factory could include automated solutions for ease in data collection and analysis. An Industrial Affiliate Program (IAP) project dealing with component recognition through a vision system is being worked by a graduate student and will be deployed in the pre-oven inspection area. Such inspection strategies are meaningful in the Model Factory scenario given that students will not become mature in visual inspection; i.e. they will not have the opportunity to learn all details of each product, given the time they can invest in working in the assembly process before graduation.

A database could be designed to store data from all assembly process stations, allowing better data analysis capabilities to what is currently available. Such integration is especially challenging for the pick-and-place machines. At present, the Fuji software in use, known as Flexa, collects a significant amount of data about component inspections, machine interruptions, and units produced. If exported from Flexa into an SQL-based database, various real-time graphs could be maintained to summarize hourly results. Such effort would be an excellent senior design project or Master's project for software engineering students.

Another process that could be strengthened in terms of quality is paste dispensing. A Sentry 2000 from Cyber-Optics inspection machine is available and should be put online in the near future. This machine uses infra-red technology to

measure paste height, area or volume, depending on the user needs. Such measures are relevant since the amount of paste dispensed per pad is considered the most critical contributor to PCB assembly quality.

The introduction of new products in the activities of the Model Factory would require the inclusion of Design Control (clause C) as a key element of the quality system. At present the College of Engineering, and particularly the Electrical Engineering department, has computer-aided design (CAD) tools for printed circuit assembly design and development. A software that has been used by Model Factory students is Altium Designer 6, which provides functionality for all stages of the design effort: design and analysis of schematics, signal integrity, fan out, power, etc.

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APPENDICES

Appendix A

Deming's universal 14 points for management

1. **Create consistency of purpose with a plan.** The objective is constancy of purpose for continuous improvement. An unwavering commitment to quality must be maintained by management. Quality, not shot term profit, should be the heart of organization purpose. Profit will follow when quality becomes the objective and purpose.
2. **Adopt the new philosophy of quality.** The modern era demands ever increasing quality as a means of survival and global competitiveness. Inferior material, poor workmanship, defective products, and poor service must be rejected. Reduction of defects is replaced by elimination of defects. The new culture of quality must reflect a commitment to quality and must be supported by all employees.
3. **Cease dependence on mass inspection.** Quality cannot be inspected in; it must be built in from the start. Defects discovered during inspection cannot be avoided – it is too late; efficiency and effectiveness have been lost, as has continuous process improvement. Continuous process improvement reduces costs incurred by correcting errors that should not have been made in the first place.
4. **End the practice of choosing suppliers based on price.** Least cost is not necessarily the best cost. Buying from a supplier based on low cost rather than a quality/cost basis defeats the need for a long-term relationship. Vendor quality can be evaluated with statistical tools.
5. **Identify problems and work continuously to improve the system.** Continuous improvement of the system requires seeking out methods for improvement. The search for quality improvement is never-ending and results from studying the process itself, not the defects detected during inspection.
6. **Adopt modern methods of training on the job.** Training involves teaching employees the best methods of achieving quality in their jobs and the use of tools such as statistical quality control.

7. **Change the focus from production numbers (quantity) to quality.** The focus on volume of production instead of quality leads to defects and rework that may result in inferior products at higher costs.
8. **Drive out fear.** Employees need the feel secure in order for quality to be achieved. Fear of asking questions, reporting problems, or making suggestions will prevent the desired climate of openness.
9. **Break down barriers between departments.** When employees perceive themselves as specialist in one function or department without too much regard for other areas, it trends to promote a climate of parochialism and set up barriers between departments. Quality and productivity can be improved when there is open communication and coordination based on the common organization goals.
10. **Stop requesting improved productivity without providing such methods to achieve it.** Continuous improvement as a general goal should replace motivational or inspirational slogans, signs, exhortations, and work force targets. The major cause of poor productivity and quality is the management systems, not the workforce. Employees are frustrated when exhorted to achieve results that management systems prevent them from achieving.
11. **Eliminate work standards that prescribe numerical quotas.** Focus on quotas, like focus on production, may encourage and reward people for numerical targets, frequently at the expense of quality.
12. **Remove barriers to pride of workmanships.** A mayor barrier to pride of workmanship is a merit or appraisal system based on targets, quotas, or some list of personal traits that have little to do with incentives related to quality. Appraisal systems that attempt to coerce performance should be replaced by systems that attempt to overcome obstacles imposed by inadequate material, equipment, or training.
13. **Institute vigorous education and retraining.** Deming emphasizes training, not only in the methods of the specific job but in the tools and techniques of quality control, as well as instruction in teamwork and the philosophy of a quality culture.
14. **Create a structure in top management that will emphasize the preceding 13 points every day.** An organization that wants to establish a culture based on

quality needs to emphasize the preceding 13 points on a daily basis. This usually requires a transformation in management style and structure. The entire organization must work together to enable a quality culture to succeed.

Appendix B

Juran's ten steps to quality improvement

1. Build awareness of opportunities to improve.
2. Set goals for improvement.
3. Organize to reach goals.
4. Provide training.
5. Carry out projects to solve problems.
6. Report progress.
7. Give recognition.
8. Communicate results.
9. Keep score.
10. Maintain momentum by making annual improvement part of the regular systems and processes of the company.

Appendix C

Crosby 14 points

1. **Management commitment.** Top management must become convinced of the need for quality and must clearly communicate this to the entire company by written policy, stating that each person is expected to perform according to the requirement or cause the requirement to be officially changed to what the company and the customers really need.
2. **Quality improvement team.** Form a team composed of department heads to oversee improvements in their departments and in the company as a whole.
3. **Quality measurement.** Establish measurements appropriate to every activity in order to identify areas in need of improvement.

4. **Cost of quality.** Estimate the costs of quality in order to identify areas where improvements would be profitable.
5. **Quality awareness.** Raise quality awareness among employees. They must understand the importance of product conformance and the costs of non-conformance.
6. **Corrective action.** Take corrective action as a result of steps 3 and 4.
7. **Zero defects planning.** Form a committee to plan a program appropriate to the company and its culture.
8. **Supervisor training.** All levels of management must be trained in how to implement their part of the quality improvement program.
9. **Zero defects day.** Schedule a day to signal to employees that the company has a new standard.
10. **Goal setting.** Individuals must establish improvements goals for themselves and their group.
11. **Error cause removal.** Employees should be encouraged to inform management of any problems that prevent them form performing error-free work.
12. **Recognition.** Give public, non-financial appreciation to those who meet their quality goals or perform outstandingly.
13. **Quality councils.** Composed of quality professionals and team chairpersons, quality councils should meet regularly to share experiences, problems, and ideas.
14. **Do it all over again.** Repeat steps 1 to 13 in order to emphasize the never-ending process of quality improvement.

Appendix D

Organization of QSR

Subpart	Title and Sections	Summary
A	General Information 820.1, 820.3, 820.5	Covers scope, definitions, limitations, authority for the QSR. This subpart requires that each manufacturer establishes and maintaining a Quality System that is appropriate to the specific medical device being designed or manufactured (and meets QSR).
B	Management Responsibilities 820.20, 820.22, 820.25	The first section defines responsibilities for the executive management in the company – establishing quality policy, organizational structure, quality plan, and quality procedures. They must also conduct management reviews on the adequacy of the Quality System. Note that the term "establish" means to define, document, and implement. Many times, companies fail to document the process. The second section requires that quality audit procedures are followed to assure that the company is in compliance with QSR. Finally, the last section describes personnel requirements, especially training.
C	Design Control 820.30	This subpart is of great interest to the R&D personnel and also to start-up companies. It identifies the design and development control requirements.
D	Document Control 820.40	This subpart is also essential to the company, even in early start ups because it describes controls needed for document approvals, distribution, and handling. If the company is using electronic record-keeping systems, then another regulation also comes into play (21 CFR Part 11).
E	Purchasing Control 820.50	The focus of this subpart is to make sure that all purchased product and services conform to specified requirements. To do this, the manufacturer should have processes to evaluate the suppliers, contractors, and consultants and have the proper documentation system (purchasing documents) to show the specified requirements.

Subpart	Title and Sections	Summary
F	Identification and Traceability 820.60, 820.65	Procedures to identify product throughout the production, storage, and installation processes are required to prevent mix-ups. Certain types of devices (such as implants or life support) are also required to be traceable to a control number for each unit, lot, or batch of finished devices.
G	Production and Process Controls 820.70, 820.72, 820.75	This subpart has three major sections. The first section requires that the manufacturer establishes, controls, and monitors production processes to ensure that a device conforms to its specifications. A procedure defining how to change product specifications, production method, process, or even other procedures must be written and followed. Such a Change Control procedure is often a core SOP for a company. This section also includes controls on environmental conditions, personnel (e.g., cleanliness, clothing, etc), contamination control, building design, and equipment. All equipment used in the manufacturing process must meet specified requirements and must be maintained, inspected, and adjusted. The second section requires that the manufacturer ensures that inspection, measuring, and test equipment are suitable for its intended purposes and capable of producing valid results. This includes a calibration program. The last section covers process validation. Processes where the results cannot be verified by inspection and test must be validated and approved according to established procedures.
H	Acceptance Activities 820.80, 820.86	This subpart covers the procedures the manufacturer will use for acceptance activities such as inspections, tests, or other verification activities. There must be procedures for receiving acceptance, in-process acceptance, and final acceptance for finished medical devices. Acceptance records must be kept and the acceptance status must be identified to ensure that only accepted product is distributed, used, or installed.

Subpart	Title and Sections	Summary
I	Nonconforming Product 820.90	This subpart requires that the manufacturer establishes how it controls product that doesn't conform to specified requirements (for example, product or components that fail receiving, in-process, or final inspection). The procedures should address identification, documentation, evaluation, segregation, and disposition of the nonconforming product.
J	Corrective and Preventive Action 820.100	Corrective and preventive action often forms the core of a working quality system. These procedures should specify that one analyzes multiple sources to detect recurring quality problems. Once found, the cause of the nonconformities relating to product, processes, and the quality system should be investigated. The corrective actions must be identified, implemented, and verified or validated.
K	Device labeling 820.120, 820.130	Labeling activities must be controlled. These controls include integrity, inspection, storage and operations. This subpart also requires that device packaging and shipping containers are designed and constructed to protect the device from damage during processing, storage, handling, and distribution.
L	Handling, Storage, Distribution, and Installation 820.140, 820.150, 820.160, 820.170	This subpart covers control of processes required to ensure that devices are prevented from mix-ups, damage, deterioration, contamination, or other adverse effects due to handling, storage, or distribution. Storage and distribution procedures should also ensure that no obsolete, rejected, or deteriorated product is used or distributed. During distribution, only devices approved for release may be distributed and purchase orders must be reviewed to ensure that ambiguities and errors are resolved prior to distribution. Distribution records must also be maintained. Finally, if a device requires installation, adequate installation and inspection procedures must be established.

Subpart	Title and Sections	Summary
M	Records 820.180, 820.181, 820.182, 820.184, 820.186, 820.198	All records required by QSR must be maintained and reasonably accessible to responsible officers of the manufacturer. These records must be made readily available for review and copying by FDA during an inspection. These records shall be legible and stored in such a way to minimize deterioration and loss. If electronic record keeping is used, 21 CFR Part 11 also applies. The required retention period for these records is described in this subpart. This subpart also specifies the types of documents that the manufacturer must maintain in the Device Master Record, the Device History Record, the Quality System Record, and Complaint Files.
N	Servicing 820.200	If servicing is a specified requirement for the device, the manufacturer must establish and maintain instructions for performing and verifying that the servicing meets the specified requirements. This subpart also specifies what belongs in a service report and the relationship of service reports and complaints.
O	Statistical Techniques 820.250	If appropriate, the manufacturer shall establish procedures for identifying valid statistical techniques in process procedures and product characteristics. If sampling plans are used (for example, incoming inspection), these plans needs to be written and based upon valid statistical rationale.

Appendix E

Gap Analysis Checklist

Question	Answer Yes or No	Comments
Management Responsibility		
Does the organization have a Quality Policy?		
Has the organization established an adequate organizational structure to ensure that devices are designed and produced in accordance with the requirements?		
Has top management ensured that responsibility and authority are defined and communicated within the organization?		
Does top management ensure that customer requirements are determined, and are met with the aim of achieving customer satisfaction?		
Does top management review the QS, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness?		
Quality Audit.		
Has a documented procedure been establishes and does the requirements for an Internal Audit Program been defined?		
Personnel		
Are personnel performing work affecting quality competent on the basis of appropriate education, training, skills and experience?		
Has the organization established procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities?		
Design Controls		
Did the organization established a documented procedure for design and development?		
Document Controls		
Does the organization have a Documentation Control Procedure?		
Does the organization have the latest version of documents available at all designated locations and have all obsolete documents been removed to prevent unintended use?		

Question	Answer Yes or No	Comments
Purchasing Controls		
Does the organization established a documented procedure to define purchasing activities?		
Does the organization evaluate and select suppliers based on their ability to supply product in accordance with in the organization's requirements?		
Has the organization established and implemented inspection or other activities necessary for ensuring purchase product meets specified purchase requirements?		
Identification and Traceability		
Has the organization established documented procedures for identification and traceability?		
Production and Process Controls		
Does the organization controls and monitor production processes to ensure that a device conforms to its specifications?		
Where deviations from device specifications occurs: ▪ Does the organization has established and maintain process controls procedures that describe any process controls necessary to ensure conformance to specifications?		
Does the organization established and maintain procedures for changes to a specification, method, process, or procedure?		
Has the organization determine, provided and maintained the infrastructure needed to achieve conformity to product requirements?		
Does the organization controls and monitors production processes to ensure that a device conforms to its specifications?		
Has the organization establish and maintain procedures for changes to a specification, method, process, or procedure?		
Does the organization determined and manage the work environment to achieve conformity to product requirements?		

Question	Answer Yes or No	Comments
Production and Process Controls (cont.)		
Does the organization establish and maintain requirements for personnel and product or environment could reasonably have an adverse effect on product quality?		
Does the organization ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately placed and installed to facilitate maintenance, adjustment, cleaning, and use?		
Does the organization establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment?		
Process Validation		
Can the process be validated with a high degree of assurance and approved according to established procedures?		
Receiving, In-process and Finished Device Acceptance		
Does the organization has established and maintain procedures for acceptance of incoming product?		
Has the organization established and maintain acceptance procedures to ensure that specified requirements for in-process product are met?		
Has the organization established and maintain establish and maintain procedures for finished device acceptance to ensure that the finished devices meets acceptance criteria?		
Non-conforming Product		
Does the organization has documented procedure to manage non-conforming product?		
Has the organization established documented procedures or documented work instructions for preserving the conformity of product during internal processing and delivery to the intended destination?		

Question	Answer Yes or No	Comments
Corrective and Preventive Action		
Has a documented procedure been establishes and does define the requirements for corrective and preventive actions?		
Has the organization established a documented procedure for a customer feedback system to provide early warning of quality problems and for input into the corrective and preventive action processes?		
Labeling and Packaging Control		
Has the organization established and maintain procedures to control labeling activities?		
Does the organization ensures that device packaging and shipping containers are designed to protect the device from damage during processing, storage, handling, and distribution?		
Handling, Storage, Distribution, and Installation		
Does the manufacture established and maintain procedures to ensure handling and storage in order that mix-ups, damage or adverse effects to product do not occur during handling?		
Has the organization established and maintain procedures for control and distribution of finished devices?		
Does the organization has, in devices requiring installation, established and maintain adequate installation and inspection instructions, and where appropriate test procedures?		
Records		
Does the organization maintained at the manufacturing establishment or other location where FDA designated to perform inspections?		

Question	Answer Yes or No	Comments
Device Master Record		
Does the organization maintain device master records for each type of device that includes the following information: a) Device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications, b) Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications, c) Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used; d) Packaging and labeling specifications, including methods and processes used, e) Installation, maintenance, and servicing procedures and methods.		
Complaint Files		
Does the organization established and maintain procedures for receiving, reviewing, and evaluating complaints?		
Servicing		
Does the organization has established and maintain instructions and procedures for performing and verifying that the servicing meets the specified requirements?		
Has the organization determined and implemented arrangements for communication with customers relating to: a) Product information? b) Enquiries, contracts or order handling, including amendments? c) Customer feedback, including customer complaints? d) Advisory notices?		

Question	Answer Yes or No	Comments
Statistical Techniques		
Does the organization determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the QS and to evaluate continual improvement of the effectiveness of the QS?		

Appendix F

FDA – QSR CFR 21 Part 820

Subpart A – General Provisions

§820.1 – Scope

(a) Applicability:

(1) Current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation. The requirements in this part govern the methods used in, and the facilities and controls used for the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (the act). This part establishes basic requirements applicable to manufacturers of finished medical devices. If a manufacturer engages in only some operations subject to the requirements in this part, and not in others, that manufacturer needs only comply with those requirements applicable to the operations in which it is engaged. With respect to class I devices, design controls apply only to those devices listed in 820.30(a)(2). This regulation does not apply to manufacturers of components or parts of finished devices, but such manufacturers are encouraged to use appropriate provisions of this regulation as guidance. Manufacturers of human blood and blood components are not subject to this part, but are subject to part 606 of this chapter.

(2) The provisions of this part shall be applicable to any finished device as defined in this part, intended for human use that is manufactured, imported, or offered for import in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(3) In this regulation the term “where appropriate" is used several times. When a requirement is qualified by “where appropriate", it is deemed to be “appropriate" unless the manufacturer can document justification otherwise. A requirement is “appropriate" if non – implementation could reasonably be expected to result in the product not meeting its specified requirements or the manufacturer not being able to carry out any necessary corrective action.

(b) Limitations: The quality system regulation in this part supplements regulations in other parts of this chapter except where explicitly stated otherwise. In the event that it is impossible to comply with all applicable regulations, both in this part and in other parts of this chapter, the regulations specifically applicable to the device in question shall supersede any other generally applicable requirements.

(c) Authority: Part 820 is established and issued under authority of sections 501, 502, 510, 513, 514, 515, 518, 519, 520, 522, 701, 704, 801, 803 of the act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383). The failure to comply with any applicable provision in this part renders a device adulterated under section 501(h) of the act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action.

(d) Foreign manufacturers: If a manufacturer who offers devices for import into the United States refuses to permit or allow the completion of a Food and Drug Administration (FDA) inspection of the foreign facility for the purpose of determining compliance with this part, it shall appear for purposes of section 801(a) of the act, that the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, or servicing of any devices produced at such facility that are offered for import into the United States do not conform to the requirements of section 520(f) of the act and this part and that the devices manufactured at that facility are adulterated under section 501(h) of the act.

(e) Exemptions or variances: (1) Any person who wishes to petition for an exemption or variance from any device quality system requirement is subject to the requirements of section 520(f)(2) of the act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in §10.30 of this chapter, the FDA's administrative procedures. Guidance is available from the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance, (HFZ-220), 1350 Piccard Dr., Rockville, MD 20850, U.S.A., telephone 1-800-638-2041 or 1-301- 443-6597, FAX 301-443-8818.

(2) FDA may initiate and grant a variance from any device quality system requirement when the agency determines that such variance is in the best interest of the public health. Such variance will remain in effect only so long as there remains a public health

need for the device and the device would not likely be made sufficiently available without the variance.

§820.3 – Definitions

(a) **Act** means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201- 903, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321-394)). All definitions in section 201 of the act shall apply to the regulations in this part.

(b) **Complaint** means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.

(c) **Component** means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.

(d) **Control number** means any distinctive symbols, such as a distinctive combination of letters or numbers, or both, from which the history of the manufacturing, packaging, labeling, and distribution of a unit, lot, or batch of finished devices can be determined.

(e) **Design history file (DHF)** means a compilation of records which describes the design history of a finished device.

(f) **Design input** means the physical and performance requirements of a device that are used as a basis for device design.

(g) **Design output** means the results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the device master record. The total finished design output consists of the device, its packaging and labeling, and the device master record.

(h) **Design review** means a documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.

(i) **Device history record (DHR)** means a compilation of records containing the production history of a finished device.

(j) **Device master record (DMR)** means a compilation of records containing the procedures and specifications for a finished device.

(k) **Establish** means define, document (in writing or electronically), and implement.

(l) **Finished device** means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

(m) **Lot or batch** means one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.

(n) **Management with executive responsibility** means those senior employees of a manufacturer who have the authority to establish or make changes to the manufacturer's quality policy and quality system.

(o) **Manufacturer** means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.

(p) **Manufacturing material** means any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a byproduct constituent produced during the manufacturing process, which is present in or on the finished device as a residue or impurity not by design or intent of the manufacturer.

(q) **Nonconformity** means the non – fulfillment of a specified requirement.

(r) **Product** means components, manufacturing materials, in – process devices, finished devices, and returned devices.

(s) **Quality** means the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.

(t) **Quality audit** means a systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are

implemented effectively, and that these procedures are suitable to achieve quality system objectives.

(u) **Quality policy** means the overall intentions and direction of an organization with respect to quality, as established by management with executive responsibility.

(v) **Quality system** means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

(w) **Remanufacturer** means any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.

(x) **Rework** means action taken on a nonconforming product so that it will fulfill the specified DMR requirements before it is released for distribution.

(y) **Specification** means any requirement with which a product, process, service, or other activity must conform.

(z) **Validation** means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

(1) **Process validation** means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

(2) **Design validation** means establishing by objective evidence that device specifications conform with user needs and intended use(s).

(3) **Verification** means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

§820.5 – Quality system

Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part.

Subpart B – Quality System Requirements

§820.20 – Management responsibility

(a) **Quality policy.** Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality. Management with executive

responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization.

(b) **Organization.** Each manufacturer shall establish and maintain an adequate organizational structure to ensure that devices are designed and produced in accordance with the requirements of this part.

