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Determining continual improvement process methods within quality management systems

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ABSTRACT

DETERMINING CONTINUAL IMPROVEMENT PROCESS METHODS WITHIN QUALITY MANAGEMENT SYSTEMS

**by
Diane M. Bové**

Institutionalized standards require organizations to actively define and implement quality management systems, which includes active participation in continual improvement efforts. Interpretations and practices vary on implementation methodology.

Traditional views of quality do not integrate the technical disciplines into a defined science which would support a standardized approach for continual improvement implementation.

In order to optimize improvement efforts, a conceptual hypothesis is proposed to integrate quality through combining and collaborating implementation efforts of engineering, control, assurance, improvement and costs. The purpose of this thesis is to establish a roadmap to assist in choosing effective quality improvement methodologies and toolsets that assist in enhancing customer satisfaction, which is desirable as part of a total quality management philosophy.

Research is warranted to evaluate the bodies of knowledge into an extended science that establishes standardized practices in the area of quality improvement.

**DETERMINING CONTINUAL IMPROVEMENT PROCESS METHODS
WITHIN QUALITY MANAGEMENT SYSTEMS**

by
Diane M. Bové

**A Thesis
Submitted to the Faculty of
New Jersey Institute of Technology
in Partial Fulfillment of the Requirements for the Degree of
Master of Science in Engineering Management**

Department of Industrial and Manufacturing Engineering

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APPROVAL PAGE

**DETERMINING CONTINUAL IMPROVEMENT PROCESS METHODS
WITHIN QUALITY MANAGEMENT SYSTEMS**

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Dedicated To Olga DeGregorio

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CHAPTER 1

INTRODUCTION

1.1 Origin of Management Systems

The concept of continual improvement originates from the classical approach to management which was the result of early scientific studies endeavored for purposes of emphasizing efficiency and recommending that managers continually strive to increase organizational efficiency.

Concerns originated as it related to the increase of production levels. Manufacturing output was but one aspect of a two-part scientific study of the classical management approach, conducted first by studying jobs of workers at lower levels of organizations. The second part placed significant emphasis on the comprehensive analysis of management itself, concentrating more on the study of the effectiveness of the management function as a whole.

The result of the combined study of economizing efficiencies and best practice functioning of management equated to a method of management analyzed and simply stated as *scientific management*, first introduced by Frederick W. Taylor (1856-1915) who was later called the “father of scientific management” when he initiated a study of shovel workers at the Bethlehem Steel Company. Later, Taylor’s studies would be complemented by Frank Gilbreth (1868-1924) and Lillian Gilbreth (1878-1972) in their motion study analysis of bricklayer productivity, and ultimately a third major contributor, Henry L. Gantt (1861-1919) initiated early improvement aspects through his contribution of systemizing organizations through task scheduling for which performance would be rewarded. Gantt’s chart, the primary scheduling tool that he improvised, is still used by

many organizations today. His innovation of planning, scheduling tasks, and incentive driven performance to enhance accomplishment of tasks was considered fundamental to organizations.

1.2 Progressive Outcomes Relative to Management Systems

The primary goal of these original studies was to increase worker efficiency by scientifically designing jobs and then formulating functions that could be managed. The investigative tool for this early research was motion study, with considerations to reduce jobs to efficiencies of movement. This early study of motion analysis eventually resulted in the establishment of job performance standards, which were intentioned to eliminate unnecessary movements for purposes of efficiencies. Factors considered ranged from specifics in the work environment to behavioral attributes concerning workers. Herein originates the behavioral approach to management where the emphasis was to strive to increase production through an understanding of people. The progression is clearer to review in the following terms:

- **Product Level Efficiencies (Classical Approach)**

Once the subject of production performance level was addressed, the emphasis of classical and behavioral approaches to management stretched into organizations for many diverse management problems such as scheduling, locating new plant facilities, and product packaging (Certo, Samuel C., 1980).

- **Human Resource Efficiency (Behavioral Approach)**

Some of the contributing thoughts on the make-up of organizing for good working conditions allowing for achieving efficiency were to allocate and manage authority and

power as well as to spawn discipline. Also inspired were concepts of unity of command, unity of direction, division of work, centralization and decentralization, subordination of individual interests to the general interests, order, equity, initiative, bonuses and incentives, group piecework systems, and social “spirit de corps” to encourage harmony.

- **General System Theorem**

The system approach to management was beginning to reveal itself through premises based upon general system theory. The main premise of general system theory was that in order to fully understand how an entity functioned in its entirety, it must be viewed as a system. A system is defined as a number of interdependent parts functioning as a whole for some purpose. Consider that an organization is established for a common interest, and exists as an entity that itself is a formalized group of people with one or more shared goals (Wikipedia, 2006).

If we conceive that the combination of scientific management (production level efficiency originations), behavioral management (people related efficiency origins), and general system theory (integration of systems origins), together these sciences represent the three key coordinates for a purposeful organization to exist. The outcome was to understand that the end result of combining these approaches was the discovery of an early “management system science” which today serves as the underlying fundamental to modern day management systems that seek to achieve minimum requirements, allocate and manage resources, control and measure, and strive for continual improvement.

1.3 Purposeful Organizational Systems

During the last century, organizations have become structured of three primary and related processes: assigning authorities reflecting responsibilities; motivating individuals and groups to achieve identified performance measures; and rewarding people through wages, bonuses, prestige, promotions and increased responsibilities (McWatters et al., 2001). Absent from the equation of many organizations is a defined continual improvement process within the organizational structure allowing for its management system to remedy identified deficiencies.

Most management systems have clearly defined components of expectation specifics. Organizations are provided, to name a few, guidelines for supply chain management, production management, storage and handling requirements, change control processes, document management, auditing, reviews, and corrective and preventive action management. It could be said that the aforementioned are the key components of any quality management system.

Elaborating on the subject of corrective and preventive action (CAPA), sufficed to say that inherent to any CAPA system would be the ability to focus on proper identification of the problem, investigation of the discrepancy, determination of its root cause and implementation of an effective solution(s), both remedial and long-term, so as to prevent recurrence (ASQ, 2000).

CHAPTER 2

ESTABLISHING ORGANIZATIONAL OBJECTIVES

2.1 Management by Objectives

Organizational objectives are targets to which a management system is directed. If an organization's input, processing, and output reach its organizational objectives, then the organizational purpose is justified. Accomplishing purpose means that an organization concerns itself with being efficient, productive, and profitable. In all cases, maximization is the underlying thrust, for it is natural that continued strides for improvement would gravitate to these essential objective characteristics.

When achieving organizational objectives is approached strategically, it is often referred to as management by objectives (MBO). However, in the context of modern management systems, there fails to be a direct correlation to the ever similar subject since many management systems that drive improvements are incorporated to an organization as a quality management system (QMS) and not given rise as a managerial program. The main commonalities of MBO and QMS are that organizational members develop objectives together. Both programs often generate elaborate documentation and defined written goals with careful communication of goals, detailed performance evaluations and increased paperwork to an organization. However, the advantages to implementation of both programs often outweigh the effort associated with work involved to coordinate the programs. This is because companies with defined objectives and targets to which there is direction and focus, along with analysis to assure achievement towards those goals, are usually able to accomplish their intentions and further, to pinpoint problems that prevent

them from reaching their objectives, thus satisfaction to achieving planned purpose outweighs implementation negatives. The key is to implement as efficiently as possible.

2.2 Objective Essentials

An objective must relate to organization purpose. Appropriate goals must be set. The quality management system will effectuate measurement and monitoring of organization goals in that the QMS defines a requirement to have defined quality objectives and that those objectives be additionally transcended into functional levels for purposes of comprehension and implementation.

Realistic objectives are understood to be achievable within specified time frames. Additionally, a well-defined objective will include the specifics as to how that objective will be measured, and over what time those measurements will be assessed. It is usually by the metrics evaluation that an objective is determined to be achieved or not (Certo, Samuel C., 1980).

CHAPTER 3

PROPOSED ARCHITECTURE OF A QUALITY MANAGEMENT SYSTEM

3.1 Improvement Needs Warranting Formal Science of Quality

It is said that in Total Quality Management (TQM), “nothing happens until you measure it” as scorekeeping is considered necessary to achieve improvements (Turban et al., 1999).

The philosophy of TQM is focused management for providing leadership, training, and motivational to continuously improve an organization’s management and product and/or service processes in order to satisfy internal and external customers.

The objectives of implementing TQM are to achieve defect-free performance, adherence to schedules, cycle-time reduction, and best possible costs. Distinct to TQM in comparison to other quality programs is its focus on processes rather than product or service along with its preventative effort approach rather than post product and service development, and lastly, its integration and involvement of all employees in an organization and not just those that are directly associated with the product or service delivery. TQM is a total organizational approach. Further, it is directed towards three key concepts:

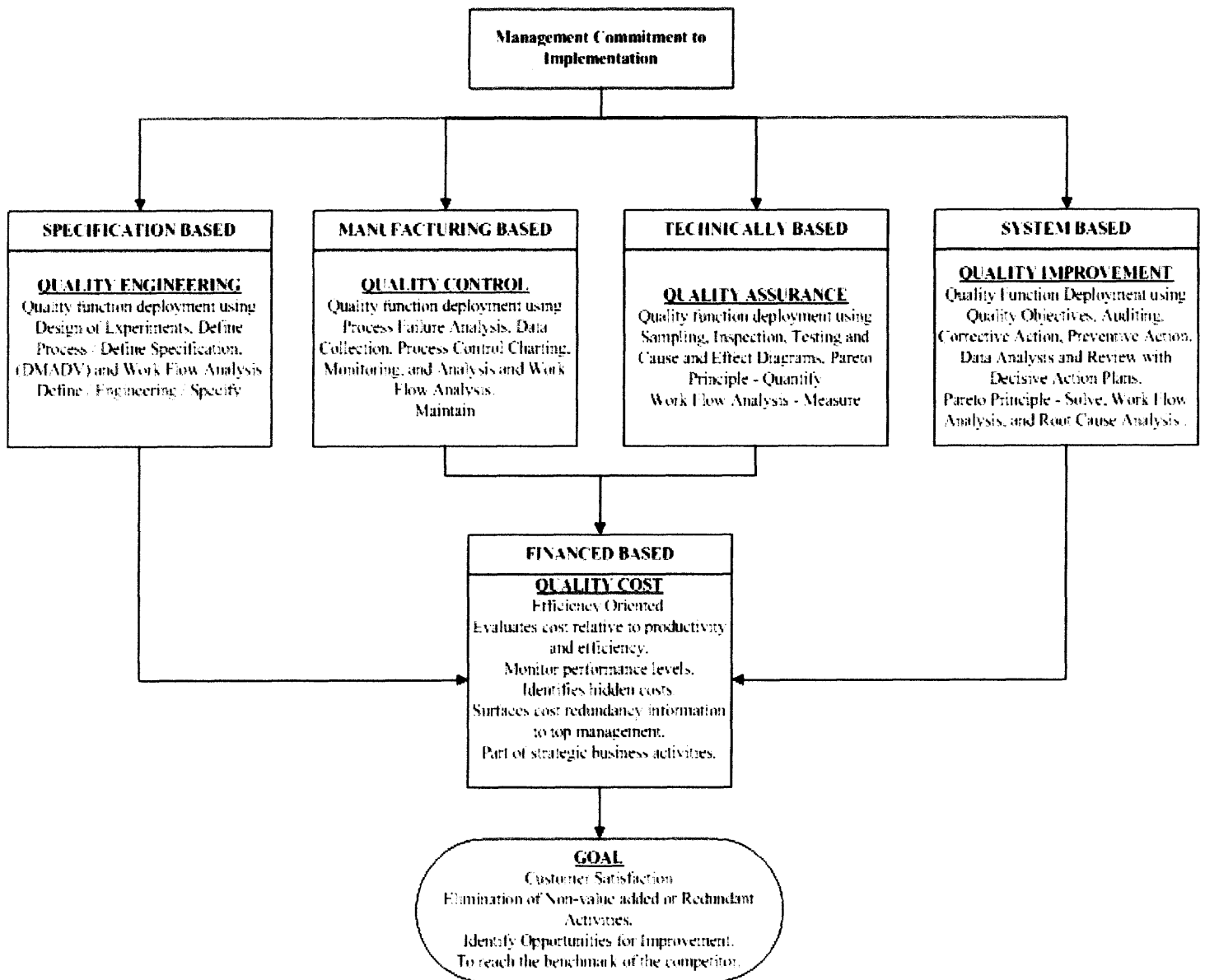
- Involvement – Total Organizational Approach
- Continual Improvement – Both Internal and External Productivity and Effectiveness
- Customer Satisfaction – Inherent to Success and Continuity

In working with this traditional approach to Total Quality Management, it is proposed that there be a new architectural design considered for effective management of quality in an organization through the integration of its various forms in an effectual manner. For purposes of this discussion, the concept of total integration of a quality management system initiative is referenced as a separate science, herein termed by the author as the “Science of Quality.”

The Science of Quality is best explained as a methodology to create a fully comprehensive integration and implementation of quality efforts that result in effectuating planning, managing, objective setting, controlling, performance measuring, and quality costs benefits analysis and improvement strategies.

The author concedes that the structure of quality in an organization would best be modeled as shown in Figure 3.1 below, which outlines where the thrusts of relevance and subject matter apply to the science. This proposed architecture for quality is comprehensive in that it demonstrates how and where quality related activities can be classified and how they can be functionally considered within an organization.

SCIENCE OF QUALITY



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Figure 3.1 Proposed Architecture for a Science of Quality.

3.2 Identification and Integration of Quality Science

An organization's continual improvement process can achieve great strides through the use of what could be considered five branches of the Science of Quality. The author further defines and stratifies that the Science of Quality be developed into specific branches relating to:

- Quality Engineering
- Quality Control
- Quality Assurance
- Quality Improvement
- Quality Cost

Given the requirements of internationally recognized standards along with the simple basis of meeting management objectives in the course of routine business operations, sufficed to understand that achieving productivity and performance levels with efficiency remains the goal since the early days of the study of management of science. Nearly 100 years later, those objectives remain the same. Options available to progress to achieving objectives are many. This research effort it is intended to review the various methods of the more effective and commonly recognized quality tools as well as advanced techniques that contribute to continual quality improvement to determine whether there is justification to support the advancement of quality as a stand-alone science.

This document explains where improvement methods may contribute towards achieving the objectives as shown in the form of a defined breakdown of categorical quality sciences, where the branches of quality are collaboratively integrated by networking quality into the relevant levels of a quality management system within an

organization. A selection process methodology as to what classification of subject is at hand might be achieved by first understanding the different branches and their primary disciplines and concentrations relative to quality, to which the reader may refer to functional applications information shown in Table 3.2 below.

Table 3.2 Proposed Science of Quality Functional Application Table

Quality Science Branch	Orientation and Description	Primary Basis
Engineering	Design oriented. Concentration of this branch relates to the contribution of quality into the aspects of product and/or service design, expectation, reliability, and life cycle.	Specifications based.
Control	Manufacturing oriented. Production and service processes must be maintained according to specifications defined at Engineering stage.	Manufacturing based.
Assurance	Management oriented. Provides for verification and compliance activities through application of sampling, inspection and testing to defined, expected, and understood parameters.	Technically based.
Improvement	Management oriented. Focuses on performance based metrics. Identifies inefficiencies and supports reduction of defects, errors, and returns. Eliminates non-value added activities.	Systems based.
Cost	Efficiency oriented. Evaluates costs relative to productivity and efficiency. Monitors performance levels. Identifies hidden costs. Surfaces costs redundancy information to management. Part of strategic business activity.	Finance based.

3.3 Discussion on Improvement Using Total Quality Management

An organization's continual improvement process can achieve great strides through the use of what could be management, objectives, controls, measurements, and change with one critical element of all facets being cost relevance.

TQM is modeled in a strikingly similar pattern as business strategic planning processes for design and for business process reengineering (BPR). The seven-step process for TQM consists of the following:

1. Establish the management and cultural environments.
2. Define the mission of each component.
3. Set performance goals.
4. Establish improvement projects and action plans.
5. Implement projects using improvement methodologies.
6. Evaluate performance.
7. Review and repeat.

One process that is critical to the effectiveness of TQM is continuous improvement which relies on performance measurements to detect where improvements can be made, both in the form of deficiencies that exist as well as in the form of measuring where improvements might be made by being proactive on already existing systems that might be improved by enhancements, or, by developing new systems that could potentially enhance performance.

Continuous improvement comes in many forms. For purposes of this discussion, the author selects an example that will draw upon the key concepts of TQM, previously explained above inherent to Involvement, Continual Improvement, and Customer

Satisfaction. The example to show how continuous improvement can be deficient and yet not understood as such would be as follows: Assume that a company formulated goals that had been planned without customer input(s), then a simple method of improvement would be to incorporate customer input. Industry uses a common phrase called “voice of the customer” and methods of listening or obtaining information relevant to the customer desires are many in that the voice of the customer can relate to fulfillment of contract requests or looking outward to the customer and trying to partner to find better ways to supply, support, or assist the customer in their unique needs. One might say how can goals be planned without customer input, yet this happens often when companies get involved in inventing or designing a product that they then manufacture and move to the marketplace. Once the produced item becomes available in the market, assume further that a customer goes into purchasing mode and this relationship remains the stable until one day the very same customer no longer buys the company’s product. Quite possibly, the customer then buys a similar product from a competitor, and perhaps it might be at a similar price and quality. One would wonder why, and based on what reason, that this could happen. Perhaps it could be learned that the buyer decided they needed one slight feature enhancement or a shorter shipping schedule, to name just a few possibilities. Perhaps had the original company in this example been able to be customer focused to learn what they might be able to do better to enhance their business relationship with that customer, they might have been able to accommodate and fulfill the need. This simple example is one that speaks to whether having a commitment to a total quality management system would have assisted. It is management system required that a company have commitment to customer needs and it a usual and common policy

statement that often speaks to being customer focused. Yet, without opening avenues of communication and without willingness to learn from the customer what exactly would enhance their satisfaction, such as through the use of the intentioned sections of the ISO 9001:2000 standard, the most commonly referenced and internationally recognized quality management system standard, there might be a loss of a potential to continuously improve because of the evident lack of implementation of being customer focused to enhance satisfaction as would be ordinarily required to be compliant to such standard (ASQ, 2000).

