

# THESIS REPORT

Master's Degree

Framework for the Development of a Quality Manual  
Using the Systems Engineering Approach

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M.S. 93-20



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## Abstract

Title of Thesis: Framework for the Development of a Quality Manual Using the Systems Engineering Approach

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Spurred by the global competitive environment, many efforts have been devoted to developing effective quality systems. Most of them, however, do not last due to poor documentation of the quality procedures. Lack of systematic planning by management, the time-consuming nature of creating and updating documents, and improper implementation of quality standards are all detrimental to the establishment of the quality system. A quality manual, serving as the core of the quality system, is a collection of documented procedures to assure that quality standards in design, manufacturing, and service are fully implemented in a company.

The contribution made by this thesis work to the quality control and management area is quality manual development framework developed through the Systems Engineering approach. The developed framework includes the following components:

1. the ISO 9000 standards, which provides the goals
2. the Systems Engineering methodology, which provides methods for reaching the goals
3. information technology (IT), a tool to control documentation
4. training, a tool used to integrate IT into the company environment
5. company, which provides the creativity and resources

The developed framework is capable of implementing all twenty elements required by ISO 9000. Key factors under consideration include customer satisfaction, market share, and company image, as well as internally improving work efficiency and reducing rework and scrap costs. The framework also defines the information flow mechanism to perform data collection, storage, analysis, and reporting of information in order to meet quality objectives.

The framework has been used in developing a computer program, which imitates a prototype quality system for ISO 9000 certification. It is being tested with success in a realistic quality improvement program at Compression Telecommunications Corporation (CTEL). As a result, a quality manual is being developed, and significant quality improvement is being achieved. CTEL is awaiting review of the documented quality system by a certified quality auditor.

**Framework for the Development of a Quality Manual  
Using the Systems Engineering Approach**

by

Michael Paul Woo

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of The University of Maryland in partial fulfillment  
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## Dedication

To Mom, Dad, Brothers, Sister, friends, G. Zhang, Wing, and Irene



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## **Chapter 1. Introduction**

### **1.1 Historic Review of Quality**

Before looking at how to implement a quality system or even fully understanding all the benefits of quality, the term quality must be defined well. Generally speaking, quality is a basic business strategy that provides goods and services whose features completely satisfy both internal and external customers by meeting their explicit and implicit expectations. Furthermore, this strategy utilizes the talents of all employees to the benefit of the organization in particular and society in general, and provides a positive return to the shareholders.

This issue of quality is so popular now that even the presidential candidates talked about it during the 1992 election! Based on a recent interview by the American Society for Quality Control (ASQC), it seems like Clinton and Bush understand quality. However, trying to explain quality to others is not an easy task. For those who know nothing about quality, the lack of a mathematical background makes quality less tangible and more difficult to define. On the other hand, for those who have an idea of what quality is, this absence of formal metrics results in many interpretations and different understandings of quality. This situation, though, is changing and must continue to progress because the U.S. now must compete not only within itself, but also with the rest of the world.

The idea of quality control has evolved during each technological period in history. During Medieval times, quality control consisted of doing the best job and taking pride in your work. When the individual craftsman was replaced by guilds working under a manager, quality was assured through inspection. This idea continued into the industrial age. However, around this time, several people started applying statistics to aid in quality control. The founding fathers of statistical quality control include people such as Walter A. Shewhart, who contributed many ideas including the control charts, Harold F. Dodge and Harry G. Romig who together developed the Dodge and Romig Tables for sampling plans, Eugene L. Grant and J.M. Juran, who were both leaders in field of quality management, Ellis R. Ott, a founding member of the American Society for Quality Control, and W. Edwards Deming, who has become a symbol in the area of quality management. To provide guidelines to aid management, Deming developed his set of 14 points:

- Point 1: Be consistent in improving products and services
- Point 2: Adopt the philosophy of quality is job #1
- Point 3: Cease dependence on total inspection
- Point 4: Do not make business decisions based solely on price
- Point 5: Strong commitment to improvement
- Point 6: Educate and retrain employees to perform job
- Point 7: Institute leadership
- Point 8: Drive out the fear of talking to executives
- Point 9: Break down barriers between staff areas
- Point 10: Eliminate slogans and targets
- Point 11: Eliminate numerical quotas
- Point 12: Remove barriers to pride of workmanship
- Point 13: Institute a vigorous program of education and retraining for new skills.

Point 14: Take action to accomplish the transformation to a quality program

One of the results of all these past developments has been the creation of quality standards and standards groups, such as the ISO 9000 standard, the International Organization for Standardization (ISO), and the American National Standards Institute (ANSI), which is the United States representative to the ISO. The ISO 9000 standard was developed by the International Organization for Standardization, which was formed in 1946 to create standards in the areas of manufacturing, trade, and communications. It is a mix of many different standards from different industries including the military, the nuclear power plant regulations, the Food and Drug Administration (FDA), and certain British standards. This international standard is the equivalent of the United States ANSI/ASQC Q90 series. The mapping of the ISO standard to the U.S. standard is  $ISO\ 900n = Q9n$ , where  $n = 1, 2, 3, \text{ or } 4$ . The ISO 9000 series international standards themselves provide generic guidance that focuses on the procedure of developing quality products, not the product itself.

As the world enters the information age, the new challenges will be generated by globalization. One of the challenges is due to an increase in vigorous worldwide economic competition. To compete in a global market, many have chosen quality improvement as their company goal. In a 1993 survey, conducted by the American Electronics Association, it was discovered that 87% of the managers surveyed believed that quality, not service or technology, was the main factor needed to compete

successfully. [1] The main reasons are both external and internal. Reasons external to the company include higher customers' expectations of system functions and quality, expectations of shorter overall life cycle of a product, new contractual requirements, and faster progress in technology. By placing emphasis on quality, a company will have more satisfied customers, increase their market share, and improve their company image. Quality can also increase the overall income of a company.

The reasons internal to the company include the need to improve work efficiency as well as the need to reduce costs. Using quality standards to continuously evaluate current procedures to reach higher levels of quality, a company can improve the working environment of workers, and also make the transition smoother for new employees or employee changes. This effort to increase worker productivity can lead to shorter product development cycle.

## **1.2 Fundamental Principles of Quality**

There are three fundamental principles in quality engineering, which is the study and application of these principles:

1. **Customer Focus:** Quality is based on the concept that everyone has a customer and that the requirements, needs, and expectations of that customer must be met every time if the organization as a whole is going to meet the needs of the external customer. This concept requires a thorough collection and analysis of customer requirements, and when these requirements are understood and accepted, they must be met.

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1 King, Julia, "Quality Conscious", pp. 89-91.

2. **Process Improvement:** Continuous improvement of key manufacturing and business processes is fundamental in quality engineering. All the processes should be reliable by reducing and controlling variability. When the process output is undesirable, redesigning of the process is necessary to produce an output that is better able to meet the customer's requirements.
3. **Total involvement:** Employees at all levels, leaders of management, and suppliers should actively participate in the continuous improvement of product quality. The top management should organize and establish the quality engineering system through education, training, communications, reward, and recognition.

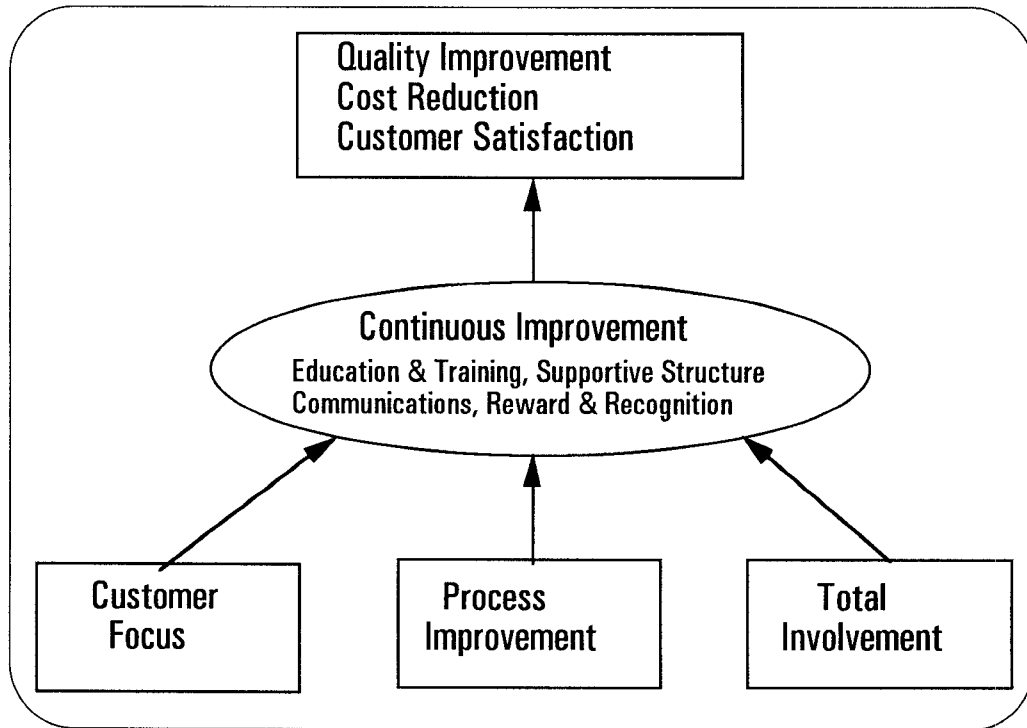


FIGURE 1.1: Quality Principles

### **1.3 The Need for a Quality Manual**

Any effective quality system requires the development of a quality manual, which is a collection of documented procedures to assure quality. Every quality system should be represented by a quality manual. This is due to the fact that each company has its unique system to assure customers of its product quality. Documenting procedures is critical in a quality system to ensure continuous and consistent operation when employees are away from the office for vacation, when employees leave, or when new employees are hired. The success of a quality system depends on human beings, not machines. A quality system with people working systematically using well-designed procedures is a good system. However, if such procedures reside only in the minds of the employees and not on paper, then such a system can not operate consistently at a high level.

Companies that have a quality program understand the importance of documenting their quality system. However, this documentation process is a weak link in most quality systems, according to consultants at SGS Yarsley and AT&T Quality Registrars. There are several possible reasons for this. They include:

1. Creating, editing, and controlling documents is time-consuming
2. Time is not allocated for documentation.
3. Management does not emphasize the need to document.
4. Proper documentation procedures do not exist, or are vague.
5. Lack of training in skills for documentation.
6. Necessary tools are not available for the documentation effort.

The research addresses this need with the framework for the development of the quality manual using the Systems Engineering approach. This development of this framework required the selection of a quality standard as the driving force supplying the goals. Then a method was needed to achieve these goals. The developed framework incorporates the company's creativity and efforts, along with information technology and training as tools to create the quality manual.

Throughout this thesis, reference is made to the quality manual development efforts at Compression Telecommunications Corporation, which is a growing telecommunications firm that designs, manufactures, and supports their own telecommunications test equipment. Their customers include U.S. telephone companies as well as others in Europe and Asia. CTEL is moving into the worldwide market, and need to create, refine, and document processes to compete successfully.

#### **1.4 Thesis Organization**

The following chapters describe the development of the framework. Chapter 2 examines several quality standards, and suggests one as the guideline for the framework developed in thesis work. Chapter 3 defines the Systems Engineering methodology and then modifies it to fit the quality guideline selected. Chapter 4 discusses the importance of using information technology to introduce new possibilities of streamlining the documentation process. Examples of applying information technology to develop more

efficient information systems are cited in this chapter. The research in each of these chapters results in the creation of the framework, which is described in Chapter 5. This chapter highlights some of the efforts of CTEL during the early development stages of their quality system. Finally, Chapter 6 concludes with the advantages of using this framework to develop a quality manual.

## Chapter 2. Quality Management and Standards

### 2.1 Introduction

The development of the framework, as illustrated in Figure 2.1, begins with the selection of a set of quality guidelines. The guideline selected affects the level of quality created. There are three major levels of quality that can be implemented in a company. They are listed in the order of most comprehensive to least comprehensive:

1. Quality assurance
2. Quality control
3. Inspection

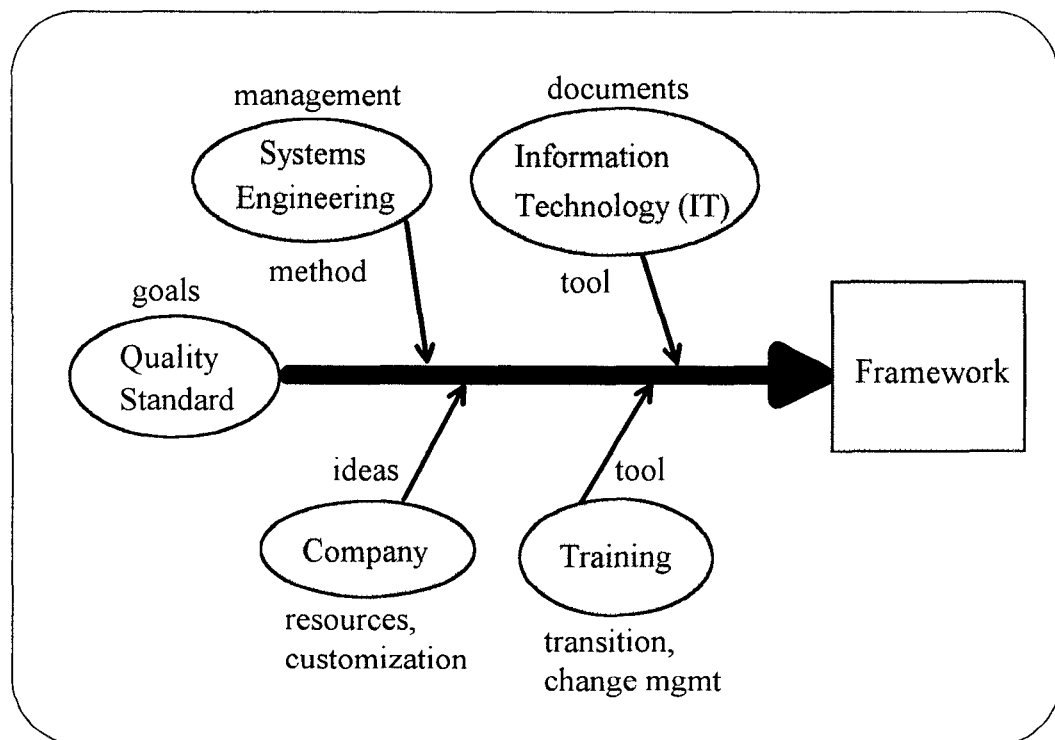


FIGURE 2.1: Focus on Quality Guidelines

The most comprehensive level of quality implementation that can be reached by a company is the quality assurance level. It involves everyone in the organization including managers, engineers, manufacturers, suppliers, marketing personnel, and even customers. To achieve this high level of implementing quality, a company must use both plan for quality in the design, manufacturing, and maintenance phases of the system life cycle. The goals at this level are to find and reduce sources of variation in the product life cycle and to correct failures through a maintenance plan. The second level is quality control. The main goal here is to prevent defects, but not correct failures. The tools used include sophisticated inspections and controls such as sampling plans. Finally, the third and least effective level of quality implementation is inspection. The goal at this level is to react to system failures, not to prevent them. Companies at this level do not usually consider quality early in the design phase of the system. Therefore, they resort to corrective actions. Defects are fixed as they occur. The results are more frequent defects, lower level of customer satisfaction, and higher maintenance costs in terms of money and time.