(1) **Responsibility and authority.** Each manufacturer shall establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform these tasks.

(2) **Resources.** Each manufacturer shall provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, to meet the requirements of this part.

(3) **Management representative.** Management with executive responsibility shall appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for:

(i) Ensuring that quality system requirements are effectively established and effectively maintained in accordance with this part; and

(ii) Reporting on the performance of the quality system to management with executive responsibility for review.

(c) **Management review.** Management with executive responsibility shall review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of this part and the manufacturer's established quality policy and objectives. The dates and results of quality system reviews shall be documented.

(d) **Quality planning.** Each manufacturer shall establish a quality plan which defines the quality practices, resources, and activities relevant to devices that are designed and manufactured. The manufacturer shall establish how the requirements for quality will be met.

(e) **Quality system procedures.** Each manufacturer shall establish quality system procedures and instructions. An outline of the structure of the documentation used in the quality system shall be established where appropriate.

§820.22 – Quality audit

Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited. Corrective action(s), including a re – audit of deficient matters, shall be taken when necessary. A report of the results of each quality audit, and re – audit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the matters audited. The dates and results of quality audits and re – audits shall be documented.

§820.25 – Personnel

(a) **General.** Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed.

(b) **Training.** Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented.

(1) As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs.

(2) Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions.

Subpart C – Design Controls

§820.30 – Design controls

(a) **General**

(1) Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section, shall establish and maintain procedures to

control the design of the device in order to ensure that specified design requirements are met.

(2) The following class I devices are subject to design controls:

(i) Devices automated with computer software; and

(ii) The devices listed in the following chart.

Section	Device
868.6810	Catheter, Tracheo – bronchial Suction
878.4460	Glove, Surgeon's
880.6760	Restraint, Protective
892.5650	System, Applicator, Radionuclide, Manual
892.5740	Source, Radionuclide Tele – therapy

(b) **Design and development planning.** Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process. The plans shall be reviewed, updated, and approved as design and development evolves.

(c) **Design input.** Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.

(d) **Design output.** Each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that

are essential for the proper functioning of the device are identified. Design output shall be documented, reviewed, and approved before release. The approval, including the date and signature of the individual(s) approving the output, shall be documented.

(e) **Design review.** Each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development. The procedures shall ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed. The results of a design review, including identification of the design, the date, and the individual(s) performing the review, shall be documented in the design history file (the DHF).

(f) **Design verification.** Each manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the DHF.

(g) **Design validation.** Each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the DHF.

(h) **Design transfer.** Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

(i) **Design changes.** Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

(j) **Design history file.** Each manufacturer shall establish and maintain a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.

Subpart D – Document Controls

§820.40 – Document controls

Each manufacturer shall establish and maintain procedures to control all documents that are required by this part. The procedures shall provide for the following:

(a) **Document approval and distribution.** Each manufacturer shall designate an individual(s) to review for adequacy and approve prior to issuance all documents established to meet the requirements of this part. The approval, including the date and signature of the individual(s) approving the document, shall be documented. Documents established to meet the requirements of this part shall be available at all locations for which they are designated, used, or otherwise necessary, and all obsolete documents shall be promptly removed from all points of use or otherwise prevented from unintended use.

(b) **Document changes.** Changes to documents shall be reviewed and approved by an individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise. Approved changes shall be communicated to the appropriate personnel in a timely manner. Each manufacturer shall maintain records of changes to documents. Change records shall include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective.

Subpart E – Purchasing Controls

§820.50 – Purchasing controls

Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.

(a) **Evaluation of suppliers, contractors, and consultants.** Each manufacturer shall establish and maintain the requirements, including quality requirements, which must be met by suppliers, contractors, and consultants. Each manufacturer shall:

(1) Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.

(2) Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.

(3) Establish and maintain records of acceptable suppliers, contractors, and consultants.

(b) **Purchasing data.** Each manufacturer shall establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received product and services. Purchasing documents shall include, where possible, an agreement that the suppliers, contractors, and consultants agree to notify the manufacturer of changes in the product or service so that manufacturers may determine whether the changes may affect the quality of a finished device. Purchasing data shall be approved in accordance with §820.40.

Subpart F – Identification and Traceability

§820.60 – Identification

Each manufacturer shall establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation to prevent mix-ups.

§820.65 – Traceability

Each manufacturer of a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action. Such identification shall be documented in the DHR.

Subpart G – Production and Process Controls

§820.70 – Production and process controls

(a) **General.** Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Where process controls are needed they shall include:

(1) Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;

(2) Monitoring and control of process parameters and component and device characteristics during production;

(3) Compliance with specified reference standards or codes;

(4) The approval of processes and process equipment; and

(5) Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

(b) **Production and process changes.** Each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure. Such changes shall be verified or where appropriate validated according to §820.75, before implementation and these activities shall be documented. Changes shall be approved in accordance with §820.40.

(c) **Environmental control.** Where environmental conditions could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures to adequately control these environmental conditions. Environmental control system(s) shall be periodically inspected to verify that the system, including necessary equipment, is adequate and functioning properly. These activities shall be documented and reviewed.

(d) **Personnel.** Each manufacturer shall establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and product or environment could reasonably be expected to have an

adverse effect on product quality. The manufacturer shall ensure that maintenance and other personnel who are required to work temporarily under special environmental conditions are appropriately trained or supervised by a trained individual.

(e) **Contamination control.** Each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.

(f) **Buildings.** Buildings shall be of suitable design and contain sufficient space to perform necessary operations, prevent mix-ups, and assure orderly handling.

(g) **Equipment.** Each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use.

(1) **Maintenance schedule.** Each manufacturer shall establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met. Maintenance activities, including the date and individual(s) performing the maintenance activities, shall be documented.

(2) **Inspection.** Each manufacturer shall conduct periodic inspections in accordance with established procedures to ensure adherence to applicable equipment maintenance schedules. The inspections, including the date and individual(s) conducting the inspections, shall be documented.

(3) **Adjustment.** Each manufacturer shall ensure that any inherent limitations or allowable tolerances are visibly posted on or near equipment requiring periodic adjustments or are readily available to personnel performing these adjustments.

(h) **Manufacturing material.** Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.

(i) **Automated processes.** When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented.

§820.72 – Inspection, measuring, and test equipment

(a) **Control of inspection, measuring, and test equipment.** Each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained. The procedures shall include provisions for handling, preservation, and storage of equipment, so that its accuracy and fitness for use are maintained. These activities shall be documented.

(b) **Calibration.** Calibration procedures shall include specific directions and limits for accuracy and precision. When accuracy and precision limits are not met, there shall be provisions for remedial action to reestablish the limits and to evaluate whether there was any adverse effect on the device's quality. These activities shall be documented.

(1) **Calibration standards.** Calibration standards used for inspection, measuring, and test equipment shall be traceable to national or international standards. If national or international standards are not practical or available, the manufacturer shall use an independent reproducible standard. If no applicable standard exists, the manufacturer shall establish and maintain an in-house standard.

(2) **Calibration records.** The equipment identification, calibration dates, the individual performing each calibration, and the next calibration date shall be documented. These records shall be displayed on or near each piece of equipment or shall be readily available to the personnel using such equipment and to the individuals responsible for calibrating the equipment.

§820.75 – Process validation

(a) Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved

according to established procedures. The validation activities and results, including the date and signature of the individual(s) approving the validation and where appropriate the major equipment validated, shall be documented.

(b) Each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met.

(1) Each manufacturer shall ensure that validated processes are performed by qualified individual(s).

(2) For validated processes, the monitoring and control methods and data, the date performed, and, where appropriate, the individual(s) performing the process or the major equipment used shall be documented.

(c) When changes or process deviations occur, the manufacturer shall review and evaluate the process and perform revalidation where appropriate. These activities shall be documented.

Subpart H – Acceptance Activities

§820.80 – Receiving, in-process, and finished device acceptance

(a) **General.** Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other verification activities.

(b) **Receiving acceptance activities.** Each manufacturer shall establish and maintain procedures for acceptance of incoming product. Incoming product shall be inspected, tested, or otherwise verified as conforming to specified requirements. Acceptance or rejection shall be documented.

(c) **In-process acceptance activities.** Each manufacturer shall establish and maintain acceptance procedures, where appropriate, to ensure that specified requirements for in-process product are met. Such procedures shall ensure that in-process product is controlled until the required inspection and tests or other verification activities have been completed, or necessary approvals are received, and are documented.

(d) **Final acceptance activities.** Each manufacturer shall establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or

batch of finished devices meets acceptance criteria. Finished devices shall be held in quarantine or otherwise adequately controlled until released. Finished devices shall not be released for distribution until:

(1) The activities required in the DMR are completed;

(2) the associated data and documentation is reviewed;

(3) the release is authorized by the signature of a designated individual(s); and

(4) the authorization is dated.

(e) **Acceptance records.** Each manufacturer shall document acceptance activities required by this part. These records shall include:

(1) The acceptance activities performed;

(2) the dates acceptance activities are performed;

(3) the results;

(4) the signature of the individual(s) conducting the acceptance activities; and

(5) where appropriate the equipment used.

These records shall be part of the DHR.

§820.86 – Acceptance status

Each manufacturer shall identify by suitable means the acceptance status of product, to indicate the conformance or nonconformance of product with acceptance criteria. The identification of acceptance status shall be maintained throughout manufacturing, packaging, labeling, installation, and servicing of the product to ensure that only product which has passed the required acceptance activities is distributed, used, or installed.

Subpart I – Nonconforming Product

§820.90 – Nonconforming product

(a) **Control of nonconforming product**

Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need

for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented.

(b) **Nonconformity review and disposition**

(1) Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.

(2) Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR.

Subpart J – Corrective and Preventive Action

§820.100 – Corrective and preventive action

(a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

(1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;

(2) Investigating the cause of nonconformities relating to product, processes, and the quality system;

(3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

(4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;

(5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

(6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

(7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

(b) All activities required under this section, and their results, shall be documented.

Subpart K – Labeling and Packaging Control

§820.120 – Device labeling

Each manufacturer shall establish and maintain procedures to control labeling activities.

(a) **Label integrity.** Labels shall be printed and applied so as to remain legible and affixed during the customary conditions of processing, storage, handling, distribution, and where appropriate use.

(b) **Labeling inspection.** Labeling shall not be released for storage or use until a designated individual(s) has examined the labeling for accuracy including, where applicable, the correct expiration date, control number, storage instructions, handling instructions, and any additional processing instructions. The release, including the date and signature of the individual(s) performing the examination, shall be documented in the DHR.

(c) **Labeling storage.** Each manufacturer shall store labeling in a manner that provides proper identification and is designed to prevent mix-ups.

(d) **Labeling operations.** Each manufacturer shall control labeling and packaging operations to prevent labeling mix-ups. The label and labeling used for each production unit, lot, or batch shall be documented in the DHR.

(e) **Control number.** Where a control number is required by §820.65, that control number shall be on or shall accompany the device through distribution.

§820.130 – Device packaging

Each manufacturer shall ensure that device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution.

Subpart L – Handling, Storage, Distribution, and Installation

§820.140 – Handling

Each manufacturer shall establish and maintain procedures to ensure that mix-ups, damage, deterioration, contamination, or other adverse effects to product do not occur during handling.

§820.150 – Storage

(a) Each manufacturer shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mix-ups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate.

(b) Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.

§820.160 – Distribution

(a) Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution. Where a device's fitness for use or quality deteriorates over time, the procedures shall ensure that expired devices or devices deteriorated beyond acceptable fitness for use are not distributed.

(b) Each manufacturer shall maintain distribution records which include or refer to the location of:

(1) The name and address of the initial consignee;

(2) The identification and quantity of devices shipped;

(3) The date shipped; and

(4) Any control number(s) used.

§820.170 – Installation

(a) Each manufacturer of a device requiring installation shall establish and maintain adequate installation and inspection instructions, and where appropriate test procedures. Instructions and procedures shall include directions for ensuring proper installation so that the device will perform as intended after installation. The manufacturer shall distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device.

(b) The person installing the device shall ensure that the installation, inspection, and any required testing are performed in accordance with the manufacturer's instructions and procedures and shall document the inspection and any test results to demonstrate proper installation.

Subpart M – Records

§820.180 – General requirements

All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available for review and copying by FDA employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up.

(a) **Confidentiality.** Records deemed confidential by the manufacturer may be marked to aid FDA in determining whether information may be disclosed under the public information regulation in part 20 of this chapter.

(b) **Record retention period.** All records required by this part shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer.

(c) **Exceptions.** This section does not apply to the reports required by §820.20(c) Management review, §820.22 Quality audits, and supplier audit reports used to meet

the requirements of §820.50(a) Evaluation of suppliers, contractors, and consultants, but does apply to procedures established under these provisions. Upon request of a designated employee of FDA, an employee in management with executive responsibility shall certify in writing that the management reviews and quality audits required under this part, and supplier audits where applicable, have been performed and documented, the dates on which they were performed, and that any required corrective action has been undertaken.

§820.181 – Device master record

Each manufacturer shall maintain device master records (DMR's). Each manufacturer shall ensure that each DMR is prepared and approved in accordance with §820.40. The DMR for each type of device shall include, or refer to the location of, the following information:

(a) Device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications;

(b) Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications;

(c) Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used;

(d) Packaging and labeling specifications, including methods and processes used; and

(e) Installation, maintenance, and servicing procedures and methods.

§820.184 – Device history record

Each manufacturer shall maintain device history records (DHR's). Each manufacturer shall establish and maintain procedures to ensure that DHR's for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the DMR and the requirements of this part. The DHR shall include, or refer to the location of, the following information:

(a) The dates of manufacture;

(b) The quantity manufactured;

(c) The quantity released for distribution;

(d) The acceptance records which demonstrate the device is manufactured in accordance with the DMR;

(e) The primary identification label and labeling used for each production unit; and

(f) Any device identification(s) and control number(s) used.

§820.186 – Quality system record

Each manufacturer shall maintain a quality system record (QSR). The QSR shall include, or refer to the location of, procedures and the documentation of activities required by this part that are not specific to a particular type of device(s), including, but not limited to, the records required by §820.20. Each manufacturer shall ensure that the QSR is prepared and approved in accordance with §820.40.

§820.198 – Complaint files

(a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:

(1) All complaints are processed in a uniform and timely manner;

(2) Oral complaints are documented upon receipt; and

(3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 or 804 of this chapter, Medical Device Reporting.

(b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.

(c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.

(d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint

files or otherwise clearly identified. In addition to the information required by §820.198(e), records of investigation under this paragraph shall include a determination of:

(1) Whether the device failed to meet specifications;

(2) Whether the device was being used for treatment or diagnosis; and

(3) The relationship, if any, of the device to the reported incident or adverse event.

(e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include:

(1) The name of the device;

(2) The date the complaint was received;

(3) Any device identification(s) and control number(s) used;

(4) The name, address, and phone number of the complainant;

(5) The nature and details of the complaint;

(6) The dates and results of the investigation;

(7) Any corrective action taken; and

(8) Any reply to the complainant.

(f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.

(g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either:

(1) A location in the United States where the manufacturer's records are regularly kept; or

(2) The location of the initial distributor.

Subpart N – Servicing

§820.200 – Servicing

(a) Where servicing is a specified requirement, each manufacturer shall establish and maintain instructions and procedures for performing and verifying that the servicing meets the specified requirements.

(b) Each manufacturer shall analyze service reports with appropriate statistical methodology in accordance with §820.100.

(c) Each manufacturer who receives a service report that represents an event which must be reported to FDA under part 803 of this chapter shall automatically consider the report a complaint and shall process it in accordance with the requirements of §820.198.

(d) Service reports shall be documented and shall include:

(1) The name of the device serviced;

(2) Any device identification(s) and control number(s) used;

(3) The date of service;

(4) The individual(s) servicing the device;

(5) The service performed; and

(6) The test and inspection data.

Subpart O – Statistical Techniques

§820.250 – Statistical techniques

(a) Where appropriate, each manufacturer shall establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics.

(b) Sampling plans, when used, shall be written and based on a valid statistical rationale. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and to ensure that when changes occurs the sampling plans are reviewed. These activities shall be documented.

Appendix G

DMR Index

DEVICE MASTER RECORD INDEX

Approvals			History of Changes		
Rev	**Date**	**Authority**	**Rev**	**Description**	**Date**
A					

Appendix H

Management Review SOP

Approvals			History of Changes		
Rev	**Date**	**Authority**	**Rev**	**Description**	**Date**
A					

TABLE OF CONTENTS

1.0 PURPOSE

1.1 Define and document the process of conducting and documenting the Management Review Meetings.

2.0 SCOPE

2.1 Applies to management review meetings conducted at Model Factory.

3.0 DEFINITIONS

3.1 None

4.0 REFERENCE DOCUMENTS

4.1 Project Improvement Sheets.

4.2 Tabulated defects collected data.

5.0 EQUIPMENT & TOOLS

5.1 No equipment and tool are required.

6.0 SAFETY

6.1 No safety equipment required in this procedure.

7.0 TRAINING REQUIREMENTS

7.1 No training is required.

8.0 PROCEDURE

8.1 A management review takes place at least monthly, this meeting is held by the Management personnel.

8.2 The meeting will addresses the functioning of the quality system including:

- 8.2.1 Pending issues from previous meetings
- 8.2.2 Quality Reports & Trends
- 8.2.3 CAPA’s

8.2.4 Audit findings, pending actions and schedule

8.2.5 Projects status

8.2.6 Other Issues as production problems, changes to the quality system to improve its effectiveness or regulatory compliance issues.

8.3 A record of attendance will be generated. The record will include name and the signature of all attendees.

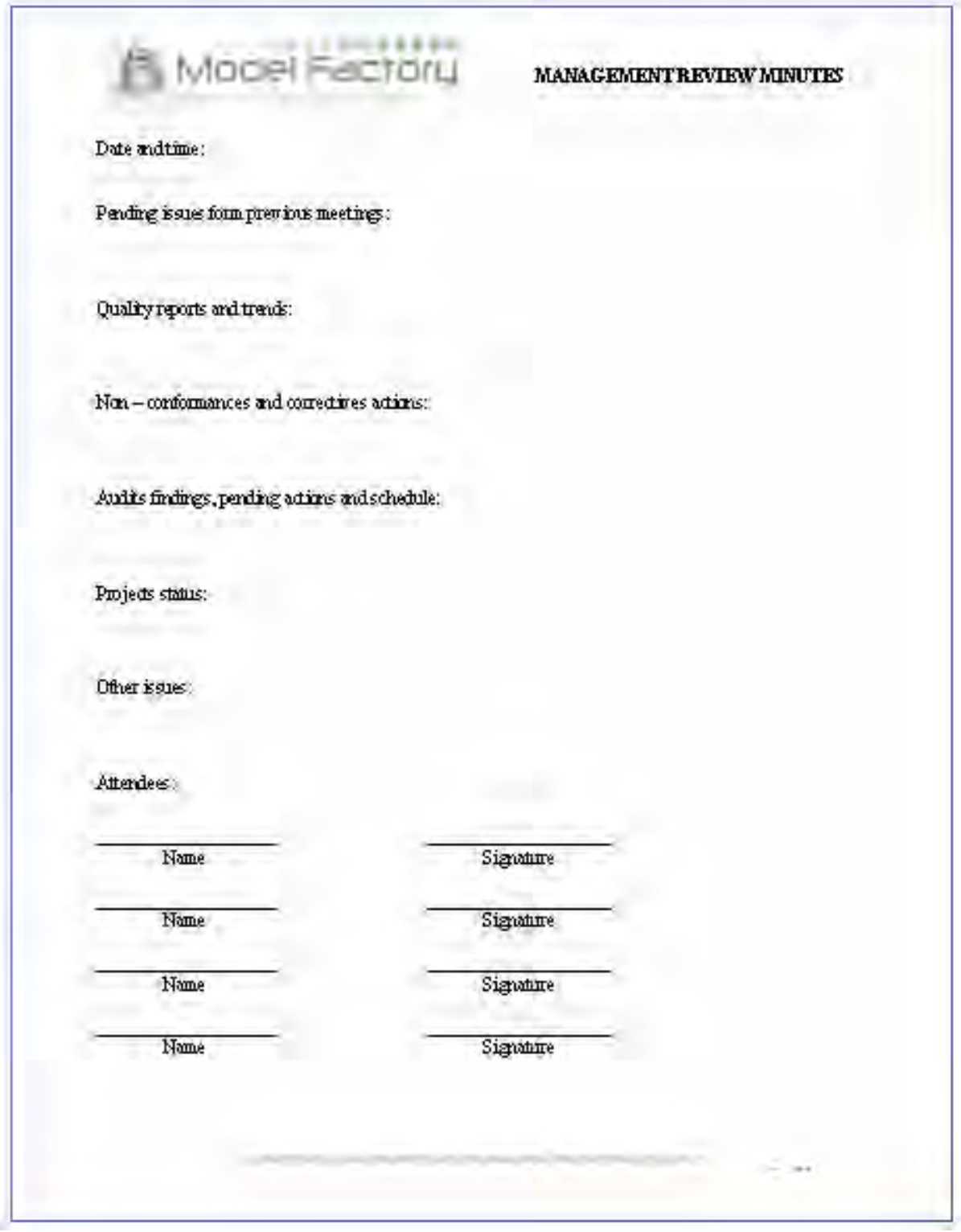
8.4 The meeting minutes will be documented and distributed to the attendees.