In TQM, we see the three business essential concepts quite clearly in this example and in QMS. We also see the identification of being required to practice the TQM essentials. What is lacking in both approaches of total quality management and quality management system standardization is clarify and definition on how to take the next steps in business and industry. Steps 4 and 5 of TQM say to establish improvement projects and action plans and then implement those projects using improvement methodologies. QMS say to continually improve using the QMS information. Both TQM and QMS say customer satisfaction is primary.

There are also other concepts of continual improvement that are known as excellence performance in processes methods which speak much about where to find places to further improve, such as focusing on giving value to customers by building excellence into all aspects of one's organization. The process excellence approach also looks to learn what is to the liking of customers, understanding what they need, and deliver it. This relentless pursuit provides numerous opportunities to continually

improve, both inward, by focusing on a company's own internal processes as well as outward, by focusing on the customer.

Issue is hereby taken by the author in that the standards that require management systems to address the two key essential items, that is, customer focus and enhanced satisfaction as well as continual improvement for excellence of processes, do not identify the means to proceed to these objectives (ASQ, 2000). This is where the SOQ further assists since it complements an understanding of how to proceed forward in improvement, based on and depending upon what the issue at hand actually is – engineering design related, process control related, compliance assurance related, enhanced improvement related, or cost effectiveness related.

Once an area is identified and understood utilizing the guidance of SOQ, the highest achievement oriented tools available would be recommended to methodically support and assist an organization on where it needs to go and/or define what it needs to do next, relevant to that specific subject. The guidance is in essence defining which branch of SOQ aligns with the issue and further, which tools align with that particular branch of the SOQ.

Industry today leans towards use of traditional tools, many of which were initially effective in their first generation of use, while more advanced tools are available. In Chapter 4, there is a discussion on strategizing towards continual improvement utilizing various toolsets. The use of SOQ in conjunction with both traditional and more modern methods of accomplishing improvement effectiveness is discussed. Learning the newer quality improvement tools is an essential for business today, if the desire is to remain competitive and intuitive on the demands made by customers. How we educate

on the SOQ is a separate topic, but consider how SOQ could contribute in a typical philosophical view that has been existing for the past five decades in manufacturing, understanding that it was the science of management as discussed in Chapter 1, that moved the subject of quality into this direction. The following is a typical situation: Industry seeks out quality control specialists to do the tasks of what quality engineers do best, design. By the same token, quality assurance specialists are tasked with controlling what quality control in manufacturing should be doing. Along the way, the quality improvement expectation and implementation effort often finds itself erroneously placed in the hands of quality control. Quality cost performance and benefits analysis queries why the assurance lets problems occur. The quality engineer believes the task was satisfactorily completed on their contribution to responsibility of quality product somewhere before production began and the quality assurance management is the likely place where general quality issues all center themselves to reside. In many cases, this approach, as well intentioned as it may have been, leads to chaos because the varied disciplines that all make up the science of industrial age quality is not understood by industry in a comprehensive manner as of yet, which is still a relatively new body of science, surfacing with the establishment and formalization of quality quantification performance standards, only in the 20th century, and focused primarily towards quantifying quality specifics (ASQ, 2001).

Briefly summarizing what has been stated to this point is theorem explaining quality as a science unto itself along with management of organizations relating quality as an aspect, and not necessarily a functional science. Additionally, quality management system implementation is understood to require management involvement. Standards

often lack direction on how to achieve improvement, yet require same, and a gap results in the inability to implement continual improvement effectively.

One of the best ways to demonstrate continued improvement is to identify a deficiency and correct it; it's an improvement. There is also not a routine method for how corrective action should be addressed. Most quality management system standards implementation call out for taking corrective action with the process identifying what is termed "cause" which the author determines when used in this context, asks for an implementer to investigate why the problem or deficiency occurred. Since standards do not define how to go about cause analysis, but critical to the success of corrective action implementation is a comprehensive understanding of how cause occurred initially, the use of toolsets for conducting cause analysis also vary, and are subject to interpretation. The methodology proposed for identifying cause of occurrence after it has happened requires a straightforward common sense approach. The discussion in Chapter 4 calls for logical thinking to attain continual improvement utilizing proposed toolsets to assist in sorting through the possibilities of occurrences of deficiencies in products and processes in order to reduce the likelihood of incident and deficiency occurrence.

This is considered by the author a more practical approach that could be defined as a best practice as to how to prevent incident. It is understood that incidents may occur, but to have at hand, implementation of a proactive means to prevent occurrence is more effective than awaiting the deficiency to happen, and then having the task of determining why later. Utilization of SOQ would not be a logical and/or feasible means by which to proceed since the object of SOQ is to identify where subject matter functionally resides so that it may be addressed by the respective area to contribute to the best possible

product, process, or service in advance of an occurrence. Thus, given that there is no best practice on how to continually improve, arguable it by implementation of SOQ utilizing effective toolsets that may come to define best practice on the subject of continual improvement. TQM is a discipline. The methodology to build TQM into an organization is based on a number of varying tools and techniques from diverse fields (Turban et al., 1999).

Organizations vary their methodologies based upon their relevant industries as well as their past experiences. Some of the more effective methods along with a description of what they each are and how they contribute to effectuate improvement efforts follow. The question to address is to ascertain which methods should be used in a traditional quality management system seeking to achieve continuous improvement.

Categorically speaking, TQM benefits an organization in that all become empowered and when administered correctly, that is, with the top-down approach and with complete management commitment, motivation is a general characteristic observed amongst employees.

Investments in training usually provide for their return to the organization in the form of efficiency, that is, doing things right the first time and effectiveness, that is, doing the right things.

One of the implementation approaches is known as the “A STAR” approach.

Accept TQM principles.

+

Structure the program.

Train the chain.

Activate the program.

Refine continuously.

For an incentive, there is the “WIN A PRIZE” element.

Willing to accept the room for improvement.

Improve the process.

Nothing less than commitment from management.

+

Accept the customer as the most important part of all processes.

+

Prevention emphasis, not just correction. Proactive emphasized, not just reactive.

Recognition and awards are necessary.

Interface with suppliers.

Zero error is the goal.

Employee participation is a must.

As can be seen, to embrace a program such as TQM, there becomes a spirited effort that promotes the program in many ways. This is addressed in the following section related to teams, as so much of an organization's success on improvement efforts will relate more to the team effort and management approach than to the technicalities of the quality related methods and tools to be applied for measurement, monitoring, and control, for when it comes down to the reality of a situation, it is in the definition, analysis, and improvement maintenance that a TQM effort succeeds, of which most of the initiatives in those capacities relate to people.

Therefore, it is appropriate to be noted that although TQM may be promoted as an enthusiastic seven-step process with many benefits to an organization, there are times when TQM programs fail. Some of the most common reasons for a TQM effort to not succeed are:

- Non-participation by management
- Lack of long-term commitment to the TQM effort
- Separation of TQM from the day-to-day business
- Employees viewed as problems instead of management or process (Stout, 1993).

3.4 Defining Team Support

Generally, the term “team” is used to refer to a group. Since a team consists of people that form a group, the functionality is such that the cohesiveness of a team results because the group has a common purpose. The group holds themselves accountable in that they collectively have a common interest. Some of the key elements of the group level interest are that members:

- Share responsibility to the end product
- Commit to a common approach to accomplish their work
- Independently manage their own individual responsibility while sharing towards the collective effort
- Collectively manage their relationships and representations outside of their organized group.

Effective teams can accomplish a variety of tasks depending upon their ability to be fast, flexible, and purposeful. Corporate teams today can take many forms, such as

management teams, work teams, and improvement teams, depending upon the interest to which they serve.

Project Teams are specialized. Members participate to a defined goal, and usually consist of resources that complement each other. Such would be the case for an improvement team or a problem-solving team. Work teams involve people who share responsibilities to complete a portion or a whole. There may be individual specialists within a work team or a cross-functional, cross-trained type of team where the members have learned each other's jobs. A management team represents different functions and processes and must coordinate its efforts and priorities for the overall system to operate efficiently and effectively (Oriel Incorporated, 2003).

3.5 Advantages and Disadvantages of Teams

Creating a team is more than designating team members with an assignment. Successful teams are also energized from a spirit of being contributory to a cohesive unit where everyone is pulling together to reach a common goals (Nelson, 1997).

Essential to a team is that there be empowered. To be fully empowered means to be able to make decisions that require knowledge. Availability of knowledge comes up as a concern since many people, by human nature, tend to hold onto knowledge by self insecurity or unrelated, knowledge is possessed by subject matter specialists so the issue becomes one of transferring the knowledge to the empowered team.

Empowerment is said to cause employees to perform better. Support tools for empowerment relate to the quality of work as well. Thus, a ramp up for team performance enhancement may require training people on its necessary skill levels.

Team training and functioning is an investment into a company's individuals with the hope to increase motivation, increase opportunities, and inspire creativity to support the efforts that lead to continuous improvement. Teams often are self-directed and may relieve middle and upper management from involvement in certain tasks, allowing them more time to address other issues. It is also said that teamwork increases employee loyalty, reduces turnover, absenteeism, and illness as employees participate with increased pride and self-respect, which results in increased productivity (Turban et al., 1999).

CHAPTER 4

STRATEGY FOR CONTINUAL IMPROVEMENT

4.1 Discussion on Continual Improvement Strategy

Strategies for continual improvement are many and the type of improvement tools vary widely; much of this is because of individual interpretation(s), knowledge, industry exposure, and organizational planning and commitment variables.

By definition, continual improvement of a quality management system is to increase the probability of enhancing satisfaction of customers and other interested parties. Actions for improvement are inclusive of analysis and evaluation of existing situations to identify areas for improvement. Examples elaborated upon in this paper are limited to those that reach directly to the defined subject matters of improvement that are inferred in this definition; establishing objectives for improvement, searching for solutions, evaluating possible solutions to make selections, implementing selected solutions, measuring, verifying, analyzing and evaluating results of the implementation, and formalization of changes. Results are continuously reviewed. Further opportunities for improvement are continually determined. The cycle is such that feedback and continuity of an information and data gathering loop, analysis methods, and decision making are all indicative of a vibrant continual improvement process within an organization (ASQ, 2000)

Philosophies vary widely on the subject of quality improvement and the subject of error-proofing to the degree possible and it was W. Edwards Deming, often referred to as the father of quality, that encouraged companies to cease reliance upon inspection to cause quality instead to become an improvement process and instill quality from the

onset. The concept intended was for companies to prevent the nonconformity. However, where a quality management system is not capable of this, then it should at a minimum be set up to detect and contain the nonconformities, preventing further processing and/or shipment of nonconformities (ASQ, 2002).

An effective effort towards strategizing for continual improvement can be better understood using an approach that combines critical initiatives. First, products and processes have basic, fundamental, and specific requirements that must be met in order to achieve customer satisfaction. There are four (4) fundamental essentials that would be considered part of a TQM methodology and can be clearly distinguished utilizing SOQ concept analysis. The tools recommend are already proven successful in the market and are a four-step process by which a company can achieve total quality management, process control, and continual improvement benefits, utilizing methods (Ranky, 2006) as follows:

1. Process Mapping utilizing CIMpgr;
2. Component Oriented Requirements Analysis (CORA);
3. Statistical Process Control (SPC) utilizing process control and control charts;
4. Process Related Failure Risk Analysis (PFRA).

These four (4) tools are each explained below:

1. Process Mapping utilizing CIMpgr: The CIMpgr process mapping method is a process which can more specifically be defined as a thorough process modeling system with defined coordinates for each step of a process. The following Figures 4.1.1 through 4.1.4 elaborate on process flow to include parameters for the four (4) sides of each activity, termed I (Input), O (Output), C (Control), R (Resource). The

idea is that each process has a relevant input that yields an output. However, each process also has limitations associated with its activity by its controls and its resources. One of the most overlooked aspects of process mapping and process flow analysis is the concurrent activities being conducted in an organization simultaneously. While concurrent engineering addresses this subject to a degree and projects management understands the method of multiple tasks simultaneously occurring, the quality function deployment into cross-functional areas is another means by which an organization can continually improve itself. Figure 4.1.4 provides a conceptual process layering view of the primary processes, secondary, and multi-layered integration of processes. This is a view that provides management a concise understanding of situational occurrence that could potentially be improved when implemented.

Given that integration of quality is part of a collaborative networked total quality management philosophy, it seems only natural that process flow analysis be a movement that would strategically address the various areas where deployment of quality support would be warranted.

Figure B.1 as shown in Appendix B provides a view of concurrent process engineering occurrences in an organization.

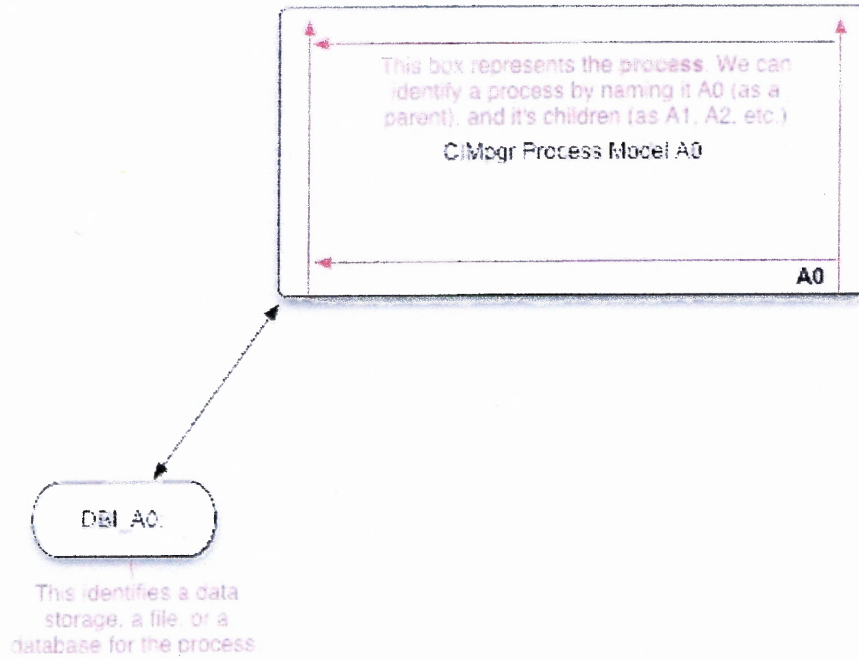


Figure 4.1.1 CIMpgr Process Activity Box Example.
(Source: Ranky, 2006)

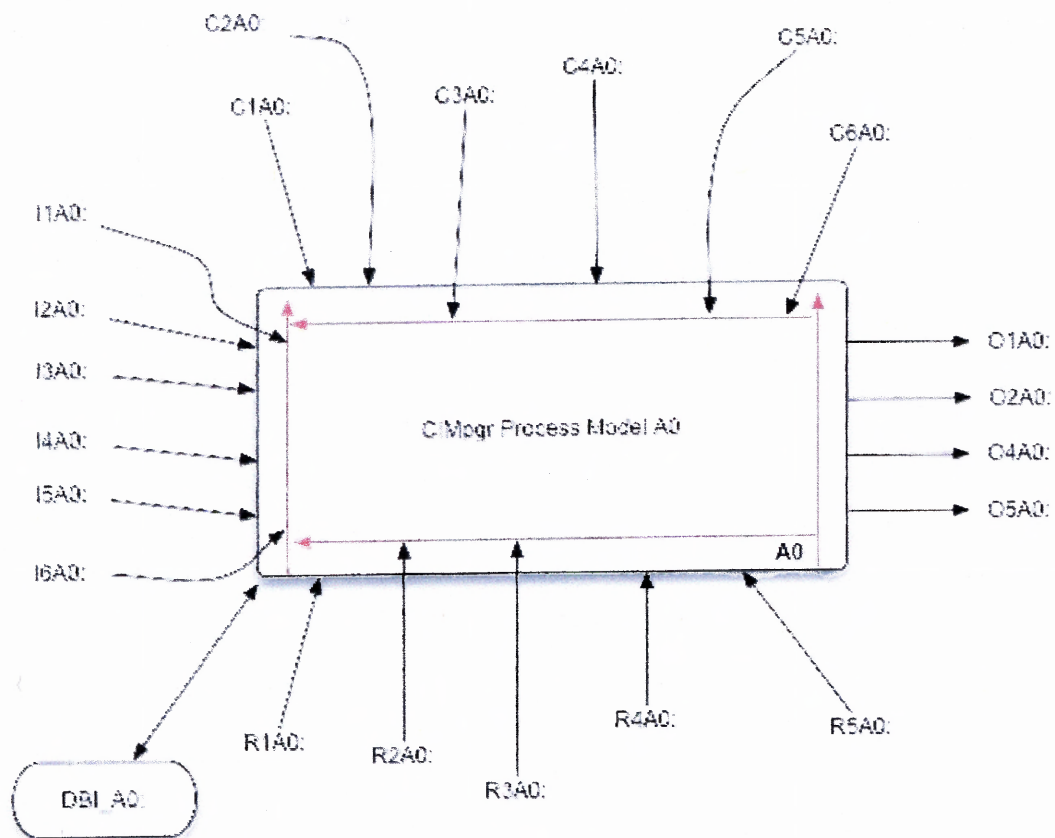


Figure 4.1.2 CIMpgr Process Activity Box Example Showing Parameter Directions.
(Source: Ranky, 2006)

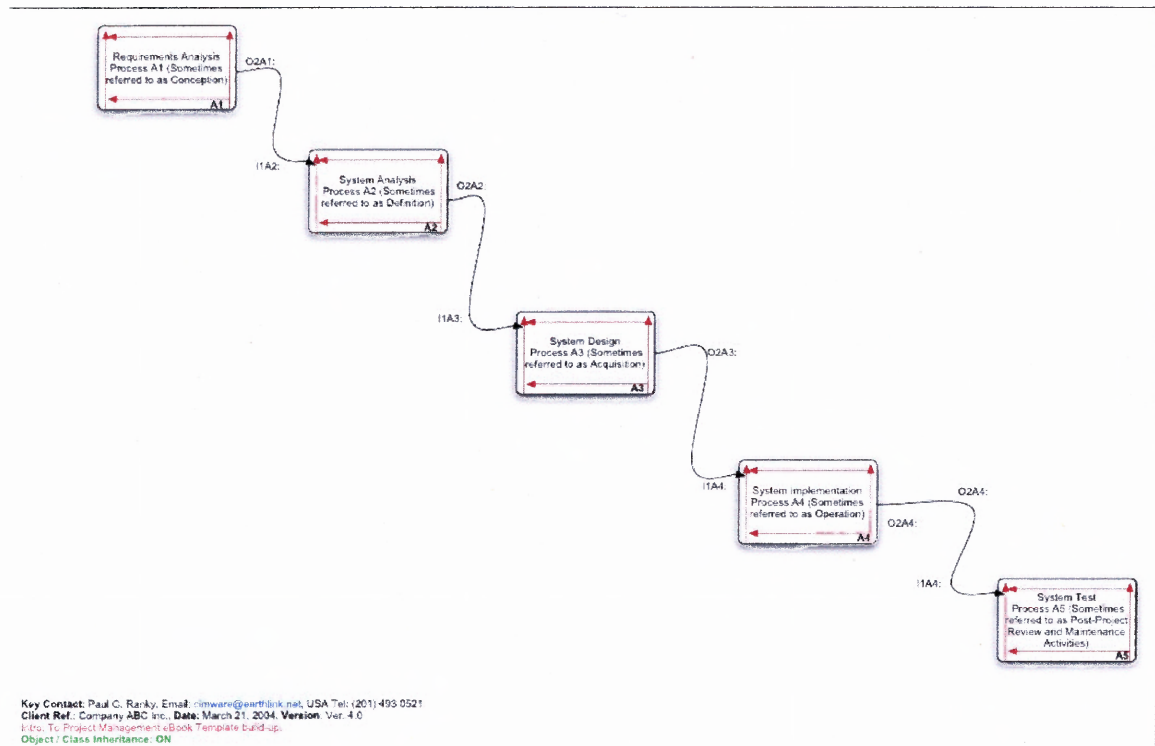


Figure 4.1.3 CIMpgr Process Activity Box Example Showing System Process Flow.
 (Source: Ranky, 2006)

Complex CIMpgr process models are layered for simplicity. This process (or in other words object, or class) hierarchy example consists of Layers 0, 1 and 2; with a possible extension of Layers i, j, ...etc.