## **2.2 Total Quality Management (TQM)**

Based on my survey of literature on Total Quality Management, I have come up with the following list of elements that make up TQM:

1. strong commitment to quality from managers
2. creation of a quality committee to observe, plan, advise, ...

3. constant communication
4. education
5. interaction among managers
6. discipline
7. quality improvement process
8. use of statistics
9. recognition and reward for quality work
10. company-wide initiative that includes customers and suppliers
11. implemented top-down
12. application of well-known business practices
13. requires time

An organization is the relationship structure of work assignments and responsibilities to functions and persons within the organization. [2] Whatever the functions may be, there are several workers to perform these functions. Planning and controlling of these functions are part of management's activities to the company's commitment of quality design. Management activities in planning and controlling consist of:

1. Determining goals on a long, medium, and short term basis.
2. Correlating quality maintenance objectives to ensure that the goals are valid.
3. Assigning the proper people with sufficient training to fulfill all functions.
4. Seeking the broadest possible participation of staffs in fulfilling company's goals.
5. Communicating objectives and plans as widely and clearly as possible.

For an organization to achieve its goals, management must be able to fully integrate all the activities and functions with employees, managers, and all supervisors.

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2 Sinha, M.N., and W.O. Willborn, The Management of Quality Assurance

This integration is important because it helps the company in meeting the needs of their customers and attaining quality control in the workplace.

In order to meet customer's need and attain quality control, operations and performance must be planned, monitored, and controlled, so that deviations are recognized in time and corrections made to prevent their recurrence. The overall approach is for management and all employees to be culturally and physically interrelated in the working environment. This interrelationship can be achieved through Total Quality Management. TQM has been defined as the application of management methods and activities to control the company's operating procedures with the objective of achieving continuous improvement [3], in quality control and customers relationship.

Quality improvement often requires considerable self-examination of the organizational structure, and a willingness to make widespread and sometimes uncomfortable changes from its current structure to a new structure. The degree of transition difficulty depends on how management makes these institutional changes and how well the factors of the change process itself are understood and implemented. Before the organization can make structural changes, basic quality concepts must be understood and adopted as the vision for improvement. Continuous improvement should be a routine part of everyone's job, but making this actually happen is difficult. Therefore, continuous improvement implies a constant attempt to change the

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3      Booher, H. R., MANPRINT: An Approach to System Integration

operational and functional structure of the organization for the better. [4] Changes to the organization operational and functional structure are commitments to quality assurance in the workplace.

In addition with TQM, management can implement a quality plan that provides the organization with road maps and guides to deliver quality systems. The purpose of the quality plan is to reduce the need to subsequent quality improvement by doing everything right the first time. [5] A quality plan can be very successful with strong management commitment, employees participation, and project teams. According to Burger [6], a quality plan consists of six steps and different tools to help in producing quality products or systems. These steps are:

1. Planning starts with a goal. Without a clear and correct goal, no plan has value.
2. Once the goal is set, then the required resources (time, money, cooperation, skills, documents, etc.) are identified.
3. Next, actions must be specified when and by whom! In other words, set a timetable and assign responsibilities.
4. The plan must be documented. The method of getting from today's status quo to the goal must be set down on paper as the plan evolves.
5. As the plan is being implemented, measurements and checks are regularly performed to monitor progress. This includes time schedules, cost targets, and use of personnel.
6. Since planning is an ongoing and iterative process. the plan may have to be modified. A really complete plan incorporates the process by which it can be modified.

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4 Pyzdek, T., and R. W. Berger, Quality Engineering Handbook  
5 Pyzdek, T., and R. W. Berger, Quality Engineering Handbook  
6 Ibid

Implementing TQM in a company involves choosing a strategy, creating a vision, being persistent, setting benchmarks, and networking with other companies who are also trying to implement quality programs. Examples of companies who have succeeded in incorporating quality into their companies include Ford Motor Company, and General Motors. Competition in the American-dominated automobile industry started with the oil embargo in 1973. The rising fuel prices led consumers away from the large American cars to smaller foreign cars. This trend continued due to the higher reliability and fuel efficiency of Japanese cars. After losing money for the first time, \$1.6 billion in 1980, Ford management realized the need to improve the quality of their products. With the help of Deming, Ford performed an self-evaluations to determine all sources of defects. One major revelation came from their study comparing the same transmission design that was built by Ford and Mazda. Why did the Mazda-built transmissions have a lower failure rate than the Ford-built ones? After breaking down the transmission and measuring the small components against the design, Ford found out that the variations in the Mazda parts were smaller than Ford's. When the parts where assembled together, these variations added up to a larger total variation in the Ford transmissions. These small variations, then, were the source of errors in the Ford transmissions. By controlling the variations and improving other areas, Ford was able to reduce their repair rates by 45% and increase their market share by 19.2% in five years. The other reaction to their first-time loss was the creation of a new \$3.25 billion

car line, the Ford Taurus and Mercury Sable. With an emphasis on doing it right the first time, the Taurus has become a very profitable venture. In 1992, Taurus outsold the longtime top-selling Honda Accords to become the best seller of that year.

In 1980, under circumstances similar to the Ford Motor Company, General Motors' chairman, Roger Smith, announced the creation of Saturn Corporation, a multibillion dollar new car company. The goal of Saturn was to completely redesign the car making process from beginning to end by adding innovative processes and materials, and emphasizing quality of product and organization. Some of the new ideas included the formation of teams, replacing hourly wages with salary wages that were dependent on company profits, empowering the teams with more authority and control over their work, rotating different jobs among technicians within a team, requiring 92 hours of job-related training every year, adding human factors issues in the design of the manufacturing process, and using new polymer pellets materials to create dent-resistant panels. After a ten year redesign effort, Saturn Corp. opened its first plant in Spring Hill, Tennessee in 1990. The combination of new manufacturing processes, low maintenance materials, easy servicing car design, and one price tag for a car has resulted in an affordable, high-quality car that is currently in very high demand.

### **2.3 Quality Guidelines**

Quality is defined as the ability and features of a product or service to meet the

needs of both the internal and external customers. Prior definitions had considered quality solely in terms of satisfying customer needs. Such a definition is incomplete because all quality efforts must consider boundaries set by company policy and availability of resources. For example, most smaller companies can not fully implement all the guidelines defined by TQM due to their limited human resources, assets, and capital. Therefore, quality guidelines must be tailored to best suit the company. This may require a company to implement a subset of TQM and have the ability to meet customer requirements up to a certain point.

Although quality is now a fashionable buzzword, there are several awards and programs that have been around for awhile and could possibly be used as guidelines for implementing a quality system. They are:

1. Deming Prize Criteria
2. Malcolm Balderidge National Quality Award Criteria
3. ISO 9000 international standard

### **2.3.1 Deming Prize Criteria**

The Deming Prize is named after one of the biggest champions of the quality movement, W. Edwards Deming. Deming, a well-known person in the field of quality management, first learned statistical quality control while studying under Walter A. Shewhart in the 1930's. Afterwards, he applied the sampling techniques to the 1940 census, and soon was called to help the World War II cause by teaching statistical

quality control to the military and its manufacturers. Deming and statistical quality control reached their peak in popularity prior to and during the war. When the war was over, the lack of competition and the advent of the scientific management method led people away from quality control.

However, the Japanese, who were willing to listen to almost any rational plan to get back on its feet, called on Deming to help their industry become competitive. He agreed to educate the engineers on statistical quality control methods for free. But from his experience in postwar America, Deming learned that it is not good enough to teach the technical staff and get them enthusiastic about SQC. He decided that it was equally important to convince people at the top about this method. Deming succeeded in doing this in Japan, and consequently, Japan has become very successful in many markets.

The Deming prize was established in 1951 by the Union of Japanese Scientists and Engineers (JUSE) using proceeds from Dr. W. Edwards Deming's published lectures, proceeds that Deming refused to accept. The prize is a silver medal with the profile of Deming. It is awarded to the winner of two major categories -- the Deming Prize for an individual accomplishment in statistical theory, and the Deming Application Prize for a company's accomplishment in applying statistics to improve a quality program.

This award started out rewarding those mainly with accomplishments in the use of statistical quality control tools, but now has included Total Quality Control (TQC), the Japanese version of TQM. The criteria for the Deming Prize cover the following areas:

1. Company quality policy and plans
2. Quality management structure
3. Level of commitment to education
4. Quality of company's information system
5. Data analysis methods
6. Type of standards set and used
7. Process control
8. Quality assurance
9. Measurements of quality efforts
10. Long range plans

The Deming Prize criteria incorporates both Deming's 14 points of quality management as well as some other quality management concepts. Deming felt that such a philosophy was needed for managers to complement the use of statistics by engineers and technicians.

The first criteria focuses on a company's quality policy and plans. This relates to the following group of Deming's 14 points:

- Point 1: Be consistent in improving products and services
- Point 2: Adopt the philosophy of quality is job #1
- Point 5: Strong commitment to improvement
- Point 7: Institute leadership
- Point 8: Drive out the fear of talking to executives
- Point 9: Break down barriers between staff areas
- Point 10: Eliminate slogans and targets

Point 14: Take action to accomplish the transformation to a quality program

In this criteria, Deming is trying to point out that the quality effort begins at the top with management and the policies they set. A lack of consistent dedication by management is a major obstacle to any company trying to achieve higher quality. Also, imitating success rather than developing system that fits the company also is detrimental to a company's quality efforts.

The second criteria deals with the company structure management for the quality efforts. The delegation of responsibility, determination of skills and quantity, and interpersonal communication are evaluated by this criteria. Deming cited two major obstacles to satisfying this criteria. They are high turnover rate of management, and management blaming workers for problems.

Commitment of financial resources and time to education is the third criteria to satisfy. This is emphasized in the following Deming's 14 points:

Point 6: Educate and retrain employees to perform job

Point 13: Institute a vigorous program of education and retraining for new skills.

Without proper knowledge, workers cannot perform their job as well. Also, Deming points out that the theory-based teachings of management at the universities do not prepare students for the management of quality efforts in a company.

The fourth criteria covers the quality of a company's information system. It examines what type of data is collected, how it is stored, and what type of analysis is performed on the stored data. Also examined is how fast the retrieval of data and reporting of information found from the analysis is delivered to those who require it. This is an area where information technology can be applied to improve the process.

The fifth and sixth criteria of the Deming Prize are data analysis methods, and the type of standards set and used in the quality system. Statistics is the basis of many of Deming's beliefs. Proper use of statistical methods is examined. This relates to the emphasis on education. Standards, such as acceptance and rejection levels, are very important because they determine how statistical results are interpreted.

Process control usually refers to the use of statistical quality control methods. The criteria examines the activities and procedures designed to control quality, costs such as excessive medical costs, and excessive costs of warranty and lawyers fees. In point #3, Deming states that quality must be achieved through prevention rather than by total inspection.

A major area that needs to be well-designed is the quality assurance procedures.

Deming addressed this in several of his 14 points:

- Point 4: Do not make business decisions based solely on price
- Point 11: Eliminate numerical quotas
- Point 12: Remove barriers to pride of workmanship

This is an area where many things can go wrong. A lack of total company involvement in quality efforts, applying technology to business process without evaluating process first, trying to achieve quality by inspection, and insufficient prototype testing are all processes that are detrimental to the quality efforts.

The last two criteria evaluate a company's methods for measuring quality efforts and long range plans in relation to quality. Deming strongly believed that short term goals hindered an efforts to improve quality in a business. An example of this is stressing quantity over quality. Often, revenue forecasts are set without proper consideration of the product quality. Management by objective using performance reviews is discouraged by the Deming Prize criteria. Quality concepts, such as level of satisfaction, are currently very difficult to measure quantitatively, so excessive reliance on measurable factors such as money can impede the quality system development.

The criteria of the Deming Prize are aimed at improving the quality of products and services rendered by companies. However, it is not enough for a company to follow a systematic approach of defining requirements, performing feasibility studies, creating specifications, designing, implementing design, and testing. Quality starts at the top with management. If management decides that it wants to implement Systems Engineering principles without emphasis on quality, then requirements will not be stated with quality control issues, feasibility studies will be performed without considering the quality of the possible solutions, designs may be designed with only

not quality, and testing may not include some type of quality metrics, such as statistical quality control.