8.5 A record of the minutes acceptance is required from all attendees, must sign a copy of the minutes indicating their acceptance of the minutes

9.0 APPENDIX

9.1 Appendix A - Meeting minutes

Appendix A



Model Factory

MANAGEMENT REVIEW MINUTES

Date and time:

Pending issues form previous meetings:

Quality reports and trends:

Non – conformances and correctives actions:

Audits findings, pending actions and schedule:

Projects status:

Other issues:

Attendees:

Name	Signature
Name	Signature
Name	Signature
Name	Signature

MANAGEMENT REVIEW MINUTES

Date and time:

Pending issues form previous meetings:

Quality reports and trends:

Non – conformances and correctives actions:

Audits findings, pending actions and schedule:

Projects status:

Other issues:

Attendees:

_____	_____
Name	Signature
_____	_____
Name	Signature
_____	_____
Name	Signature
_____	_____
Name	Signature

Appendix I

Employee Training SOP

Approvals			History of Changes		
Rev	**Date**	**Authority**	**Rev**	**Description**	**Date**
A					

TABLE OF CONTENTS

1.0 PURPOSE

1.1 This procedure establishes the process for training of personnel. The process ensures that the human resources needed to implement the quality policy, achieve the quality objectives, and to maintain the quality management system are adequately trained to perform their assigned responsibilities.

2.0 SCOPE

2.1 The requirements established in this procedure applies to all the personnel involved Model Factory.

3.0 DEFINITIONS

3.1 Employee – where used within this procedure, the term “employee” or “employees” includes all personnel employed at or working by Model Factory.

3.2 Independent Study – training that is typically assigned by a supervisor or manager and is completed by the employee themselves, not dependent on an instructor or trainer. Independent Study training materials may consist of printed materials (e.g., controlled documents, books, manuals) or other audio, video or computer-based materials.

4.0 REFERENCE DOCUMENTS

4.1 It will depend on the training theme and will be distributed to the employees in paper and/or electronically.

5.0 EQUIPMENT & TOOLS

5.1 Various methods can be used to conduct training. In some cases, more than one method can be utilized or may be necessary to fulfill specific training requirements. Acceptable training methods include, but are not limited to:

5.1.1 New hire orientation

5.1.2 Supervisor or trainer one-on-one with employee

5.1.3 Instructor-led classroom, videoconference, or teleconference

5.1.4 On-the-Job Training (OJT)

5.1.5 Independent study

5.1.6 Electronic media (e.g., CD-ROM-based)

6.0 SAFETY

6.1 No safety equipment required for this procedure.

7.0 TRAINING REQUIREMENTS

7.1 Employees shall be trained as needed to perform their assigned task shall me made aware that Model Factory manufactures sub–assemblies of medical devices in accordance with various regulations and standards.

7.2 All inexperienced employees shall be trained to perform their assigned jobs. On-the-job training shall be monitored closely by a supervisor. All employees shall be made aware of design and/or production defects in the device and/or raw material labeling that may occur from the improper performance of their jobs and defects that they should look for and detect.

8.0 PROCEDURE

8.1 The education, background, training, and experience of prospective employees shall be considered with respect to their requirements of the job.

8.2 All prospective employees have as a requirement to have taken or be taking the course ININ 4050 or equivalent course about print circuit board (PCB) assembly.

8.2.1 All examinations related to the course will be part of the Model Factory training.

8.2.2 As part of the course visits to local electronic industries will be documented.

8.2.3 All visits to the customer’s facilities will be documented.

8.3 All new employees has to take a 12 hours training as follows:

8.3.1 Four (4) hours in the Paste Dispensing Station.

8.3.2 Four (4) hours in the Pick and Place Station.

8.3.3 Two (2) hours in the Pre–Oven Inspection Station.

8.3.4 Two (2) hours in the Post–Oven Inspection Station.

8.4 Management and technical employees are responsible for assuring that the new employees are trained or otherwise qualified for the assigned jobs.

8.5 Before assigning an employee for the first time to a new job, management shall check the employee training record to verify that the employee has been trained and/or qualified for the job.

8.6 All employees are to be advised that they are to perform their jobs as instructed and/or as covered by standard operating procedures (SOP's) and/or work instructions.

8.7 All classroom and/or on-the-job training shall be documented by their supervisor and trainer of the employee on the form as shown in Appendix A.

8.8 A separated form for each employee with a record of their training shall be filed and shall be updated at the end of each training session as shown in Appendix B.

9.0 APPENDIX

9.1 Appendix A – Training Record Form

9.2 Appendix B – Individual Training Record

Appendix A

Training Record	Page # of
Name or Type of Training:	Date:

Reason for Training		Training Method
☐ New or change to a document	☐ Retraining	☐ Classroom / 1-on-1
☐ New Hire	☐ CAPA #:	☐ Video/teleconference
☐ Position Change	☐ Audit #:	☐ Other:
☐ Other:		

Material to be covered: (Explain or attach a copy of agenda and/or training materials, or complete listing of controlled documents below)

If Task-based Controlled Document, provide the following:

Document #	Revision	Document Title

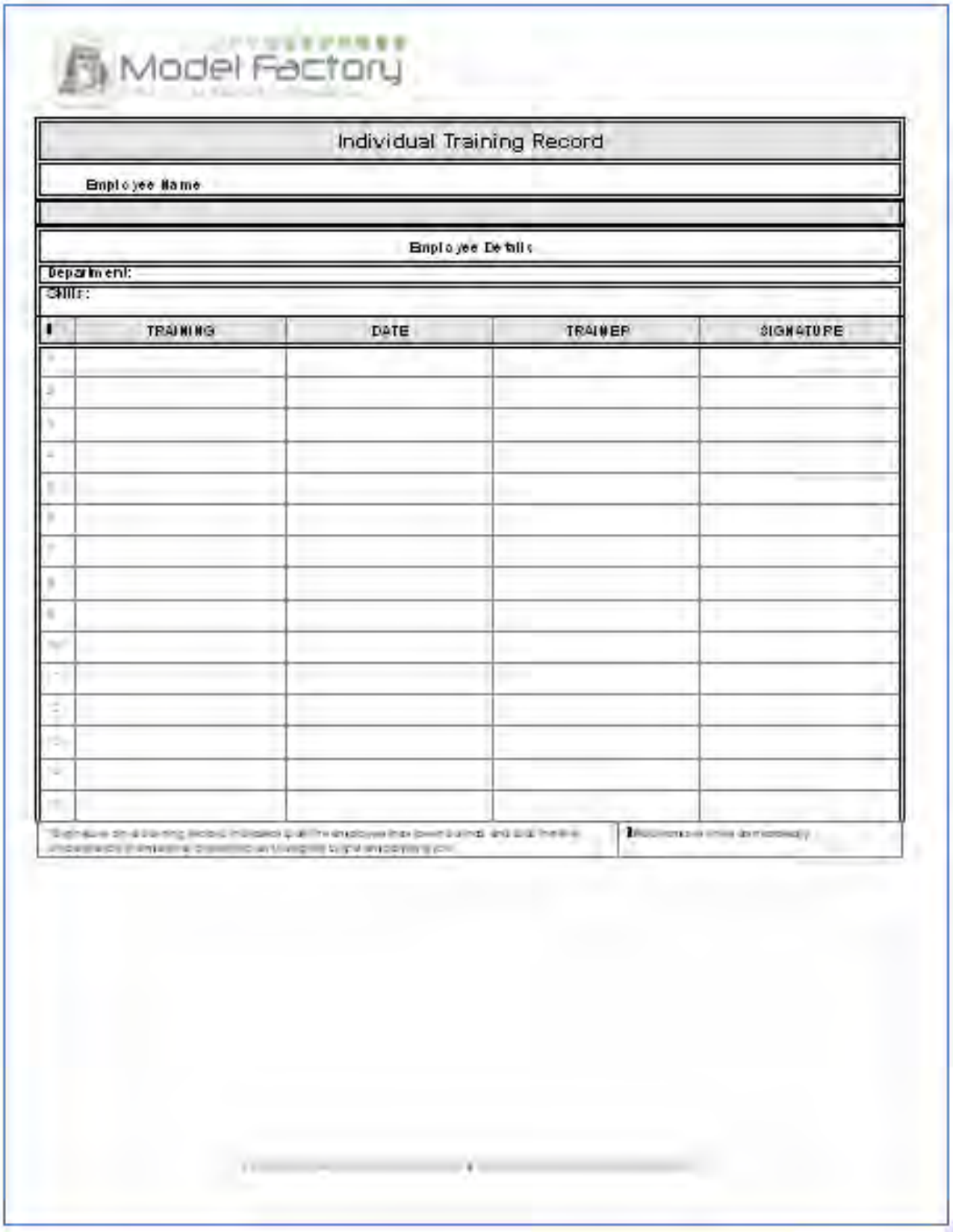
#	PRINTED NAME	DEPARTMENT	JOB TITLE	SIGNATURE*
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

*An employee signature on a training record indicates that the employee has been trained and that he/she understands the material presented as it applies to the employee's job.

Add/remove lines as necessary.

Trainer's Printed Name	Trainer's Signature	Date
Trainer's Printed Name	Trainer's Signature	Date

Appendix B



Model Factory

Individual Training Record				
Employee Name				
Employee Details				
Department:				
Skills:				
#	TRAINING	DATE	TRAINER	SIGNATURE
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

Training Record

Page # of

Name or Type of Training: **Quality Assurance and Regulatory Requirements** **Date:** **mm/dd/yy**

Reason for Training		Training Method
☐ New or change to a document	☐ Retraining	☒ Classroom / 1-on-1
☐ New Hire	☐ CAPA #:	☐ Video/teleconference
☐ Position Change	☐ Audit #:	☐ Other:
☐ Other:		

Material to be covered: (Explain or attach a copy of agenda and/or training materials, or complete listing of controlled documents below)

†If Text-Based Controlled Document, provide the following:

Document #	Revision	Document Title

†	PRINTED NAME	DEPARTMENT	JOB TITLE	SIGNATURE*
1				
2				
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11				
12				
13				
14				
15				

***An employee signature on a training record indicates that the employee has been trained and that he/she understands the material presented as it applies to the employee's job.**

†**Add/remove lines as necessary.**

Trainer's Printed Name	Trainer's Signature	Date
Trainer's Printed Name	**Trainer's Signature**	**Date**

Model Factory
University of Puerto Rico@Mayagüez

Individual Training Record

Employee Name

Employee Details

Department:

Skills:

†	TRAINING	DATE	TRAINER	SIGNATURE
1				
2				
3				
4				
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15				

***Signature on a training record indicates that the employee has been trained and that he/she understands the material presented as it applies to the employee's job.**

†Add/remove lines as necessary.

Appendix J

Document and Change Control SOP

Approvals			History of Changes		
Rev	**Date**	**Authority**	**Rev**	**Description**	**Date**
A					

TABLE OF CONTENTS

1.0 PURPOSE

1.1 The intent of this procedure is to assure that the products are, and remain, in the product specifications and are still under the quality system.

2.0 SCOPE

2.1 This policy establishes the procedure to be followed for engineering changes to the devices, temporary or permanent changes in the manufacturing process and/or products manufactured at Model Factory.

3.0 APPLICABILITY

3.1 The responsabilities and procedures established by this policy shall apply to all released documents. This policy becomes effective immediately upon approval and releasing.

4.0 APPLICABLE DOCUMENTS

4.1 The latest version of the documents that applies for changes of the product or processes shall be changed in the DMR.

5.0 DEFINITIONS

5.1 Disposition – this action statement defines the updating or disposition of non–corforming materials, components, in–process assemblies, and finished devices in aggrement to product specifications at all applicable locations such as stockroom, production lines, and finished goods storage.

5.2 Effective Date – The effective date will be provided by EBI, and will be the approval date of the documents.

5.3 ECO – acronim for Engineering Change Order.

6.0 REFERENCE DOCUMENTS

6.1 ECO issued and received by customer.

6.2 Product or processes changes.

7.0 EQUIPMENT & TOOLS

7.1 Microsoft ® Word / Excel Software

7.2 Fuji Flexa Software

8.0 SAFETY

8.1 No safety equipment required in this procedure.

9.0 TRAINING REQUIREMENTS

9.1 The employee making the changes should be trained or assisted by the technical employees.

10.0 PROCEDURE

10.1 Permanent changes to product and/or processes

10.1.1 Examine the ECO submitted by customer or the Permanent Change record.

10.1.2 Identify the entity, device or process to be changed.

10.1.3 Write the origin date of the permanent change.

10.1.4 Write the effective date of the permanent change.

10.1.5 Write a detailed description of the permanent change.

10.1.6 Write a list the attached documents to the permanent change.

10.1.7 Place the Permanent Change record in a place to be available to be readed and confirmed by the employees.

10.1.8 Examine the DMR index and take out the related documentation that the change will affect.

10.1.9 Do the required changes to the affected documents, records and procedures and replace the documents with previous revision code in the DMR.

10.1.10 The affected documents will be replaced by the updated documents and placed in the DMR area for documentation not in compliance.

10.1.11 Disposition of production materials should be arranged with the customer.

10.1.12 Retraining in accordance of Training SOP.

10.2 Temporary changes to product and/or processes

10.2.1 Write the origin date of the Temporary change record.

10.2.2 Write the effective date of the Temporary change record.

10.2.3 Write a detailed description of the Temporary change record.

10.2.4 Write the duration of the temporary change and/or the closure date.

10.2.5 Write the actions to be taken during the temporary change.

10.2.6 Place the Temporary Change record in a place to be available to be readed and confirmed by the employees.

10.2.7 Place a copy of the Temporary Change record in the affected station.

10.3 Document approval and history of the changes

10.3.1 Each standard operating procedure (SOP) have an document approval and descrription of changes page, ussually in the fisrt page.

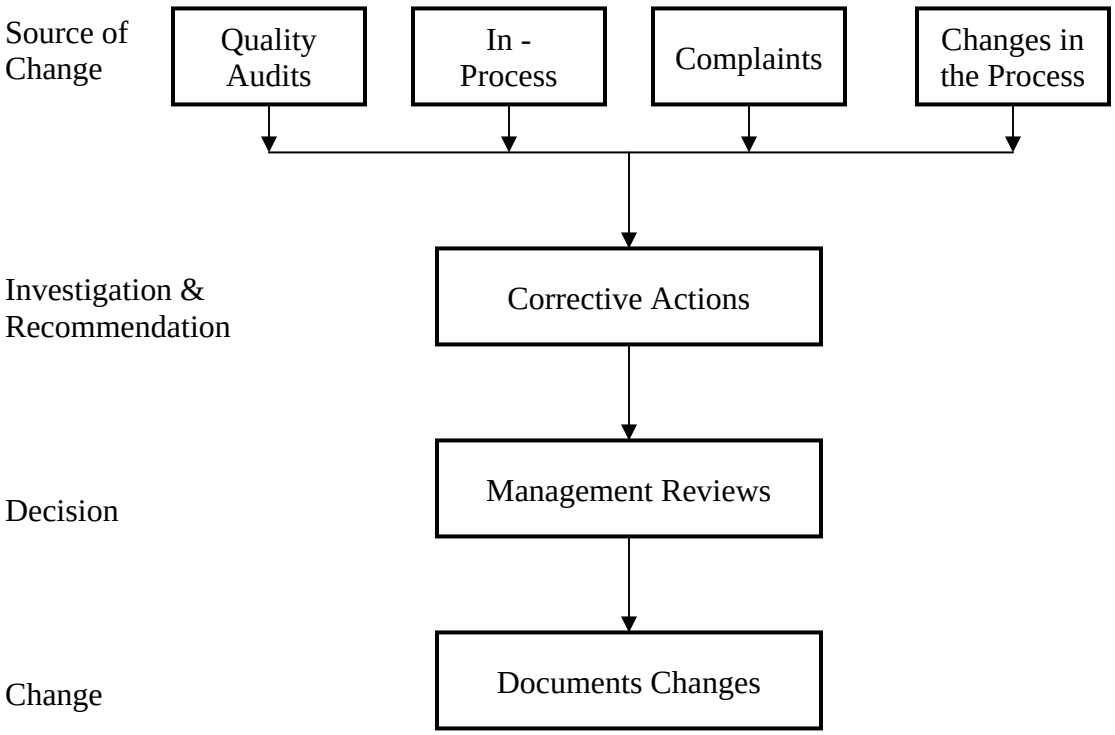
10.3.2 When an SOP has a change in the History of changes write the revision to change.

10.3.3 The description of the change and the date of the change

10.3.4 In the document approval write the new revision letter, i.e. B, C.

10.3.5 The effective date of the change and the sign the autorization column.

10.4 Description of the change process

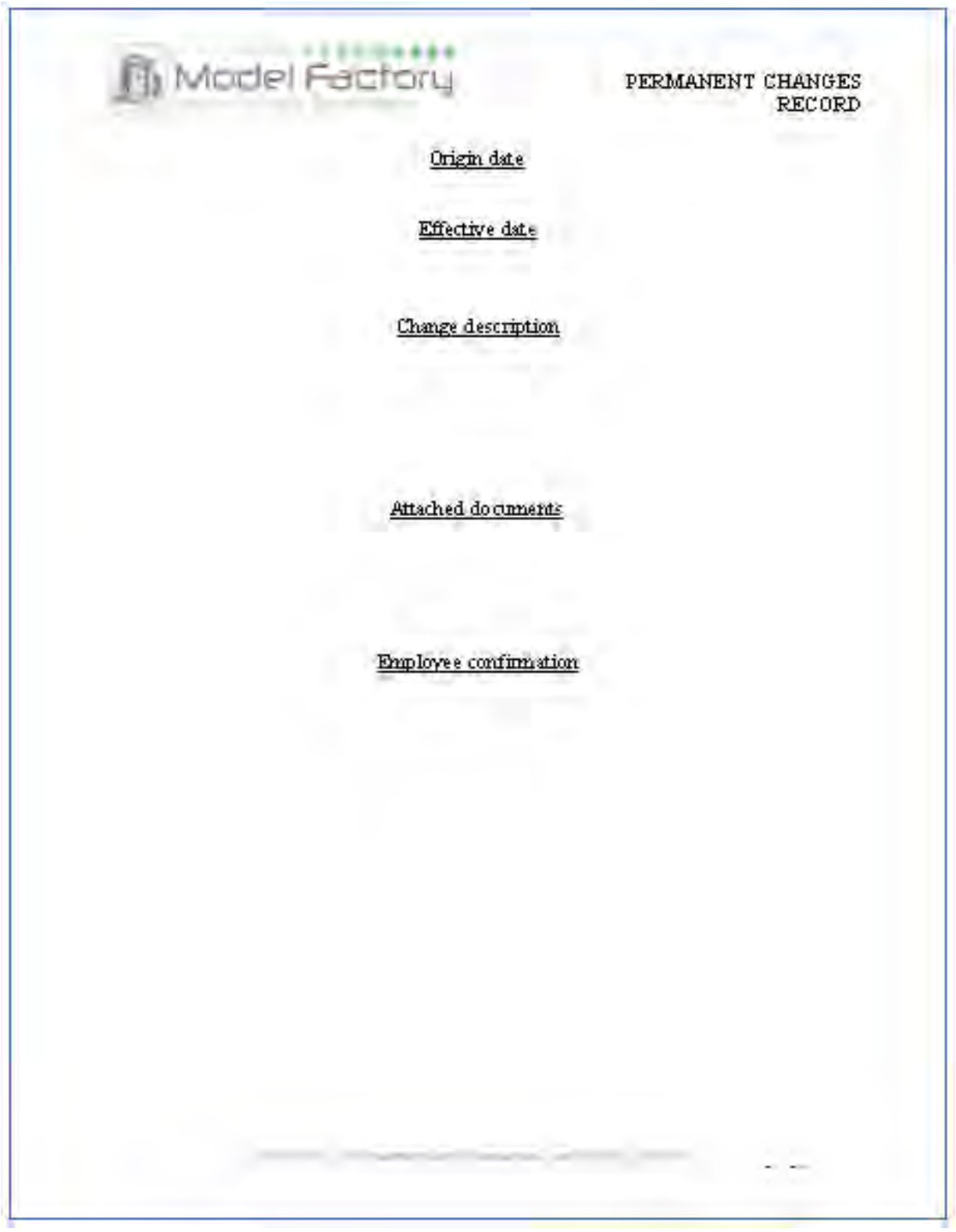


11.0 **APPENDIX**

11.1 Appendix A – Permanent Change record

11.2 Appendix B – Temporary Change record

Appendix A



Model Factory

PERMANENT CHANGES RECORD

Origin date

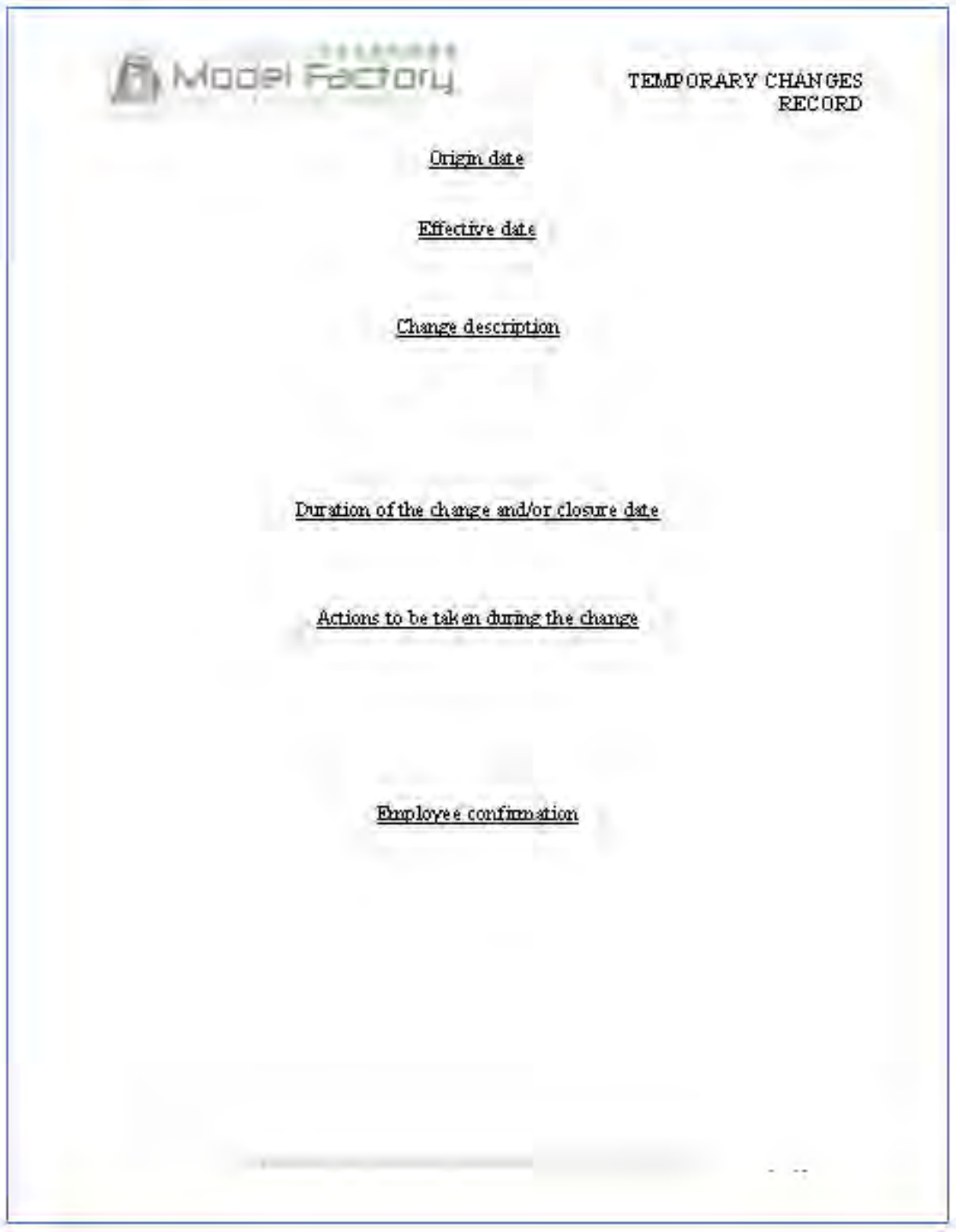
Effective date

Change description

Attached documents

Employee confirmation

Appendix B



Model Factory

TEMPORARY CHANGES RECORD

Origin date

Effective date

Change description

Duration of the change and/or closure date

Actions to be taken during the change

Employee confirmation

Origin date

Effective date

Change description

Attached documents

Employee confirmation

Origin date

Effective date

Change description

Duration of the change and/or closure date

Actions to be taken during the change

Employee confirmation

Appendix K

Equipment Maintenance SOP

Approvals			History of Changes		
Rev	**Date**	**Authority**	**Rev**	**Description**	**Date**
A					

TABLE OF CONTENTS

1.0 PURPOSE

1.1 This quality specification defines the procedures to be adopted to ensure that a routine schedule of maintenance to the equipment is done.