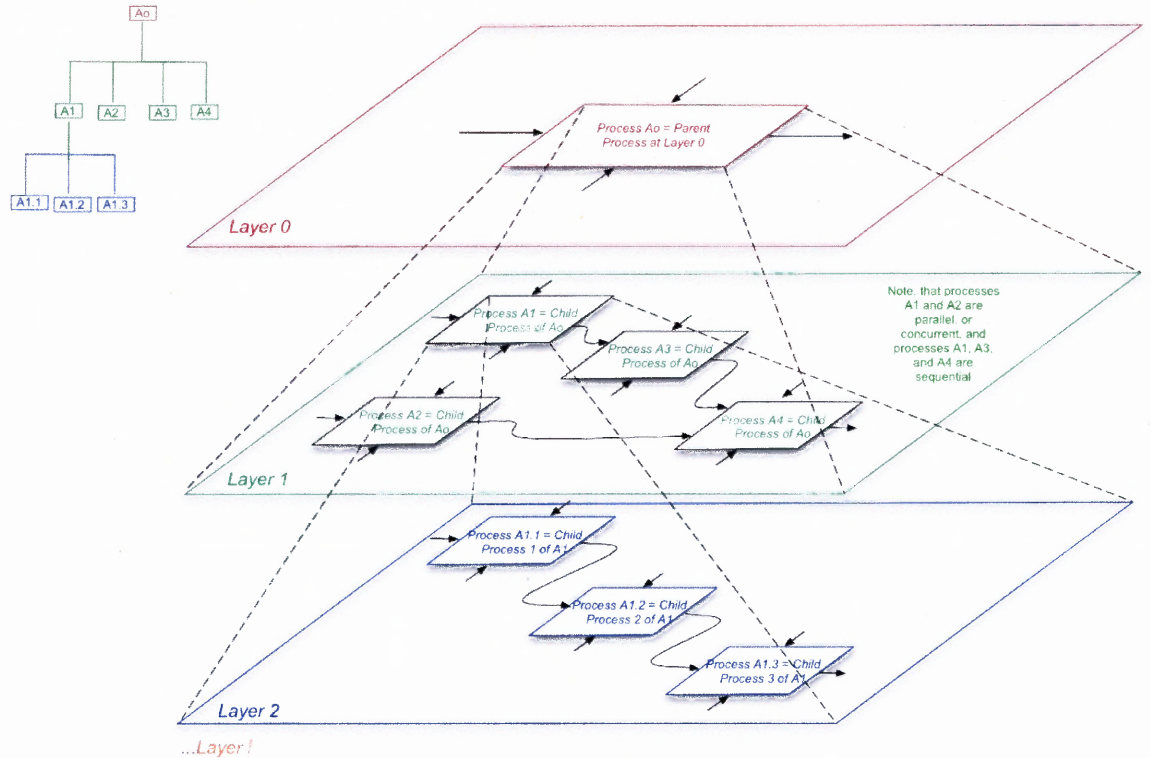


Figure 4.1.4 CIMpgr Process Activities Layering.
(Source: Ranky, 2006)

2. The Component Oriented Requirements Analysis (CORA): The Component Oriented Requirements Analysis is a method where one can focus attention to various criteria that become relevantly weighted to be considered. The objective is to minimize dissatisfaction by customers and simultaneously assist in providing solutions methodology for identified issues.

CORA is a customizable spreadsheet developed by Dr. Paul G. Ranky for purposes of prioritizing quality function deployment (QFD). The CORA spreadsheet provides for a systematic method to assess specific customer requirements. The CORA

spreadsheet is preformatted in Excel. The document integrates user needs, engineering considerations, and computational calculations for benchmarking a situation and/or feature in comparison to a competitor. CORA is a matrix type methodology. The preformatted spreadsheet and matrix asks for relationship levels of Low, Medium, or High importance with assigned levels of 1, 3, and 9, respectively. Given that the intention is to have a high level of customer satisfaction with the end product design and/or service, the key point is to provide a traceable path of how certain elements were considered in the early stages of the product development cycle and addressed in a relevant order of priority. The priority numbers of 1, 3, and 9 assign importance of the relationship, respectively. Those are the fixed numerical numbers assigning level of importance. Those numbers are programmed to calculate relevant scores of the importance of the requirements. The importance ratings are the scores that are calculated to benchmark and/or compare values relating to the final product. Importance rating values are usually between 1 and 5, 5 being the most important.

The QFD / CORA methodology distinguishes between two different importance ratings, one for customer priority needs, the other how our company could satisfy those needs, and at what technical level. This is shown within the spreadsheet calculation summary. Parameters are identified by criticality and their acceptable range levels are provided for. A typical in-depth QFD / CORA analysis and study consists of four (4) major phases as follows:

Phase 1 - translates the customer expectations to design requirements. This phase is dominated by how market research is turned into design specifications.

Phase 2 - translates design requirements into critical part characteristics. This

phase requires accurate estimation of weighting criteria.

Phase 3 - translates critical part characteristics into critical process parameters. This phase identifies where increased controls and monitoring would be appropriate.

Phase 4- translates critical process parameters into project planning and production requirements.

Each of these phases provides information for the next level, which is then prioritized to show the key requirements. CORA is an intelligent and systematic approach to generate solutions with priorities to achieve customer satisfaction, both internally and externally. CORA supports an organization's ability to understand how to develop critical process control points, process stability, process performance targets, and focus on reduction of variability of its processes. These are practical and important priorities to an organization implementing the principles of Total Quality Management.

Analysis of CORA spreadsheet information reveals how planned product rated in terms of comparison to objectives by assigning a parameter value. Continued thinking on the information generated from a CORA activity is to assess factory capabilities, quality control, quality assurance, and product conformance. These four parameters naturally become directed to an overall system process and trigger further requirements and expectations relevant to the supply chain. An example of a CORA problem is shown below in Figure 4.1.5 below where the quality function deployment indicators, at the end of the exercise, and upon interpretation, related to prioritizing production planning, product design, and quality control (Ranky, 2006).

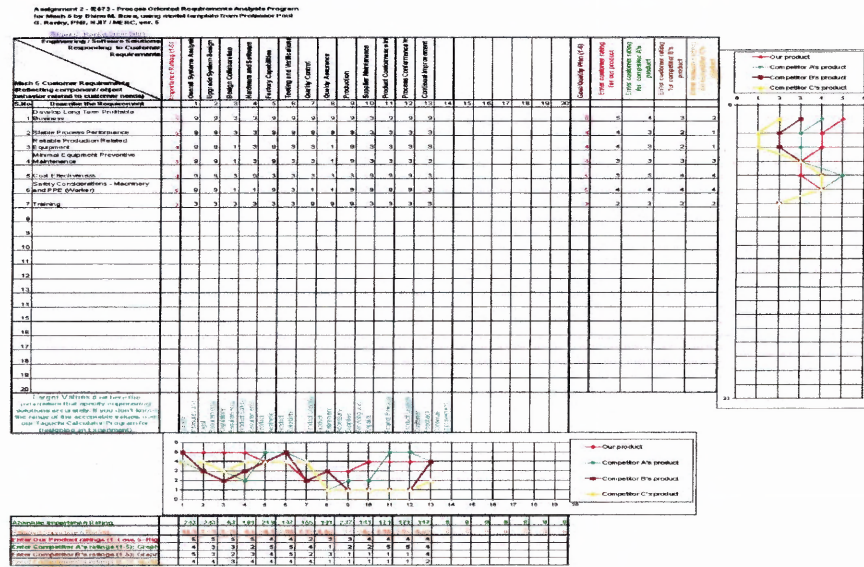


Figure 4.1.5 Example of a Component Oriented Requirements Analysis.
 (Source: Ranky, 2006)

3. Statistical Process Control (SPC): The use of SPC is a process control method and utilizes both statistical process control charts and statistical control charts. The most common maintenance of a process is through the use of control charts that record and index data points. In order to understand a process capability, an organization must rely on techniques to understand the process. Usually, organizational management consults with the personnel responsible for the process and reviews what is known as a control chart. This may sound like a simple activity, but inherent to this activity is an understanding that accurate and reliable techniques are in place to support this effort and that communication is open with the responsible manager(s). Oftentimes, analyzing data that control charts reveal is inhibited because of inaccurate maintenance of the control charts. It is a most common problem within industry to find both misinterpretation of and/or incorrect usage of control charts

Control charts should assist and enable management to have a clear picture of the process situation at hand. Data collection and its review process should be aided with statistical methods that simplify the situation to understand the status of variation, and to define variation as either common cause or special cause. Managing this analysis stage requires effort to realize that in all cases, without exception, special cause variation must be addressed. Without such understanding and commitment, the reliability of the statistical control that has been achieved and represented, along with its standardized capability index that is computed based on the process performance, would be compromised.

The origin of studying process data began in the 1920's at bell Laboratories, while studying data; a distinction was made between controlled and uncontrolled variation due

to what we now call common and special cause variation. To separate the two, Dr. Walter Shewhart developed the control chart, which has been successfully utilized in industry since its introduction at Bell Laboratories.

Control charts were found to be able to effectively direct attention toward variation by plotting data points according to a plan that would substantiate logical groups, streams, or statistically based samples. These data points would formulate control limits to serve as a basis for interpreting the data for statistical control. Once a process is in statistical control, it can then be interpreted for process capability. Effectuating improvements in process control and process capability requires that common and special cause variations be identified and addressed, the process modeled again after correction, and then beginning the cycle of analysis once again with more data being gathered, interpreted and used as a basis for action.

Based on the data collected, trial controls served as limit data. A chart was drawn to serve as a guide for analyses. Keeping in mind that control limits are not objectives, nor are control limits specifications; they are simply based on the process as recorded, and including the process's natural variability. Utilizing a sampling methodology, data collected were compared to the original control limits established to see whether variation appeared and if so, did such variation derive from common causes. If so, the process, considered as stable, continued, and if necessary, the control limits adjusted after recalculation.

The idea of sampling and recording utilizing control charts is to take periodic samples of a process, determine if the averages of those samples cluster, level off, or vary unexpectedly. The control chart is essentially a means for determining and signaling

when the process level has actually shifted to a new level based on variation of sample results.

Observations are collected in what are called rational subgroups, and maximized to show the source of a change in the process. The Shewhart chart consists simply of three parallel lines: two outside lines, called upper and lower control limits, and a center line. In practice, sample results are plotted on the chart in sequence. The center line reflects the average of the data, while the control limits are calculated to have a high and low, upper and lower control limit established based on the plotted data not falling outside the limits that are established. It is then considered that the process is running as expected. In some cases however, the process is running at a level that points the plot outside limits in a favorable direction or outside desired expectation limits, which are both causes for initiating process improvement methods to curtail further process instability.

Process capability has been defined by one of the early gurus of quality, Joseph Juran, as follows; "Process capability is the measured, inherent reproducibility of the product turned out by a process."

A control chart, in control for twenty to thirty samples, is generally considered to be evidence of a stable process. Charts out of control, that is, with points outside the limits, are indicative of lack of stability (Schilling).

No discussion of SPC would be complete without explanation of the fact that a process is said to be operating in statistical control when the only source of variation is a common or natural cause. Thus, once a process is understood to be at a specific statistical level, it is implied that variation from special causes has been detected and/or

eliminated. This makes for the SPC to be performance predictable and capable of meeting expectations. The object of the process of executing SPC is to provide the statistical signal when assignable causes of variation occur, so that reactive measures can be taken to eliminate detected problem.

The terms natural variation and assignable variation are utilized in this discussion and are best explained as follows:

Natural Variation – are those occurrences that affect almost every process and are considered to be expected. While individuals cause for the variations may be different, as a group, natural variations form a pattern that can be described as a distribution. The distribution is characterized by two points – the mean (the average value) and the standard deviation (the measure of dispersion).

Assignable Variation – are those occurrences that can be traced to a specific reason. In order for a process to remain in process control, it is necessary for assignable variations to be identified and eliminated.

Control charts most certainly help distinguish the difference between natural variation and assignable variation. There are two types of control charts to assist us with SPC, and they are briefly explained as follows:

- **Variables Control Charts** – Since variables are characteristics that have continuous dimensions, they have an infinite number of possibilities, so the control chart has an average (mean) or \bar{X} (x bar) and a range of continuity or R which are used to monitor the process. The \bar{X} tells when changes occur in the central tendency (the mean of a process) while the R tells if a gain or a loss of dispersion has occurred.

- **Attributes Control Charts** – Since attributes are usually relevant to defective or non-defective, and attribute points involve measuring defectives, or counting them, there are two distinct types of attribute control charts known as P-Charts for measuring the percent (%) defective in a sample and C-Charts for measuring the quantity count (#) of defects. An example of how an attributes control chart for fraction non-conforming (P-Chart) is shown in Appendix C. An example for an attributes control chart for number of defects (C-Chart) is shown in Appendix D.

Managers need accurate information. Managers rely on the subject matter experts. Numerous methods exist to provide management systems and the relevant personnel accurate measuring systems, statistical methodologies, data gathering tools, and mathematical calculation efforts. It is within the implementation of the basic fundamentals of process control, that management systems can provide valuable and useful information for decision making purposes.

The subject of analysis and improvement requires that special causes be addressed, that the process is knowingly achieving its expected statistical control, and it is often the basic control chart that serves as the monitoring tool. Process capability can also be continuously monitored through this method, with a watch toward excessive common cause variation. Should processes not produce consistent output to its achievable and expected limits, the process itself must be investigated so that management can take action to improve the system to achieve customer requirements.

The easiest way to accomplish monitoring, analysis, and improvement of a process is through long-term evaluation of process performance through the use of

reliable and accurately maintained control charts, defining process control limits, expectations, variations, and capability (Automotive Industry Action Group, 1995).

When data is plotted on individual process control charts, it is important to know what type of chart one is evaluating and to understand that an X-Bar Chart is relating to the sample means being plotted in order to control the mean value of a variable while an R-Chart is being plotted in order to control the ranges of a variable.

Control charts for variables are concerned with quality characteristics being measured on a numeric scale and the most important goal becomes maintaining control over both the process mean and its variability. Examples of generic directions for constructing a control chart are shown in Appendices C and D for P-Charts and C-Charts respectively.

4. Process Failure Risk Analysis (PFRA): The use of a component oriented process failure risk analysis method is a means to ensure identification of potential quality failure risks. PFRA is a team oriented problem solving method which when applied during the planning stages of a project can be a primary tool to minimize problems associated with process related failures. Once again, the use of a preformatted spreadsheet is implemented. While PFRA is focused on being analytical, it is very much a quantitative methodology. It supports the team approach in that is of value to the planners, engineers, product managers, line personnel, and management collectively. PFRA is both qualitative and quantitative and offers the team the opportunity to brainstorm on various aspects such as high risk processes, failure prevention methods, maintenance and plant operations facilities issues, equipment methodology, training, risk reduction efforts and costs associated with the possible non-prevention of risk. Although PFRA is useful when

applied during the planning stages of a process, it is also very effective to periodically update the PFRA to keep it current and as a regular method to document and evaluate product and process changes. See Figure 4.1.6 for an example of a completed PFRA spreadsheet.

Process ID	Describe the Process for Each Process Step and Optionally Illustrate the State of the Device/ Part/ Subassembly/ Object AFTER the Process is Complete	Specify the Tool(s) Used in Each Process Step	Spec...
1	Examine strap mounted plastic hook on RHS	Adult human hand and eye	
2	Examine briefcase mounted hook on RHS	Adult human hand and eye	

Figure 4.1.6 Example of a Process Failure Risk Analysis Tool.
(Source: Ranky, 2006)

PFRA is primarily concerned with potentialities; it attempts to identify and address items that would result in negative quality of a product or process. The approach is component-oriented, meaning that it is an analysis of product and/or process on a step by step basis as found in and based upon information from the aforementioned object-oriented process modeling method, CIMpgr.

Relevance to product reviews and evaluation of bills of materials is a common use for the PFRA tool. Relevance to review of processes and evaluation of individual work steps is common. The focus is to drive down into the specific elements and components

that make up the products and processes. The idea is to analyze issues as a team so as to define potential problems that could result in a product and/or process failure, and to address them utilizing this analytical, quantitative, computational tool. Through the team approach, the problems break down further with the input and expertise of the relevant problem solvers so that solutions can be generated, ideally, in advance of the incidents occurring.