In order for quality to be included in the company process, management must provide leadership. It must be the driving force behind the quality program. Management should drive out fear in their companies. If there is a problem, then workers should feel comfortable about telling management. Without this communication, a quality program can not succeed. Feedback at all levels is necessary. Management should promote the idea of workers getting training in quality issues. Statistical quality control is a tool, and without knowledge of this tool, it can not be used to benefit the company. Many of Deming's points try to give some power to the workers. These points try to show that the worker should perform his job to please the customer, not his manager. A worker trying to meet quotas or any other numerical target is focused on pleasing the manager, not the customer. Using the Deming Prize criteria, a company can learn to see that the customer should be the main focus of all activities.

### **2.3.2 Balderidge National Quality Award Criteria**

The Malcolm Balderidge National Quality Award (MBNQA) is given each year to companies whose quality program meets the award's criteria. The National Institute of Standards and Technologies (NIST) manages the award and makes the

determination of who satisfies the criteria. As this quality award has become more popular, these criteria have become a standard by which companies follow in implementing a quality program. Similar to the Japanese's Deming Prize, the Balderidge Award encompasses the elements of TQM. However, most companies do not implement or modify their quality program just to win this award. Rather, the criteria are guidelines that companies can gather around and discuss. Its main intention is "to serve as a working tool for planning, training, assessment, and other uses". [7] The main goal of the MBNQA criteria is to increase America's competitive edge over the world.

The Balderidge award evaluates a company's processes, how well it implements those process, and the results of these efforts. Overall customer satisfaction is usually measured to quantify the evaluations. There are seven (7) major categories in the Malcolm Balderidge National Quality Award and specific point values associated with each category, as shown below.

1.0 Leadership	90 pts
2.0 Information and Analysis	80 pts
3.0 Strategic Quality Planning	60 pts
4.0 Human Resource Development and Management	150 pts
5.0 Management of Process Quality	140 pts
6.0 Quality and Operational Results	180 pts
7.0 Customer Focus and Satisfaction	300 pts

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7 Sullivan, Rhonda L., "Inside the Balderidge Award Guidelines", p. 26.

Within each major category, there are subcategories and associated points.

Underlying the seven major categories are ten (10) core concepts:

1. Customer-driven quality
2. Leadership
3. Continuous improvement
4. Full participation
5. Fast Response
6. Design quality and prevention
7. Long-range outlook
8. Management by fact
9. Partnership development
10. Public responsibility

The first category includes the ten core concepts of the Balderidge award. This makes sense because the company leader(s) should be the driving force behind a company's move to a higher quality standard. As Deming learned from his experience in America during and after World War II, quality starts from the top. The executives can not expect the company to improve its quality program through "lip service". Instead, they must lead by actions. This would include contacting customers themselves, getting feedback from employees, either teaching or actually going to classes, and developing a long-range plan designed to continue improvement. Another important point that should be emphasized is leadership by data and data analysis, not just by intuition. Statistical analysis is an objective method to interpret the data. Even though past experience is invaluable to the decision-making process, there is a need for

objective reasons to back up a decision. Statistics is a tool that would complement experience in making decisions.

Category 2 is mainly about the role that information systems plays in the quality program development. Obviously, the collection and analysis of company data would be difficult if there did not exist a quality information system. Even though this category has less weight as indicated by the maximum points given in this category, the information and analysis is actually very important. It can be considered the backbone of a company. Data, documentation, and records are all present in the other six major categories, so there is a need for the information system to create a smooth flow of information between each group inside a company. This integration of data is the key to a quality information system.

Category 3 evaluates the strategic quality planning of a company. Basically, this category will evaluate both the process used and how well the process was executed. A company that is successful in this category will determine the business process to improve, and then use TQM to go about changing this process. It is important to integrate the quality process of improvement with business planners. This will enable the company to improve the quality of business processes that are related to customer satisfaction. A short term and long term plan must be created.

A very important consideration for the Balderidge award is category 4, which looks at the development and management of human resources. The areas deals with

human factors issues including communication between worker and manager, education and retraining of all employees, and the use of the teamwork idea. A quality program is one in which the manager can develop a worker to reach his/her potential through education, training, communication, and analysis of employee data. An employee is the most productive when working up to his potential. Education is very important because it brings all workers to the same level of understanding of a new process. The use of teamwork is very productive when it comes to problem solving, design verification, and maintaining good worker morale.

Category 5 deals with the evaluation of the product design process. It assesses how a company translates a customer's need to formal specifications, and speculations to design. This category also evaluates how well a company finds errors in the design process, and improves the process. Improvements include process simplification, reduction in time and money wasted, and shortened feasibility studies cycle time. The overall management process to consider using is the Systems Engineering method discussed earlier.

Category 6 evaluates the company's results of implementing their quality program. These results are quantified measurements that reflect how much the company's processes have improved customer satisfaction, and how much the company has improved internal processes. In terms of customer satisfaction, data should be collected relating to the product. The analysis of the company itself requires collection

of company-related data such as waste reduction, energy efficiency, and environmental improvement. The use of statistics here would be helpful when comparing different processes, or determining trends. The cause-and-effect charts is a useful tool to use for self-improvement after viewing the results of this category.

The final and most heavily weighted category is category 7 -- customer focus and satisfaction. It contains one-third of the total points because quality is a customer-centered idea. Everything that a company does to improve has the customer in mind. Any activity that does not affect the level of a customer's happiness is not considered high-priority in the list of things-to-do. The company must fully understand the customer's needs, and be able to resolve complaints promptly. It is difficult sometimes to objectively quantify customer satisfaction, but this process is also evaluated for the level of constant improvement.

### **2.3.3 ISO 9000**

ISO 9000 is made up of five standards -- ISO 9000, 9001, 9002, and 9003. The Q90/ISO 9000 is a general standard that defines fundamental quality concepts, provides guidance in selecting and tailoring one of the three quality models (9001, 9002, 9003), and provides guidance on using ISO 9004. Q91/ISO 9001 and Q92/ISO 9002 deal with the relationship between customer and supplier. ISO 9001 requires quality procedures to be created for product design, manufacturing, maintenance and

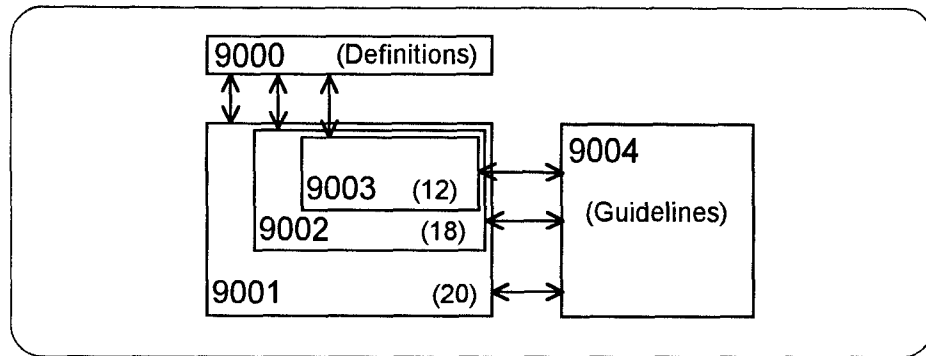


FIGURE 2.2: Relationship Between ISO 9000 Standards

TABLE 2.1: ISO 9000 Comparison			
	ISO 9001	ISO 9002	ISO 9003
1.1 Management Responsibility	x	x	x
1.2 Quality System	x	x	x
1.3 Contract Review ●*	x	x	
1.4 Design Control	x		
1.5 Document Control ●*	x	x	x
1.6 Purchasing	x	x	
1.7 Purchaser-Supplied Product	x	x	
1.8 Product Identification and Traceability	x	x	x
1.9 Process Control	x	x	
1.10 Inspection and testing	x	x	x
1.11 Test equipment inspection, calibration and maintenance ●*	x	x	x
1.12 Inspection and test status	x	x	x
1.13 Control of nonconforming product	x	x	x
1.14 Corrective action	x	x	
1.15 Handling, storage, packaging and delivery	x	x	x
1.16 Quality records ●*	x	x	x
1.17 Internal quality audits	x	x	
1.18 Training ●*	x	x	x
1.19 Servicing	x		
1.20 Statistical Techniques	x	x	x

symbols: ●\* = often poorly handled

support. The ISO 9002 model requires quality procedures in product manufacturing and support. The last standard, Q93/ISO 9003, defines the area of testing and inspection. Finally, the ISO 9004 standard covers in detail the elements of quality, and their application for internal use. When a company states that it is compliant with the ISO quality standard, it usually means that it has met the Q91 and Q92 standards. [8]

The main idea behind Q91/ISO 9001 and Q92/ISO 9002 is that companies must first define and document requirements, then develop the product to meet these requirements, and finally, inspect and record the products.

#### **2.4 Comparing ISO 9000, Deming Prize, and Malcolm Balderidge Award**

One of the three previous quality standards is needed for the development of the framework. This will be determined by comparing the level of emphasis on the product life cycle, cost factors, amount of time and human resource requirements, and consistency with TQM principles using a trade-off analysis. The comparison will be a relative one comparing one against another. The goals, methods, management, training, customer interface, design control, procurement, process control, handling and shipping, after-sales service, inspection and testing functions of the three quality guidelines will be examined as part of the trade-off analysis.

In terms of goals, the ISO 9000 and Balderidge Award are clearly defined, but the Deming Prize is vague and more theory-oriented. The ISO 9000 and Deming Prize

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8 Arter, Dennis R., "Demystifying the ISO 9000/Q90 series standards", p. 65.

seek improvement by focusing mainly on the customer and continuous internal improvement. On the other hand, the Balderidge award uses benchmarking (comparison against competitor with highest quality) to set goals for increasing the company's competitiveness. All three require lots of documentation with ISO 9000 being the least and Balderidge being the most. The ISO 9000 is process-oriented with continuous improvements through evaluation of audit results and records. The Deming Prize places emphasis on management involvement and statistical theory. The Balderidge award is results-oriented.

To achieve the goals, the Deming Prize and Balderidge Award have well-defined methods. However, the ISO 9000 does not define specific methods for satisfying their defined guidelines. It lets each company determine how they will implement the ISO 9000 standard. All three are consistent with the definition of quality by requiring the involvement of all employees in the company. The degree of this involvement is higher for the Balderidge Award, and Deming Prize. The Deming Prize demands the most time and effort from the management.

In terms of the product life cycle, all three require quality procedures in training, customer interface, design control, procurement, process control, handling and shipping, and after-sales service. Deming places more emphasis on statistics and process control. However, for inspection and testing, the Deming Prize differs from the other two. Deming emphasized prevention instead of inspection to improve quality.

Overall, all three quality guidelines cover the basic system life cycle. There are also several other areas outside the life cycle that are covered by these guidelines. An example is the leadership effort in advertising quality to the public. The ISO 9000 does not mention this. The Deming Prize acknowledges this more as a passive activity. Being the most well-defined and comprehensive guideline, the Malcolm Award requires companies to actively champion the quality concepts to the public. The ISO 9000 provides basic requirements for the quality system. Other elements, such as public responsibility, employee recognition, leadership and customer satisfaction benchmarking, the concepts of driving out fear and removing barriers, and the elimination of management by objective are all absent from the ISO 9000 standard, but present in the other two award criteria.

The Malcolm Balderidge Awards and Deming Prize criteria both comprehensively cover the TQM principles. The advantage of using such criteria is that a company that conforms to all these guidelines will have a complete quality system. The disadvantage is that the award guidelines requires a lot of company resources to fully implement. Smaller companies may not have the capability to meet the Balderidge guidelines, and others that do attempt may either fall short or lose too much valuable company resources. Many companies prefer to achieve a subset of the Balderidge guidelines to create a quality system that is within their means.

On the other hand, the ISO 9000 standard provides a very generic and basic set of goals that any company can be achieved in twelve (12) to eighteen (18) months depending on the quality model chosen. This time period is relatively shorter when compared to the number of years required for the other two.

All these comparisons can be summarized in a trade-off analysis, which is shown in Table 2.2. Based on the four criteria selected, the ISO 9000 is the quality guideline of choice.

Features	Weight (W)	Candidates					
		ISO 9000		Balderidge		Deming	
		score (S1)	W*S1	score (S2)	W*S2	score (S3)	W*S3
Life cycle coverage	1	5	5	6	6	6	6
TQM coverage	2	2	4	8	16	7	14
Costs	5	8	40	2	10	4	20
Time and human resource requirements	2	7	14	1	2	3	6
TOTAL:			63		34		46
RANK:			1		3		2

score: 1 = low rating, 10 = high rating

rank: 1 = highest, 3 = lowest

By starting with the ISO 9000, a company does not lose any effort if it decides to reach TQM later. The reason is because ISO 9000 has the basic elements of TQM. Compared to Balderidge, the ISO 9000 is a baseline solution to reaching TQM. A

quality system that is based on the ISO 9000 can be upgraded later as the company grows to cover TQM in more detail.

The quality system developed using the ISO 9000 provides a competitive advantage for a company by improving the internal quality system, fulfilling customer requirements, providing a marketing tool, and reducing costs by reducing the number of audits. The European Economic Community's (EEC), as part of the unification effort, and many Asian countries will start requiring that all suppliers be certified. According to Longwell, "Asian manufacturers have also been aggressive in adopting the [ISO 9000] standards, ...". [9] The following ISO 9000-certified North American electronics distributors have mentioned their certification status in their advertising:

1. Arrow Electronics Inc (Melville, NY)
2. Avnet Inc (Great Neck, NY)
3. Pioneer Technologies Inc (Gaithersburg, MD)
4. Hall-Mark Electronics Inc (Dallas, Texas)

## **2.5 Closer Look at ISO 9000**

Based on the comparison above, the ISO 9000 international quality standard will be the guideline used as the baseline for the quality manual. However, before it is integrated into the quality manual framework, the ISO 9000 should be examined more closely. Remember, it is a standard that certifies a process, not a product.

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9 Longwell, John, "To Certify or Not To Certify", p. 197.