2.0 SCOPE

2.1 This procedure applies to all the equipment that requires preventive maintenance in use at facilities of Model Factory.

2.2 An implemented maintenance program shall ensure that specified equipment standards are maintained and all requirements are met.

3.0 DEFINITIONS

3.1 Authorized Preventive Maintenance Person – an Individual who is designated under this procedure to perform preventive maintenance. Some types of equipment may require special qualifications or training.

3.2 Preventive Maintenance Requirements – specific instructions for maintaining a particular piece of equipment.

3.3 Preventive Maintenance Intervals – the period of time; i.e.: daily, weekly, monthly, etc., between scheduled inspections.

4.0 REFERENCE DOCUMENTS

4.1 QF Series Tape Feeder – Operator's Guide

4.2 DEK 265 – INTALLATION & MAINTENANCE GUIDE

4.3 DEK 265 – TECHNICAL REFERENCE MANUAL

4.4 FUJI MANUALS – Electronic document

4.5 ELECTROVERT ATMOS 2000CR – Instructions Manual

5.0 PROCEDURE

5.1 The Technical employees are responsible for implementation and upkeep of the plant equipment maintenance schedule.

5.2 A comprehensive record of the plant equipment maintenance shall be maintained by the Model Factory technical employees.

5.3 A record log is also issued for each piece of equipment that requires maintenance, see Appendices A and B. The extent of servicing and maintenance at each scheduled activity shall be specified on the corresponding equipment maintenance schedule record. Each maintenance activity shall be recorded on the corresponding equipment maintenance log and all entries shall be made in ink, signed and dated.

5.4 A schedule of equipment maintenance shall be followed as a safeguard against breakdown of equipment to prevent loss of production time.

5.5 An equipment register with all equipment manuals for specific piece of equipment shall be maintained. This register shall be kept ready accessible for the Model Factory personnel.

5.6 The manuals included on this register shall be maintained as part of the Master Device Records, to be used as part and/or reference of the equipment maintenance procedures.

5.7 The intervals of planned maintenance shall be set by the technical employees, who shall take due note of the manufacturers' recommended sequence schedule for individual equipment.

5.8 Whenever scheduled or unscheduled maintenance is performed on process equipment a first piece of the product shall be submitted to the technical employees for evaluation before the equipment can be released for regular production.

5.9 If the repair was major it shall be evaluated to determine if re-qualification of the equipment is necessary.

6.0 EQUIPMENT & TOOLS

6.1 Equipment and/or tool required for the maintenance equipment.

7.0 SAFETY

7.1 None safety is necessary for this procedure.

8.0 TRAINING REQUIREMENTS

8.1 Only skilled maintenance personnel are going to perform the maintenance to ensure that all necessary work is completed efficiently and correctly.

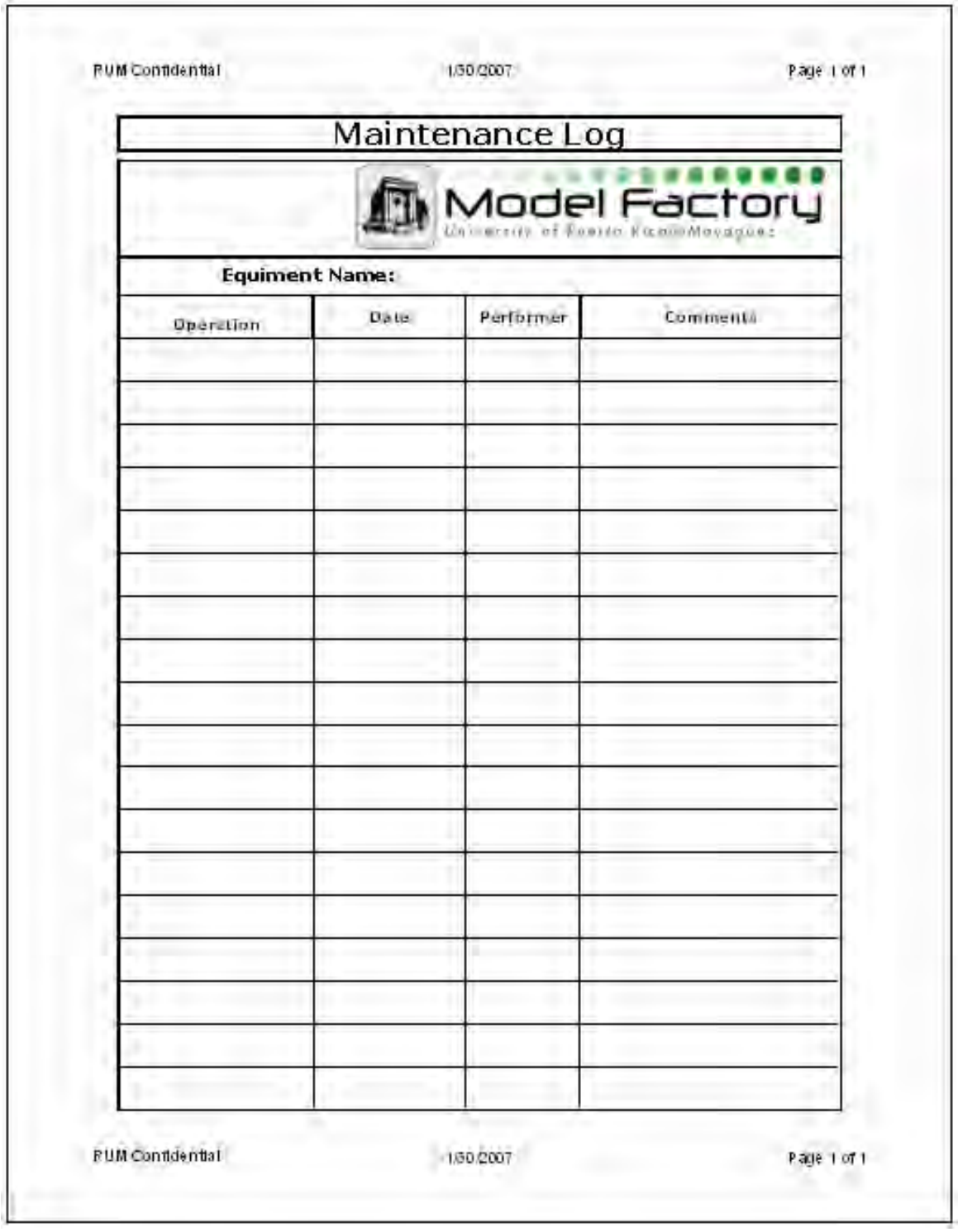
8.2 Where deemed necessary, sub-contract services shall be employed to effect necessary work.

9.0 APPENDIX

9.1 Appendix A – Maintenance Log

9.2 Appendix B – Maintenance Schedule

Appendix A



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Maintenance Log

Model Factory
University of Puerto Rico@Mayagüez

Equiment Name:

Operation	Date	Performer	Comments

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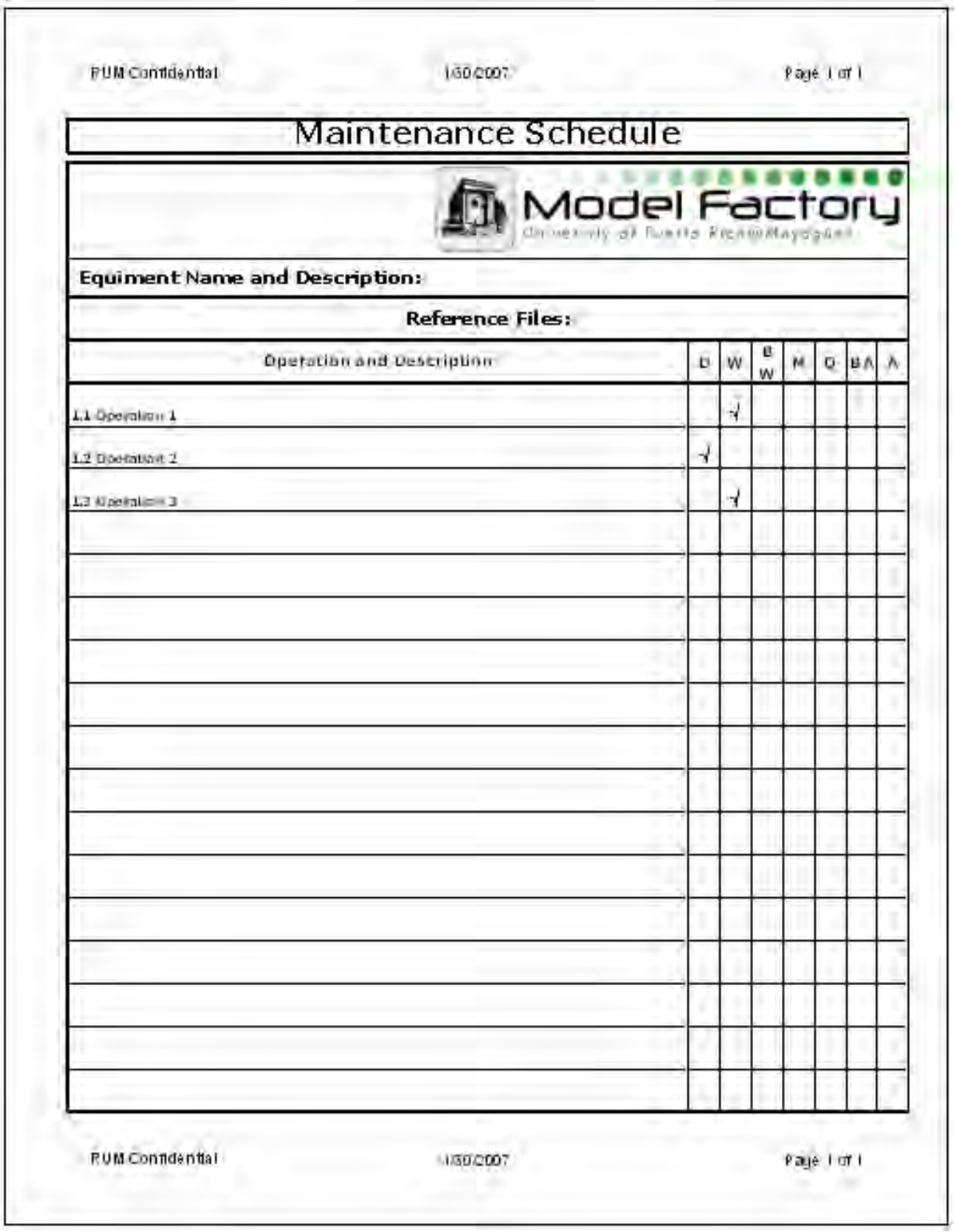
Appendix B



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Maintenance Schedule

Model Factory
University of Puerto Rico@Mayagüez

Equiment Name and Description:

Reference Files:

Operation and Description	D	W	B W	M	Q	B A	A
1.1 Operation 1		√					
1.2 Operation 2	√						
1.3 Operation 3		√					

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Maintenance Log

Model Factory
University of Puerto Rico@Mayagüez

Equiment Name:

Operation	Date	Performer	Comments

Maintenance Schedule

Model Factory
University of Puerto Rico@Mayagüez

Equiment Name and Description: **DEK 265**

Reference Files: DEK Technical Reference Manual

Operation and Description	D	W	BW	M	Q	BA	A
1.1 Cleaning the Squeegees	√						
1.2 Cleaning the Stencil	√						
1.3 Cleaning the surface of the machine		√					
1.4 Check machine belts			√				
2.1 Rail System Lubrication						√	
2.2 Squeegee System Lubrication						√	
2.3 Camera Axis System Lubrication						√	
2.4 Check Air Pressure System					√		
2.5 Replace Auto Cleaning System							√
2.6 Check Sensors					√		

Maintenance Schedule

Model Factory
University of Puerto Rico@Mayagüez

Equiment Name and Description: **Fuji IP-3**

Reference Files: IP_MANTMANO-5.1E

Operation and Description	D	W	BW	M	Q	BA	A
1.1 Cleaning the Nozzles		√					
1.2 Cleaning out the waist tape box	√						
1.3 Cleaning the surfase of the camera		√					
1.4 Cleaning the reject parts box and conveyor	√						
1.5 Cleaning rotary joint guide area		√					
1.6 Discharge the air regulator drain					√		
1.7 Cleaning the Y-table vacuum generator					√		
1.8 Cleaning the control box cooling air fans				√			
2.1 X-1 & X-2 axis Lubrication				√			
2.2 Y axis Lubrication				√			
2.3 Linearscale rubber shild Lubrication				√			
2.4 Placeing head Lubrication				√			
2.5 Nozzle changer unit Lubrication				√			
2.6 Conveyor Lubrication				√			
2.7 Feeder Lubrication							√

Maintenance Schedule

Model Factory
University of Puerto Rico@Mayagüez

Equiment Name and Description: Electrovert ATMOS 2000 CR Oven

Reference Files: Electrovert Manual No. 117-02-1

Operation and Description	D	W	B W	M	Q	BA	A
1.1 Right angle drives lubrication		√					
1.2 Screw shafts lubrication		√					
1.3 Chain drives lubrication		√					
1.4 Conveyor chain			√				
2.1 Nitrogen Line Filter Replacement							√
3.1 BTU Oven Temperature Profile				√			

Maintenance Log

Model Factory
University of Puerto Rico@Mayagüez

Equiment Name: DEK 265

Operation	Date	Performer	Comments
2.1 - 2.6	Jan 30, '08	G. Soto	
2.1 - 2.6	March 28, 2008	G. Soto	Need for J. Aveillez
Machine overhaul	May 27, 2008	J. Aveillez	Refer to part list
PCB replacement	June 18, 2008	J. Aveillez	Refer to packing list

ML TECH SERVICE
BO. ALGARROBO #126
LA BOLERA MAYAGUEZ P.R. 00682
Phone 787-430-9257 Fax 787-832-8831

Date: 05/28/2008

Invoice number: 186435

INVOICE TO:

Recinto Universitario de Mayaguez
Finance Director
UPR Mayaguez campus
PO Box 9003, Mayaguez PR 00681-9003

PO#: R805812

Item **Description of Work and parts ordered**

DEK 265 MK1 machine parts replaced and calibration:

5-27-2008 > Work Done
> Replaced various damaged parts in order to improve machine reliability and optimize printing quality.
> All parts replaced were adjusted and tested as of manufacturing specs.
> Calibration as of, camera vision, camera Offset, camera focus and print height has been performed and tested using customer products and validated by the technical operator.

Note: For specific details of the work done during this activities, please refer to the service report number 268.

Parts:

Qty	Description	Serial number	Unit Price	Price
2	Camera Y belts	112444	*$268.21*	**$536.42**
4	Rail Guide bar	107424	*$ 62.44*	**$249.76**
4	Board clamp linear ball	107827	*$ 25.16*	**$100.64**
1	Squeegee holder rear	112147	*$125.45*	**$125.45**
1	Squeegee holder front	112146	*$125.45*	**$125.45**
1	Board stop sensor	107904	*$388.80*	**$388.80**
1	Board stop linear bearing	112894	*$641.41*	**$641.41**
2	Transport green belts	122022	*$ 13.78*	**$ 27.56**

- Shipping and handling included

Labor Charges:
> 05/27/08 One day of service at $625.00 per day **$625.00**

Total : ***$2,820.49***

PACKLIST

DATE 06/18/08

ML tech service
Bo. Algarrobo # 126, La Bolera
Mayaguez P.R. 00682
Phone: 787-430-9257

To:

UPR Mayaguez campus
PO Box 9004, Edificio Martinez Nadal oficina 117
Mayaguez P.R. 00680

Ship To:

UPR Mayaguez campus
PO Box 9004, Edificio Martinez Nadal oficina 117
Mayaguez P.R. 00680

RMA NUMBER	P.O. NUMBER	SHIP DATE	SHIP VIA	F.O.B. POINT
N/A		06/18/08	Ground transportation	P.R.

QUANTITY	DESCRIPTION	UNIT PRICE	AMOUNT
1	*Euro system control card (114546)*	N/A	N/A

SUBTOTAL	N/A
SALES TAX	
SHIPPING & HANDLING	0
TOTAL DUE	**N/A**

Note:
In attention to Mr. Pedro Resto

I DECLARE THE ABOVE TO BE TRUE AND CORRECT Pedro Resto 06/21/08

Appendix L

Process Validation SOP

Approvals			History of Changes		
Rev	**Date**	**Authority**	**Rev**	**Description**	**Date**
A					

TABLE OF CONTENTS

1.0 PURPOSE

1.1 This procedure defines process validation methods of the manufacturing processes.

2.0 SCOPE

2.1 This procedure applies to manufacturing processes at Model Factory.

3.0 DEFINITIONS

3.1 Verification – confirmation by examination and provision of objective evidence that the specified requirements have been fulfilled.

3.2 Process Validation – establishment by objective evidence that a process consistently produces a result meeting predetermined specification.

3.3 Prospective Validation – validation conducted prior to introduction of a new product or process.

3.4 Retrospective Validation – validation conducted on an existing process using accumulated data.

3.5 Revalidation – validation for a process that has been previously validated.

3.6 CAR – Corrective Action Request

4.0 REFERENCE DOCUMENTS

4.1 FDA, CDRH, Quality System Manual, Section 4: Process Validation, 1997 FDA, CDRH, Guideline on General Principles of Process Validation, 1997 Kane, V. (1986)

4.2 Quality Management Systems – Process Validation Guidance, 2004 The Global Harmonization Task Force (GHTF).

5.0 EQUIPMENT & TOOLS

5.1 Equipment and tools needed to validate the processes and equipment.

6.0 SAFETY

6.1 No safety is required for this procedure.

7.0 TRAINING REQUIREMENTS

7.1 Only technical employees with the expertise on the machines shall validate the processes at Model Factory.

8.0 PROCEDURE

8.1 New product introduction:

8.1.1 Under customer surveillance.

8.1.2 Customer keeps data and makes the validation protocols and documentation.

8.2 Process changes:

8.2.1 Sample size to be determined in conversations between customer and Model Factory representatives.

8.2.2 In case of major process modification, the customer will verify product quality.

8.2.3 If the product quality is not under specifications a CAR will be generated.

8.3 Documentation:

8.3.1 Records of validation activities will be issued and retained by the customer.

9.0 APPENDIX

9.1 None

Appendix M

Non Conformance SOP

Approvals			History of Changes		
Rev	**Date**	**Authority**	**Rev**	**Description**	**Date**

TABLE OF CONTENTS

1.0 PURPOSE

1.1 To establish and implement a procedure and form for recording non – conformance products with specifications.

2.0 SCOPE

2.1 Applies to all components and finish devices manufactured in Model Factory that repairing can not be done or will expose the device to malfunctioning.