Routine use of PFRA at the start of a project and then routine follow-up use of PFRA throughout a project's lifecycle can lead to benefits of continued improvement. Collectively, engineers, line managers and process operators work to identify and solve problems together thinking through them to see what solutions they can come up with, and then apply their collective problem solving skills to tasks. Questions that the team asks routinely of each other relate to understanding the possibilities of what might go wrong with a product or the processes either in assembly or disassembly. The same question could be asked relevant to the process, that is what could go wrong with set-up or execution of a process that could be potentially prevented by brainstorming prior to implementation or at installation, or routinely thereafter. The idea is to prevent failure and reduce risk of failure.

To summarize, the positive of the PFRA tool is that studies can be conducted to solve problems before they occur. This offers the benefit of ongoing improvement and/or enhancement to a product or process early on, at the concept stage, by invoking the collective minds of personnel to assist in choosing the most appropriate technology and infrastructure to support the products and processes that might otherwise go undetected in traditional quality function deployment that does not incorporate such a comprehensive

and integrated preventative approach. Figure 4.1.7 shows depicts a Venn Diagram using the combined methodologies of Requirements Analysis, Process Analysis, and Risk Analysis, surrounded by the outer circle that encompasses technology, both legacy and modern, based on technological advancement, but with the idea of showing statistics, measurement, and technological support to the analysis tools to provide a feedback controlled architecture system.

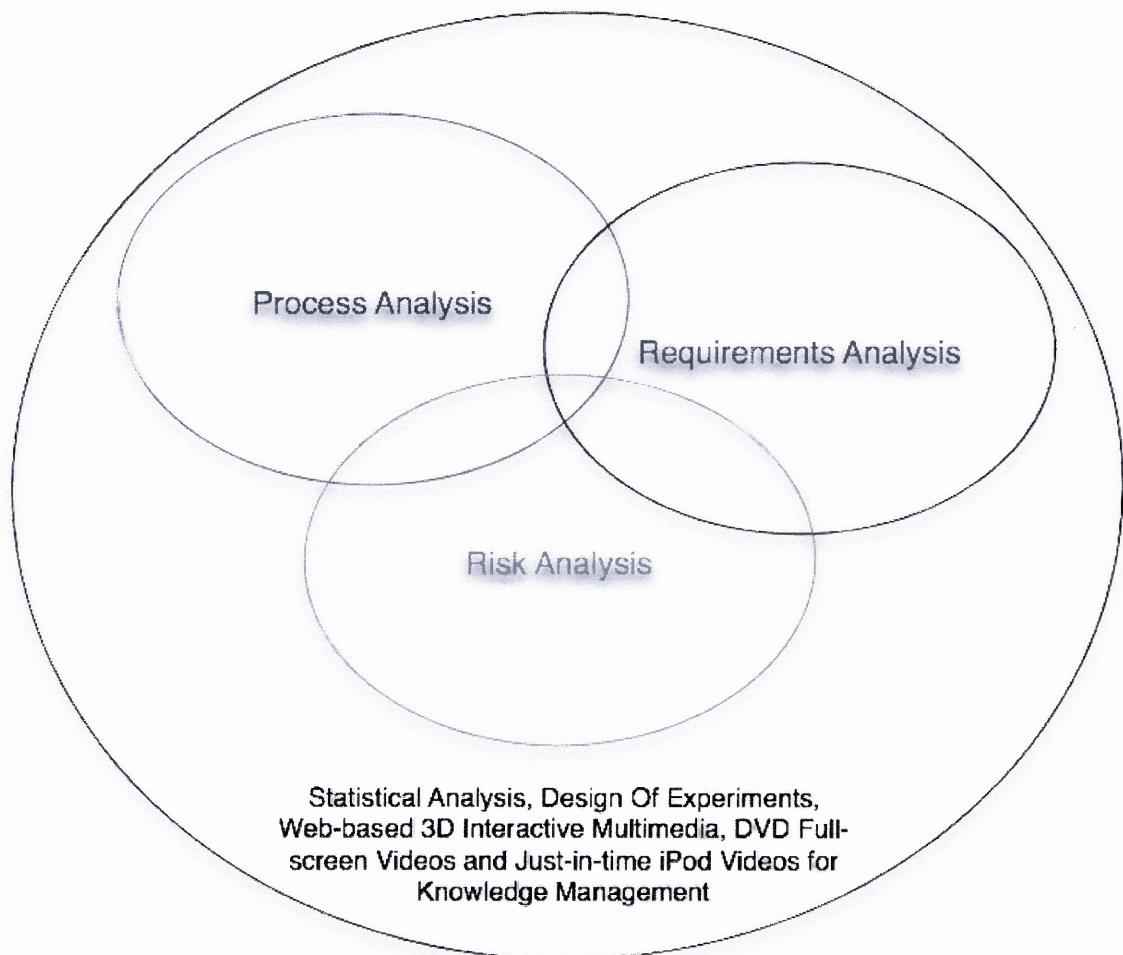


Figure 4.1.7 Venn Diagram of Analysis Tools Complemented by Statistics, Measurement, and Advanced Technology.
(Source: Ranky, 2006)

4.2 Commentary on Benchmarking

Benchmarking compares an organization's performance by some specified measurement to that of another. For example, benchmarking is often used to compare either performance as it relates to that of one's competition, or perhaps to one's current level of performance versus one's desired target performance. Imperative to successful benchmarking is to accurately construct facts. Data collection, data validity, and data sources must be reliable.

Database services support benchmarking accuracy by providing services that are able to compare an organization to others in its industry, industry sector, and company size. It should be noted here that benchmarking has its drawbacks in that some organizations resist its relevance and applicability to their company and/or industry. There is also an underlying concern related to the findings being insightful enough to recommend change which could potentially be resisted (Kerzner, 2006).

Management analysis of data gathered in the benchmarking process must be steadfast and realistic. Consider that if benchmarking is a comparison of one's operation to the understood "best-in-class" then the goal implied is to beat the "best-in-class" or at a minimum, to excel beyond the organization's current level of productivity or performance, to aspire towards a level that brings one's company closer to the top performer. It is not until you outperform the "best-in-class" that you "become" the benchmark (Stout, 1993).

4.3 Process Control and Process Improvement Cycle

The discussion on the subject of continuous improvement would not be worthy without explaining the relationship of the stages shown in Figure 4.8 below. Consider that all processes are subject to improvement somewhere in this cycle so as to recognize that analysis of a process requires understanding what a process should be doing, what can go wrong to or vary the process, and what the process is doing at a moment in time.

Management is oftentimes challenged to maintain its routines when other non-routine occurrences arise. The implementation commitment to process control is the primary element of maintenance of any continual improvement program that is expected to be effective. Further, what is considered to set successful companies apart from others is having both total control of an entire process from start to finish as well as total integration of quality controls (Graves, 2006).

The cycle of continuous analysis of information to this aspiration is necessary and can be best represented using a diagram example of how the pursuit must be ongoing. It is variation and inefficiency that often causes counter productivity, and the general management principle of "Plan, Do, Check, Act" is required continuously to move toward becoming the benchmark (Kelley, et al., 2001).

Figure 4.3 shows the stages of a continual process improvement cycle by analyzing processes, monitoring and maintaining process, and ultimately improving processes, only to continuously repeat the cycle. Key to the example of continuous process improvement is the indicator that in all phases, statistical control, process monitoring, and understanding of variation is considered essential.

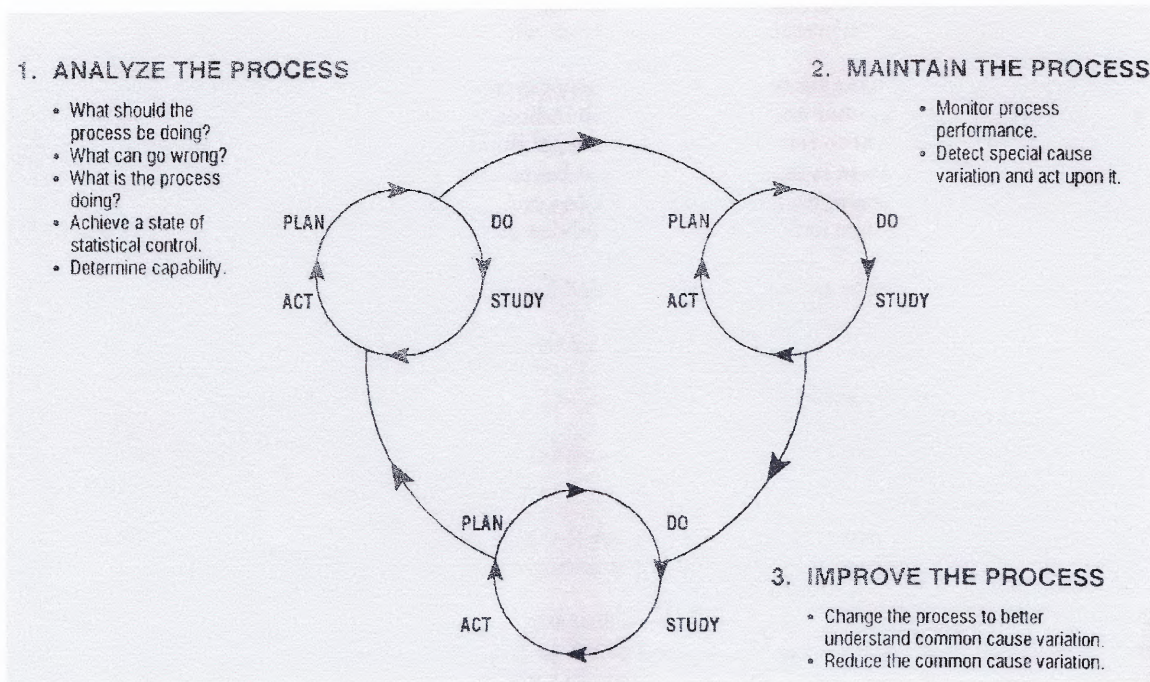


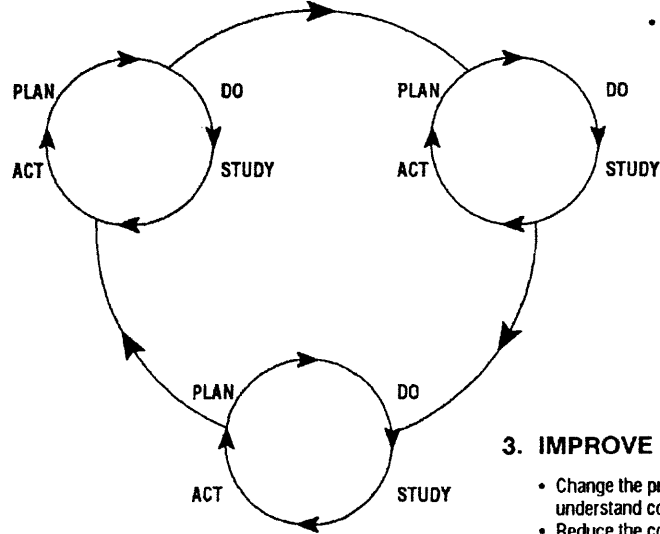
Figure 4.3 Stages of a Continual Process Improvement Cycle.
 (Source: Automotive Industry Action Group, 1995)

1. ANALYZE THE PROCESS

- What should the process be doing?
- What can go wrong?
- What is the process doing?
- Achieve a state of statistical control.
- Determine capability.

2. MAINTAIN THE PROCESS

- Monitor process performance.
- Detect special cause variation and act upon it.



3. IMPROVE THE PROCESS

- Change the process to better understand common cause variation.
- Reduce the common cause variation.

Figure 4.3 Stages of a Continual Process Improvement Cycle.

(Source: Automotive Industry Action Group, 1995)

4.4 Discussion on Cause-and-Effect Diagrams

Cause-and-Effect Diagrams are commonly referred to as Fishbone Diagrams, because of the analogous shape to the skeleton of a fish with a head, spine, and bones, or, Ishikawa Diagrams, named after the developer of this tool. The Cause-and-Effect Diagram methodology is used to clearly understand what is considered a possible problem so that you can investigate the causes associated with that problem.

A Cause-and-Effect Diagram is constructed in a simple manner and is best used when a specific problem has been initially identified so that possible causes can be explored and understood along with the relationship of the focused causes. One caution to emphasize is that causes are not data and the causes proposed should be considered possibilities, opinions, or theories, but not data until proven later through a data collection plan. Collection of good data is essential to support the effective use of a cause and effect diagram so as to narrow the focus of the problem and verify possible causes.

Figure 4.4 models the Cause-and-Effect process diagram and its acronym. The purpose of using the model is to identify causes and construct the problem in the form of the “fishbone” to a five-fold method of investigation as follows:

The Head – Represents the focused problem under investigation.

The Large Bones (Spine) – Represents the primary possible causes and their relation to the problem.

The Smaller Bones (Fins) – Represents the specific possible causes and their relation to the problem.

In relating the possible causes and their relationship, the construction of the diagram is such that the large bones are categorized into four (4) distinct areas,

sometimes referred to as the 4M's: Manpower, Machines, Methods, and Materials. Administratively, it is often more helpful to use the 4P's: Policies, Procedures, People, and Plant. Cause-and-Effect diagrams create a quick visual of the likely instances of problems and it is evident through the constructing of a cause-and-effect diagram that problems become broken down into component parts to be solved incrementally. The actual activity of constructing the cause-and-effect diagram involves asking people to think through the possible causes of a situation, relevant to each area – people resource related (manpower); process methodology related (methods); components and raw materials (materials); equipment considerations (machinery).

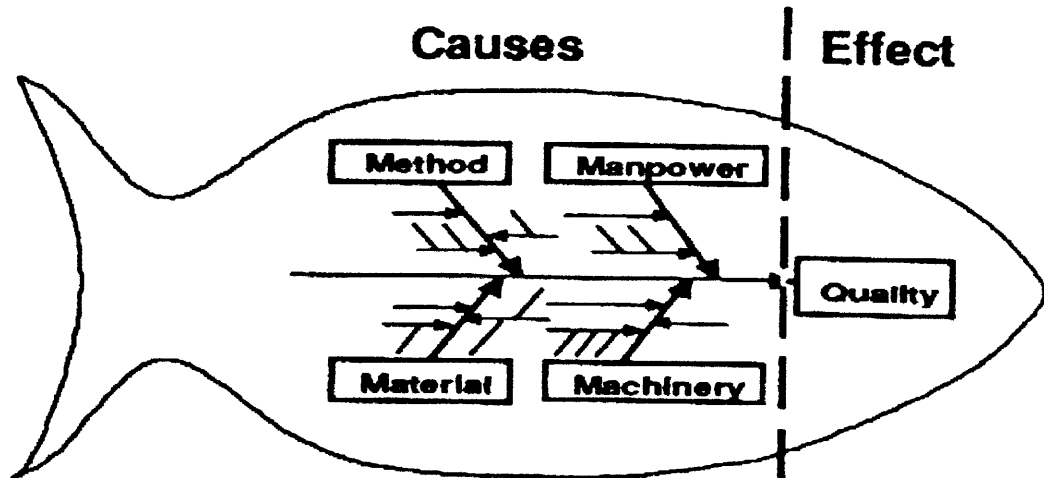


Figure 4.4 Cause-and-Effect “Fishbone” Diagram.
(Source: GOAL/QPC, 1988)

The term brainstorming is invoked to reference this think activity. Team efforts in brainstorming can be accomplished through the use of a facilitator placing the brainstormed ideas into appropriate major categories (large bones) and then asking for the cause of why it would happen, then listing onto the branches (smaller bones) those responses. Another option outside of the team brainstorm effort is to circulate questions

and have them returned to a facilitator to coordinate responses and examine the process further. Nonetheless, it is interpretation that is the next step. One must look for causes that recur and reach consensus, or gather data to determine relative frequencies of the different causes to better assess a situation. (GOAL/QPC, 1988).

As can be seen by utilization of the Cause-and-Effect diagram, the query as to why, what possible reasons, what possible modes, what effects, we realize that we can logically determine causes. If problems have been identified, the next step is to quantify the information in a simple and understandable manner that can show the problems needing to be solved. The next section provides one of the most user-friendly methods to identify, quantify, and begin a very important process of correction and/or prevention.

4.5 Discussion on Pareto Charts

Collected data can be focused upon by proper categorization and interpretation of its meaning. The Pareto Chart is a traditional summation of data showing a series of problems by their varying level of occurrences, and also summed in their entirety.

Constructing a Pareto Chart is only a first step in understanding a problem. The second step is to correctly interpret the chart and then implement a plan to address the particulars. An example of this very subject is demonstrated in Figure 4.5.1 where an example of gathered data is shown to be grouped by type of injury, but then further broken down into the reasons, causes, as to why those injuries occurred; the further data analysis is shown in an additional Pareto Chart, stemming from the original information (injury data). The purpose for selecting an example such as this is to simply show what management needs to do when problems are identified, and quantified, and that is, to get

to the root cause of the problem so as to address the particulars and not only “cure” the symptom. Quality management systems can benefit by utilization of very basic principles towards improvement that do not require extensive calculations, more so, good problem-solving skills and corrective and preventive action management.

Cause-and-effect diagrams generate the queries that ask reasons as to why situational problems are occurring so that management can consider the options to correct the identified problem(s). The Pareto Chart provides a simplified means of quantifying and stratifying data in a summary fashion. Some people refer to Pareto Charts as histograms of calculated and quantified information. A second example of a Pareto Chart is shown in Figure 4.5.2.

It should be noted however, that it is only in the use of data for further benefit, such as corrective or preventive measures, that it is considered useful. The method by which data is presented to management is best provided in a manner that allows for quick and easy interpretation so that analysis can be accomplished and decisions be made to act upon the situation at hand. At the heart of any quality management system is the implied understanding that accurate data is collected, simplified into a means of review for analysis by management. Effectivity of any system is dependent upon such activity (ASQ, 2000).