ISO 9001, 9002, 9003 are external points of view based on a third-party auditor. ISO 9004 is an internal view expressed by the company itself. There are three terms that are related, but have subtle differences -- supplier, purchaser, and subcontractor. Supplier is the entity providing a product to a customer. Another words, the supplier is the producer. The company becoming certified is usually called the "supplier" in ISO 9001, 9002, and 9003, and "company" in ISO 9004. The purchaser is the one who orders and buys the products from the supplier. In ISO 9001, 9002, and 9003, the company receiving the goods and services are called the "purchaser", but considered the "customer" in ISO 9004. Finally, the subcontractor, as labeled in ISO 9001, 9002, and 9003, is the organization that supplies goods and services to the supplier or company. In ISO 9004, the subcontractor is called the supplier also. This usage of supplier with two meanings is a source of confusion to those who are new to this standard.

### **2.5.1 20 Quality Elements of ISO 9001, 9002, and 9003**

Throughout the standard, several themes are repeated. They are:

- Theme 1: Document what you plan to do, and do what you say that you will do.
- Theme 2: Prevent problems from occurring rather than finding and fixing them.

The ISO 9000 standard is document-intensive effort. Its development therefore, must

be well planned. A possible documentation model for the ISO 9000 is displayed in Figure 2.3. [10]

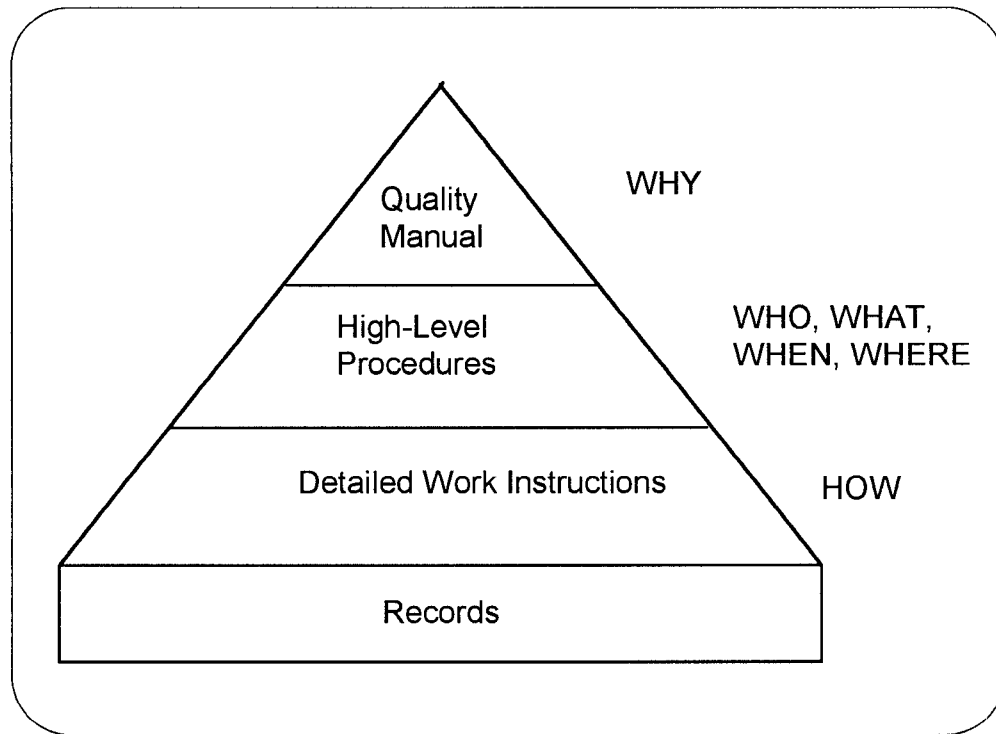


FIGURE 2.3: Documentation Model

The first element of ISO 9000 is management responsibility. The goal here is to define the role of management in developing a quality system. Management activities include creating a quality policy and structures, defining roles and skills and authority, providing resources, and reviewing the quality system.

Management is responsible for driving the quality efforts, and it starts by providing a direction for the company. Common topics in quality policies include on customer satisfaction, commitment, and continuous improvement. The final version of the quality policy must be documented as part of the quality manual.

Examples of quality policies include the following:

Computer manufacturer:

"A new product must perform better than the product it replaces and better than the competition's and this must be the case at the time of the first regular customer shipment." [11]

Another computer manufacturer:

"In selecting suppliers, decision makers are responsible for choosing the best source even if this means internal sources are not selected." [12]

Black and Decker:

"We at Black and Decker are dedicated to meeting the requirements of the customer, both internal and external. In an environment of continuous improvements, our commitment is to satisfy the customer by providing error-free products and services. Quality is the most important element of our business."

Company in manufacturing industry:

" It is the policy of Landesfel Electronics to manufacture and deliver products which conform to the specifications laid down in this manual to our customers. This includes not only manufacture to specification, but price, delivery, reliability and all interface between us and our customers from inquiry to delivered goods.

To achieve this policy a quality assurance system has been developed and installed as described in this manual to which management gives full support." [13]

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11 Juran, J.M., Quality Planning and Analysis, p. 121.

12 Ibid, p. 121.

13 Rothery, Brian, ISO 9000 -- Second Edition, p.57.

Company in laboratory industry:

" It is the policy of the National Metro Laboratory to achieve and maintain a top international standard in the running of its business. The Director shall have overall responsibility for the implementation and control of a system which carries out this policy. All members of staff are aware of the contents of this manual, which lays out fully the whole system of quality assurance that will enable this quality policy to be carried out." [14]

Management is also responsible for organizing employees to create and implement the quality system. This calls for defining each person and their responsibility to product quality, delegating authority, and matching the person with the task. For example, reviews and audits of a design or department can not be performed by the creator or a member of the targeted department. A management representative should be selected as an interface between employees and management.

A very important responsibility of management is to provide the tools and resources necessary to carry out the procedures such as inspection, process control, and internal audits. The tools include proper training, test equipment, and adequate authority.

As the driving force, management must analyze the data collected from the verification procedures and decide on a course of action to continuously improve the quality system. Review procedures must be well thought out and documented. Once the decision is made on how to resolve a problem, management must be able to

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14 Rothery, Brian, ISO 9000 -- Second Edition, p.57.

communicate this solution to the company, and make sure the correct people will implement the solution.

The second element is the quality system. The goal of this element is to make sure that all the procedures and personnel are correctly defined and documented to assure quality. To satisfy this element, the company needs to prepare documents of quality procedures and detailed instructions, implement them, and collect data based on the implementation for records. Each department should create and document the detailed work instructions, and then derive the high level procedures for the quality manual.

Contract review is a very important part of the ISO 9000 because it deals with understanding the customer's requirements in the early stages of the product life cycle. The goal of this third element is to make sure that the contract accurately represents a product that meets the customer requirements. Verification procedures with the correct personnel should be applied to assure that customer requirements are met. Procedures should be defined to work out any disagreements between the customer and supplier. Once an agreement has been reached, the supplier should be able to meet all demands in the contract. The result should be some type of checklist to match customer requirements with the company resources and products. Based on interviews with several registrars and quality consultants, including SGS Yarsley and the AT&T

Quality Registrars, this element has often been handled poorly in the past. Contract review is usually skipped or left undocumented.

Element #4 of the ISO 9000 should be made up of documented procedures to assure prevention of defects in the early design phase of the product life cycle. To reach this goal of prevention, a design plan should be created and documented. All design inputs in the form of specifications, recommendations, and resource constraints should be clearly identified and documented. These input sources must always be updated as the design progresses. Verification procedures need to be applied in this element also, and results should be recorded. Also, any design process need to create procedures to account for inevitable design changes.

The fifth element covers the area of document control. The goal here is to create an effective method to collect, store, retrieve, and analyze both documents and data to facilitate the development of the quality manual. This is another element that is often poorly handled based on the experience of consultants and registrars. This goal can only be realized by controlling the version of documents such as drawings, work instructions, specifications, and test procedures using a numbering system, master list, organized storage system, and documented procedures of an approval process. Once documents are accepted into the library, it must be available upon request. Procedures should be created for handling old versions of documents.

Procedures should be established to assure quality in the product components (required performance, timely delivery, and required costs) through subcontractor compliance. This is the goal of the sixth element, which covers purchasing. Procedures should be created and documented for specifying parts, setting criteria for selecting subcontractors (parts supplier), setting acceptance levels, verification, review, inspection, handling, labeling, and settling disputes.

Define procedures that specifically describe part(s) to be purchased. These documents may be in the form of specifications, drawings, and purchase orders. The information is related to type, class, packaging, speed, color, and size. Approval requirements should be included.

Procedures should require companies to create criteria that subcontractors must meet before doing business. This can be done by on-site evaluation of subcontractor's facilities and personnel, assessing product samples, evaluating historical performance based on quality records, references from other customers, or a written test given to subcontractors. The criteria to judge by include:

1. timely delivery
2. number of technical defects
3. financial security
4. market position
5. communication skills
6. customer satisfaction policies.

Procedures should also be developed for reaching an agreement between subcontractor and company on the level of quality acceptable. One of the following procedures can be used:

- a. evaluate subcontractor's quality system
- b. inspection sampling records by subcontractor
- c. 100% inspection process by subcontractor
- d. implementation of formal quality management system by subcontractor as specified by the company
- e. company in-house inspection

Verification and review procedures apply in this element also. Verification is not limited to the company. This can include exchange of inspection data. Also, customers can go to the subcontractor to verify their facilities. The verification procedures should call for a continual periodic assessment of the subcontractor's quality system.

Sometimes disputes arise due to inspections, or mistakes, or misunderstandings. Procedures are needed for settling disputes related to quality assurance. Improving communications between two parties is usually a good start to settling or preventing disputes.

This element also stresses the need for procedures to handle incoming, uninspected, inspected, and defective parts by separation, labeling, and precautionary actions such as wearing gloves. Parts should be labeled for identification and traceability. Inspection procedures should be created with costs and available

resources in mind. All the tools, gauges, meters, and testers should be calibrated before using. All personnel directly involved in the inspection should receive proper training.

Results of receiving inspections should be accurately recorded for future analysis of the subcontractor's performance. Historical data will reveal quality trends. This data includes product compliance with specified requirements, total cost for supplier, delivery arrangements, and perhaps, a description of the subcontractor's quality system.

There are certain situations or projects that require the customer, called the purchaser in this element, to supply a part to the supplier for integration into the final product. Examples of customer-supplied components include cassettes, boxes, video cards, motherboards, labels, tires, and even services such as delivery. This element, the seventh one, requires the supplier to develop and document procedures to store and maintain the customer-supplied part, and also, to verify that the part will help meet the customer requirements after being integrated into the final product. If a service is supplied by the customer, then its effectiveness and relevance should be documented.

Element #8 is requires procedures to be created and documented for product identification and traceability. The goal is to label parts and products with the appropriate level of detail necessary to allow specific materials and parts to be traced.

The key process to define involves the labeling of the any part that will be integrated into the final product. A part should be labeled as one of the following conditions:

- a. not inspected
- b. inspected and accepted
- c. inspected and on hold for decision
- d. inspected and rejected

The goal of the ninth element, process control, is to reduce the production process variations that cause defects. This prevention method is achieved by measuring the output, statistically analyzing the data for nonconformance, finding the cause of defects in the production process, and altering or fine-tuning the process to prevent defects in the future. The documented procedures should cover up-front planning, implementation, documentation, process measurements, and workmanship definitions. First, a company must create comprehensive steps that should be taken to manufacture a product. These steps should be implemented under work conditions that have little variations. Environmental variations such as noise, temperature, telephone calls, and meetings will affect the work flow of employees, and therefore, introduce inconsistencies in their production work. Variations can also come from materials, equipment, and personnel.

All planned processes that affect quality should be documented. This documentation is often called work instructions. These work instructions should describe the job responsibilities, the skill required to perform this job, the specific

equipment to perform the inspection and tests, and the quality of work expected. Quality records should show that the individual was hired because of a particular skill. The records should also show that workers have the received the necessary on-the-job training that is necessary to maintain and/or improve the quality of a product.

Verification of processes is also important in controlling production processes. This is usually accomplished by taking measurements at certain points of the production process and then performing some objective analysis on the measurement data. Such analysis can be done using one of the following statistical tools:

- a. cause-and-effect charts
- b. pareto charts
- c. histograms
- d. control charts
- e. acceptance sampling
- f. design of experiments
- g. proper maintenance of equipment
- h. process capability study

The goal is to make sure that what is actually built meets either an intermediate requirement or the final product requirement. The personnel performing this verification should have some training in statistical quality control.

Deming defines two types of variation causes. One is common causes and the other is special causes. The above procedures handle the special causes of variation. Common causes are variations due to natural built-in variations, such as worker's ability, procedures, and machine limitations. The source of these variations are much

harder to identify because of its nature. Special causes, on the other hand, are those that can be found and eliminated. Examples of these causes include machine malfunctions, unsuitable worker, and poor component quality.

ISO 9000 also defines certain processes as special. These are processes whose evaluation involves some degree of subjectivity, and therefore, can not be fully verified against the defined requirements. Examples include metal parts, plastics, baked goods, financial software, software user interface overall "look and feel", chemicals, and other processed materials. These processes will require more comprehensive measurements, statistical quality control, and more frequent verifications of equipment, personnel, and environment.

Element #10 deals with inspection and testing of assembled products. The main goal of this element in the ISO 9000 is to verify that the subcontractors are complying with contractual agreements of delivering parts. This compliance assures quality of final product using receiving, in-process, and final inspection. The quality of the final product partly depends on inspection and testing, but the degree of these activities should depend on the costs and resources available. This standard does not require inspection and testing. It only requires procedures that will determine if a subcontractor has fulfilled his contractual responsibilities. It is a verification procedure. However, this verification usually involves some type of inspection for comparison procedures.

Basically, this overlaps the procurement's incoming inspection procedures. Do not allow incoming parts to be used until they have been inspected and/or tested. Before incoming parts are inspected, they should either be placed in a separate area that is specifically assigned and labeled for parts not yet inspected, or the parts themselves should be tagged as uninspected/untested. Verify that the part, style, quantity and function satisfy the specifications document, which is usually in the form of a purchase order, that was sent to the supplier. Inspection procedures should specify what feature or characteristic, such as dimension, color, and material should be examined for compliance to the requirements.