3.0 DEFINITIONS

3.1 Conformance – an affirmative indication or judgment that a product or service has met the requirements of a relevant specification, contract or regulation.

3.2 Customer delight – the result of delivering a product or service that exceeds customer expectations.

3.3 Customer satisfaction (CS) – the result of delivering a product or service that meets customer requirements.

4.0 REFERENCE DOCUMENTS

4.1 Defect Data Collection Sheet

4.2 CAPA SOP

5.0 EQUIPMENT & TOOLS

5.1 No equipment and tools are required for this procedure.

6.0 SAFETY

6.1 No safety equipment is required in this procedure.

7.0 TRAINING REQUIREMENTS

7.1 No specific training is required in this procedure.

8.0 PROCEDURE

8.1 If a non–conformance is detected in the Paste Dispensing Station.

8.1.1 Check and review the defect with the management or technical employees.

8.1.2 Fill the Non–Conformance Form and indicate in the PCB the defect found and designated non–conformance number with the date (mm–dd–yy), hyphen and a three digit number beginning with 001; i.e. 16/12/06 – 001.

8.1.3 Place the PCB in the designated area with the Non–Conformance Form.

8.1.4 Send the PCB to the client for disposal

8.2 If a non–conformance is detected in the Final Inspection Station.

8.2.1 Check and review the defect with the management or technical employees.

8.2.2 Fill the Non–Conformance Form and indicate in the PCB the defect found and designated non–conformance number.

8.2.3 Place the PCB in the designated area with the Non–Conformance Form.

8.2.4 Send the PCB to the client for disposal.

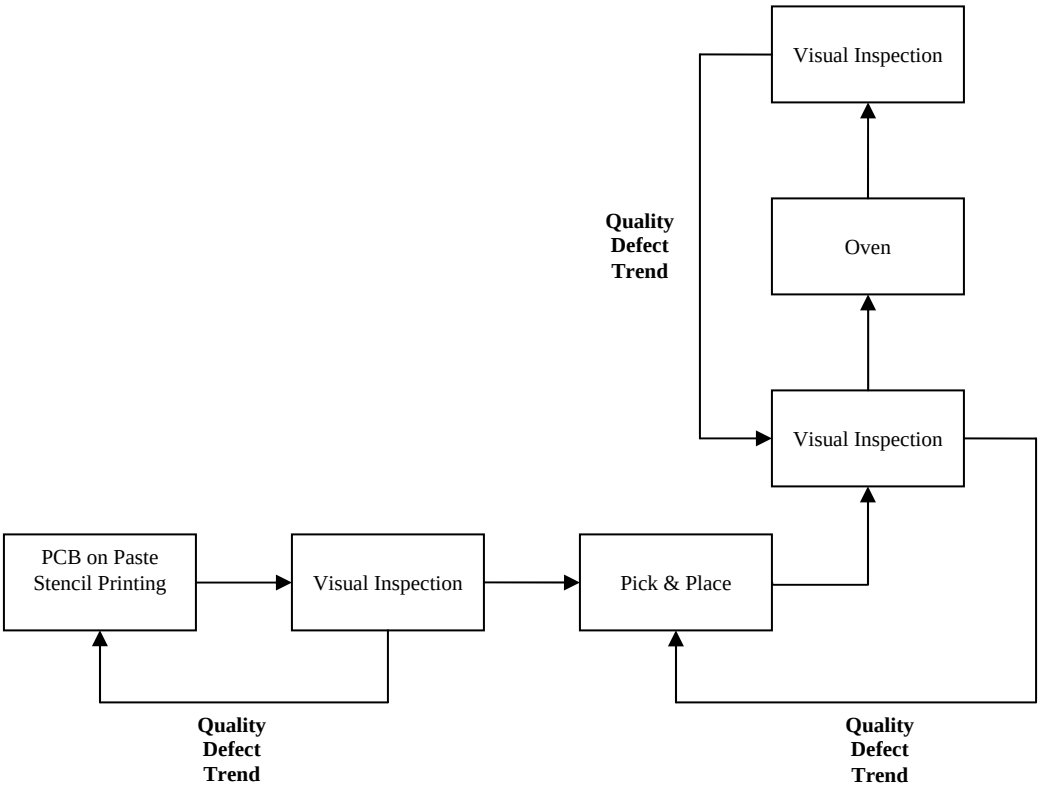
8.3 If the defect is one that can be repaired and can complete the assembly process:

8.3.1 Record the defect in the Defect Data Collection Sheet.

8.3.2 If a trend on a specific defect is identified, a verbal warning to the employee in the previous station should be the action to take.

8.3.3 If the defect persists, the defect should be evaluated by the Model Factory managers to determine if a CAPA procedure is required.

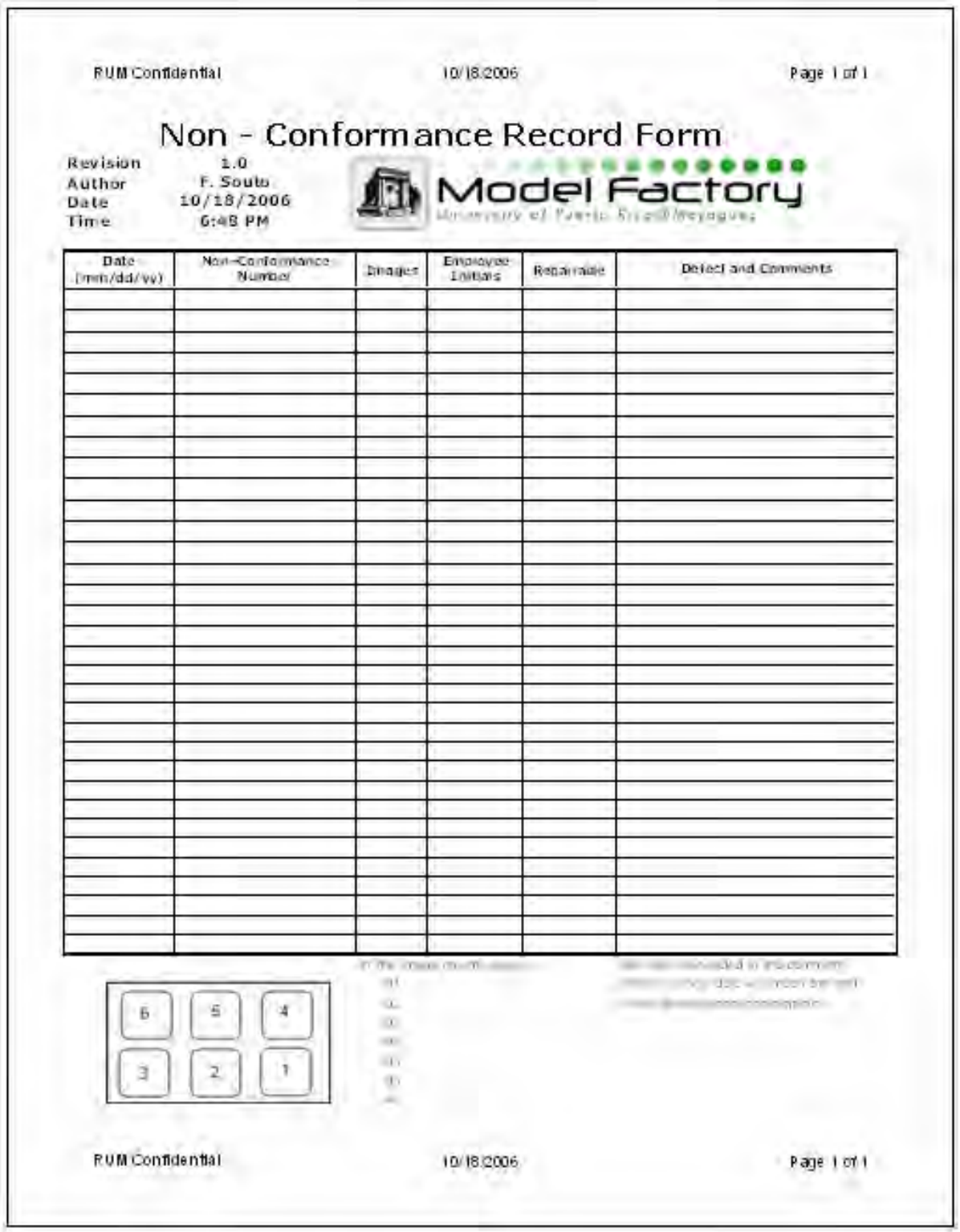
8.4 Quality Defect Trend Flowchart



9.0 **APPENDIX**

9.1 Appendix A – Non–Conformance Record Form

Appendix A



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Non - Conformance Record Form

Revision 1.0
Author F. Souto
Date 10/18/2006
Time 6:48 PM

Model Factory
University of Puerto Rico@Mayagüez

Date (mm/dd/yy)	Non-Conformance Number	Images	Employee Initials	Repairable	Defect and Comments

6 5 4
3 2 1

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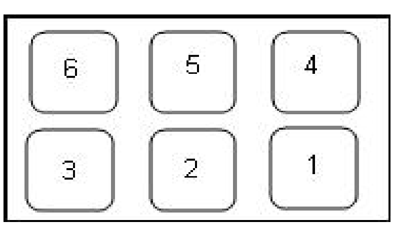
Non - Conformance Record

Revision 1.0
Author F. Souto
Date 7 / 8 / 2008
Time 1:53 PM

Model Factory
University of Puerto Rico@Mayagüez

Date (mm / dd / yy)	Non–Conformance Number	Images	Employee Initials	Defect and Comments



In the image column specify:
- 01
- 02
- 03
- 04
- 05
- 06
- All

Use lines as needed in the comment column, a new date will mean the end of the previous non-conformance

Appendix N

Corrective Action and Preventive Action (CAPA) SOP

Approvals			History of Changes		
Rev	**Date**	**Authority**	**Rev**	**Description**	**Date**
A					

TABLE OF CONTENTS

1.0 PURPOSE

1.1 To establish and implement a procedure and forms for recording complaints, analysis, response, projects information sheets and projects improvements sheets to ensure CAPA.

2.0 SCOPE

2.1 It is the policy of Model Factory that all complaints regarding safety, performance, or quality of our products or services will be subjected to management review and/or investigation and will result in prompt response and corrective action when indicated.

2.2 This policy is applicable to and must be complying with by all personnel when a production and/or quality issue exists and/or a client's complaint is received.

2.3 Complaints can be originated by an internal or external customer.

3.0 DEFINITIONS

3.1 Complaint – any indication of the failure or a device to meet customer or user expectations for quality or to meet performance specifications.

3.2 Product Performance – the product in some way does not perform to client expectation.

3.3 Product Safety – all safety complaints are covered by this procedure.

3.4 Product Reliability – failure rate or need for service adjustments greater that client expectation, i.e. beyond tolerable level of expected wear or malfunction.

3.5 CAPA – Corrective Action and Preventive Action.

3.6 Corrective Action – the implementation of solutions resulting in the reduction or elimination of an identified problem.

3.7 Preventive Action – action taken to remove or improve a process to prevent potential future occurrences of a non-conformance.

3.8 Internal Client – the recipient (person or department) within an organization of another person's or department's output (product, service or information)

3.9 External Client – person or organization that receives a product, service or information but is not part of the organization supplying it.

4.0 REFERENCE DOCUMENTS

4.1 None

5.0 EQUIPMENT & TOOLS

5.1 Personal Computer

5.2 Microsoft ® Word / Excel Software

5.3 Corrective Action Form. See Appendix A.

5.4 Complaint Log. See Appendix B.

5.5 Project Information Sheet. See Appendix C.

5.6 Project Improvement Sheet. See Appendix D.

6.0 SAFETY

6.1 No safety equipment is required in this procedure.

7.0 TRAINING REQUIREMENTS

7.1 Al least one of the team employee attending, performing, and processing the production and/or quality issue and/or the complaint should be part of the management or a technical employee of Model Factory.

8.0 PROCEDURE

8.1 Upon receipt of a customer complaint, the management completes Corrective Action Form. If the complaint is written the letter should be attached to the form.

8.2 Management

8.2.1 Enter the complaint into the Complaint Log.

8.2.2 Write the origin date.

8.2.3 Write the description of the problem. Fill in the julian date, product, reference designator, part number, quantity affected and EBI impact in its respective field.

8.2.4 Write the scope of the non–conformance.

8.2.5 Write the reason of the mistake once of the non–conformance problem is investigated.

8.2.6 Write the actions already taken to solve the non–conformance.

8.2.7 Write the actions to be taken field.

8.2.8 Write the closure date of the non – conformance.

8.2.9 Send the Corrective Action Form to customer.

8.3 Model Factory internal projects management forms.

8.3.1 To fill the Project Information Sheet

8.3.1.1 Write the project name, assigned team, and date of origin.

8.3.1.2 Fill the issue statement, objectives, deliverables, milestones, staffing and investment/cost as instructed in the project information sheet.

8.3.2 This sheet will be used to establish and manage the projects in the Model Factory.

8.3.2.1 To fill the Project Improvement Sheet

8.3.2.2 Write the project name and date of origin.

8.3.2.3 Fill the project issue, original status, analysis, action, results, standardization, remaining problems, and future problems of the project as part of the project process and improvement.

8.3.2.4 Once the project has finalized write the closure date of the project.

8.4 Expose the Corrective Action Form, the Complaint Log, Project Information Sheet, and Project Information Sheet to employees and store in the DMR.

9.0 APPENDICES

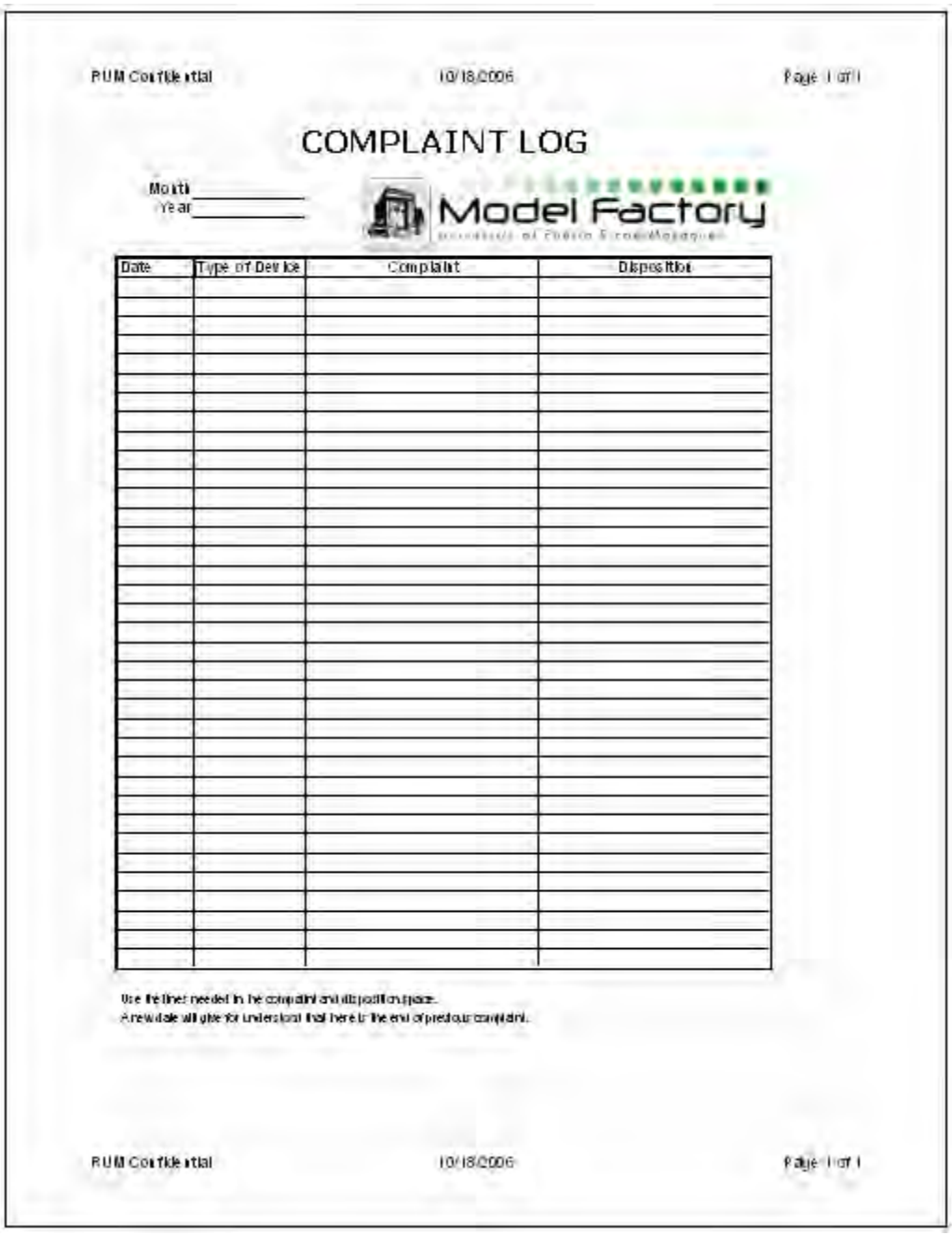
9.1 Appendix A – Complaint Log

9.2 Appendix B – Corrective Action Form

9.3 Appendix C – Project Information Sheet

9.4 Appendix D – Project Improvement Sheet

Appendix A



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COMPLAINT LOG

Month _____
Year _____

Model Factory

Date	Type of Device	Complaint	Disposition

Use the lines needed for the complaint and disposition space.
A new date will give for understood that here is the end of previous complaint.

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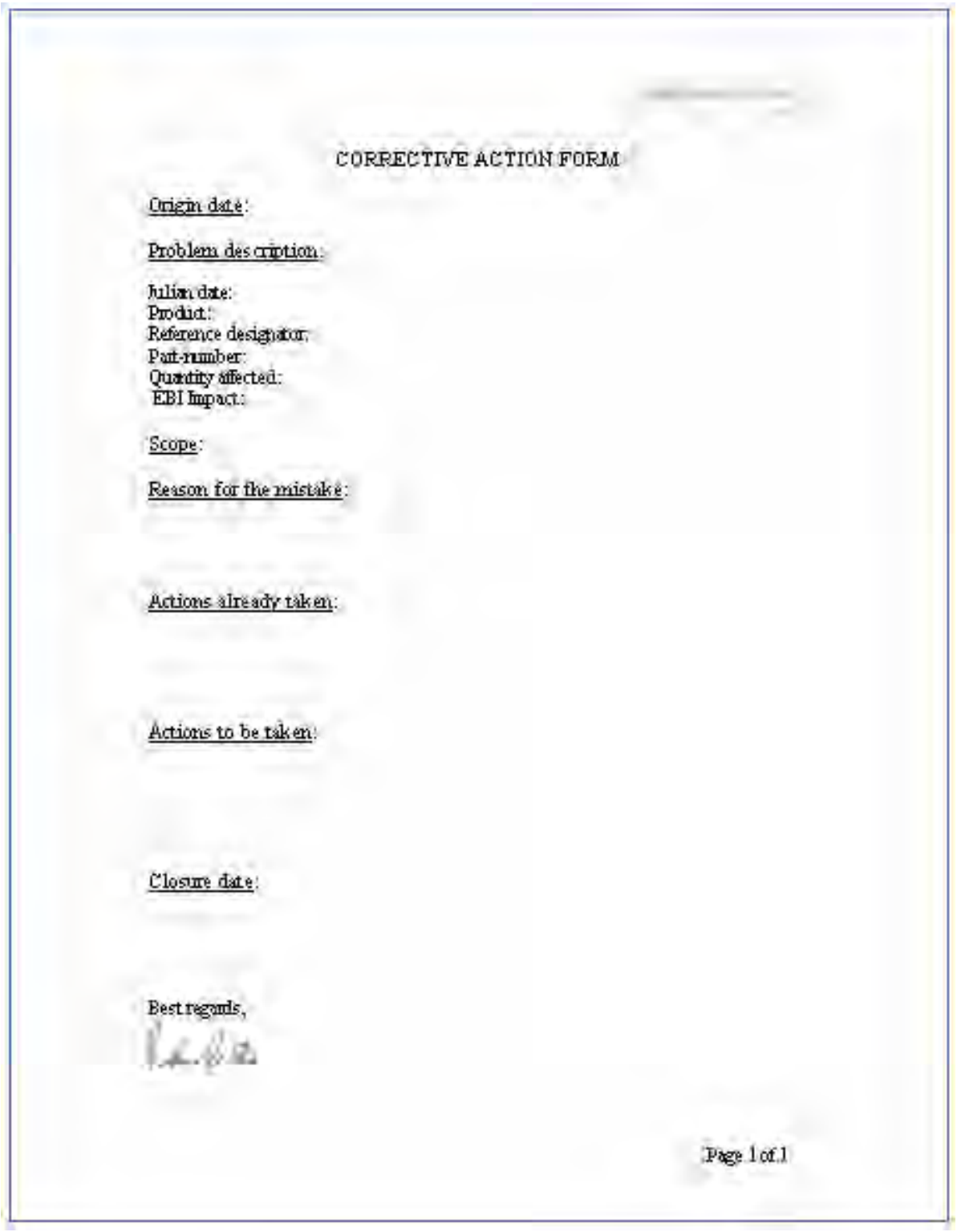
Appendix B



CORRECTIVE ACTION FORM

Origin date:

Problem description:

Julian date:
Product:
Reference designator:
Part-number:
Quantity affected:
EBI Impact:

Scope:

Reason for the mistake:

Actions already taken:

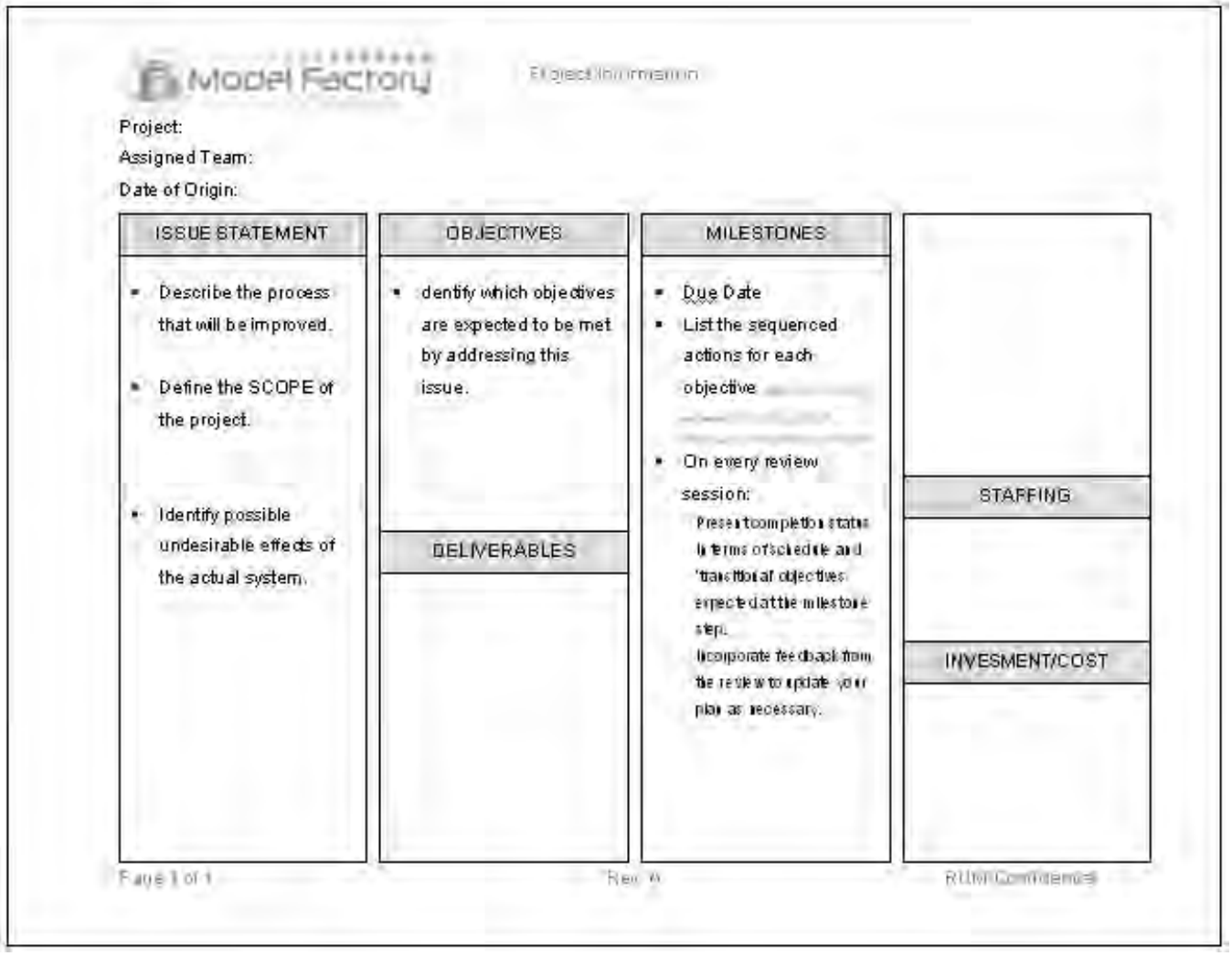
Actions to be taken:

Closure date:

Best regards,

Page 1 of 1

Appendix C



Model Factory

Project Information

Project:
Assigned Team:
Date of Origin:

ISSUE STATEMENT	OBJECTIVES	MILESTONES	
• Describe the process that will be improved. • Define the SCOPE of the project. • Identify possible undesirable effects of the actual system.	• dentify which objectives are expected to be met by addressing this issue. DELIVERABLES	• Due Date • List the sequenced actions for each objective • On every review session: Present completion status in terms of schedule and transitional objectives expected at the milestone step. Incorporate feedback from the review to update your plan as necessary.	STAFFING INVESMENT/COST

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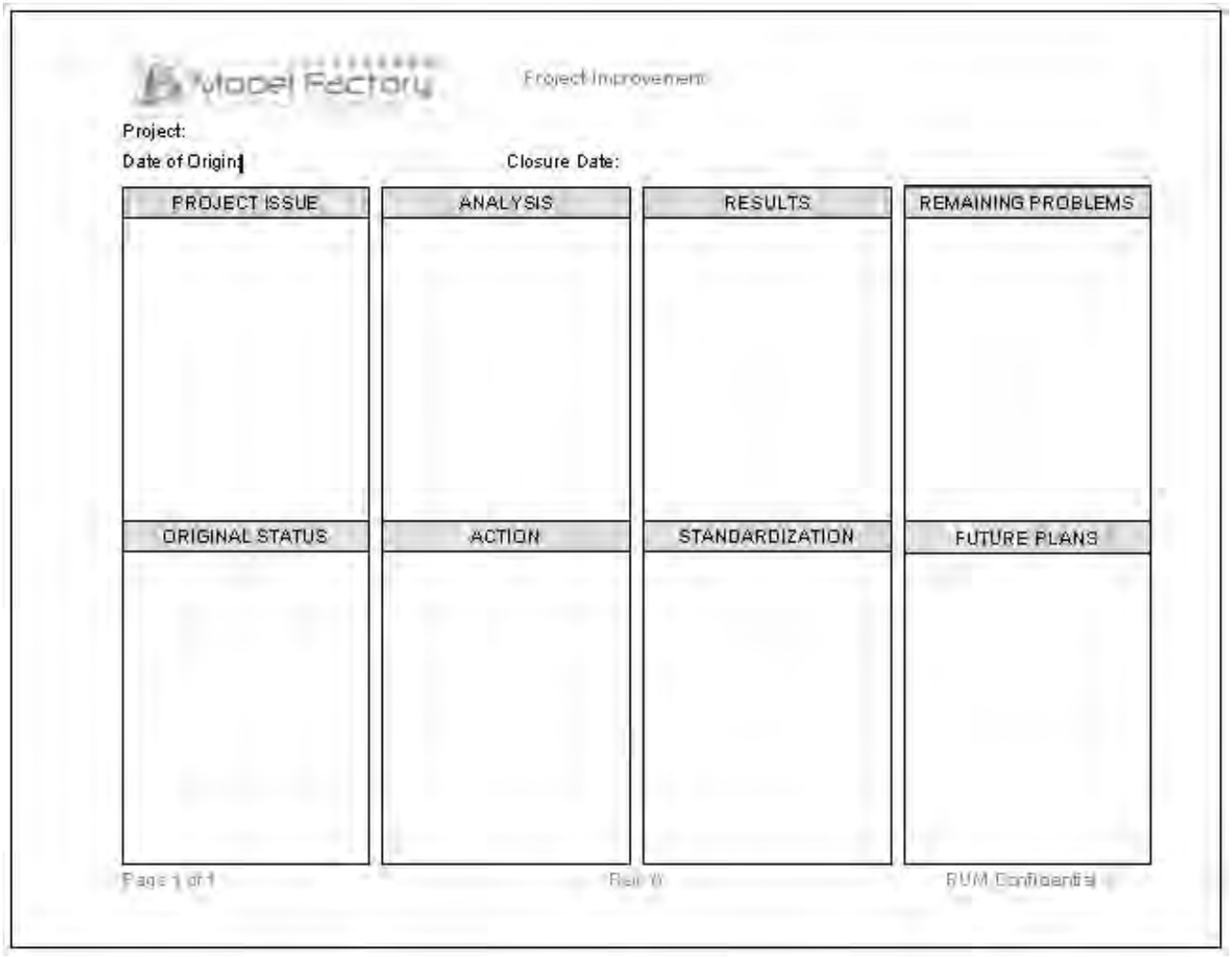
Appendix D



Model Factory Project Improvement

Project:

Date of Origin: Closure Date:

PROJECT ISSUE	ANALYSIS	RESULTS	REMAINING PROBLEMS
ORIGINAL STATUS	**ACTION**	**STANDARDIZATION**	**FUTURE PLANS**

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COMPLAINT LOG

Month ____________
Year ____________

Model Factory
University of Puerto Rico@Mayagüez

Date	Type of Device	Complaint	Disposition

Use the lines needed in the compalint and disposition space.
A new date will be the end of previous complaint.

Model Factory
University of Puerto Rico@Mayagüez

CORRECTIVE ACTION FORM

Origin date:

Problem description:

Julian date:
Product:
Reference designator:
Part-number:
Quantity affected:
EBI Impact:

Scope:

Reason for the mistake:

Actions already taken:

Actions to be taken:

Closure date:

Best regards,

Model Factory
University of Puerto Rico@Mayagüez

Project Information

Project:

Assigned Team:

Date of Origin:

ISSUE STATEMENT	OBJECTIVES	MILESTONES	
▪ Describe the process that will be improved. ▪ Define the SCOPE of the project. ▪ Identify possible undesirable effects of the actual system.	▪ Identify which objectives are expected to be met by addressing this issue.	▪ Due Date ▪ List the sequenced actions for each objective (each action having an owner and the expected deliverable of the action: end result) ▪ On every review session: o Present completion status in terms of schedule and 'transitional' objectives expected at the milestone step. o Incorporate feedback from the review to update your plan as necessary.	**STAFFING** **INVESMENT/COST**
	DELIVERABLES		

Model Factory
University of Puerto Rico@Mayagüez

Project Improvement

Project:

Date of Origin: Closure Date:

PROJECT ISSUE	ANALYSIS	RESULTS	REMAINING PROBLEMS

ORIGINAL STATUS	ACTION	STANDARDIZATION	FUTURE PLANS

Fábrica Modelo

CORRECTIVE ACTION FORM

Origin date: January 16, 2006

Problem description: Incorrect Julian date (still using 05 instead of 06)

Lot: 06011-M (January 11, 2005)
Any other first-week 2006 production
Product: Charger 102965.D00A and Driver 102970.D00A
Reference designator: N/A
Part-number: N/A
Quantity affected: All lot
EBI Impact: ???

Scope: Julian year had not been changed to 06.

Reason for the mistake: Human error! In the phone conference held between UPRM and EBI, Carlos Diaz requested that the two year-digits (set in MS Word files to 05 for 2005) be erased, forcing the person in charge of filling the Batch History Record to write-in the two year digits.

Actions taken:

1. Emphasize Julian year digits (06) for 2006 in all documentation.
2. Erased two year-digits from Batch History Record MS Word files. Done by Pedro Resto on 01/18/06.

Closure date:

In effect starting 01/18/06.

Best regards,

Pedro Resto

01/18/2006

01/18/2006

01/13/06

01/18/06

01/18/06

Fábrica Modelo

CORRECTIVE ACTION FORM

Origin date: January 16, 2006

Problem description: Inverted polarity

Lot: 05355-M (December 21, 2005)
Product: Charger 102965.D00A
Reference designator: C9
Part-number: 833063.C106M
Quantity affected: 324 PCB's (54 panels)
EBI Impact: 3.5 hours of rework labor.

Scope: The remaining 252 PCB's did not have the inverted polarity problem; however, 30 additional PCB's (five panels) had the swapped resistors problem (R22, R23, R25).

Reason for the mistake: We were running out of new component reels and were feeding these components manually, from the P&P vision system rejects. When these components are rejected by the machine, they are easily identifiable and can be put aside for later use. Operators involved were experienced, given the fact this happened after finals and a selected number of students were running production.

Nelson Mendez believes that even though the components were being consistently positioned with the wrong orientation in the plastic carrier.

Actions to be taken:

During the 01/18 meeting, the following actions were discussed and agreed upon:

1. Define, document, and train personnel on a standardized re-feeding approach. Until the training is provided, no re-feeding is allowed. Done
   Owner: Nelson Mendez Due date: 01/20/06
2. Enhance component recognition tactics, including component types, and polarity requirements.
   Owner: Nelson Mendez Due date: 01/20/06 Done
3. Enhance component inspection tactics; use label with affected reference designator(s) whenever a reel is replaced in the first two panels with the components with the new reel. This should alert the inspector on particular "risky" reference designators.
   Owner: Fernando Souto Due date: 01/20/06 Done
4. Enhance the post-pick & place inspection. Design and develop an ergonomic solution with lens and monitor to facilitate the visual inspection.
   Owner: Ivan Rodríguez Due date: TBD; depends on availability and cost of required equipment.

Closure date:

Pending planned actions.

Best regards,

01/18/06

01/18/06

01/18/06

Fábrica Modelo

CORRECTIVE ACTION FORM

Origin date: January 16, 2006

Problem description: Wrong parts (exchanged reels)

Lot: 05343-M (December 9, 2005)
05355-M (December 21, 2005)
Product: Charger 102965.D00A

Reference designator:	R22	R23 and R25
Part-number:	010039.A557	010039.A501

Quantity affected: 501 PCB's (83.5 panels) out of 576 PCB's from 05343-M;
30 PCB's (5 panels) out of 576 PCB's from 05355-M.
EBI Impact: 41.5 hours of rework labor.

Scope: The thirty PCB's in lot 05343-M are believed to be produced on December 9, 2005, but were left for the next shipment.

Reason for the mistake: Part number 010039.A501 is a common part with a unique position for all three products in IP3-B, MFU #3, slot 37. Part number 010039.A557 is a Charger part, positioned in IP3-A, MFU #2, slot 8.

After further discussion of the mistake it is believed that on December 9, the reels of both parts depleted in their respective feeders and both required reel changes. New reels were placed in the wrong feeders. It could not have been a feeder exchange since all labels in MFU#2 are green (Charger) and no one noticed the blue label used by 010039.A501's feeder. Since the components are very similar and tiny, the inspector(s) doing the "first piece" pre-oven and post-oven inspections did not notice.

Actions taken:

1. Checked if components are currently positioned in the correct slots; performed by Rodolfo Morales on 01/16/06.

Actions to be taken:

During the 01/18 meeting, the following actions were discussed and agreed on:

1. Divide the "big" reel replacement table into two areas, dedicating each side for an IP3 machine (A and B). Place a transparent acrylic wall in between.
   Owner: Nelson Mendez Due date: 01/27/06
2. In case more than one reel depletes on a given machine (A or B) simultaneously, these will be replaced one at a time, never having more that one feeder in the changeover table side dedicated to the machine.
   Owner: All team members Due date: 01/18/06.

3. In the FIRST system, use the Reference field to provide: (1) initials for reel-pickup person, (2) initials for checker-person, (3) IP3 machine (IP3A or IP3B), (4) device # (from 01on extreme left to 83 on extreme right);
   Example: NMR/JVG/IP3B/D75
   Owner: All team members Due date: 01/18/06.
4. Request to Doug McKay, from FIRST, to add a clock time field whenever a component reel is issued; helps remember when the reel replacement activity occurred.
   Owner: Pedro Resto Due date: 01/18/06.

Closure date:

Pending planned actions.

Best regards,

Fábrica Modelo

CORRECTIVE ACTION FORM

Origin date: January 16, 2006

Problem description: Wrong part

Julian date: 05347-M (December 13, 2005)
Product: Driver 102970.D00A
Reference designator: R9
Part-number: 010039.A201
Quantity affected: 6 PCB's (1 panel)
EBI Impact:

Scope: Only 1 out of 96 panels.

Reason for the mistake: During the 01/17/06 meeting, team members related this problem to two (2) part skip incidents in IP3, that were then added in Final Inspection (after the reflow oven).

Actions to be taken:

1. Establish as tactic not performing part skips in tiny (e.g. 010039-xxxx) components.
   Owner: All team members   Due date: 01/18/06.
2. Enhance rework tactics focusing on tiny components and verification of polarity requirements.
   Owner: Rodolfo Morales   Due date: 01/27/06.

Closure date:
Pending.

Best regards,

01/18/06

01/18/06

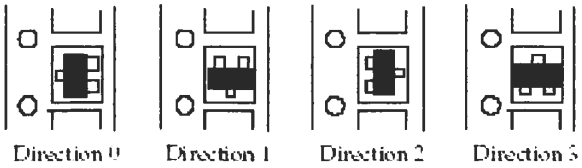
01/18/06

SOP#12-A
Last Revision 01/18/2006

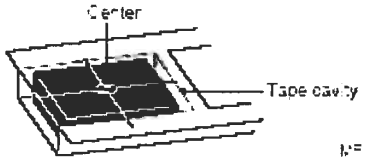
Reject parts re-feeding reference.

a) Identify part run-out component for re-feeding option.

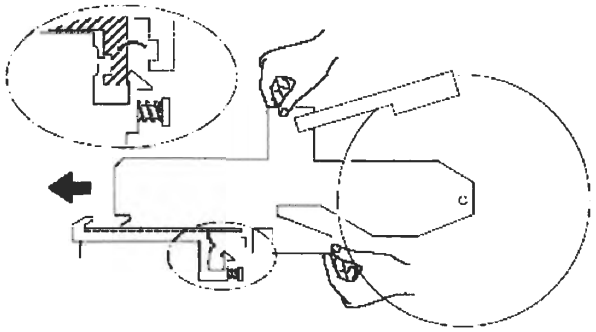
b) Identify part position in the feeder carrier.



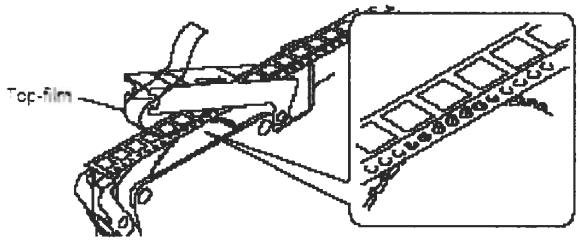
c) Savage same component feeder carrier of part for re-feeding.



d) Install feeder on feeder base station.

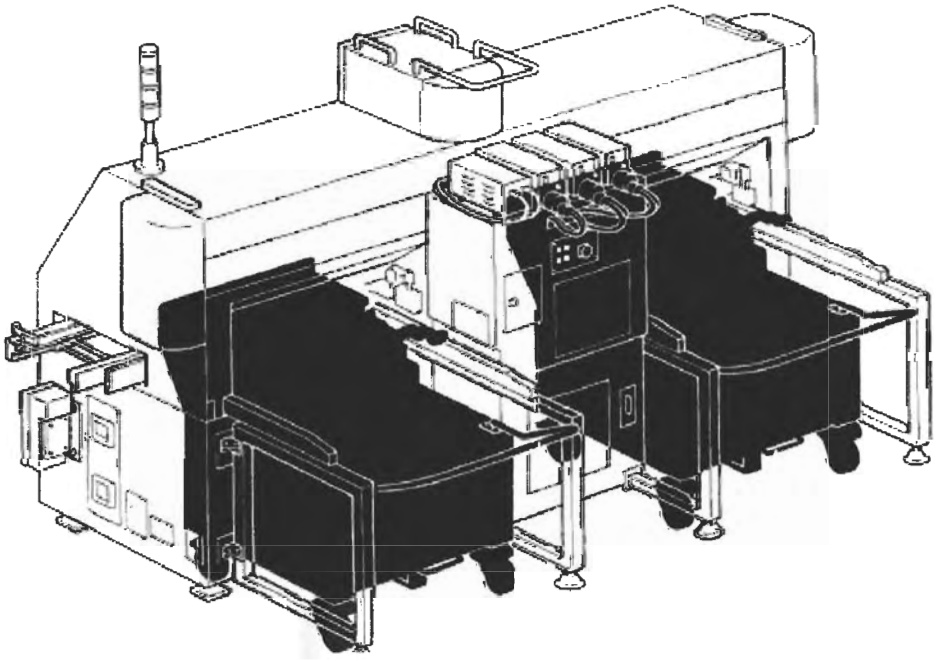


e) Install component carrier in the feeder.



f) Place the components in the same orientation of original packaging.

g) Install feeder in the machine device location.



h) Identify the boards with a label displaying part number and reference designator of the component in the affected panels.

Part#.....
Reff.....

i) Verify all boards with special attention to the re-feeding component for correct polarity orientation in each reference designator.

MEETING MINUTES

Subject: EBI Corrective Actions Meeting Date: 01/17/06

Attendees: Pedro Resto, Nelson Méndez, Rodolfo Morales, Eduardo González, Fernando Souto, ~~Dan~~ César Abréu, Damaris Arroyo, Carlos E. Bonet, Diana Y. Alonso, Gregory R. Soto, Juan J. Vega, Fernando Santos, Freddy Jusino

Agenda:
1. Corrective action review and needed response
2. Carlos Díaz (Quality System) visit on 01/26/06
3. EBI new product introduction
4.
5.

	Action item	Owner	Date
1.	Exchanged reels : adopt inputs in Reference field suggested by Nelson (First)	Operators	Starting 01/18
2.	Exchanged reels : divide the feeder banks for reel replacement into areas for IP III A & B	Nelson	01/27
3.	Exchanged reels : request Dong to add a clock time field to capture when the reel is changed	Pedro (request to Dong)	01/18
4.	Inverted component: define refeeding approach and document (CQ)	Nelson	01/20
5.	Enhance component identification: recognition including characteristics and polarity (CQ)	Nelson	01/20
6.	Enhance rework tactics; scenario related to part skips @ PLP (RQ)		
7.	Eliminate year digits from Batch History Record	Pedro	01/18

Next meeting Date:_____ Time:_____ Place:_____

Fábrica Modelo

CORRECTIVE ACTION FORM

Origin date: March 5, 2007

Problem description: A bin whose panels had 07-050-M Julian date labels was included as part of a 07-047-M history batch record. This batch record had a total of 576 products when it should have had 288. The 07-050-M batch record had only 288 when it should have had 576 products.