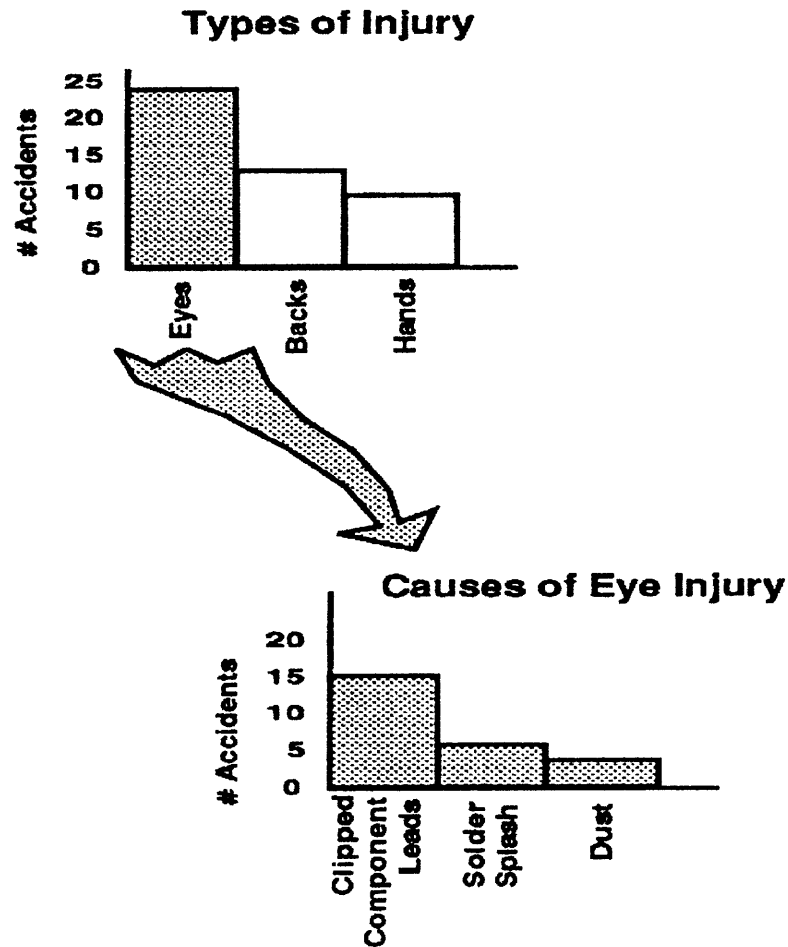


Figure 4.5.1 Pareto Chart Exemplifying Cause Analysis.
(Source: GOAL/QPC, 1988)

The Pareto Chart, as a graphical tool, assists in breaking down problems into manageable parts. The Pareto Chart is based on the Pareto Principle, which states that it is a small number of causes that often account for the most problems. In many situations, it is estimated that 80% of problems are caused by only 20% of the contributors (Joiner Associates, 1995).

Cost of Quality for Internal Rejects - Zinc Line

July

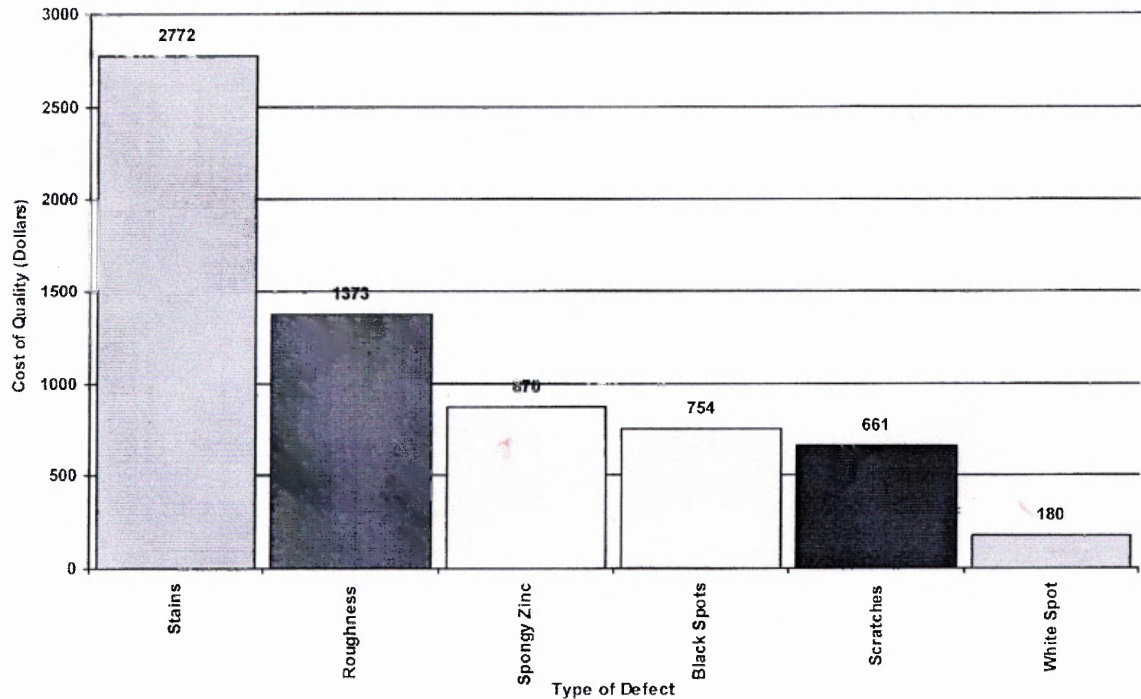
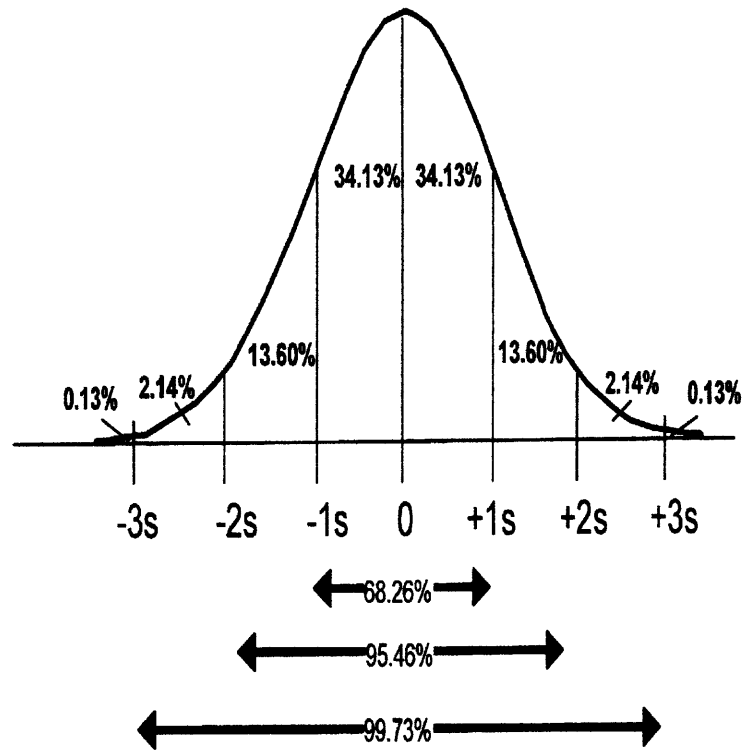


Figure 4.5.2 Pareto Chart Relating Costs of Quality to Type of Defects.
(Source: Extreme Quality International, LLC. 2004)

4.6 Six Sigma Methodology

Six sigma is a statistical concept that represents the amount of variation present in a process. Six sigma emphasizes using a standardized score obtained from the use of rigorous statistical methods. The measurement of variation present in a process relative to an average is expressed as a measurement of risk, utilizing a standard deviation as a measure away from that average, also known as the mean. Utilization of the six sigma method calls for two assumptions. The first one relates to the data distribution, and stems from probability theory, where data is plotted onto a chart with defined “x”

and “y” coordinates representing the chart’s intended measurements. The “x” axis on the chart is the horizontal line that usually represents the specification, while the “y” axis on the chart is typically incrementally indicating a measurement system to that specification and/or expectation. When a data point is observed, it is plotted and recorded onto the chart. Six sigma charts are often commonly shown to have the data observations distributed within a well-defined bell-shaped curve, which then shows marked measures defining three equal standard deviations, each a measurement away from the mean in both the positive and negative directions. When establishing a six sigma process, it is often an assumption that the data will pattern its distribution to the desired expectation, as this would be the goal. A secondary assumption to the six sigma theory is that the probability of distribution is “normal” in that the points of measurement will be consistently representative of normal distribution, which may not be the case for processes that are not in control. These risks associated with data population and data normality are risks that must be understood relative to the use and implementation of the six sigma methodology, for it is with these assumptions at the onset that a pursuit to evaluate, measure, and strive to a process sigma level, must first be considered.



Equations for Mean and Standard Deviation

Sample Mean
$$\bar{X} = \frac{\sum_{i=1}^n X_i}{n}$$

Sample Standard Deviation
$$s = \sqrt{\frac{\sum_{i=1}^n (X_i - \bar{X})^2}{n-1}}$$

Figure 4.12 Example of Normalized Data with Normalized Distribution.
(Source: Schilling, 1982)

Six sigma initiatives have two basic methodologies that are known by their acronyms of DMAIC (Define, Measure, Analyze, Improve, and Control) and DMADV (Define, Measure, Analyze, Design, and Verify).

4.6.1 DMAIC

DMAIC is used successfully to produce improvements in process performance, once a process has defined its key Critical to Quality (CTQ) parameters. Those CTQ parameters are defined and understood for the process improvement team to assure that it is the CTQs driving the goal, and that the process goal be to attain the six sigma level and thereby meet the CTQs.

Figure 4.2 shows a typical DMAIC process flow, which involves the following five steps:

- Define a project, its purpose and its scope.
- Measure, by gathering information on the current situation to provide a clear focus for the improvement effort. Calculate process sigma.
- Analyze the situation. Define a problem statement. Identify possible root causes of deficiencies. Collect data. Confirm the problem with data to quantify a cause-and-effect relationship. Use statistical methods as appropriate.
- Improve. Create possible solutions for the root cause(s). Develop, test, and implement solutions to address root causes. Utilize data to evaluate results of effectiveness of the solutions. Evaluate benefits.
- Control. Maintain the gains achieved by standardizing work methods and/or processes. Preserve the lessons learned from the improvement effort by

developing documented standardized practices to control within a management system.

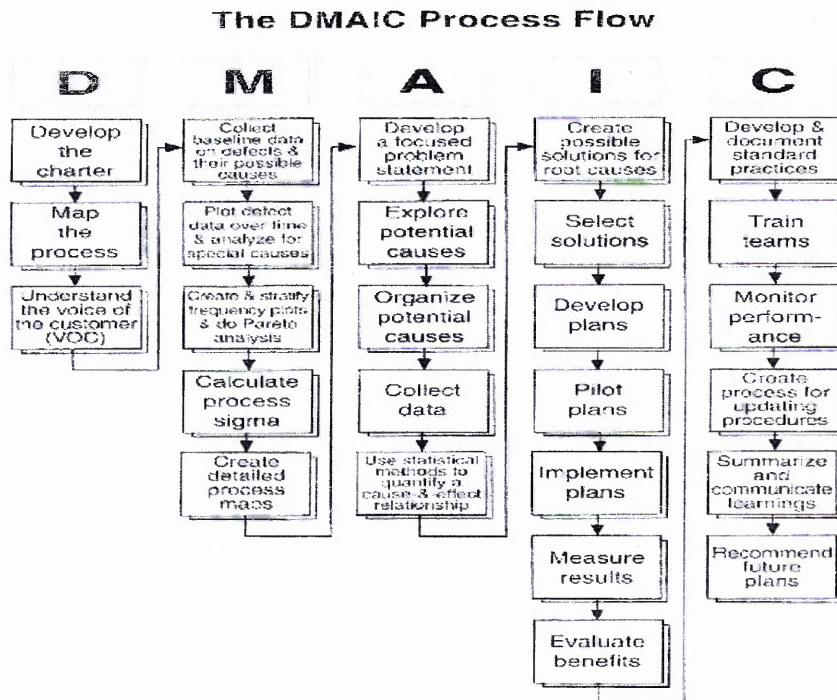


Figure 4.6.1 The DMAIC Process Flow.
(Source: GOAL/QPC, 2002)

4.6.2 DMADV

DMADV is used successfully to create a process, product, or service to meet customer requirements or in cases where a complete redesign of the product, process, or service is necessitated.

The DMADV method involves five steps:

- Define the project charter. Map the process. Understand the voice of the customer (VOC) as expressed through customer needs.

- Measure, through data collection to acquire a baseline assessment. Calculate process sigma.
- Analyze and explore options. Collect data to quantify a cause-and-effect relationship. Use statistical methods to verify as appropriate.
- Design, doing so utilizing obtained information to assure that the established product, process, or service optimizes performance and satisfies the established CTQs.
- Verify by assurance methods that prove out the integrity of the design aspects and the maintenance of the CTQs. Develop and document specifications that assure standardized techniques will continue to accurately assure design stability and to preserve the lessons learned from the DMADV effort.

4.7 Failure Mode Effects Analysis

Prevention strategy at the earliest point in a process is an almost certain way to conceptualize planning for anticipated needs for improvements. One well understood concept in the application of advanced product quality planning (APQP) which was popularized by the automotive industry as it contained specific elements of a strategic improvement process emphasizing prevention. Specifically, Failure Mode and Effects Analysis (FMEA) was one of the design related efforts whereby a potential process or product failure mode is evaluated (ASQ, 2002). Key to conducting a FMEA study is to evaluate the process or product from three distinct perspectives:

- Severity level – which corresponds to the seriousness of the effect of the potential failure mode.

- Detection level – relates to the likelihood of the current process controls to be able to detect the defect.
- Occurrence level – corresponds to the rate at which a failure mode would occur under process controls.

Scales such as low, medium, high, or on a 1 to 10 level are calculating factors in conjunction with the three parameters. The sum of each of the three parameters is multiplied to obtain, for example, a Risk Priority Number, which is then assessed further as to how the prioritization of the failure mode would be attended to. The way to move forward with the subject of FMEA to benefit continual improvement efforts is to refine how this process is utilized within an organization. Benefits to towards continual improvement include not only identifying potential risks and failure modes and their effects, but to take the prioritized potential failures and carefully select and manage the subsequent actions that follow. FMEA implementation of the tool leads to management of decided actions which in turn are the key to the proposed success, that is, to observe corrective or preventive methods in place to prevent the potential risk or failure identified (Ranky, 2006).

CHAPTER 5

RISK ASSESSMENT

5.1 Managing Risk through the QMS

Risk management first begins with understanding that incorporation of risk assessment begins with prevention concepts. As it relates to risk, there are three general philosophies relating to organizational risk management that can be accomplished through installation, implementation and continued maintenance of a quality management system. Most organizations want to:

- Manage their risk and exposure (Goodden, 2001),
- Maintain a high level of customer satisfaction (Cacioppo, 2000), and
- Eliminate unnecessary spending (Campanella, 1990).

Internal quality efforts provide for preventive measures to support each of these areas.

5.1.1 Risk Prevention Consideration for Manufacturers

Risk related to claims, liabilities, and lawsuits associated with product problems are mitigated when a comprehensive system for defining risks exists within a company's management system. Attorneys are increasingly using examples of certified quality management systems as comparative benchmarks to create perceptions on the subject of whether or not a company was proactive (prevention driven) or negligent. The difference between a manufacturer that has a documented management system that reviews designs and assurance compliance with standards is distinctly defensible compared to a

manufacturer lacking such systems. Product liability prevention now focuses in part, on what a manufacturing quality program should include.

The ISO 9001:2000 quality management system standard encompasses those items considered expected by the Defense Research Institute, which is the largest defense association in the United States. Quite logically, the afterwards of documenting a process, designing with integrity, and verifying the design to compliance standards, continues with process definition and implementation for hazard analysis, reliability testing, engineering and blueprint controls. As is the case with the ISO 9001:2000 QMS Standard, a basis for supplier selection along with inspection process definition at various phases, and records are also expected.

When a manufacturer goes to trial in a product liability case, the challenge of defending the product is accented by the defense of the inner workings of an organization as well. Manufacturers now must be able to prove to courts and juries not only that its product was a safe and reliable design, but also that every effort was made to ensure that it was developed and produced with consideration of maintaining it to be compliant as planned (Goodden).

5.1.2 Risk Prevention Consideration for Customer Satisfaction

It is said that it costs five to eight times as much to get a new customer than to maintain a present customer. This is key to understanding the efforts that might be considered to properly measure a customer's perceived satisfaction with one's organization.

With global competition and a changing economy, continued sales growth can be a challenging task. Competitors prosper in such environments when they recognize the

customer dissatisfaction as their critical strategic weapon to compete with. Many companies do not perceive that the customer base can be supported through the use of its quality management system assisting its efforts through the provision of meaningful information and measurements on customer satisfaction. Although the key driver of the ISO 9001:2000 quality management system is shown to be the customer input yielding the customer output and receiving the customer feedback to readdress any improvement issues, the measures that companies use to evaluate customer satisfaction are not always proactive, but instead are reactive. Appendix A, Figure A1 represents this concept through its diagram of customer flow points.

It is no surprise to hear companies believe that its measure of customer satisfaction is through its sales volume and its level of compliant receipts or returned materials authorizations for credit. However, satisfaction is much more and can refer to many other areas, such as satisfaction with the ongoing business relationship, satisfaction with the price-performance ratio of a product or service, satisfaction with the actual quality of the product or service. Clearly defining and understanding the expectation and then providing a measurement standard to, and that can be trend analyzed over time on a timely basis so as to take action according, could be supported by the quality management system of a business, thus reducing its risk related to lost business. A quote from the Harvard Business Review, November/December 1995 read that “the gulf between satisfied customers and completely satisfied customers can swallow a business” and this is prevalent to how opportunities to distinguish customer satisfaction might be considered (Cacioppo). Customer satisfaction attainment belongs to the customer and is

considered the customer's perception as to whether requirements have been fulfilled (ASQ, 2000).

5.1.3 Risk Prevention Relating to Quality Costs – Internal

This section is one that could be an additional science to complement management and quality related sciences in that it combines the principles of both business cost concerns with quality performance improvements.