Records should be kept of the results of the results of compliance procedures for incoming parts. Therefore, if parts pass compliance procedures, then their status should be documented. If parts are defective or fail to meet the company's specified expectations, then procedures for nonconforming parts (element 13) should be followed. These records together will be analyzed has historical data for assessing subcontractors performance.

If incoming parts are urgently needed before compliance tests can be performed, then it must first be determined if defects resulting from uninspected parts will severely affect their dependent components. Also, a solution should be determined to handle the case where the uninspected part is defective. Authority to override compliance tests for urgent use should be well-defined and delegated to people. Once

these plans have been established, the uninspected incoming part should be labeled or documented so that it can be traced as a possible source of a future defect.

This is similar to process control (element 9). The basic idea is to perform inspections and tests at certain checkpoints in the production cycle to catch problems before the final inspection. These checkpoints must be carefully planned out. For example, when producing a PC-based printed circuit board (PCB), plan a test of functions that require the least amount of components to be installed, such as power. If a microprocessor is onboard, then test its ability to access different address and data lines, different I/O ports, and any necessary interrupts.

The final product should be completely tested to verify that it meets all specifications. There are several methods to verify the final product. One is 100% inspection of the final product. Another is using an acceptance sampling plan which requires testing a predetermined sample of units that will represent the whole production lot. To set up such a plan requires some training in statistical quality control. The results of this verification process should be documented for inspection records. The records should clearly show that the specifications have been fulfilled by the product. If the product fails the verification, then corrective action procedures (element 14) should be followed.

Any quality procedure that involves taking measurements assumes that the equipment is accurate. Element #11 requires procedures to be created and documented

to handle the inspection, calibration, and maintenance of test equipment. The goal here is to understand the limitations of equipment used, and to calibrate and maintain equipment periodically to traceable national standards. To satisfy this element, any equipment involved in measurements for activities such as verification or process control, need to consider the following items:

1. Determine which equipment (gauges, oscilloscopes, meters, etc...) are required in product conformance procedures. Record this list of equipment in an easily accessible document.
2. Next, determine the accuracy and limitations of each equipment on the list. Record this precision information.
3. Establish procedures for calibrating all equipment on the list to traceable national standards. Document the results of these calibrations.
4. Determine how often the equipment should be checked and calibrated. Document this period.
5. Maintain an environment recommended for optimal operation of each piece of equipment. The variation of this environment should be controlled. This environment should be verified and documented.
6. Define procedures for the storage and handling of each piece of equipment to ensure the accuracy and function.

To ensure quality through element #12, documented procedures are needed to check the inspection status of a part before using it in production through the tagging system (element 8) on electronic documentation. At any stage of production, any item's inspection and test status should be identifiable. This verification procedure can be done using a checklist document, or a computerized database concerning the acceptance status of a part. If cost is too high, or human resources limited, then at least the label should be signed-off, or data should be entered in the computer database.

Another way to ensure that the status of parts are verified before use is to have a unique place to store parts for each of the above four possible status conditions. Also, responsibility of releasing accepted parts after inspection should be assigned to one or two individuals.

Once parts are inspected and properly labeled, the defective or nonconforming parts should be controlled. Defective parts are those that fail to meet defined specifications. This means that documented procedures should clearly state what to do with defective parts so that it is not accidentally used again. The goal is to control the flow of components that fail inspection. Nonconformities can occur in parts and products in any part of the system life cycle, including maintenance and support of an accepted finished product. To accomplish this, procedures need to be created to handle the bad parts or products. Once bad parts or products are tagged as a defect, it should be evaluated to decide on one of the following actions to take:

- a. rework
- b. accepted as-is by customer
- c. regraded for alternate use
- d. rejected or scrapped, disposal

A trade-off or risk analysis may be needed to help in deciding which of the four actions to take. The risk to consider is failure to meet the customer's requirements. If nonconforming products are reworked, then re-inspect them afterwards. For disposal, reference should be made to the storage, handling, and shipping of defective part or

product. If defective parts are evaluated and identified as returnable to the subcontractor, then procurement should be notified. Defective parts should not be thrown away without informing procurement department. Any defective part should be recorded with the evaluation and course of action in the database. A competent person with the proper skills and training should be delegated the authority to review nonconforming parts and products to determine the correct course of action.

Element #14 requires documented procedures for corrective action. The goal is to systematically analyze problems to find its cause, determine a solution, implement them, verify the solution, and document the results. According to the quality consultants, this section is often poorly handled for two reasons. First, the correction made may fix the current problem, but does not consider preventing future problems. Second, the correction is usually made at the component, product, or service level, but not the system level.

Corrective action procedures should also determine who will be responsible for fixing the problem. The working environment must be considered. Procedures should be created for actions that are in the company as well as those that are at customer locations. Any corrective action should consider its effect on the system as a whole. For example, if the customer must return the product for evaluation and repair, should another be sent so that there is no downtime on the customer side. If the nonconforming product is external to the company, then shipping and handling must be

added to the correction procedures. The skill level and number of people, equipment requirements, and schedule should be determined.

Verification applies in this element also. The corrections can be measured for effectiveness using one of the following methods:

- a. Extensive internal inspection and testing
- b. Field inspection and testing
- c. Collecting customer reactions periodically

This monitoring of the corrections should be made by one department in the company, but the analysis and implementation can involve many departments. All work done to correct a problem should be recorded in a computerized database.

When parts or products need to come in or go out of a company, it must go through the procedures for handling, storage, packaging and delivery. The goal of this fifteenth element is to establish the handling, storage, packaging, and delivery of the components and final products necessary to insure that the quality is maintained when either parts arrive in the company for production or products travel to the customer site.

Procedures for handling, storage, packaging, and delivery apply to incoming material, materials in production, and outgoing final products. Each of these activities should be documented, and any damages that result should also be recorded. Handling procedures should take into account both the nature of the product, such as weight,

material, and electronic characteristics (no magnets around IC), and the maintenance of the material. Storage should have a procedure to document parts and products that come in and those that leave. Other considerations include:

- a. security
- b. environmental control
- c. proper labeling of sections
- d. expiration dates and stock rotation

Packaging and delivery procedures should be planned ahead to prevent damage or deterioration. There should be an area on the package available for descriptions. The destination and means of the delivery should be considered. For example, if the product will be shipped by ship from one continent to another, then extra protection against water and moisture should be planned. Delivery procedures should consider the nature of the final product should be carefully considered when planning the type of delivery, delivery time, and insurance needed.

Again, verification processes apply here to determine the effectiveness of handling, storage, packaging, and delivery should be performed. This may involve a periodic review of the sites and records collected of damages compared to total shipments.

A very important requirement of the ISO 9000 is the collection of quality records, which is element #16. The goal here is to collect, store, and make available the results any observed action for the sake of verification of procedures and future

analysis to improve current processes. A quality information system supported by computers and a network can be used to generate electronic documents as the quality records. The role of the quality information system in the ISO 9000 is document management and version control.

How long should documents be kept? This is determined by any applicable government regulations, product support period, and contract requirements. The average time period is usually five (5) to seven (7) years.

The seventeenth element, internal quality audits, is used throughout the development of the documented quality system. The goal is to periodically review all elements of the quality system based on documented procedures to both verify that the system is working to meet stated quality objectives, and constantly improve the system based on documented reviews. The quality management system, which is separate from the quality system, should also be reviewed by audits for effectiveness and improved based on analysis of results and implementation of suggested corrective action. To accomplish this, procedures and personnel must be measured, the data should be collected and recorded in the quality information system. The output of this effort is a verification report for management.

Any tool or solution that will be used in the quality system needs to be integrated into the quality system. This can be done using training, element #18. The goal is to provide the necessary skills required to ensure the design, production, and

support of a quality product. This is accomplished by retrieving the requirements document of a project and performing a functional, task, and human resource analysis.

Once products have been sold and delivered to the customer, the service element receives more of the spotlight. The goal this element #19 is to provide timely product support to customers, and gather data from customer on quality problems and overall response to product. To provide customer service, a company must first have anticipate, usually during the preliminary design phase, the type of service needed by customers. Next, the skill and quantity requirements should be considered along with whether the support will be provided in-house or outsourced to a third party. Resources such as personnel, equipment, spare parts, and training should then be provided. Service procedures need to be created and documented to properly assist customers.

Since service plays a major role in the overall satisfaction of a customer, the service department should constantly get feedback from customers to analyze how well the company is meeting customer requirements. The following are possible methods of collecting customer feedback to evaluate their reactions after purchasing products:

- a. Send out response cards with the product.
- b. If the response cards do not come back within two weeks, then call the customer.
- c. Periodic surveys
- d. Warranty cards
- d. Toll-free 800 number for customer service
- e. Field reports

Data collection (records) can be facilitated by applying information technology in the form of a computerized database. Once the data has been collected, statistical analysis will show weak areas that need to be removed to improve the process. The verification process applies here to determine the effectiveness of customer service.

The final element, statistical techniques, is one that many feel was an afterthought by the ISO in creating this international standard. The goal of this element is to use statistics as an objective method of analyzing collected data to diagnose problems, quantify variables, and verify and control processes. Analysis can be done using control charts, design of experiments, factorial design, fractional factorial design, acceptance sampling plans, regression analysis to provide quantitative models for a process, analysis of variance (ANOVA) to compare data, and risk analysis.

The use of any of these statistical tools requires proper training and documented procedures. These statistical tools be applied to the following business processes:

1. Market analysis (ANOVA)
2. Product design (design of experiments)
3. Reliability specification, longevity/durability prediction (risk analysis)
4. Process control/process capability studies (control charts)
5. Determination of quality levels/inspection plans (acceptance sampling plans)
6. Data analysis (ANOVA)

The following diagram outlines the certification procedures for the ISO 9000. Once the quality manual is developed, it must be implemented and records must be collected. These records are proof that the system does work.

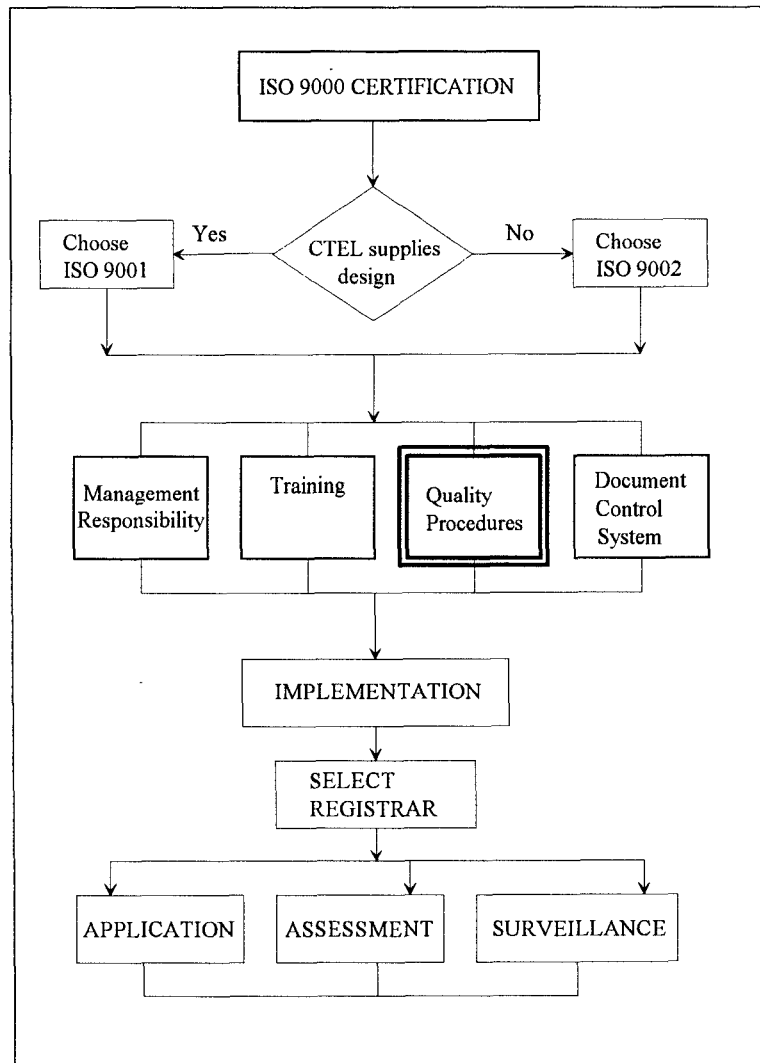


FIGURE 2.4: ISO 9000 Certification Process

## Chapter 3. Quality Through Systems Engineering

### 3.1 Introduction

In the previous chapter, the ISO 9000 standards is suggested as the quality guidelines. Quality standards, such as TQM and ISO 9000, provide goals to meet to improve quality. However, to achieve these goals a methodology must be used.