Julian dates: 07-047-M and 07-050-M
Product: Charger (102965.D00A)
Reference designator: N/A
Part-number: N/A
Quantity affected: Bin of 288 products; impact is not on the panels but on the history batch record.
EBI Impact: EBI requested the corrected history batch records.

Scope: Impact on the two history batch records for Charger.

Reason for the mistake: The history batch record is not prepared when the bin is completed, but the afternoon of the shipment.

Actions already taken:

1. Corrected history batch records were prepared and scanned to be sent to EBI as part of this e-mail.
2. A meeting was held on 03/14/07 to inform team members that history batch records need to be prepared as soon as a bin is completed.
3. History batch records are now printed ahead to avoid process interruptions.

Closure date: 03/14/07

Best regards,

Appendix O

Defect Data Collection Form

Defect Data Collection Form

Revision	1.0
Author	F. Souto
Date	7/8/2008
Time	1:50 PM

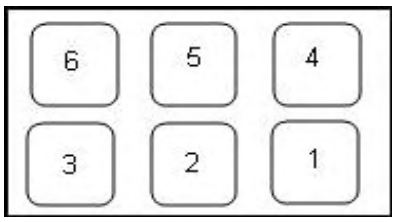
Model Factory
University of Puerto Rico@Mayagüez

Product _____

Date (mm/dd/yy)	Reference Designator	Image	Defect	Employee Initials	Repaired	Comments

Legend

01	Missing Component	09 Others
02	Skewing	
03	Tomb stoning	
04	Bridging	
05	Mis-aligned	
06	Excess of solder paste	
07	Lack of solder paste	
08	Inverted component	



Appendix P

Model Factory Work Instruction Manual

Work Instructions Manual

Approvals			History of Changes		
Rev	**Date**	**Authority**	**Rev**	**Description**	**Date**

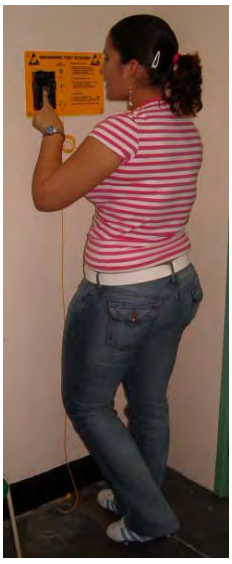
GETTING STARTED

Entrance to the production line

a. Use close shoes at all times while working in the production floor.

b. Before entering to the production floor, make sure that you are wearing shoe straps.

c. Go to the grounding test station.



d. Sign the ESD Log File: pass/failed information.

e. Wear protective gloves when working with soldering paste.

f. Throw any lead contaminated material in the “lead disposal only” trash can.

g. Wear heat protective gloves when removing boards from the oven’s conveyor.

h. Wear static protective wristband when working in the final inspection or the repair area.

DEK 265

Inspection before the DEK

a. Look for the boards at the warehouse. The boards should be removed from the warehouse using FIFO.

b. Discount the boards to be used at First station, see Pick and Place Common Message Procedures section at the Pick and Place SOP for reference.
c. Open the bag and take out the boards to be used. Each board should be inspected.
    1. In case of finding damaged images proceed to bad mark the images as instructed.
    2. In case of finding damaged boards, inform the technical employee in turn to know if the board might be repaired.
    3. If the board is found to be not reparable place it in the designated area.
d. Place the board in the DEK machine.

Turning ON and OFF the DEK machine

Warning! Use protective gloves when working with the DEK machine, except only when using the external controls.

A. Turning ON the DEK

a. Start the DEK conveyor turning the switch clockwise.

b. Release the E-stop button and press the reset button.

c. Turn the switch located in the right of the DEK machine clockwise to start the DEK.

d. Wait until the software uploads.

e. Press the system button that is below the left monitor.

f. Wait until the right monitor is in the main screen.

g. Proceed to the DEK set-up.

B. Turning OFF the DEK

a. In case of emergency push any of the red buttons located in the DEK machine.

b. Turn the switch located in the right of the DEK machine counterclockwise.

c. Press the E-Stop button of the DEK conveyor and turn it off turning the switch of the conveyor counterclockwise.

DEK Setup

a. To configure the setup of the DEK machine, please follow the next steps, pressing the following buttons in the screen:
    1. Set-up (F6)
    2. Load data (F2)
    3. Push the “Down” button (F6), until the correct product is found.
    4. Load (F1)
    5. Push exit button (F8) to exit the set-up and wait until the fiducial training is completed.
    6. Enter to the monitor menu (F7).
    7. Push the clear batch button to set to zero the batch count (F3).
    8. Push the batch limit button (F4), increase or decrease the batch limit to 8 (F6 and F7 respectively).
    9. Push the exit button twice to return to the main screen (F8).
b. To change the screen of the DEK machine, please follow the next steps:
    1. Press the “Change Screen” button (F5). The following message will appear on the monitor: “Wait while chase is centralized”.
    2. When message “Open front cover” appears, open the front cover.
    3. When message “Remove screen under two buttons control”, press the two green buttons in front of the machine until the screen is completely exposed.
    4. Make sure the screen is completely clean before taking it to the warehouse and in the case that there is a product “change over” look for the product screen to be manufactured.
    5. Put the screen in the machine, make sure it is completely clean and push it till it reaches the end.
    6. Close the front cover.
    7. Press “Change Screen” button (F5).
    8. Press “Exit” button (F8).
    9. Proceed to DEK setup (step a).

c. In case that the squeegees are not in place, please follow the next steps before loading the paste:
   1. Press the “Setup” button (F6).
   2. Press the “Change Squeegee” button (F4).
   3. The message “Open cover and change squeegee” will appear in the monitor, open cover.
   4. Look for the squeegees in the cleaning table.
   5. The first squeegee to be placed is the one that rests in the back (has the longer separation between the mounting pins), the slope of the squeegee blade must face backwards, and curl the two pins.
   6. Place the second squeegee in the front (the blade slope facing forward), and curl the two pins.

      Note: Make sure both squeegees are correctly placed.
   7. Close the cover.
   8. Press the “Continue” button (F1).
   9. Press the “Exit” button (F8).

d. Procedure for paste setup. To complete this procedure, please follow the next steps:
   1. Press “Paste Load” button (F3).
   2. Press “Manual Load” button (F2).
   3. The following message will appear in the monitor “Open cover and load paste”, when this happens follow the next steps:
      i. Look for the paste that is over the table.

      ii. Whisk the paste with the spatula, until it meets the required consistency.
      iii. Load the paste over the nearest extreme of the screen; it should be as long as the design.

4. Clean any instrument used or contaminated with paste.
5. Close cover and press the “Continue” button (F1).
6. Press the “Exit” button (F8).
7. Press the “Run” button (F1).

e. Procedure to reload data to control cards (MINT program installation).

1. Enter into maintenance by turning the key switch to **On** position.
2. Select **Diagnostics** on the menu and wait for **System Power Down** error to appear.
3. Press **System** button.
4. Highlight **System** on the menu and press **Select Module**.
5. Highlight **Exit to DOS**. Press **Run Diagnostics**. The C:\PRINTER prompt will be displayed.
6. Type **cd\MINT** then pres enter. Type **LOAD** then press enter. This starts the MINT program.
7. Select **Auto download** and wait for the program to run.
8. Exit the MINT program then turn off the machine and wait for 5 seconds.
9. Power up the machine and return the key switch to **Off** position.

DEK Procedure

a. Place board in the conveyor, until it is detected by the sensor.

b. Be aware to the monitor and the different messages it could generate. Some of the messages could be:

1. "Fiducials not found".
    i. Pess the "abort" button (F8).
    ii. Take out the board from the conveyor and place it again in the beginning of the conveyor, until it is detected by the sensor.
    iii. Press the "run" button (F1).
2. For other common messages make reference to the DEK 265 Operator's Manual, Chapter 11.

Cleaning Procedure

Note: Gloves are required for completing this operation.

a. Proceed to DEK setup (step b).
b. Unfasten the pins of the front squeegee, and dismantle the squeegee.
c. Unfasten the pins from the backside squeegee, and dismount the squeegee.
d. Working over the screen, remove the excess of paste from the squeegee, and place it on the paste container.

e. Spray alcohol to the squeegee and clean it with the cleaning cloth.

Note: Repeat this step until the squeegee is completely clean.

f. Place the clean squeegee on the table.

g. Look for the paste container and the spatula.

h. Remove the excess of paste from the screen, and place it on the paste container.

i. Close the paste container.

j. Take the paste container and the spatula to the cleaning table. And look for the alcohol and the cleaning clothes.

k. Spray alcohol to the screen and clean it using the cleaning clothes. Be sure to clean the top and bottom side of the screen.

Note: Repeat this step, until the screen is completely clean.

l. Place the screen in the correct position.

m. Close the front cover.

n. Look for the clean squeegees and place them in the correct position.

Note: Use the procedure for the mounting the squeegees.

o. Close the cover.

SENTRY

Sentry Setup

a. Release the emergency stop.

b. Press the start button.

c. In the monitor will appear three tabs.
d. In the first tab will appear all the products available for production, choose the correct one.

e. In the second tab “Panel Script”, choose the correct recipe.
f. Press the “Run Script” button.
g. The original page will appear, press the “Ok” button.
h. If a report wants to be generated, place the floppy in the correct place and press the “Report” button.
i. When production is done, press the “Stop” button.

Sentry Shutdown

a. Press the “Stop” button.
b. The original page will appear. Press the “Shutdown” icon.
c. Wait until the following message appears: “It is safe to turn off the computer”.
d. Press the red button.

Post-Sentry inspection

a. Move the board until the inspection area, under the magnifier.

b. Using the magnifier inspect the following parameters:
    1. In each image there should be enough paste all pads.
    2. Excess of paste
    3. Incorrectly dispensed.
c. If all the parameters are satisfied, the board can continue the process.
d. If one or more of the parameters are not satisfied, execute the following steps:
    1. If there is not sufficient paste in all the pads, pass the board again through the DEK machine.
    2. If there is excess of paste or it is incorrectly dispensed, clean the board using the procedure for cleaning the boards (SOP #10).
e. Move the board to the next conveyor.

PICK AND PLACE MACHINES (IP3 A AND B)

Turning ON the IP3-A and IP3-B Machines

a. Turn on the compressor turning the auto button.
b. Verify that all the emergency stops are loosened.
c. Verify doors.
d. Push the “Power On” button.
e. Wait until the machine initializes its system.
f. Press the “Reset” button.
g. Verify the air pressure valves, they should be always opened.
h. Press the “Reset” button.
i. Wait until the machine initializes.
j. The following message will appear at the monitor: “Machine Not Zero Set”. When this occurs, press the “Start” button.
k. To set the correct product to be manufacture, please follow the next steps:
    1. Press the “Program” button.
    2. Verify for which product the machine is set, if the product to be manufacture is not the one that is set, follow the next steps to change the product.
        i. Press the “Change” button.
        ii. Choose with the pointer the correct product.
        iii. Press the carrier return “CR” button.
        iv. Press the “Return” button, until the initial page is reached (page 000).
        v. Verify that the quantities to be produced and the ones scheduled are correct. If the counter wants to be set to zero, follow the next steps:
            a) Press the “Program” button.
            b) Press the “Quantity Clear” button.
            c) To indicate the quantity to be manufacture:
            a. Press the “Quantity Set” button.
            b. Enter the correct amount and press the “CR” button.
l. Press the “Auto” button.
m. Press the “Start” button.

Turning OFF the IP3-A and IP3-B Machines

a. Push the emergency stop and press the power off button.
b. Normally when the power off is pressed it is not necessary to turn off the main circuit breaker. However, for safety reasons the main circuit breaker should be turn off when the machine is to remain off for a long period of time or any time something must be done inside the control box.

Pick and Place Machines (IP3-A and IP3-B) Setup and Reel Changing

Procedure for changing feeders that are currently placed in the MFU's

Check conveyer width

a. Look for the setup bin at the warehouse for the product that is going to be manufacture.

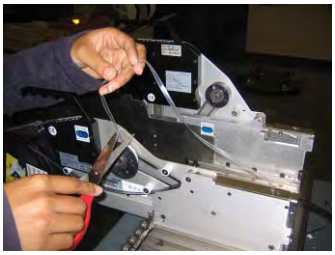
b. Take the bin to the setup area.

c. Look for the setup binder: FUJI FLEXA Pick and Place Product Feeder Setup.

1. Print the pages for the setup of the product to be manufacture.
2. Identify the page of the machine to be used.

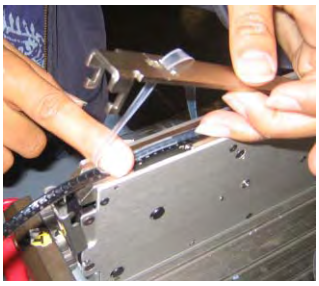
d. Start the setup with the component in the first row and continue until the last row. Remember to look for the feeders that are currently assembled with the product that is going to be manufactured.
e. Check the setup pages to collect from the MFU and slot that you are working on, the feeders with specific size that are going to be needed in the on-going setup.
f. Take out the feeder. Do not use the already assembled "Common" parts feeders, which are identify with a blue label:
    1. Check Nozzle Position
    2. Disconnect the cable of the feeder and pull the feeder up.
    3. Take the feeder to the setup table. Be careful with the nozzle it could be bended if the feeder hit the nozzle.

g. Verify that the feeder have the same specification than the component to be mounted.
    1. If it does not have the same specifications, find a feeder that meets the specification.
    2. If it has the required specifications, continue with the setup procedure.
h. Dismount the roll that is in the feeder to be used.
    1. Releases the plastic strip and cut it carefully using scissors and leave around one foot (1ft) of tape length, to be sure that the roll can could be mounted again.



2. Unfasten the lock.
    i. Raise and pull the front lid.

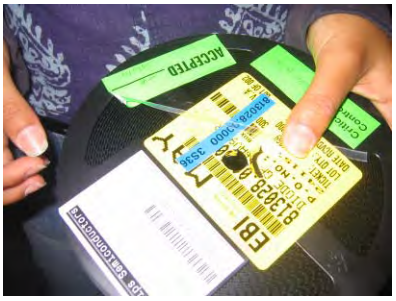
3. Raise the superior lid, holding the plastic strip in such a way that components are not loosed.



4. Using tape, seal the plastic strip with the component strip.

5. Take out the component strip by pulling it to the back, rolling up the reel.

6. Remove the label of the feeder and paste it to the reel using tape.



7. Put the reel into an antistatic bag and place it in the setup bin for the product that is been dismounted.

8. Find the reel of the component to be mounted, in the setup bin of the product to be manufacture.
9. Take out the reel from the antistatic bag.

10. Take out the label form the reel and put it on the feeder.
11. Mount the reel in the feeder:

12. Place the reel on the pin.

13. Put the component strip under the white pins and through the channel.

14. Remove the front of the plastic strip from the component strip.

15. Put the plastic strip through the slot in the feeder.

16. Close the lid.

17. Close the lock.

18. Put the plastic strip over the white roll and under the black roll.

19. Paste the plastic strip in the black roll.

20. Verify PITCH ……. IMPORTANT Components

Validate SETUP with a partner

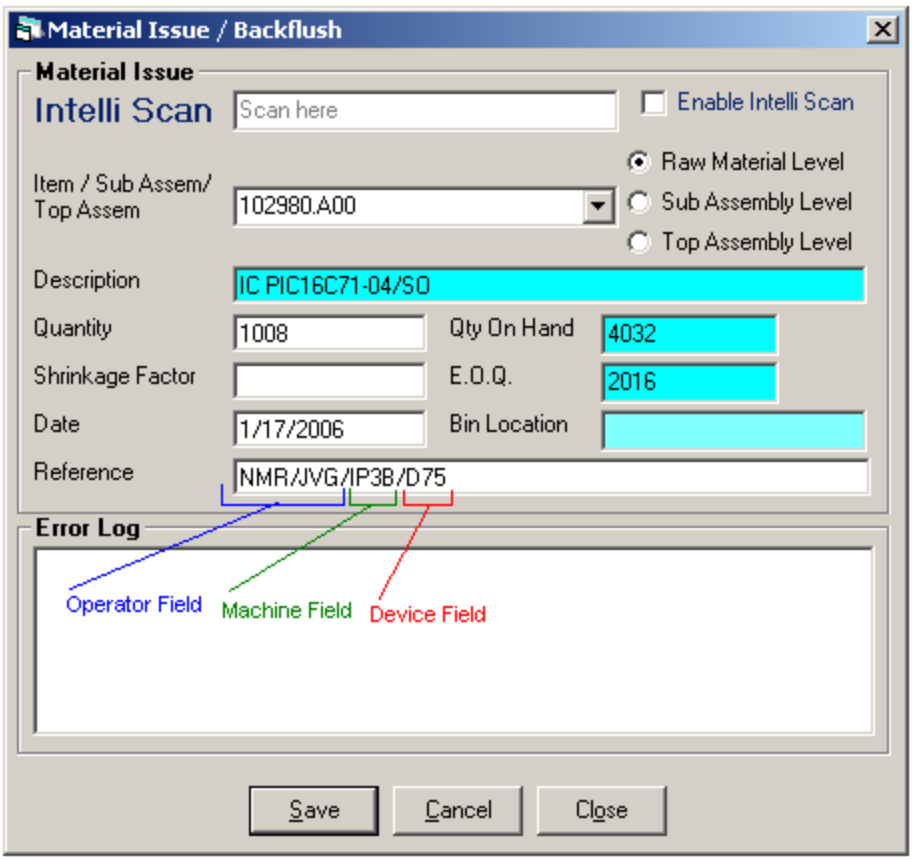
Pick and Place (IP3) Common Messages and Procedures

a. Parts Out:
    1. Verify the slot.
    2. Open the back door of the corresponding MFU.
    3. Verify the feeder
        i. If the reel is empty:
            1. Disconnect the feeder cable and take out the feeder.
            2. Place the feeder in the corresponding IP3-A or IP3-B setup table.
            3. Remove the empty reel from the feeder.
            4. Look for a new reel in the warehouse, according with the part number of the empty reel and feeder.
                a) Take the component located in the left side of the rack or according to FIFO.
                b) Validate the component with a work partner to ensure that the component to be placed is the same as the one that is going to replace.
                c) Discount the reel from the inventory using FIRST, (in the computer assign for that purpose)

d) Scan all information required to back-flush material. Remember to verify the roll component quantity.

e) Please fill reference space with the following information:

   i. Blue field to be the operator initials when removing parts from warehouse.
   ii. Green field for machine designation were parts will be used.
   iii. Red field for device location were parts will be installed.



f) If all the information is correct press the “Save” button.

g) Return to respective feeder supply base to install component on the feeder.

h) Install feeder to respective machine device location were parts run-out occurred.

5. Close the back door.
6. Place reference designator stickers on the board that the machine is assembling and the one previous to it.
7. Reset the machine:
    a. For IP3-A:
        i. Press reset button
        ii. Press start button
    b. For IP3-B:

i. Press reset button
ii. Press Escape
iii. Press Yes
iv. Press Return
v. Press Return
vi. Press Start

ii. If the reel still have components:

1. Verify what is wrong with the feeder.
    a. If the component strip is misaligned
        i. Disconnect the cable from the machine and remove the feeder.
        ii. Place the feeder in the setup table and connect it.
        iii. Set the pitch one less of the suppose pitch.
        iv. Move the components strip one or more spaces forward until the component strip is aligned.
        v. Set the correct pitch.
        vi. Disconnect the cable and remove the feeder.
        vii. Place the feeder in the corresponding slot.

b. Production Complete:
    1. Press program
    2. Press Quantity Set (Sche)
        i. Chose the product which is running
        ii. Write the new quantity to be produce
    3. Press Quantity Clear (Production)
        i. Erase the quantity already completed
    4. Press Return
    5. Press Auto
    6. Press Start

c. Check Nozzle:

   1. Notify the technician of the alert.
   2. Reset machine.

Reject parts during Change Over

a. Before finish the change over verify the IP3 scrap components pockets:
   a. Open the IP3 front door.
   b. Near the heads, at each side of the central conveyor, a gray metal pocket is place as the picture below shows. Collect the components that are at each pocket and put it on an Anti ESD bag, identify the bag with date and the corresponding assembly product, and take the bag with the components to the inventory station.

IP3 Product Recipe Change Over.

a. Verify all IP3 doors, they must be closed.
b. Verify the emergency stops are released.
c. Press the RESET button.
d. Wait until the warning green light turn on.
    1. Press RETURN
    2. Press PROGRAM
    3. Press QTY CLEAR
    4. Press QTY SET
    5. Enter the quantity to be assembled.
    6. Press CR
    7. Press CHANGE
    8. From the list select the number that corresponds to the recipe that will be assembled.
    9. Press CR
    10. Press RETURN

IP3 Conveyor Setup.

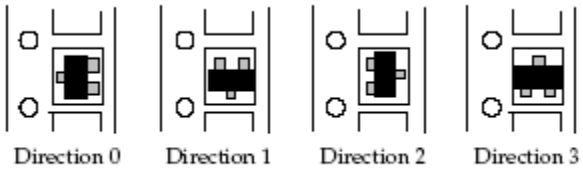
a. With the warning green light on:
    1. Press RETURN
    2. Press LOADER
    3. Press LOCK
    4. Once the UNLOCK option appear put the boar at the IP3 beginning conveyor and adjust it manually with the flywheel as show the picture below:

5. Press UNLOCK
6. Press LOAD PCB
7. Wile the board is moving through the conveyor verify if it pass freely and without any problem. If the board gets stock readjust the conveyor until achieve the adequate fit.
8. Press UNLOAD PCB
9. Press START

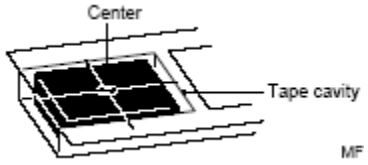
Reject parts and Re-feeding Reference

a. Identify part run-out component for re-feeding option.