If we think of every problem ever identified in an organization as an opportunity for profit improvement, we would understand best the concept of quality costs. Fundamentally, quality costs measurements can be established every product or service line that is part of an operation. These measurements become an integral part of the quality management system when you consider that identification and elimination of the cause of defects can be quantified and cost analyzed using various statistics and problem-solving techniques. Cost benefits justified for preventive action is by far a more effective way to view quality investment costs since the one thing to remember about corrective action is that you don't only pay for the process once. Yet opportunities for quality costs improvements should not only be thought of as operations personnel related. Errors result in waste, rework, and materials that may be prevented by other areas of cause, such as process design engineers, designers and fabricators of tools, methods installed by individuals who determine process capabilities, errors relating to those who provide written instructions for operators. The list can go towards the total operation of a facility for one to demonstrate that clearly anyone can contribute to failure costs. Effective corrective action, therefore, along with preventive action processes in advance, will

provide solutions. Doing so in a well-organized and formal approach supported by related costs is a benefit to justify quality costs and surface for management's visibility, the relevance of actions.

An important use of quality costs is to provide an integral part of the quality management reporting. The intention is to focus on areas needing improvement and to inform management of overall status in a more direct manner to promote and support the actions needed. Quality cost savings provides what is considered the best way to measure the overall success of the quality improvement program for if improvement is being achieved, problems are being resolved, and quality costs are reduced. Quality costing allows for the effect of the management of quality to be quantified. Some companies consider this a breakthrough understanding and it only when this concept is understood, that the quality function becomes a bona fide member of the company's management team.

Quality costs continue to all areas of a company; apropos to the aforementioned subjects of designing out risks through implementation of a quality management system along with maintaining assurance relevant to customers being satisfied, the quality costs subject has relevance to analyze major trends in both defect error rates and customer satisfaction. Strategic plans of a company that is serious about its quality management is to include an overall quality related, quality cost related strategic plan as part of the company's overall business plan.

5.1.4 Risk Prevention Relating to Quality Costs – External

There are numerous examples of costs that can be calculated, measured, and reported upon for areas relating to suppliers and quality costs. For example, we can categorize supplier quality costs into prevention, appraisal, and failure costs. Prevention costs elements could be the cost of doing supplier quality surveys. Appraisal costs elements could be related to receiving and source inspections. Failure costs relate to items such as the disposition of nonconforming purchased materials, or costs of scrap and rework of supplier-caused nonconformances. These are usually costs that are not incurred directly by the supplier at the suppliers' plant. These are usually costs incurred by the buyer in solving the problems related to the supplier's plant. Hidden supplier costs can relate to cost of processing a complaint investigation or cost of a defective product that has been processed after being received. Calculations can be made for return on investment analysis using supplier quality costs (Campanella, 2006).

5.2 Process Flow Analysis

If a company is seeking to assess its risk, one of its activities might best include process analysis. There are several ways to utilize process analysis to benefit a company. Let us first start with process flow being understood. In order for an organization to explain its activities, work flow diagrams might be considered to assist in providing a pictorial guideline of how operations are intended to flow.

Figure 5.2 shows an example of a traditional process flowchart that utilizes the commonly known shapes of boxes to depict the activities in at each interval. The activity or process is usually shown in a rectangular shape box. The decision or when a point of

question arises is usually depicted by a diamond shape. Start and stop or beginning and end points are oval shapes. Connector points showing continued marks are circular and numbered to connect the process to another point. The intention of the process outline is to indicate steps of a process, start and finish points, decision points and their variables, and to provide a general understanding of how the activity is intended to take place.

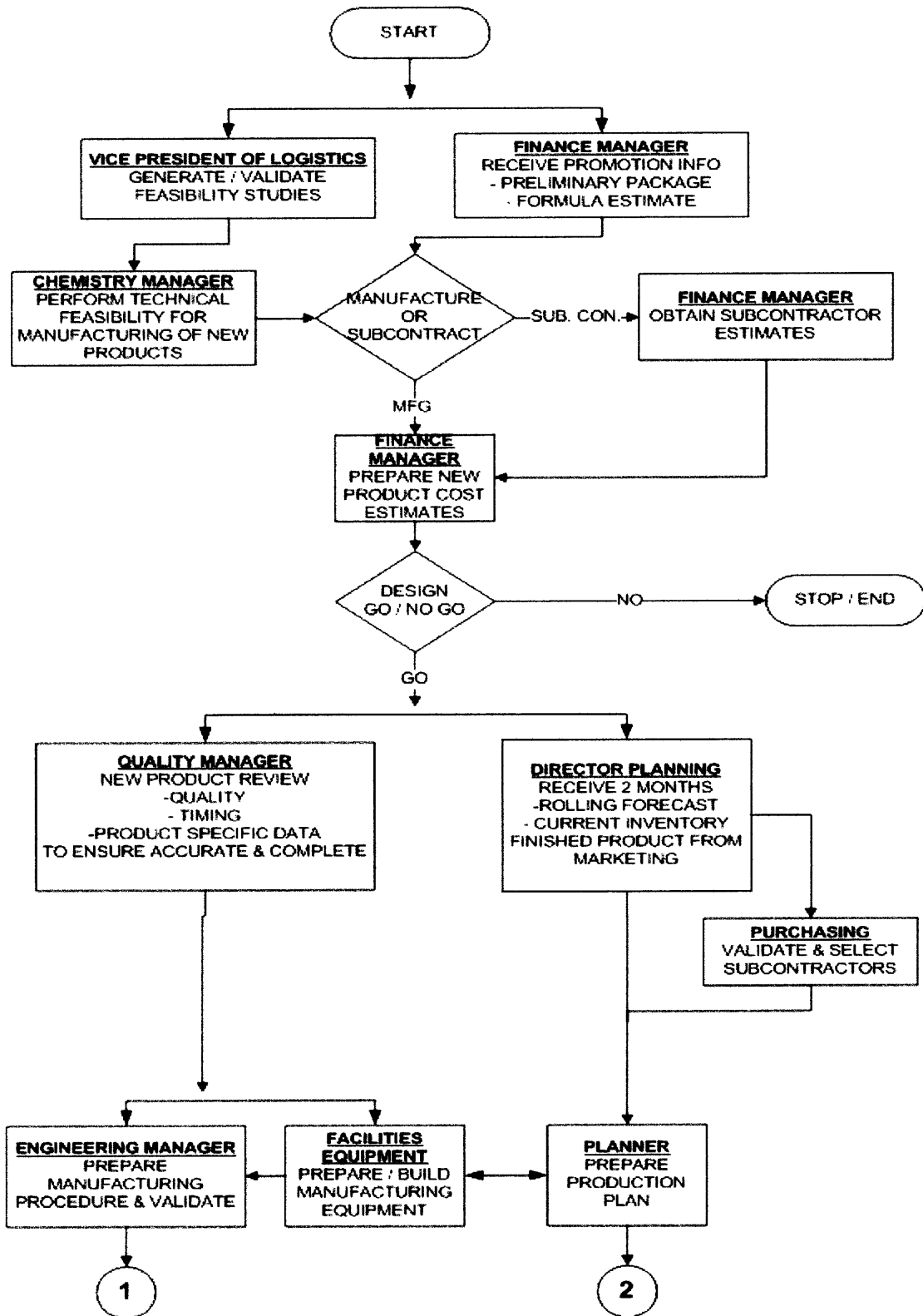


Figure 5.2 Example of a Traditional Process Flowchart.
(Source: Extreme Quality International, LLC. 2004)

5.3 The Auditing Function

Auditing goes with the territory of improvement, as the findings through self-assessment and/or supplier assessment provide for opportunities at correcting or preventing non-conformities and/or detecting deficiencies.

The strategic methodology by many organizations instituting a management system is to assess by clauses of a standard to which they are required to conduct audits, and oftentimes, this is conducted on the cycle of an annual basis (ASQ, 2002).

The approach to monitoring and measurement auditing as defined in the management system standard of ISO 9001:2000, Clause 8.2.3 requires monitoring and measuring of processes to demonstrate ability to meet planned results. Although internal audits evaluate requirements, an organization can take the audit further strategically to assess if the planned results are efficient and effective, which would also be expected of an internal audit responsibility in association with the ISO 9004:2000, Section 8.2.1.3. This accompanying document to the ISO 9001:2000 standard itself is a source providing guidelines for performance improvement of quality management systems. Examples of subjects for consideration by the internal auditing practices of a company include and are specifically referenced to include auditing to determine effective and efficient implementation of processes, opportunities for continual improvement, capability of processes, occurrence of performance measurement, and additionally, analysis of quality cost data (ASQ, 2000). It should be noted that the subject of quality costs are discussed further in Chapter 5.1.3 and 5.1.4.

Auditing requires planning and preparation and a skill set to include communication skills, both verbal and behavioral, technical writing capability, and the

ability to report concisely on the subject matter audited. An auditor must have the ability to evaluate what is being observed, understood, and documented and to accurately assess and interpret and report findings. Follow-up auditing requires knowledge to assess the planned actions and the implementation of those actions as suitable and appropriate to address identified nonconformities. In addition, an audit will often evaluate effectiveness of the action taken. While many of the improvement activities and quality system functions are able to be controlled through technical application alone, auditing requires a plethora of skills sets so that the audit process itself can be viewed as an essential contribution to a quality management system's continual improvement effort (ISO, 2002). Reference can be made to Appendix A.1 depicting the model of a continual improvement process whereby one of the activities, Measurement, Analysis, and Improvement flows information to management. Audit information from both internal and external sources is part of the information stream for management to consider in its review activities.

5.4 Preventive Action

It should be noted that outside of being a requirement a quality management system standard, such as ISO 9001:2000, many of the activities discussed are business practices that are forms of risk management.

Preventive action, when implemented, can yield a variety of benefits that can include improved processes, decreased variability in process and product, reduced waste, time savings, costs savings, better linkage with supply chains, and improved communications with the internal and external customer. By addressing preventive

action, quality cost savings can be demonstrated through prevention of various expenses such as scrap, down time, or ultimately a lost or unhappy customer. A case can be made that in most instances, continual improvement actions are inherently preventive actions since they prevent losses of profit, customers and/or market share.

What is significant about implementation of preventive action in a management system is that it is a tool that can be validated; it can not be truly implemented unless it is preceded by a commitment to gather and analyze information relative to the performance of the QMS as manifested in an organization's product or process. Data analysis makes preventive action meaningful.

The idea to catch and prevent a potential problem before it occurs rather than to allow for an occurrence is one of the best hidden tools of a QMS because an organization can be shown results in concrete terms such as productivity and profit improvements over time (Robatielle, 2002).

CHAPTER 6

CONCLUSIONS AND FUTURE RESEARCH

6.1 Conclusions

An organization's continual improvement process is as good as its management system allows, based on the information that such system is capable of providing to the decision makers. It is critical to understand that without accurate knowledge, management is limited in its ability to characterize and correct deficiencies.

A quality management system is a framework for business to operate within, though the quality system may not be regarded as the actual business process framework for which it should be. Instead, business often approach Quality as a separate subject and instead of embracing the quality management system as its center for systemizing the business continuity, it is not viewed as such. The Science of Quality theory allows for this to be seen very clearly. Quality resides as the basis for optimization of productivity, performance, improvements, and goal setting. It exists from customer request through to warranty and guaranteed satisfaction. It's responsible for brand image and loyalty. It's attributable to design, reliability, engineering, and integrity, and it a major factor to the financial performance of any company.

The proposed Science of Quality shown Figure 3.1 provides an architecture indicator of potentially, how companies could re-structure and re-shape their business thinking away from antiquated practice. While matrix organizations and hierarchy and cross functional establishments have been traditional to management, it has never been outlined before now through a logical methodology, how a Science of Quality could be used as the basis for a management structure of an organization.

Organizations are now shown a means to enhance all aspects of its business by guiding the functional matters into a structure that sets forth a pathway to implement, through the thinking process of quality integration.

In fact, one can conclude that Quality, while often considered an addition to a successful business, is actually the primary business contributor to all areas when measured by profitability, performance, and customer loyalty. In business, we often hear of how quality can destroy a business. The dichotomy of this subject is in the realization that quality is the fundamental success of all business. The Science of Quality methodology for applications allows for true functional deployment of quality into the relevant architecture of an organization, but it has to become understood as such. This is why further research is warranted to formalize this idea into a branded science which can quite easily interrelate and/or redirect modern business today, for at the core of all business success, there would not be efficiency, effectiveness, or customer demand without the Science of Quality. It simply is not understood as such which is why the direction of quality management system standardization practices, which are relatively recent to industry on an international basis, that is, since the 1970 time-frame, continues to expand its directions from control efforts, then on to sampling to verify, then to a movement to monitor, another generation to assure, followed by going back to design engineering, and of recent decades, how to become better with overtones of back to basic principles of customer satisfaction.

My conclusion is to consolidate all of these issues into a business practicum that summarizes, almost holistically, an integrated quality structure and strategy through the

comprehensive understanding and implementation of an architecture that allows for direction according to the need at hand.

Although Quality may be a relatively new science, it is my further conclusion that is a relatively ancient habit. Without further research for its formality, there would be continued limitations to its comprehensive capability within organizational management. An organization's ultimate goal will always be related to customer satisfaction. Customers are why organizations exist. Customers are both internal and external. A customer is the next person in a process. A customer is a stakeholder. The list can be furthered but the idea is that business starts someone or something at the other end with a need. Not all businesses are for profit, but all businesses are for satisfying the need at the other end. Systems support being able to achieve this.

The overall research of this topic indicated that there is an evident need to continue to develop the science of quality and link legacy with systems, and science with statistics. Modern methods for continual improvement could be evidenced with tools like layered process modeling supported by CORA and PFRA, yet integrated collectively through proper and appropriate use of SPC.

The many choices of toolsets available to management today are sometimes misdirected since there is not always clarity to distinguish what would be the most appropriate choice and/or solution for the intended need. The Science of Quality concept assists in defining direction for a user to integrate the best options for the subject matter, based on strategic deployment of effective methods.

6.2 Identification and Integration of Quality Science

There is clearly a development of a proposed formal science relating to quality and its relevant structural paths of engineering, control, assurance, improvement, and cost. Figure 3.1 defines the Proposed Architecture for a Science of Quality. Table 3.2 outlines a Proposed Science of Quality Functional Applications Map.

The discovery of this scientific approach to integration of quality into business architecture, systems, and management warrants further development of this concept to a formalized science, very much needed in business today. Significant contributions to intellectual implementation of modern-day quality, when integrated through an organizational system, would provide a resourceful means for assisting in directing continual improvement methods to be best considered.

Already demonstrated in this research is that the consolidated use of continual improvement methods and toolsets, when integrated together can be considered a pseudo-omnipotent means to establish, measure and achieve effective quality management.

Traditional management guidelines do not always concentrate on the subject of application methodologies for quality purposes. The input for quality comes from many sources, but is not always centralized. Modern management would benefit from approaching quality as an initiative with better education on what quality science can actually comprehensively encompass and provides for since this is not always understood.

It also appears Quality, as widespread and necessary as it is, has often been researched and/or developed through its use and need in industrial applications. There is an indication that this is a field of study and academics that has yet to be significantly

recognized as similarly as other areas of ingenuity. The Science of Quality approaches the subject as its own deserving science.

6.3 Future Research and Direction

There exists a requirement within an international standard relevant to quality management systems that continual improvement be demonstrated. While there are not specifics on the applicable methods to use or the statistical techniques to use, nor an indication of the extent of their use, it is a necessary requirement that organizations implement continual improvement efforts.

Improvement processes vary as well as the way in which organizations understand how to use them. No different than the standardization of how a business maintains normal balance sheets or profit and loss statements, it is warranted that a standardized way to evaluate quality related performances be institutionalized.

The first step in this process may be to assist companies with a methods selection map to bring forward a way in which Quality Management Systems can be productive and effective on the subject of continued improvement. As can be seen from the origins of management systems, quality, metrics, and improvement have been key underlying drivers since the inception of the science of management. Varied techniques have been utilized for process control, process management, and process analysis, while quality has continued to remain its own science, always uniquely relating to the objective of the customer, the product, and/or the service.

While traditionally, it is understood to speak of management science, engineering science, statistics and mathematically based sciences, in recent times, only informational

systems and computer sciences have been granted specific recognition as modern day advanced sciences. In fact, Quality is suitable to be part of the advanced academics to the degree that the five distinct branches formally outlined above in Table 6.2 are primarily addressed uniquely on a case by case basis by various industries and industrial organizations instead of a distinct branch of academic science, which it clearly should be considered, present day.

Business management is quality management and they are interchangeable. No business is without a requirement to satisfy a customer's need and expectation and no quality management system exists without it being necessitated by the business need to flourish. Simply stated, management by objectives to achieve process capability and improvement is a business system. Today, management must achieve its objectives and whether those are profit based, productivity based, or performance based, a customer exists at the other end of the equation and that requires satisfying the customer through the quality of the product and/or service provided.

What would be useful to business today is a comprehensive understanding of how to manage the quality management system, that is, how to understand what to expect from its implementation, and how to address the contribution of quality into a business in five distinctly different scientific areas, but without which any one of the areas, a business could potentially fail to meet its objectives and/or its customer expectations. Figure 3.1 and Table 3.2 present effective interpretive models to provide guidance to organizations on the use of improvement methods at the correct points of a process, and further support continual improvement within the use of an integrated quality management system. The proposed solution contributes to qualifying how to integrate

quality into an organization functionally and through its management system process. While there is no substitute for leadership of a fully maintained quality management system, with the proposed architecture of the Science of Quality, it appears that even through informal implementation, SOQ architecture would be able to support the management philosophy of an organization to incorporate quality at all levels. The outcome of this research indicates the potential for the SOQ methodology to be considered a best-practice toolset contributing to continual improvement.

APPENDIX A

CONTINUAL IMPROVEMENT OF A QUALITY MANAGEMENT SYSTEM

Figure A.1 depicts customer input at the onset routing into a company's QMS and additionally shows customer feedback routing back into the QMS, symbolizing the input, output, and feedback from customers circulating through organizational functioning.