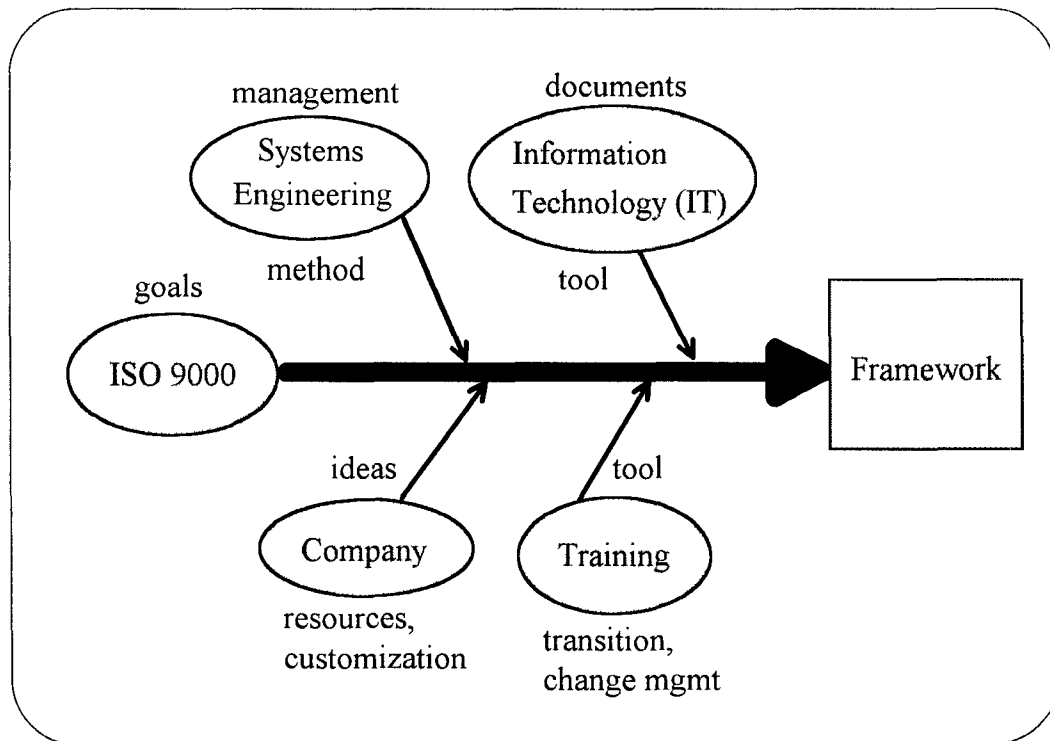


FIGURE 3.1: Focus on Framework Methodology

One method that has been gaining greater attention is the Systems Engineering process,

which defines a systems life cycle. As illustrated in figure 3.1, it examined and tailored for the developed framework in this chapter.

In terms of quality, Systems Engineering focuses on customer satisfaction, statistical quality control tools, variation control tools, and quality management. The quality manual and a quality system can both be developed using the Systems Engineering approach. Before the steps involved in the Systems Engineering process are described, the concept of a system will be defined in the following section.

### 3.2 Definition of a System

A basic, simple system consists of an input, a process, and an output as shown in figure 3.2. It is made up of components that together perform a desired function in a certain environment for a predicted lifetime. Such a system is shown in the figure below. Examples include computers, houses, automobiles, and networks. A system can be of open or closed system. An open system is one that alters its process and

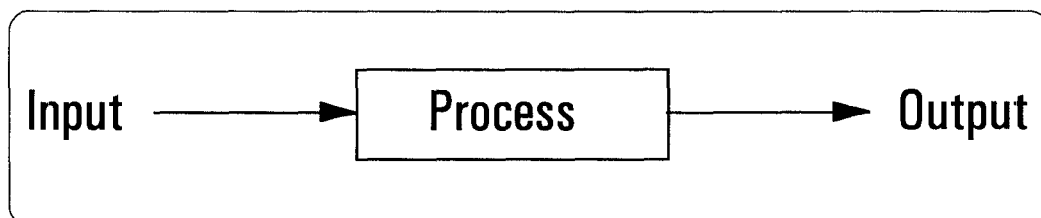


FIGURE 3.2: Simple System

output based on new information entering the input from the environment. On the other hand, a closed system does not take in new information to alter its processing. This system produces the same output independent of its environment. A more complex system can be made up of many simple systems, and may contain some type of feedback. As systems get more complex and require higher quality standards, the need for the Systems Engineering approach to product development will grow.

### **3.3 Systems Engineering Process**

Systems Engineering is a methodology used to solve problems in an orderly manner. This approach emphasizes the need to understand the problem and plan before designing solutions. It provides a road map for workers at all levels. It gives managers a clear vision on what and how to control a project throughout its complete life cycle, which includes design, manufacturing, and maintenance. The Systems Engineering method provides engineers with a well-defined set of guidelines to follow when designing. It verifies that the manufactured product conforms to customer requirements through testing and evaluations. It also considers the level of customer support required when the product finally leaves the factory and enters customer hands.

Systems Engineering is an iterative process that should be tailored for each design environment. Tailoring means applying the correct level of engineering effort to bring a system into being. Too much or too little will result in unnecessary added cost

later in the systems development life cycle. Emphasis is placed on planning ahead, and modifications through feedback.

The Systems Engineering process incorporates the design, manufacturing, and maintenance functions of product development into six phases to ensure the creation of a comprehensive life cycle design. In general, these phases are:

1. Definition of need and conceptual design phase
2. Preliminary research and design phase
3. Detail design and development phase
4. Production and construction phase
5. Operation, maintenance, and support phase
6. Phase out and disposal

This steps are illustrated in the following Figure 3.3 below.

### **3.3.1 Definition of Need and Conceptual Design**

Suppose a customer comes to company X and states that we need a helicopter to transport a 200 ton equipment to the top of a mountain. By following the Systems Engineering method, company X first analyzes this customer's needs before designing the helicopter. Based on this initial analysis, the company discovers that the customer has assumed that a helicopter is the best means of transporting the heavy equipment. A needs statement should only define the problem, not possible solutions.

This example illustrates the goal of this initial phase. When a problem is presented, don't start by engineering a design solution. Instead, establish a

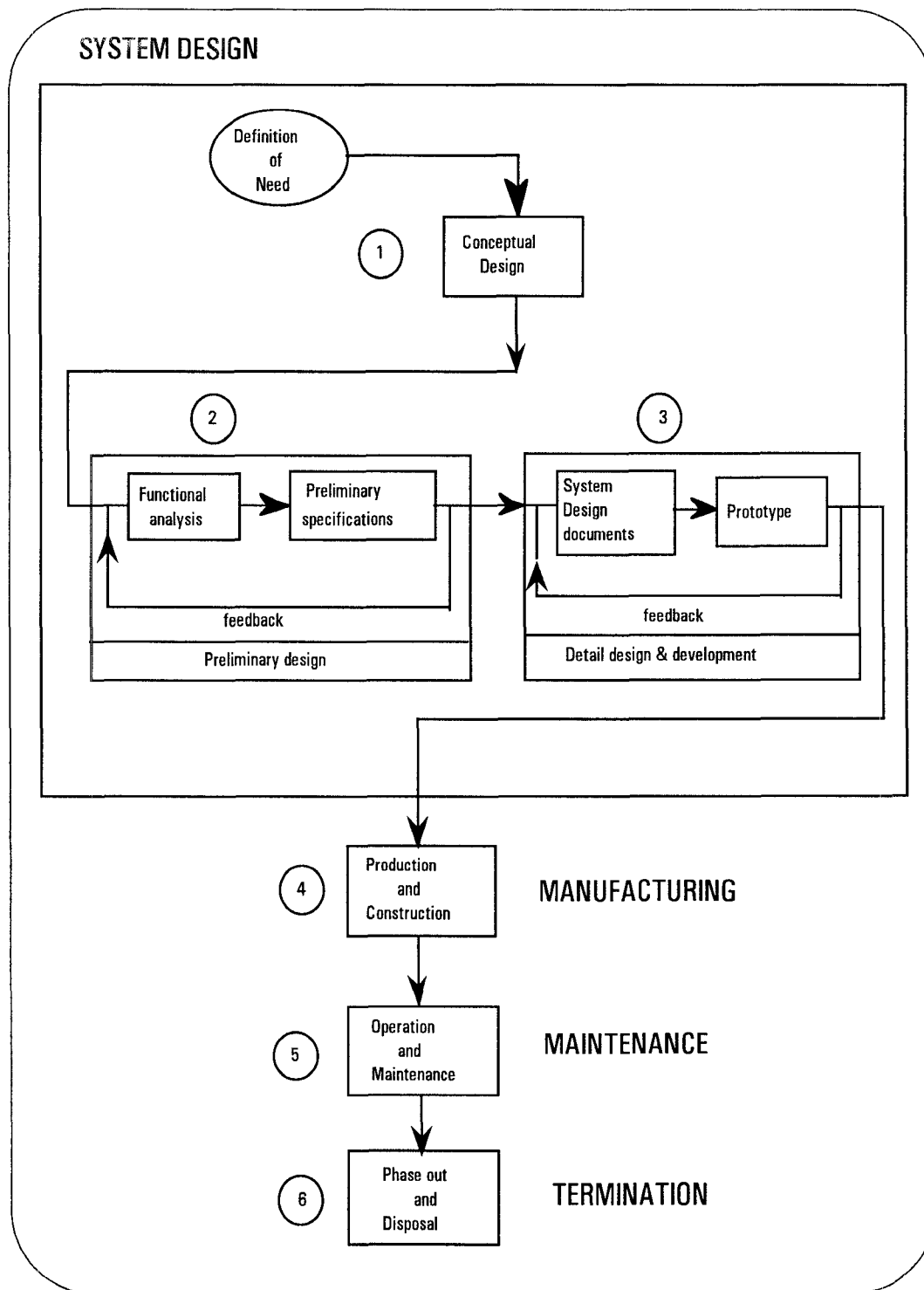


FIGURE 3.3: Systems Engineering Life Cycle Process

needs statement. The main goal of this phase is to define the operational requirements and maintenance concept of the future system. The first step is to establish a concise needs statement that represents customer's and users requirements. Satisfying the customers and users needs using proper identification processes is one of the benefits of Systems Engineering. If a customer's requests are taken directly without evaluating, then the end result is usually a dissatisfied customer. A customer and user need is a desire or objective for a system/solution because of a deficiency or problem found through basic research. To create a needs statement, first it must be established that there really is a need. This is accomplished by questioning and analyzing input from customers to completely understand their needs. The needs statement formulated must not imply a solution. This statement will include a statement of the problem, magnitude of resources available, relative priority of the system, and date of installation and operation. The establishment of a precise needs statement is very important because the focus and direction of the system life cycle and associated engineering activities that follow will be based on the needs statement. A needs statement that is either inaccurate, vague, or too restrictive will result in a product that does not fulfill a customer's requirements.

The next step in the concept design phase is the feasibility studies. The aim of feasibility studies is to examine existing and new technology that may apply to the determined need. In the previous helicopter example, payloaders and snow wiesles are

possible technologies to study. New technology should be considered, but may be riskier because it is unproven. The boundaries to this study will depend on the level of quality required by customers as determined by the above needs analysis.

After the feasibility studies are finished, the system operational and maintenance requirements need to be defined. This step defines the system mission, performance, physical parameters, use requirements, distribution, operational life cycle, effectiveness factors, and the operating environment. The mission definition describes the systems function and how the function will be accomplished. How well the system functions as well as descriptions of its size, weight, accuracy, capacity, etc.... are the focus of the performance and physical parameters. How often the system will be used, the quantity of system elements, and where the system should be transported should also be determined at this point. The operational life cycle deals with issues such as inventory to maintain overall life cycle cost, and personnel who operate the system. The systems effectiveness depends on its reliability, maintainability, and availability. Finally, the type of environment, whether it is humidity, heat, sea or land, that the system will operate in needs to be determined as part of the systems operational requirements determination.

The next step in the systems conceptual design is the development of a system maintenance concept. To keep a customer happy, define the amount of maintenance needed, basic responsibilities for support and general repair policies, test equipment required, testing philosophy, and other major elements of logistic support of a new

system. For example, if the Federal Aviation Administration (FAA) has lots of money and requires an air traffic control system that breaks down only one minute per year (high availability), then plan lots of maintenance into the system design. The maintenance environment will influence how the design will proceed. For example, if one of the maintenance requirements states that the system will have no scheduled maintenance, then the design will not include any built-in tests of the system.

This activity must be developed during the initial system design to assure that quality is always addressed in each phase of system design. Often however, maintenance is not dealt with during the initial design and the result unfortunately is a lower quality system that is less reliable and more costly to maintain.

Once the system operational and maintenance concept requirements are defined, the initial system analysis is done. During the process of analyzing different function alternatives based on results of above feasibility studies, the requirements defined earlier may need to be refined and modified due to feedback from all the preliminary design analysis.

The final step of the conceptual design phase will look at the top-level technical, management, and quality requirements and figure out how to best carry them out with checks and balances implanted in the process. Based on the results of this study plus the needs statement, the feasibility studies, and the operational and maintenance requirements, a System Engineering Management Plan (SEMP) is developed.

Besides the SEMP, the main technical document resulting from the concept design phase is the system specifications. Its contents include a description of the system and its functions, the operational requirements, maintenance concept requirements, system functional diagram and the functional interfaces, performance and physical characteristics, effectiveness and design characteristics, construction materials and operations, logistic support, quality assurance, and design documentation. This specification is a summary of the results from all activities in the concept phase, and will be used as a system technical baseline for the next step in the Systems Engineering process. Together, the SEMP and system specifications will ensure a quality system.

### **3.3.2 Preliminary Research and Design**

After the top-level requirements are defined, they are allocated as part of the preliminary system design phase. The processes in this phase include functional analysis, requirement allocation, trade-off analysis, system synthesis, and configuration definition in the form of detailed specifications. The activities of this phase will transform the system requirements into qualitative and quantitative design requirements.

System functional analysis breaks down the system operational and maintenance requirements into many functions. Functions are then further decomposed into smaller tasks, tasks are broken down into smaller subtasks, and quality requirements are

assigned at the subtask level. Functional blocks are illustrated using functional flow diagrams, which structure and define the functional requirements. Support elements and resource requirements should also be determined to assure that quality is designed into the system. This analysis will guide the definition later of equipment requirements, personnel requirements, software requirements, and maintenance and logistic requirements.

System requirements are broken down into major operational functions using criteria such as modes of operation and utilization states. The sum of these functions should define all the functions needed of the system. Next, each of the major function blocks or units are further broken down into tasks. This process continues until the packaging scheme, based on size and weights criteria, are defined.

There are maintenance functions associated to each of the operational functions defined. Specific performance requirements such as tolerances, accuracy, effectiveness, capacity, and others are assigned to each major and sublevel function block in the functional flow diagram.

The allocation of requirements establishes maximum and minimum boundaries to which the design must conform. They are design guidelines. The following should be allocated at each level of the functional flow diagram:

1. System effectiveness factors like availability, reliability, maintainability, and serviceability.
2. System performance and physical parameters such as range, size, weight, power output, capacity, and tolerances.