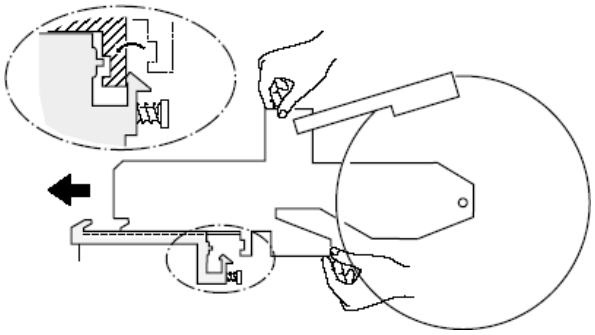
d. Identify part position in the feeder carrier.



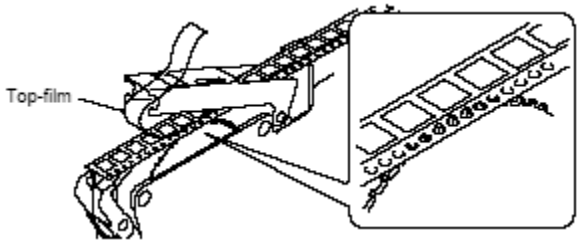
e. Savage same component feeder carrier of part for re-feeding.



f. Install feeder on feeder base station.

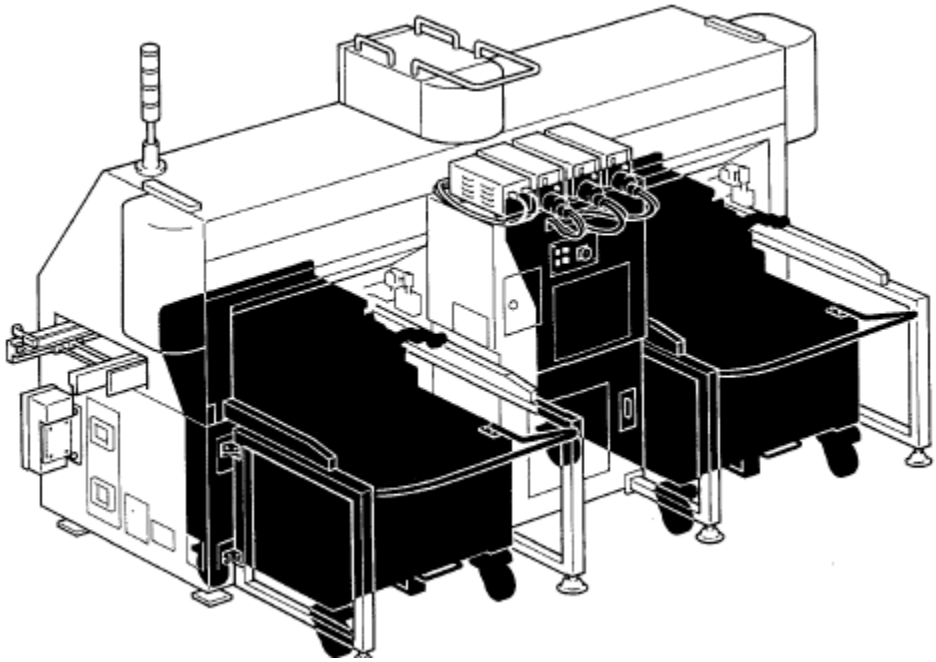


g. Install component carrier in the feeder.



h. Place the components in the same orientation of original packaging.

i. Install feeder in the machine device location.



j. Identify the boards with a circular label displaying the reference designator of the component in the affected panels.

k. Verify all boards with special attention to the re-feeding component for correct polarity orientation in each reference designator.

TURNTABLE

Set Turntable ON

a. Release the emergency stop.

b. Press the power button.

c. In the display will appear four options:
    1. Reset (F1)
    2. Auto (F2)
    3. Manual (F3)
    4. Setup (F4)
d. Press the F2 to set AUTO mode. .
e. If there is an obstruction in the conveyor, the turntable alarm will sound, to silence the alarm, press F4 twice.
f. Press F2 to turn the turntable to Auto mode.
g. Be careful with the PCB that was in the turntable and be sure that it goes to the next station.

Set Turntable OFF

a. Press the Emergency button.

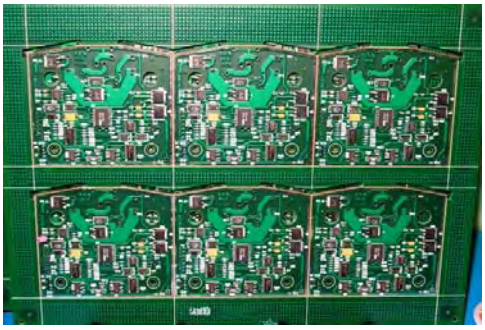
b. In the display will appear “Turntable Control Power Off”

PRE-OVEN INSPECTION

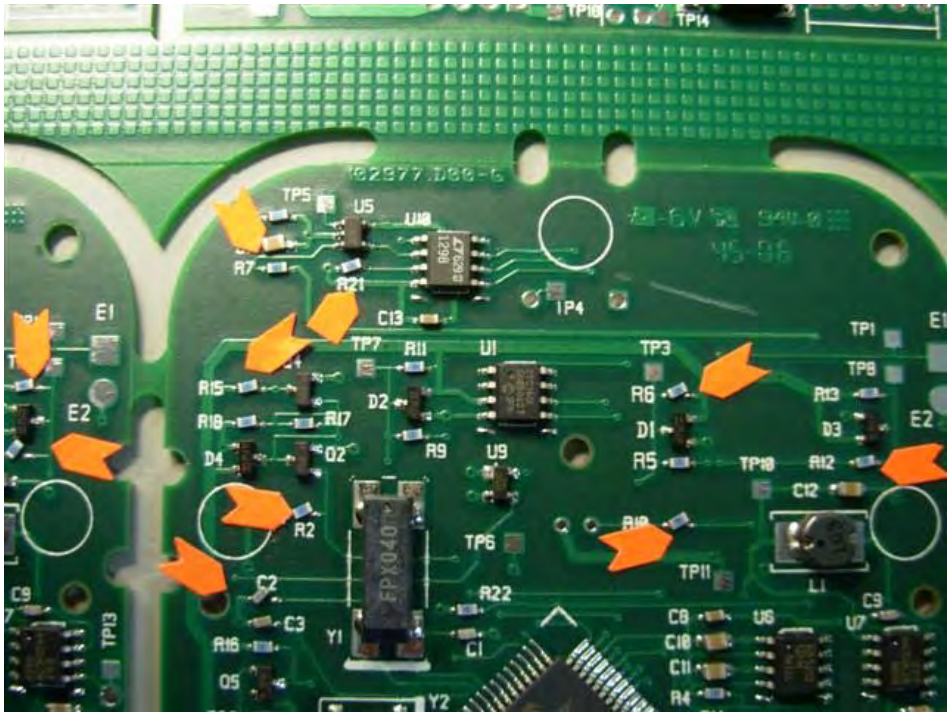
Inspection after Pick and Place Machines (IP3-A & IP3-B)

a. Having the board at the inspection area (under the magnifier), verified the following parameters:

1. The board contains all the required components of that product. (For the first board of the day, the part numbers of each component should match exactly with the ones in the example board)

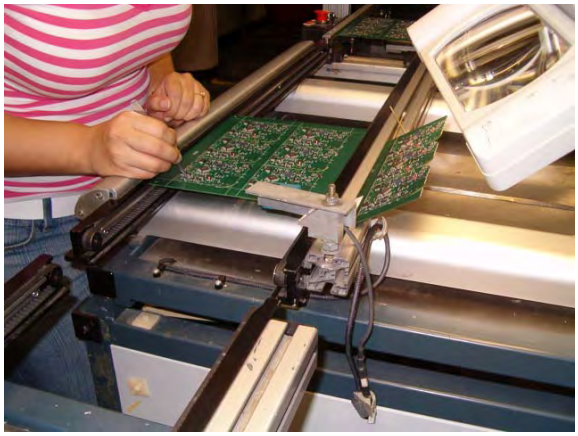


2. Components are correctly aligned.



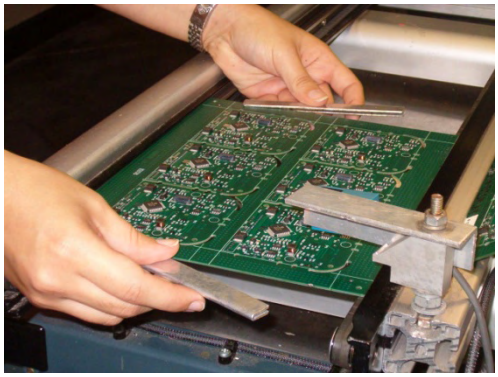
3. Polarity is correct.
4. There is enough solder paste in all the pads.
5. Components are placed with the correct side up.

b. In case that one or more of this parameters fail, please follow the next steps:



1. If a component is missing:
    i. Inform the technician.
    ii. The technician will look for the component, if it can be placed with tweezers, do it carefully.
    iii. If it can not be placed with the tweezers, mark the error with a flag and continue the inspection normally.
2. If a component is misaligned:
    i. Carefully align the component using the tweezers.
3. Incorrect polarity:
    i. Take out the component with the tweezers and place it back in the correct position, according to polarity.
4. Lack or shortage of solder paste in the pads:
    i. Mark the pad without paste with a flag and continue the process normally.
    ii. If the component do not have solder paste in the pads, take the component out, bring the component to the repair area, mark the error with a flag, and continue the process normally.
5. Inverted components
    i. Take out the component with the tweezers, clean the component to minimize solder balls and place it back with the other side looking up.

c. Once all the parameters are inspected, place brackets in both sides of the boards.



d. Press the pedals until the board reaches the next conveyor available near the oven.

e. Once there are three boards already inspected, move them towards the oven.

f. When the first of the three boards reaches the 5th zone of the oven, turn on the nitrogen, by pressing F4. (Make sure the cursor on the oven screen is placed in the N2 section to avoid turning on/off other critical areas of the oven. Listen carefully to the sound to check if nitrogen is present in the system. If not check tank and line pressure)

g. When the third of the boards reaches the 9th zone, turn off the nitrogen, by pressing F4.

REFLOW OVEN

Reflow Oven ON

a. Turn on the chiller unit located on the outside of the Model Factory in the Chardon Building's parking.
b. Once inside the building turn on the Extractor switch.
c. Turn on the oven using the power lever found at the end of the conveyor.

Oven Power Level

d. Go to the keyboard located at the beginning of the conveyor and select the Machine Software using the "tab" button.
e. Press the "Enter" button.
f. Adjust the conveyor's width according to the PCB width using the wrench. The adjustment point is located at the beginning of the conveyor next to the keyboard on a hole identified.
g. Verify that the conveyor is running, if not turn it on. To turn on the conveyor, move the cursor to the conveyor icon and press the F4 button.
h. Turn on all the zones of the oven. Move the cursor to the zone and press F4 button. Repeat this procedure until all the zones (11 zones) are on.
i. Once all the oven's zones appear in green color in the screen, the oven can receive the PCB boards.
j. Turn on the ionizing air blower at the end of the oven pressing the power switch.
k. Verify that the oven temperature is within 20 and 22 Celsius degree. Most of the times the oven temperature is between 23 and 28 Celsius degree.

Reflow Oven Shutdown

a. Turn off all zones. Move the cursor to the zone and press the F4 button. Repeat this procedure until all the zones (11 zones) are off. The F10 button (AUTO-STOP) can be used also to turn off the zones.
b. Turn off the ionizing air blower at the end of the oven pressing the power switch.
c. Turn off the extractor when the oven is cold. Consider cold as less than 60 degree Celsius.
d. Turn off the oven using the power lever.

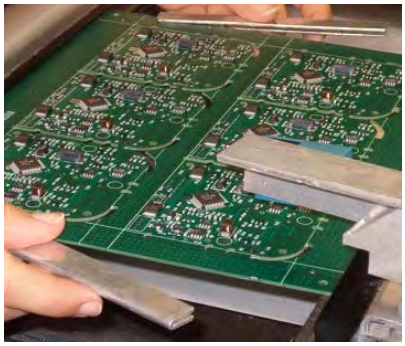
*Note: The conveyor need to be running at all times to avoid damages in conveyor's grid.

POST-OVEN INSPECTION

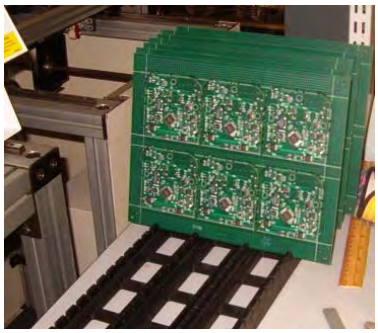
Instructions

a. Use heat resistant protective gloves when necessary. Leave the PCB's a couple of minutes close to the ionizing fan, so they achieve a safe to touch temperature.

b. Before taking the boards out of the conveyer to the inspection station, touch briefly a small portion of the PCB to ensure that it is safe to take it out with bare hands. If the PCB is hot to the touch, use gloves; Then take out the PCB's from the conveyor and remove the brackets.



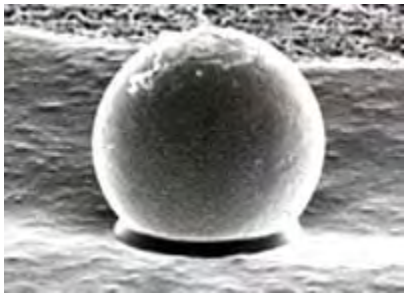
c. Place the boards in the rack labeled: "for inspection", and the brackets over the table.

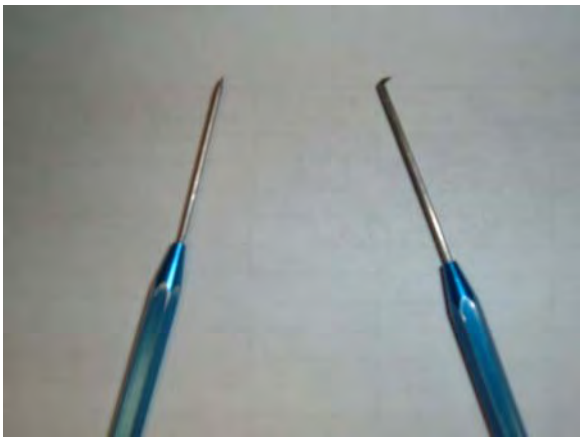


d. Take a single board from the rack and inspect the following parameters:

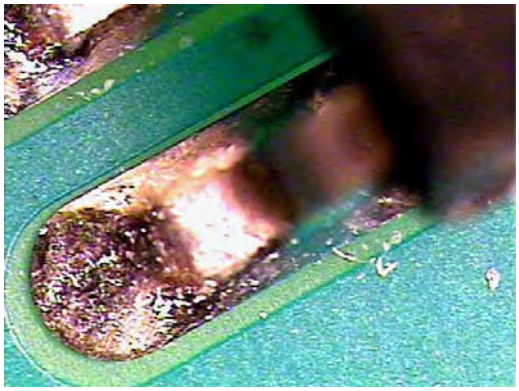
1. Soldering defects:

i. Solder balls: remove the solder ball using tweezers or other instruments.



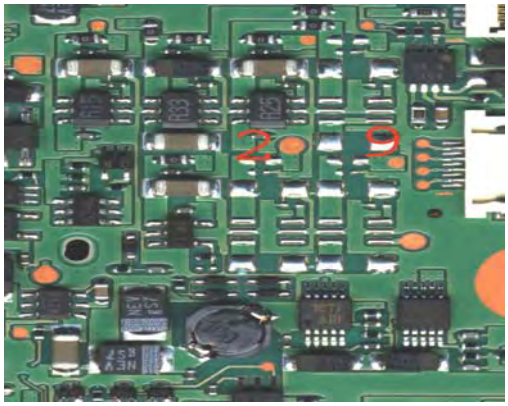


ii. Solder joints or others:



1. Mark the error with a flag.
2. Place the board in the “for repair” rack located in the repair station.

2. Components missing:



i. Mark the error with a flag.
    1. Place the board in the “for repair” rack located in the repair station.

3. Misalignment of components:
    i. Mark the error with a flag.
        1. Place the board in the “for repair” rack located in the repair station.
4. Verify that all the pads of all components are completely sold.
    i. Mark the error with a flag.
        1. Place the board in the “for repair” rack located in the repair station.

5. Inverted components.
    i. Mark the error with a flag.
        1. Place the board in the “for repair” rack located in the repair station.

e. Once the inspection is completed put the inspected board in designated place.

REPAIR STATION

Instructions

a. Take out the board from the rack and verify the flag that marks the error that the PCB has using the magnifier.
b. Depending on the error make the required reparation:
    1. Common reparations and required process:
        i. Missing component
            1. Identify the product, the reference designator of the missing component and the quantity needed in that board.
            2. Go to the person in charge of the placement process and ask to look for the recipe of the product and the reference designator in the Flexa program to identify the component part number.
            3. Look for the component using the part number given, either at the IP3's MFU's or at the parts bin.
            4. Take the required quantity of components to the repair area.
            5. Place the component it in its correct place using the iron and Sn-Pb soldering:

                a. Use the soldering iron and the tweezers.

        ii. Lack of solder
            1. Use the soldering iron to apply only the necessary amount of solder to ensure a good electrical connection. Remember that the components and the pad are heat

sensitive, so try not to leave the tip of the soldering iron touching them for a prolongued period of time.

2. Inspect the component, if the component is not in good conditions pass to step #3, if the component is in good conditions:
    a. Heat the pad.
    b. Place paste in the pad. If the paste seems not to attach firmy to the component or pad, use solder flux to clean the area.
    c. When the component is centralized, place paste in the remaining pads.
3. If component is in bad conditions, refer to step i (Missing component).

iii. Inverted component

1. Follow step ii (Lack of solder)

MATERIAL HANDLING

Recieving Material

a. In the first database station open First software and click on receiving Icon.
b. Click in receive by part, then scan part numbers on reel and enter total received quantity for each part number. Repeat until all parts received are entered.
c. After entering all parts, put each reel in its corresponding slot, always using a "first in first out" discipline. (according to FIFO the newest reel in the right side of the slot).

Component Physical Count Procedure

A. Print physical inventory template.
B. For the reels that are in use:
a. Take out the reel from the feeder as specified in procedure 12.
    1. Measure the radius as shown below and enter the measurement in millimeters on the physical inventory paper corresponding to each part number. (column labeled "radio efectivo para calcular rollos en uso")
C. For the components that are in the warehouse:
a. For each part number, count the amount of components for each slot and write it down on the physical inventory paper.
b. For each product PCB count the total amount of images that are in the warehouse. Write down the correct amount in the corresponding part of the physical inventory paper.

D. When the counting is finished, adjust quantities on FIRST corresponding to cycle count figures.

To enter the data in FIRST:

a. Press Parts
b. Take note on differences between first On hand quantities and real quantities found in the cycle count.
c. Press adjustments
d. For each part number

1. Substract or add components to adjust On Hand quantities with real values found on the cycle count. Press save.

Final Inspection (Julian Date & Date Labels)

a. Verify that the bins of the different products have the correct quantities of boards (usually 48 boards/bin or 288 images/product)
b. Make sure that each product has the correct amount of bins to be shipped.
c. Corroborate that each product have the "Production Batch Record" in accordance with the date of production and that is completely filled.
d. Make a copy of the Production Batch Record according with the amount of images. Place a copy of that page in each bin (in the identification tab).
e. Place the original copy of the Production Batch Record inside the bin.
f. Fill the Packing List and the Partial Invoice and place it inside the bins to be shipped.
g. Place a copy of all the documents send with the shipment in the historical file record.

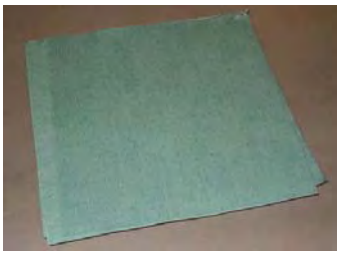
Boards Scrap Procedure

Note: To do this procedure gloves are required

a. Use tweezers to take out the components that can be re-fed and clean them with alcohol.
    i. Place these components in the area designated for re-feeding.
b. Remove all the components that still in the board using the plastic spatula and spraying the board with alcohol.

i. These components should be disposed in the lead trash container.

c. Spray the board with alcohol and clean it with wipes until there are no paste residues.



d. Place the board over the table.

e. Clean the table with alcohol.

f. Put all waste generated in this process in the “Lead Disposal Only” trash can.

Lead Waste Disposal

a. Lead waste can not be mixed with any other type of garbage.

b. Lead waste can not be dispose in regular trash cans.

c. Any material contaminated with solder paste should be dispose into a designated and labeled trash can.

d. Instructor’s Responsibilities:

   i. Provide training in the lead procedure to all the personnel working for the Model Factory.

e. Technicians responsibilities:
    i. Assure that nobody is eating in the production line at any time.
    ii. Inspect and verify that any material contaminated with lead is disposed in the designated trash can.
    iii. Coordinate that all employees that work with lead receive the annual required training.

f. Employee Responsibilities:
    i. **Do no eat,** or make up in the production area.
    ii. Use gloves.
    iii. Follow good hygienic practices.

g. Health and Safety Office at University of Puerto Rico at Mayagüez responsibilities:
    i. This office is responsible of recollecting this type of waste and make proper disposal.