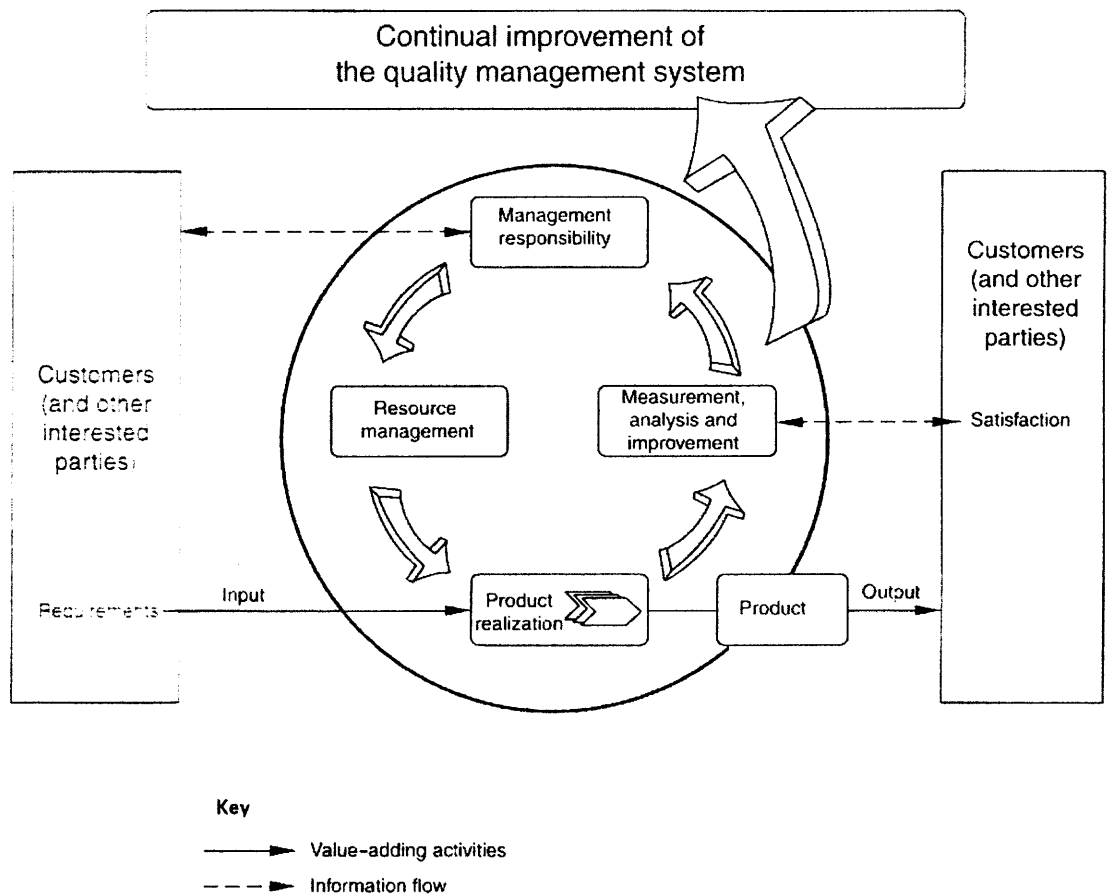
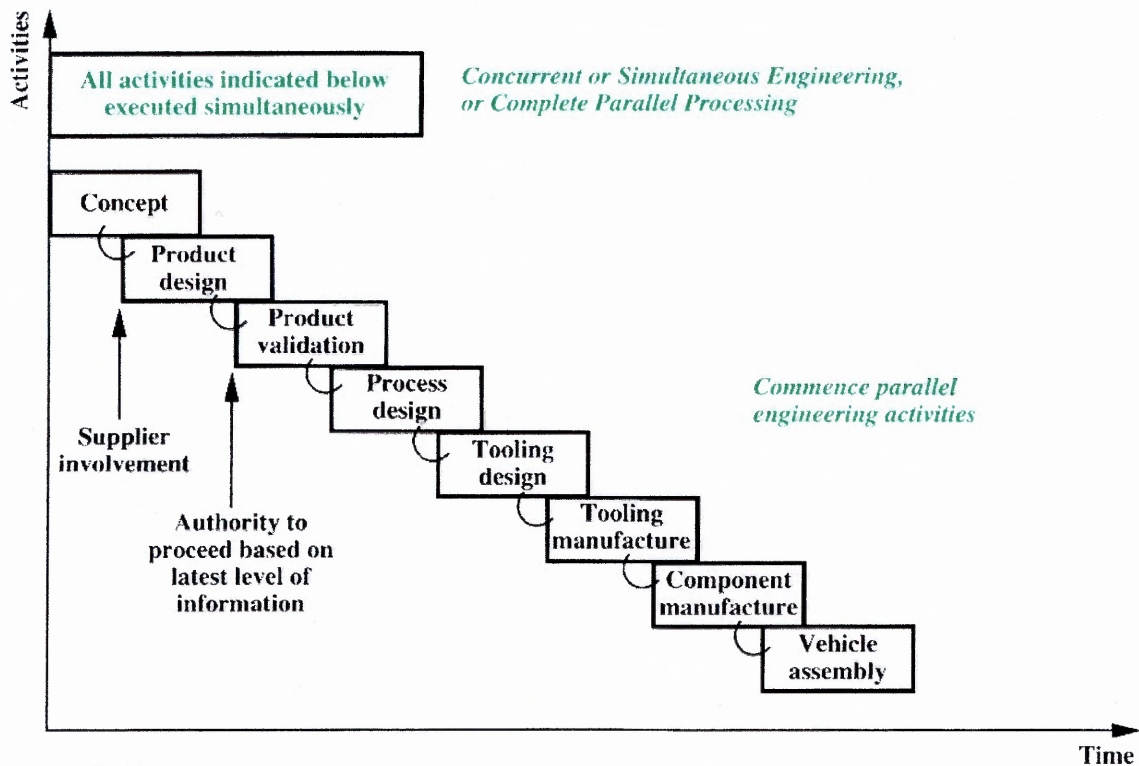


Figure A.1 Cycle of Continual Improvement Process of Integrated QMS. (ASQ, 2000).

APPENDIX B

CONCURRENT ENGINEERING AND PARALLEL PROCESSING

Figure B.1 models an example of how organizational activities are simultaneous and ongoing, creating dependencies of steps that progress simultaneously. Continual improvement possibilities lie within the individual processes as well as the overall process.



The principal activities of the commence parallel and concurrent/simultaneous or parallel engineering project lifecycle in the automobile industry

Figure B.1 Concept of Concurrent Activities Showing Interrelationship of Processes and Process Dependencies.
(Ranky, 2006)

APPENDIX C

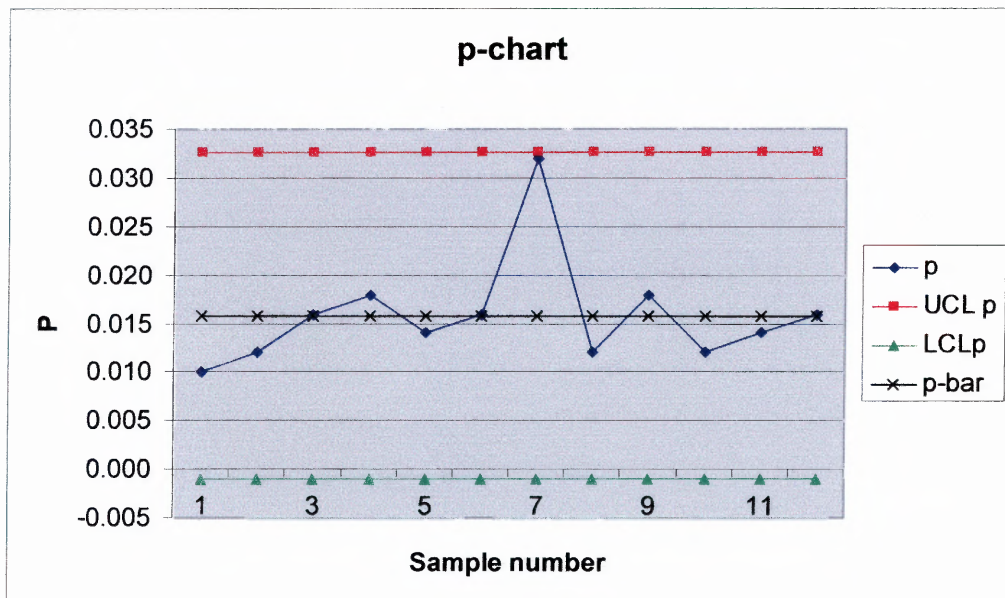
EXAMPLE INSTRUCTIONS DEMONSTRATING A P-CHART

The p-chart is a control chart for fraction nonconforming.

To construct the p-chart, we plot the fraction nonconforming for each sample. The data set and the table used for the chart can be organized that way in a spreadsheet:

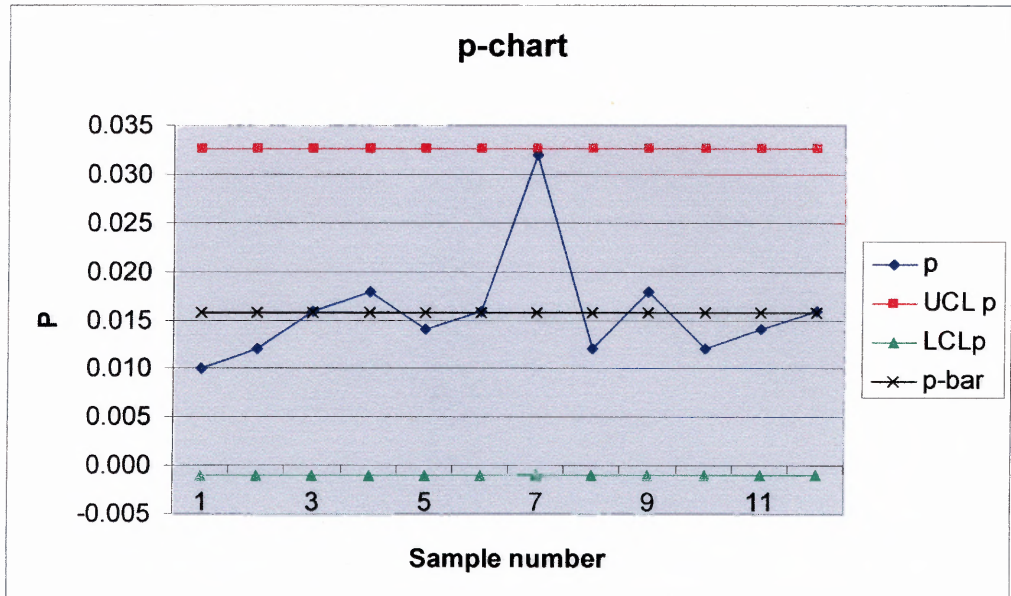
Sample number	1	2	3	4	5	6	7	8	9	10	11	12	SUM
n	500	500	500	500	500	500	500	500	500	500	500	500	
D	5	6	8	9	7	8	16	6	9	6	7	8	95
p	0.010	0.012	0.016	0.018	0.014	0.016	0.032	0.012	0.018	0.012	0.014	0.016	0.190
p-bar	0.016	0.016	0.016	0.016	0.016	0.016	0.016	0.016	0.016	0.016	0.016	0.016	
UCL p	0.033	0.033	0.033	0.033	0.033	0.033	0.033	0.033	0.033	0.033	0.033	0.033	
LCLp	0	0	0	0	0	0	0	0	0	0	0	0	

From this table we obtain the p-chart:



We can now analyze the chart to get information about the process.

Finally, we obtain the p-chart:



On this chart there are no patterns of out-of-control process, so we can conclude that the process is in statistical process (Ranky, SPC Software, 2006 with Bové, Data, 2006).

APPENDIX D

EXAMPLE INSTRUCTIONS DEMONSTRATING A C-CHART

The c-chart is a control chart for number of defects or nonconformities.

As an example, we illustrate the measured pH values of a liquid. Tests occur three times per day, during 24 days. Each sample contains three values and there are 24 samples. Here are the results:

Sample	X ₁	X ₂	X ₃
1	6	5.8	6.1
2	5.2	6.4	6.9
3	5.5	5.8	5.2
4	5	5.7	6.5
5	6.7	6.5	5.5
6	5.8	5.2	5
7	5.6	5.1	5.2
8	6	5.8	6
9	5.5	4.9	5.7
10	4.3	6.4	6.3
11	6.2	6.9	5
12	6.7	7.1	6.2

Sample	X ₁	X ₂	X ₃
13	6.1	6.9	7.4
14	6.2	5.2	6.8
15	4.9	6.6	6.6
16	7	6.4	6.1
17	5.4	6.5	6.7
18	6.6	7	6.8
19	4.7	6.2	7.1
20	6.7	5.4	6.7
21	6.8	6.5	5.2
22	5.9	6.4	6
23	6.7	6.3	4.6
24	7.4	6.8	6.3

STEP 1: Collect the data

There are 24 samples of 3 measures each. The table is written on a spreadsheet.

STEP 2: Compute values to plot (averages Xbar and ranges R)

We build a table using built-in functions to compute averages (Xbar) and ranges (R) for each sample:

For X bar

	A	B	C	D	E	F
1	Sample	X ₁	X ₂	X ₃	X-bar	
2	1	6	5.8	6.9	=AVERAGE(B2:D2)	
3	2	5.2	6.4	6.9	AVERAGE(number 1; [number2]; ...)	
4	3	5.5	5.8	5.2		

For R

	A	B	C	D	E	F	G	H
1	Sample	X ₁	X ₂	X ₃	X-bar	R		
2	1	6	5.8	6.1	=MAX(B2:D2)-MIN(B2:D2)			
3	2	5.2	6.4	6.9		MIN(number 1; [number2]; ...)		
4	3	5.5	5.8	5.2				

STEP 3: Compute central line and limits

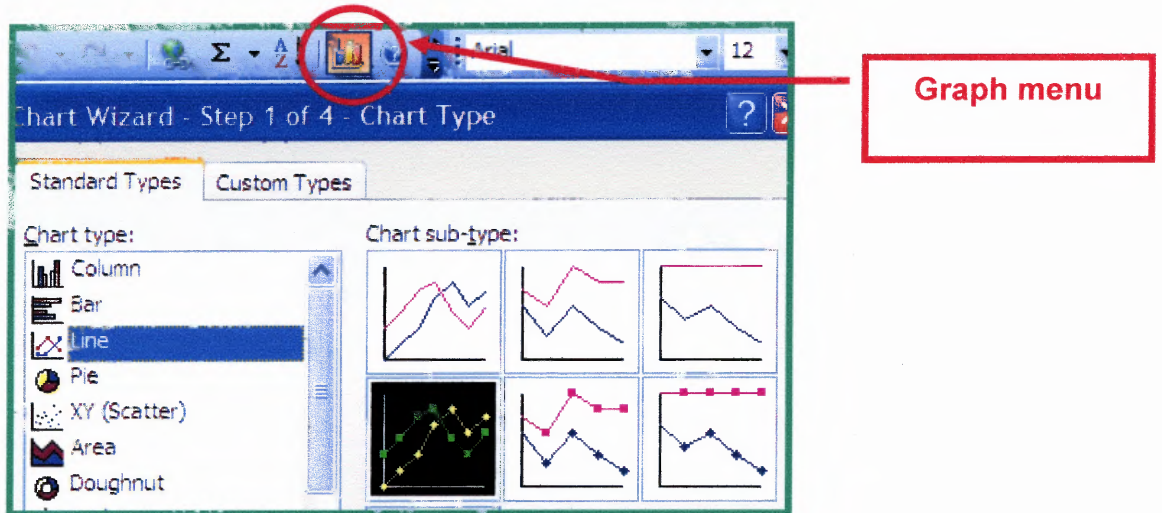
In order to compute the central line to represent the mean and the control limits, to represent the upper and lower points of an expected normalized situation, we rely on the use of the spreadsheet to calculate, as it has this mathematical function built-in to it. As coefficients are needed to calculate limits, a specific standardized table is referenced, which contains their values which depend upon on the sample size and which can be found in guidelines established for this purpose (Schilling).

Columns are used to compute the central line and the control limits. For each sample, we write the expression of the formula needed (for central line and limits) in the right bin. This way, we obtain the value of the central line, the upper limit and the lower limit. Control charts can finally be drawn.