3. System support factors like transportation, supply times, test equipment availability, facility use, and personnel effectiveness.
4. Life-cycle cost such as research and development cost, investment cost, maintenance cost, and system termination cost.

When allocating requirements, design criteria and constraints must be taken into account. Also, too many or too few constraints will hinder the allocation process. It is important to remember that the system is only as good as the least reliable component. Therefore, allocations must be made to minimize variations in each level from top to bottom because errors and weak links in each level will add up to larger variations in the overall operation and maintenance of the system.

Based on the allocation process, several designs are developed that fall within the boundaries defined, and meet the needs requirements. The next step is to determine which design is the best solution for the customer/user. Trade-off analysis, and possibly risk analysis, will be used to determine the best solution for the defined problem. These analysis are based on weighted evaluation criteria selected based on the level of analysis complexity desired and/or permitted by time. If time permits, experiments will be performed to create empirical data used in the decision-making process later. The result is a baseline solution to the problem defined.

The purpose of all the above is to provide one set of requirements and one baseline for engineering and management functions of the Systems Engineering process. The idea of one requirement for all helps keep the system development efforts

moving in the direction to produce a quality product that will meet the customers needs.

### **3.3.3 Detail Design and Development**

The efforts of the preliminary design phase, which includes the concept and configuration of the system, leads to the detail design and development phase. The goals of this phase are to decide whether a specific task should be allocated to either machines or humans, and to further define the configuration for hardware, software, and support. The main tool of this phase is rapid prototyping of critical parts of the system. Quality is achieved here through design of experiments. There are three major steps:

1. System product design
2. System prototype development
3. System prototype test and evaluation

The detail design should consider functional capability, reliability, maintainability, manability, producibility, supportability, economics, and social acceptability. The functional capability considers the technical performance of the subsystems. The reliability consideration examines the availability and MTBF rating of the lower level components. Maintainability looks at the safety and serviceability of the maintenance task. Concerns of manability deals with human factors issues. The

subsystems must be designed to be efficient for production using existing manpower and materials. This is the idea of producibility. Supportability is similar to maintainability, but considers the accessibility, standards, and diagnostic provisions in the life cycle. A design that is economical is one that analyzes the life cycle cost, maximizes the cost-benefit ratio, and considers cost estimate issues such as design-to-cost. A system design that is socially acceptable is environmentally safe, and has a low safety risk. When designing with these objectives in mind, there will be a need to balance these goals and understand the tradeoffs. For example, a system design that requires high reliability and high performance will probably overrun the budget due to high costs.

The first step in the detail design phase is to gather all the goals and objectives established in the previous phases. Next, the design teams need to be created. This design team will consist of the appropriate skill level and skill mix of engineers, engineering technicians, and nontechnical personnel, such as marketing, procurement, and accounting people. Human factors studies will aid in the development of this team.

The next step in the detail design is the progress and evolution of design documents including specifications, plans, drawings, material lists, reports, and analysis. During the engineering documents development step, subsystems and lower levels of the primary system and the logistic support need to be further defined. The

engineering at this step starts with a functional diagram of the whole system. Then the high level functions are broken down into smaller tasks and possibly subcomponents. The level of detail will depend on the materials and skills available, and the maintenance concept. Implementing each task will require some trade-off analysis to determine the best solution for the given requirements. This trade-off analysis will involve cost-effectiveness as one of the evaluating criteria. The analysis of this criteria will look at cost-effectiveness figures-of-merit (FOM) such as a benefit-life cycle cost analysis. The tools that can be used for to accomplish these design documents include CAD, CAD/CAM, CASE, ICASE, CAED, concurrent engineering, and existing standards.

Once the final design documents have been created, reviewed, and refined, the next step in the detail design and development phase is to convert these papers to physical models and prototypes. There are three types of models:

1. Engineering model
2. Service test model
3. Prototype model

These models can be used in experiment designs when predictions of system output is needed. The main difference between these models is the degree of accuracy in implementing the paper design. The engineering model is an analog to the final product. The function is the same as the final product, but the look and feel, and form

and fit are different. This model is developed to verify certain functions of the engineering design. The service test model more closely resembles the final product. The function and physical dimensions are the same, but the components used are different than the final product. The prototype model is an exact implementation of the final design. In this prototyping step, any desired scale may be used, and the level of detail will be proportional to the level of risk acceptable.

Once a physical model has been created for either a subcomponent or the entire system, it must be evaluated. Besides verifying designs, the models can be used by the maintenance and human factors designers to review their design. The model gives the human factors personnel a tool to predict performance, and perform task analysis. Prototypes are good tools in formal design reviews (FDR) and marketing. Physical models also allow production and industrial engineers to critique the design from a manufacturing point of view. This test step will involve designing experiments, creating factorial designs, and analyzing data statistically. The result of these tests and evaluations is either acceptance of the detail design documents or redesign and retesting.

### **3.3.4 Production and Construction, Evaluation, Use and Support**

For the final three (3) phases of the Systems Engineering process, there will be lots of testing performed. Inspections will be in the form of sampling plans and

inspection data will be analyzed statistically. There are several phases of testing in the system life cycle. They are:

1. Type 1 test
2. Type 2 test
3. Type 3 test
4. Type 4 test

The type 1 test evaluates models built in the preliminary and detail design phases discussed above.

In the production and/or construction phase, production of limited quantities are authorized if the detailed design is approved. A type 2 test evaluates prototypes and production models during the production stage of the life cycle. The type 3 test evaluates the production model at the test site. This test may involve a sampling plan. It is used in the product evaluation stage.

During the operation and maintenance phase, test and evaluation of limited production quantities proceeds here. Even when the system is placed into operation and maintenance phase, systems engineers still monitor, and review it to ensure compliance with customer and users requirements. A type 4 test is a continuous evaluation of the final product in operational use during the use and support phase.

The maintenance plan starts working full time at this point. Any failures or malfunctions are handled by the maintenance personnel. If the maintenance concept

has been considered carefully in the concept design phase, then the costs of operation and maintenance should be under control.

Every product designed, whether it is the domestic refrigerator or the high tech military missiles, all have a life cycle, which includes termination. This phase out or disposal concept must also be accounted for in the design. Otherwise, the overall system cost cannot be controlled. An example is some of the older missiles used by the army. Because their termination was never considered in their design, termination is very costly. The result is that these missiles are put away in storage, which also cost money.

### **3.4 The Tailored Systems Engineering Process for Quality Manual**

#### **Development**

When tailored for the development of a quality manual, the Systems Engineering process be transformed to a quality effort chain. This chain, which is similar to the value-added chain discussed in Chapter 1, includes the steps to convert a company's time and effort into a quality manual. These steps are:

1. Requirements analysis
2. Management
3. Concept Exploration
4. Quality System Baseline Design
5. Detail Design
6. Implementation
7. Maintenance and Support
8. System Upgrade

The following sections will discuss this quality effort chain in more detail.

### 3.4.1 Requirements Analysis

The first item that needs to be considered are the company's requirements for the quality system. This is illustrated in the figure below.

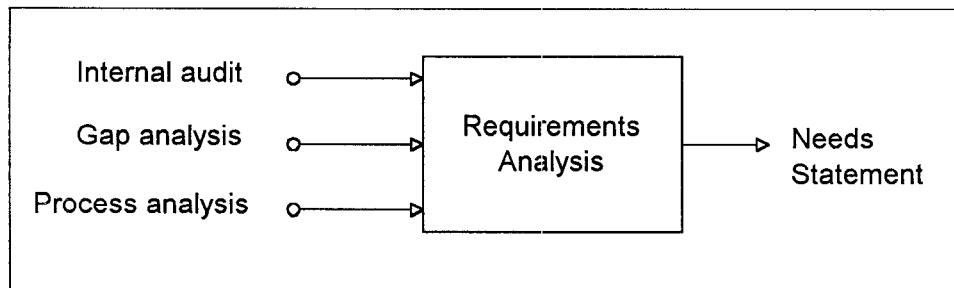


FIGURE 3.4: Quality Effort Chain -- Requirements Analysis

It must determine what deficiency or problem exists and needs to be solved. To find this deficiency, an internal audit is the first step. This involves tracing the data and processes from an initial customer inquiry through each department and all the way to product delivery and servicing. Since this is a total company effort, each department should be responsible for documenting in detail all its procedures and all interfaces with other departments. Then a representative from each department should meet to work out the data and processes at the interfaces.

To create the present model of company data and process flows, the detailed work documents should be examined and represented at a higher level using the flowcharts, dataflow diagrams, black box modeling process, or a combination of these. Flowcharts are capable of capturing the process flow of an operation, but cannot accurately represent the data. On the other hand, data flow diagrams can accurately model the data path, but not the their processes. The black box modeling process has the ability to capture both the data and their processes, and can be represented both graphically as well as textually.

Once the company's current process is modeled, it must decide what goals need to be reached. A list can be made of each to determine the current process that meets a goal, and those goal that need a process. This comparison of goals to current processes is called a gap analysis.

Along with a gap analysis, there should also be a process analysis to identify processes that should be changed or removed because they do not add value to the company process.

In this requirements analysis, the company must determine that the need really does exist, and that a solution will add value to the company process. Once a need is found, the result of the requirements analysis is a needs statement. This statement must define the problem without implying a solution.

In the case of CTEL, the need was obvious. Since their present and future plans involve selling products to European companies, they saw the need to become ISO 9000 certified to meet contractual requirements set by their European customers. Also, CTEL management needed to improve the quality of their products to stay competitive as they moved into markets outside the United States.

**3.4.2 Quality Management System**

Once the requirements have been defined, the second step is to define the quality management system. The quality management, shown in figure 3.5, is made up of defining objectives, setting standards, and delegating responsibility to create or

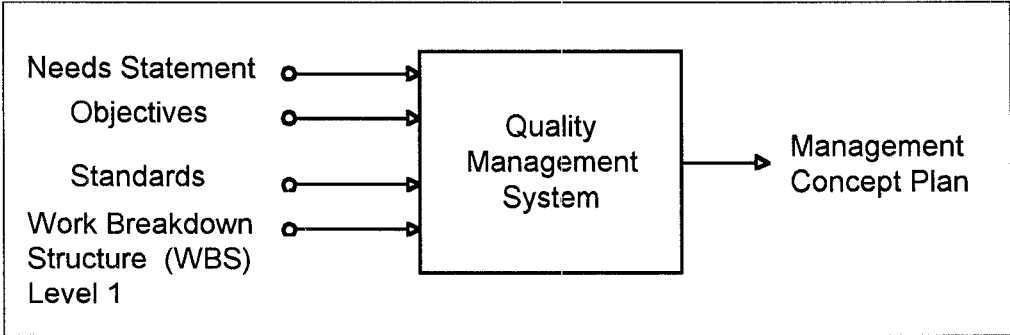


FIGURE 3.5: Quality Effort Chain -- Quality Management System

improve the quality system. The objectives should be summarized in a quality policy statement. The creation of this statement should involve the entire company, and once

developed, should be a daily reminder to each employee of why they should follow procedures of the quality system.

The quality manager has the authority and task of assigning personnel to certain responsibilities in the quality system. Responsibilities include creating a quality team, documenting in detail work procedures, inspecting equipment, controlling defective parts, performing internal audits, controlling documents, and reviewing results of the quality system.

The management of the quality system development must begin with a work breakdown structure (WBS). The WBS takes a goal or objective and breaks it down into more manageable functions. At this stage of the development, the WBS will be very high-level since more analysis must be done before an accurate WBS can be created. The end result of this phase is a management concept plan.

### **3.4.3 Quality System Concept Exploration**

The concept exploration phase is made up of a feasibility study, system operations definition, and maintenance requirements. The result of these efforts is the system specification. This phase is illustrated in figure 3.6. The feasibility studies should examine information technology-based solutions that may apply to the quality manual development. Since information technology and training are necessary

ingredients in this framework recipe, the amount and type of IT and training should be analyzed.

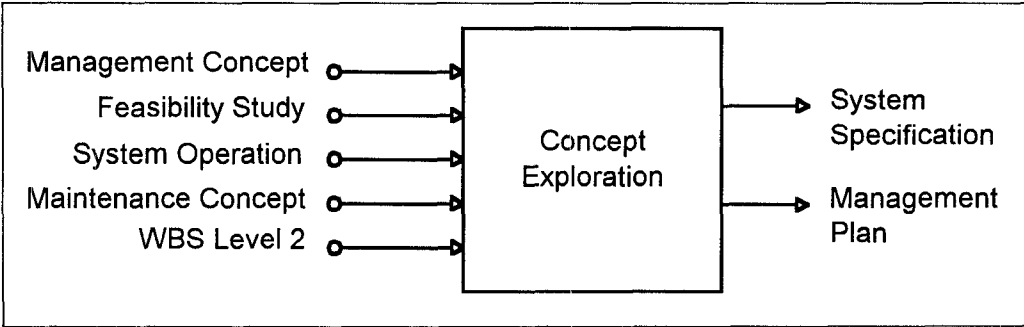


FIGURE 3.6: Quality Effort Chain -- Concept Exploration

The second part of the concept exploration phase requires a definition of the quality system operations. The definition should include a statement of the system function, performance, personnel requirements, machine requirements, and operating environment.

For CTEL, the quality system would be well-documented so that both current and future employees could follow easily and knew exactly what each of their roles were in the company regarding quality. The quality system would continuously audit itself, document problems found, determine and implement solutions, and verify that the solutions were valuable to the system. Also, the quality system should be able to collect data easily, analyze data quickly, and be able to provide access to any reports.

CTEL's quality system created procedures for the inspection and testing of incoming parts and products manufactured. CTET management also required that all employees receive training to have an understanding of the ISO 9000 standard.

The third part of the concept exploration phase is the creation of the maintenance concept. To maintain a quality system, the support responsibilities had to be defined, required test equipment needed to be identified, and verification responsibilities needed to be created. Support in a quality system is needed for ISO 9000 concepts, statistical techniques, interpreting data analysis reports, and the quality information system.