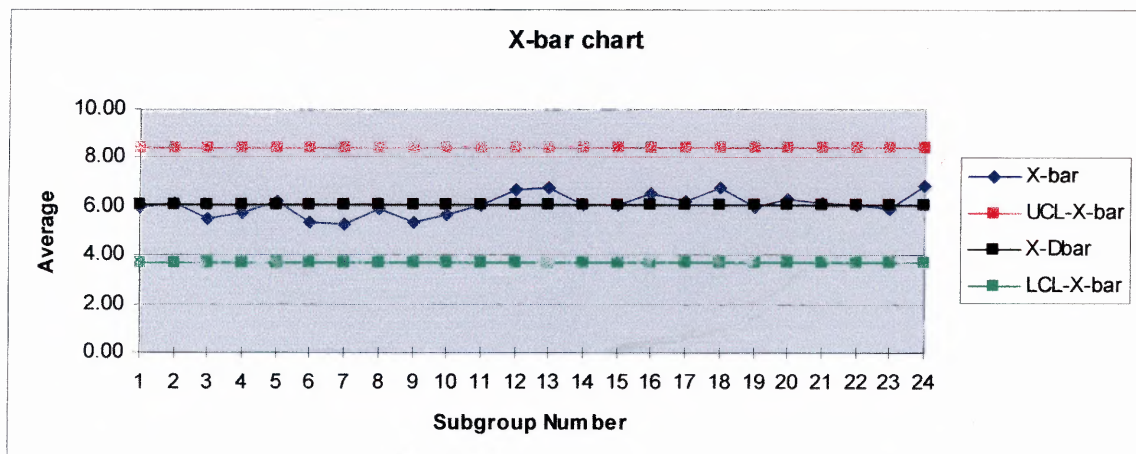
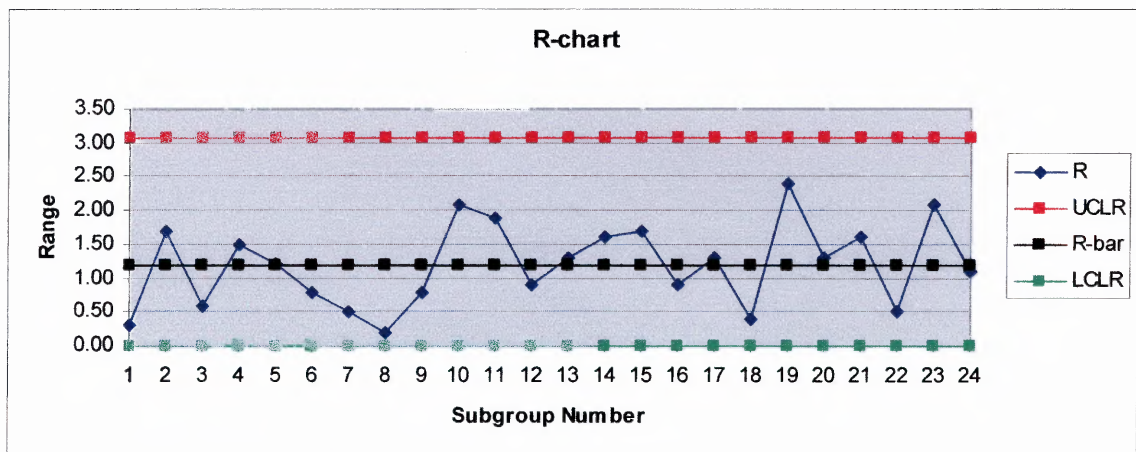
Subgroup	X_1	X_2	X_3	X-bar	$UCL-X_{\bar{c}}$	X-Dbar	$LCL-X_{\bar{c}}$	R	UCL_R	R-bar	LCL_R
1	6	5.8	6.1	5.97	7.29	6.06	4.84	0.30	3.08	1.20	0.00
2	5.2	6.4	6.9	6.17	7.29	6.06	4.84	1.70	3.08	1.20	0.00
3	5.5	5.8	5.2	5.50	7.29	6.06	4.84	0.60	3.08	1.20	0.00
4	5	5.7	6.5	5.73	7.29	6.06	4.84	1.50	3.08	1.20	0.00
5	6.7	6.5	5.5	6.23	7.29	6.06	4.84	1.20	3.08	1.20	0.00
6	5.8	5.2	5	5.33	7.29	6.06	4.84	0.80	3.08	1.20	0.00
7	5.6	5.1	5.2	5.30	7.29	6.06	4.84	0.50	3.08	1.20	0.00
8	6	5.8	6	5.93	7.29	6.06	4.84	0.20	3.08	1.20	0.00
9	5.5	4.9	5.7	5.37	7.29	6.06	4.84	0.80	3.08	1.20	0.00
10	4.3	6.4	6.3	5.67	7.29	6.06	4.84	2.10	3.08	1.20	0.00
11	6.2	6.9	5	6.03	7.29	6.06	4.84	1.90	3.08	1.20	0.00
12	6.7	7.1	6.2	6.67	7.29	6.06	4.84	0.90	3.08	1.20	0.00
13	6.1	6.9	7.4	6.80	7.29	6.06	4.84	1.30	3.08	1.20	0.00
14	6.2	5.2	6.8	6.07	7.29	6.06	4.84	1.60	3.08	1.20	0.00
15	4.9	6.6	6.6	6.03	7.29	6.06	4.84	1.70	3.08	1.20	0.00
16	7	6.4	6.1	6.50	7.29	6.06	4.84	0.90	3.08	1.20	0.00

Coefficients:	A_2	1.023
	D_4	2.574
	D_3	0

COEFFICIENTS



By selecting the right data ranges and plotting 4 series (central line, two control limits and Xbar or R), we obtain two control charts ready to be analyzed.

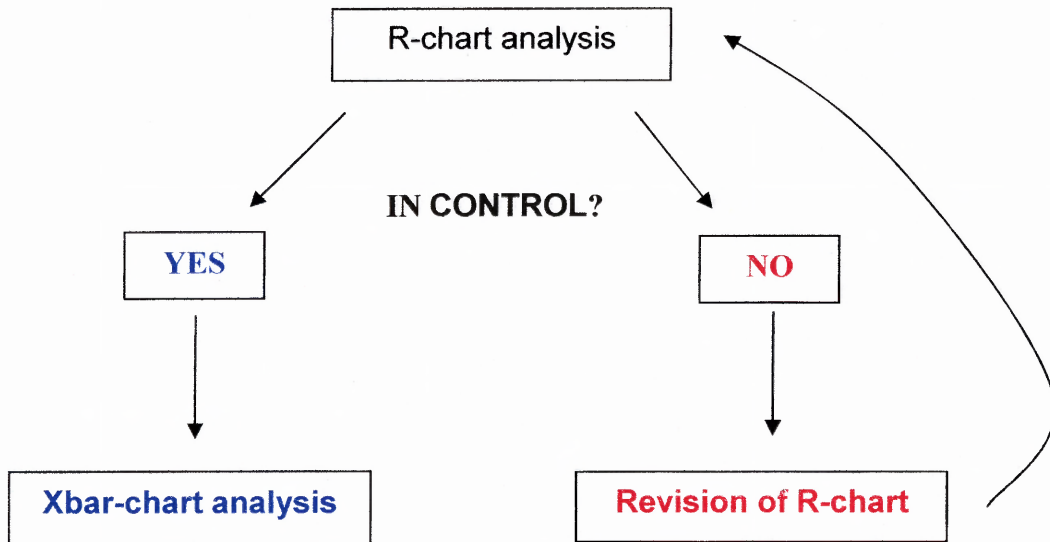


Analysis of control charts

How to study charts

Process analysis:

First of all, the study always starts with the R-chart. If the R-chart shows a process in control, then the X bar-chart can be analyzed (not before) as the following scheme shows.



Steps for studying a control chart are described below. This is usable for both of charts provided that the order of analysis is respected.

STEP 1: Observe repartition of plotted points

- First case: There are points out of control limits. We can directly conclude that the process is out of control and go to the second step.
- Second case: No points are out of limits. Two rules have to be checked before concluding.
 - If there are 7 consecutive points above or below the central line;
 - If there are 7 consecutive points increasing or decreasing,
 it detects non-random patterns and shows that the process is out of control (go to the second step).

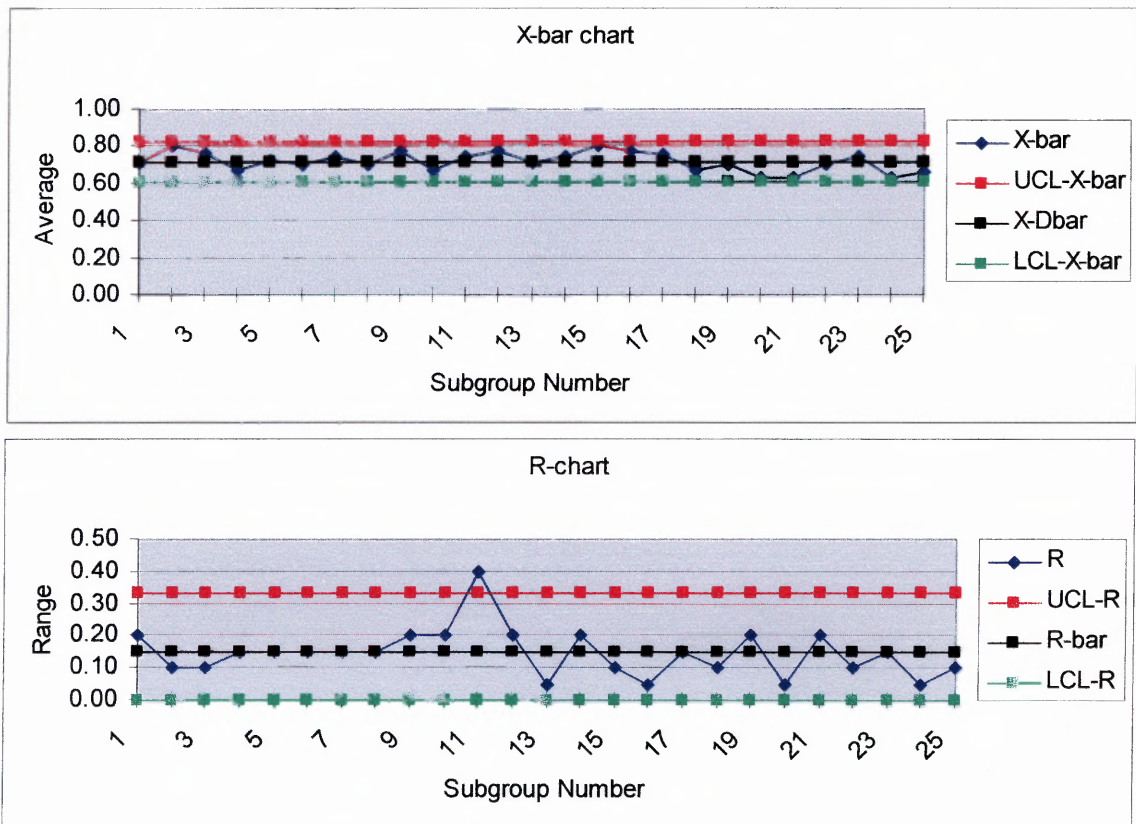
If none of these rules applies to the chart, then the process is in statistical control.

STEP 2: For a process out of control

- Investigate points which are out of limits or from a consecutive trend from the data set: identify the cause of such a point or trend.
- Once investigated, reject these points from the data set.
- Re-do the calculations to plot the new chart without these points
- Re-do the chart analysis until to obtain an in-statistical control process.

Worked out example:

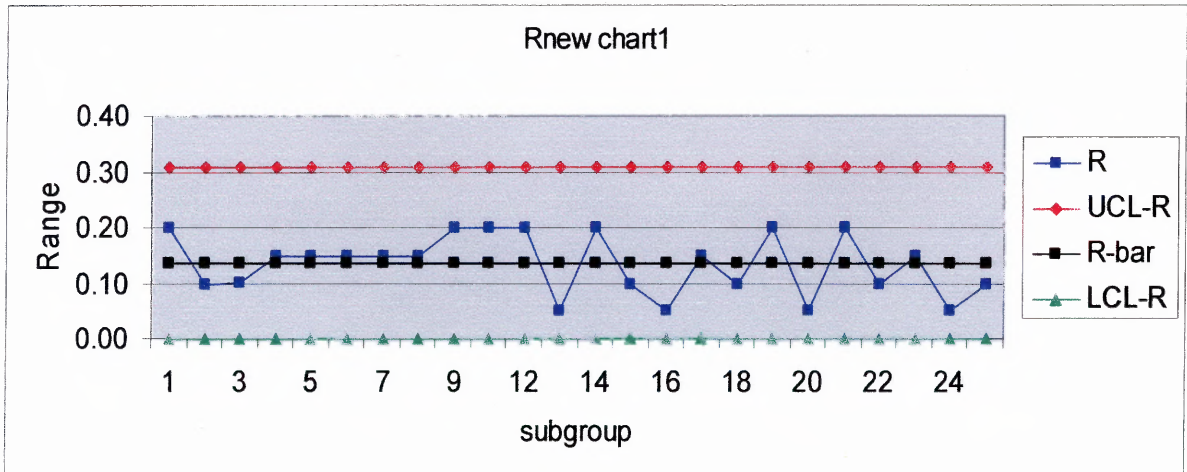
To illustrate control chart analysis, we work on an example for which the R-chart shows an out-of-control process. 25 samples of 4 rings have been tested, their diameter has been measured. After having computed central line and control limits, here are control charts:



On the R-chart, a point is out of control limits, it has to be rejected from the data set. We just have to erase the value in the spreadsheet as formulas to compute central line and control limits take in count blanks thanks to the function COUNTBLANK():

	A	B	C	D	E	F	G	H
1	Subgroup	X1	X2	X3	X4	X-bar	X-Dbar	
2	1	0.85	0.65	0.65		=F27/(25-COUNTBLANK(F2:F26))		
3	2	0.75	0.85	0.75	0.85	0.80	COUNTBLANK(range)	
4	3	0.80	0.80	0.75	0.70	0.76	0.72	
5	4	0.65	0.75	0.60	0.70	0.68	0.72	
6	5	0.75	0.70	0.65	0.80	0.73	0.72	
7	6	0.60	0.75	0.75	0.70	0.70	0.72	
8	7	0.80	0.75	0.65	0.75	0.74	0.72	
9	8	0.70	0.60	0.75	0.75	0.70	0.72	
10	9	0.75	0.85	0.85	0.65	0.78	0.72	
11	10	0.60	0.70	0.60	0.80	0.68	0.72	
12	11	0.80	0.75	0.90	0.50	0.74	0.72	
13	12	0.75	0.85	0.85	0.65	0.78	0.72	
14	13	0.70	0.70	0.75	0.70	0.71	0.72	
15	14	0.65	0.70	0.85	0.75	0.74	0.72	
16	15	0.85	0.75	0.80	0.80	0.80	0.72	
17	16	0.80	0.75	0.75	0.80	0.78	0.72	
18	17	0.70	0.85	0.75	0.70	0.75	0.72	
19	18	0.70	0.60	0.70	0.70	0.68	0.72	
20	19	0.65	0.65	0.85	0.65	0.70	0.72	
21	20	0.65	0.60	0.60	0.65	0.63	0.72	
22	21	0.55	0.55	0.65	0.75	0.63	0.72	
23	22	0.75	0.65	0.65	0.75	0.70	0.72	
24	23	0.80	0.65	0.75	0.75	0.74	0.72	
25	24	0.65	0.60	0.65	0.60	0.63	0.72	
26	25	0.65	0.70	0.70	0.60	0.66	0.72	
27	Sum					17.90		
28								

The calculations are re-done and here is the new R-chart obtained:



On this chart, no points are out of limits but there are 8 consecutive points above the central line (group 4 to 12), which is a pattern of out-of-control process. These points have to be rejected to plot a new R-chart.

This method has to be repeated until we obtain an R-chart without any patterns of out-of-control process. Then, the analysis is focused on the X-chart (Ranky, 2006).

REFERENCES

1. American Society for Quality (ASQ) (2000). American National Standard, ANSI, ISO/ASQ 9000-2000, Quality Management Systems – Fundamentals and Vocabulary. Milwaukee, WI: Quality Press, December, 2000, 1-27.
2. American Society for Quality (ASQ) (2000). American National Standard, ANSI, ISO/ASQ 9001-2000, Quality Management Systems – Guidelines for Performance Improvements. Milwaukee, WI: Quality Press, December, 2000, 1-24.
3. American Society for Quality (ASQ) (2000). American National Standard, ANSI, ISO/ASQ 9004-2000, Quality Management Systems – Guidelines for Performance Improvements. Milwaukee, WI: Quality Press, December, 2000, 1-58.
4. Cacioppo, Kevin (2000). Measuring and Managing Customer Satisfaction. [Article from Quality Digest Magazine]. September 2000, 49-53.
5. Campanella, Jack (1990). Principles of Quality Costs. Milwaukee, WI: ASQC Quality Press, American Society for Quality Control, 17-90.
6. Certo, Samuel C. (1980). Principles of Modern Management Functions and Systems. Dubuque, Iowa: Wm. C. Brown Company, Section 1, 7-66.
7. Chrysler Corporation, Ford Motor Company, and General Motors Corporation (1995). Statistical Process Control (SPC) (Second Edition). Southfield, MI: Automotive Industry Action Group, 1-47.
8. Graves, Beverly A. (2006). Total Integration is Key to Quality Control. [Article posted on Website PF™ Online]. Retrieved November 16, 2006 from the World Wide Web: <http://www.pfonline.com/articles>
9. GOAL/QPC (1988). The Memory Jogger™ A Pocket Guide of Tools for Continuous Improvement. Methuen, WA: GOAL/QPC, 4-69.
10. GOAL/QPC (2002). The Six Sigma Memory Jogger™ II (First Edition). Salem, NH: GOAL/QPC, 1-266.
11. Goodden, Randall (2001). How a Good Quality Management System Can Limit Lawsuits. [Article from Product Liability Prevention Magazine]. June, 2001, 55-59.
12. Hoyer, R.W., Hoyer, Brooke, B.Y. (2001) What is Quality? [Article from Quality Progress Magazine]. July 2001, 53-62.

13. International Standards Organization (2002). ISO 19011 Guidelines for Quality and/or Environmental Management Systems Auditing (First Edition). Geneva, Switzerland. October, 2002, 1-30.
14. Joiner Associates Incorporated (1995). Cause-and-Effect Diagrams: Plain & Simple. Madison, WI: Joiner Associates Inc., Sections A-D, 6-98.
15. Joiner Associates Incorporated (1995). Pareto Charts: Plain & Simple. Madison, WI: Joiner Associates Inc., Sections C-D, 43-59.
16. Kelley, D. Lynn, Morath, Paul (2001) How Do You Know the Change Worked? [Article from Quality Progress Magazine]. July 2001, 68-74.
17. Kerzner, Harold (2006). Project Management (Ninth Edition). Hoboken, NJ: John Wiley & Sons, Inc. Chapter 12, 490-492 and Chapter 23, 947-979.
18. McWatters, Cheryl S., Morse, Dale C., Zimmerman, Jerold L. (2001). Management Accounting Analysis and Interpretation (Second Edition). New York, NY: McGraw-Hill Irwin, Chapter 1, 13.
19. Nelson, Bob (1997). 1001 Ways to Energize Employees. New York, NY: Workman Publishing Company, Inc., Energizing Teams, 81-83.
20. Oriell Incorporated (2003). The Team Handbook (Third Edition). Waunakee, WI: Suttle-Strauss, Inc., Chapter 1, 1-16.
21. Ranky, Paul G. (2006) A Case-based Introduction to Total Quality Management and the International Quality Standards. CIMware USA and CIMware Ltd. UK. Hi-Tech, Version 4.7. Retrieved September 30, 2006 from the World Wide Web: <http://www.cimwareukandusa.com>
22. Resource Engineering, Inc. (1999). SPC Workout Workbook. Tolland, CT: Resource Engineering, Inc, 16-56.
23. Robitaille, Denise E.(2002). The Informed Outlook, Harnessing the Elusive Concept of Preventive Action. Montclair, VA: Inform and American Society for Quality (ASQ), August 2002, 3-7.
24. Schilling, Edward G. (1982). Acceptance Sampling in Quality Control. New York, NY: Marcel Dekker, Inc., Chapter 1, 1-18.
25. Stout, Leroy D., Stout's Handbook for Quality Audits and Quality/Reliability Engineering (1993). Ocean Springs, MS: LDS & Associates, Appendix B, Total Quality Management, B1-B23.
26. Turban, Efraim, McLean, Ephraim, Wetherbe, James (1999). Information Technology for Management – Making Connections for Strategic Advantage (Second Edition). New York, NY: John Wiley & Sons, Inc., Chapter 4, 112-164.

27. Wikipedia (2006). Definition of organization. Retrieved October 21, 2006 from the World Wide Web: <http://en.wikipedia.org/wiki/Organization>