CTET's maintenance concept called for periodic training in quality control concepts when needed, periodic internal audits to verify the effectiveness of the quality system, and maintaining test equipment by inspection, testing, and calibration.

During the concept exploration, the initial work breakdown structure developed earlier is refined and described in greater detail. This is level 2 of the WBS. The functions in level 1 of the WBS is now broken down into simpler and more easily identifiable tasks. The number of levels that functions are broken down to depends on the manager level of comfort. Anotherwords, the function should be broken down until the manager fully understands all the tasks at the bottom level of the WBS.

Once the work breakdown structure is established and accepted, then many other management duties will be based on it. A cost estimate starts with the WBS, and

its accuracy depends on both the estimator and his team's skill as well as on the accuracy, breadth, and depth of the WBS. Task assignment to either man or machine will also be based on the work breakdown structure. Also, scheduling the tasks and setting milestones will depend on the scope defined by the work breakdown structure.

### 3.4.4 Quality System Baseline Design

The system specification generated from the concept exploration will be expanded in the baseline design using functional and trade-off analysis to derive a detailed system specification. The goal of this phase, shown below, is to transform the

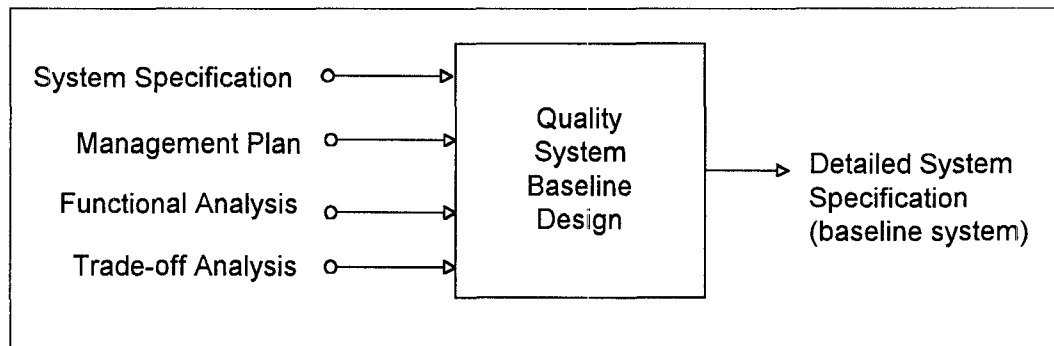


FIGURE 3.7: Quality Effort Chain -- Quality System Baseline Design

system specifications into qualitative and quantitative design requirements.

The functional analysis takes the WBS-2, breaks it down further into subtasks if necessary, and then defines the skill and quantity required for a specific task. Based on

the skills and quantity determined, management and human factors engineers will either assign it to man or machine. Also, at each function, their needs to be operational and maintenance boundaries set to guide the design later. This includes speed, accuracy, test equipment available, and cost.

Once the boundaries are set for each function, there may be several possible solutions to the need. In this case, a trade-off analysis should be performed. Possible criteria include cost, performance, conformance to standards, reliability, and resources required. A weight is assigned to each criteria, and then applied to the score of each solution. The solution with the best score should be chosen, except in cases where the differences between solutions are small.

After all the above analysis is performed, the solution selected represents the baseline quality system. This system is usually the bare minimum solution to the need, and is therefore considered the baseline. This baseline solution should then be reviewed for approval. The document created is a detailed system specification.

### **3.4.5 Quality System Detailed Design**

In this phase, put the system down on paper and then develop it. The paper design will be in the form of a quality manual, the main output shown in figure 3.8. Once the design is complete, a design review should be conducted to approve the plan. This review should receive input from at least one member from each department. At

this point, the configuration of the information system should also be defined, and any training needed should be outlined. Once the configurations are documented, it should be reviewed and approved.

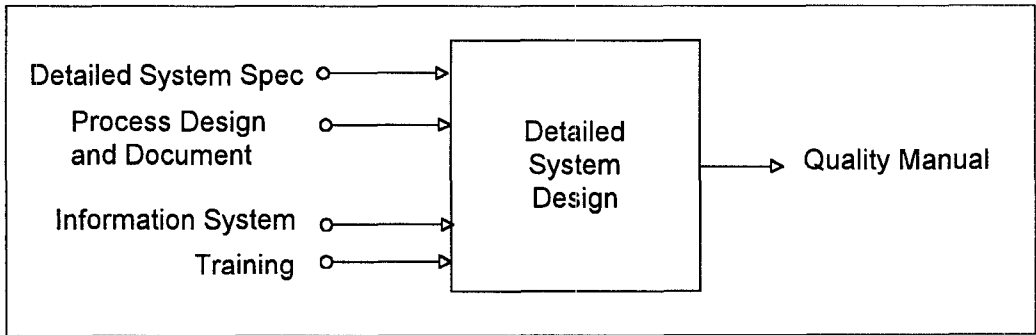


FIGURE 3.8: Quality Effort Chain -- Detailed System Design

**3.4.6 Quality System Implementation**

As illustrated in figure 3.9, the quality system development will involve implementing the procedures described in the quality manual, documenting the results,

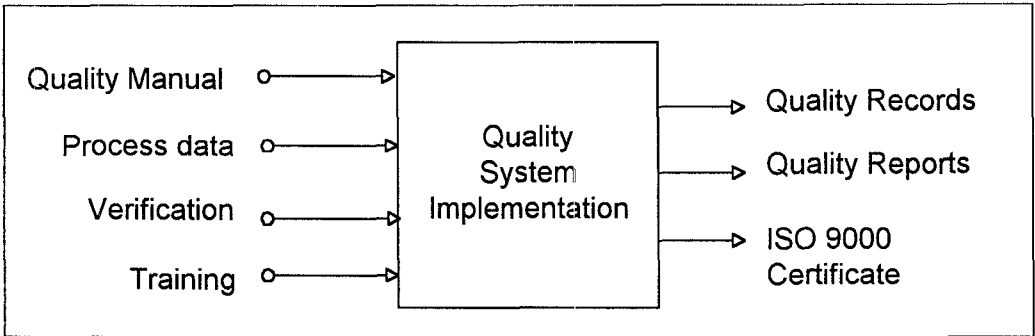


FIGURE 3.9: Quality Effort Chain -- Quality System Implementation

and verifying that the system is working as planned. Developing the information system requires installing and customizing any hardware and software. It also requires creating the blank forms to keep consistency in the quality records. Any training that is needed should be provided documented as a quality record.

Once the quality system is up and running, it should be verified that every department is operating as designed. This verification process should also be documented and stored as a quality record.

#### 3.4.7 Maintenance and Support Phase of Quality System

The next phase in the quality effort chain is the maintenance of the quality system, which is shown in figure 3.10. An internal audit of the quality system should be performed periodically. The audit can be a full one or can be done incrementally starting with the most important section. This internal audit involves following the

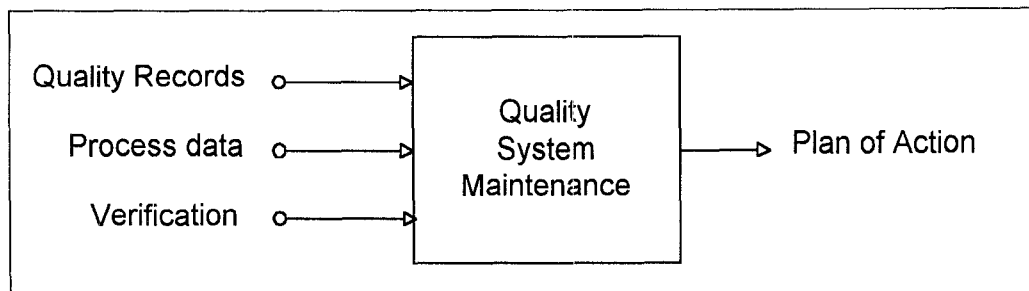


FIGURE 3.10: Quality Effort Chain -- Quality System Maintenance

process and tracking the associated paper trail in the form of quality records. If any

problems, errors, or omissions are found, then they should be documented as a record, and a suggestion for correcting the problem should be recommended. Both the recorded error and suggested solution should be presentable for the review process. Management will then review, decide on the action to take, and then assign the responsibility to the appropriate personnel.

### 3.4.8 Quality System Upgrade Phase

The quality manual and system that is developed based on the ISO 9000 and certified must make a very important decision periodically. Three years after certification, a company must go through the certification process again. The decision here, illustrated in figure 3.11, is whether to become certified under the same quality

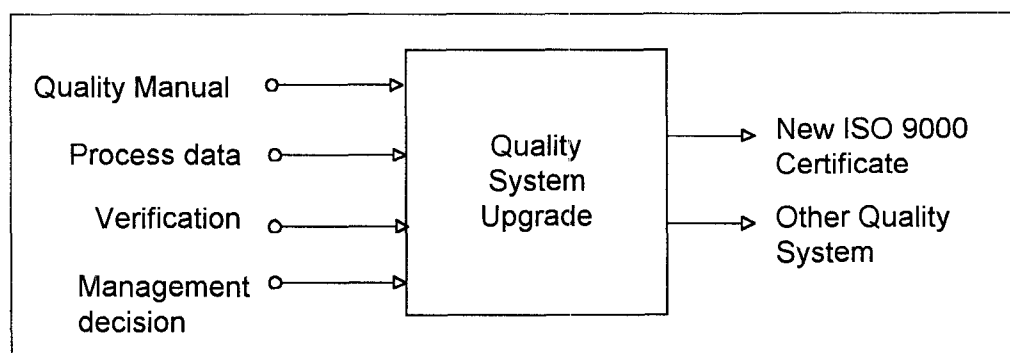


FIGURE 3.11: Quality Effort Chain -- Quality System Upgrade

model, or a comprehensive one. Another alternative is to attempt to satisfy one of the

major quality award criteria, which embrace the TQM philosophy more completely. One thing to keep in mind is that the ISO 9000 also goes through periodic reviews and updates. The next version of the standard, scheduled to be released in 1996, will incorporate more TQM concepts.

### **3.5 Measurement Parameters for Systems Engineering and SQC**

The management of quality must continuously review the quality system taking measurements and evaluating the quantitative results based on a predefined set of criteria. The criteria selected should consider the internal structure of the company as well as external factors affecting them. In order for a company to stay alive and succeed in a global economic competition with high-quality expectations, it must manage to optimize the following performance measurement parameters:

1. Costs
2. Time
3. Performance/Quality
4. Resources
5. Business policy
6. Customer satisfaction

#### **3.5.1 Cost**

The cost parameter is the most important one for any business and is directly related to product quality. When a company spends money to build a product, it must make a profit on the investment. To obtain a high return on capital investments, the

company must continually find ways to lower other costs such as overhead, production, and maintenance.

When quality is emphasized by management, the initial costs will increase due to increased efforts in planning and design for quality, and increased costs of higher quality materials. However, over the long run, these initial costs are offset by lower production and maintenance costs due to less rework and scrap, and a lower defect rate.

Some methods that are currently being used by IBM to achieve these lower costs include statistical quality control, especially for manufacturing process, use of off-the-shelf products, and use of effective management and engineering methodologies such as the Systems Engineering approach, and Total Quality Management.

### **3.5.2 Time**

Recently, the Safeway grocery food store chain implemented a new policy to cut down on the amount of time that customers must wait in check-out lines. If there are ever more than three customers in line, the Safeway will open up another check-out register to speed up customer purchases.

Customer satisfaction is a function of time. The time that is most looked at is the system acquisition time. This is the time it takes for the developer to deliver the final product to the customer. If schedules are not met and the product is delivered

late, the customer becomes unhappy, both the customer and developer lose profits, and the developer reputation is damaged.

When quality is designed into a product, the result is a reduction in product lead times, and less maintenance time required to resolve customer complaints. This reduction in work load provides a company with more time to either work on new products or improve existing products and processes.

### **3.5.3 Performance**

Performance can be measured by the final systems functionality, availability, and usability. The systems functionality is related to its response time and efficiency in performing a defined task. In the computer world, a workstation that sorts data faster using less system resources is a very capable system. The availability is the amount of continuous time that the system works when it is supposed to work. This factor is related to the systems MTBF and MTTR ratings. Also, a system that has a high performance and quality rating is one that is transparent to the user as a tool. The user should not have to fight with the final system to get a job done. To achieve this, it is necessary to look at the human factors required of the system.

### **3.5.4 Resources**

Within a company, there are two types of resources available:

1. Human resources
2. Material and equipment resources

Human resource management considers the availability of labor needed for a project. Management must also perform a task analysis to determine the proper number and degree of worker experience and skill level needed for a quality system.

Material resource management considers the availability of facilities, tools, and materials required to develop a project. It must also determine the correct size and use of facilities. The quality level of materials to be used must also be determined to ensure that the final product meets customer requirements. The result of these studies is a resource price associated with the project. If this price tag is acceptable, management must allocate resources such that the project will be accomplished within cost and on schedule.

### **3.5.5 Business Policy**

One major constraint on each system life cycle development is a company's unique business policy. This policy is made up of clear statements about their ethics, conduct, and level of commitment to Federal, State, and Local government laws. This policy must be firmly upheld by each company to avoid costly legal mistakes. It must be considered during the system acquisition stages in order to insure that the final system meets legal requirements.

### **3.5.6 Customer Satisfaction**

Finally, the main focus of any business must be customer satisfaction. A company that develops a technically superior product that the customer doesn't need is wasting its time and money. On the other hand, a company that creates a product that falls short of customer expectations and requirements will need to spend much more money to rework the product. The resulting delay would damage the relationship between customer and business. A satisfied customer is one whose requirements are met, one who is well informed of progress, and one who is delivered a product that is within cost and on time. The goal of customer satisfaction, as well as all the other performance measurements, can be achieved well using the system life cycle process.

# Chapter 4. Quality Through Information Technology

## 4.1 Introduction

A very important component of the framework for developing a quality manual is the consideration of information technology (IT). This component, illustrated in figure 4.1, will be the focus of this chapter.

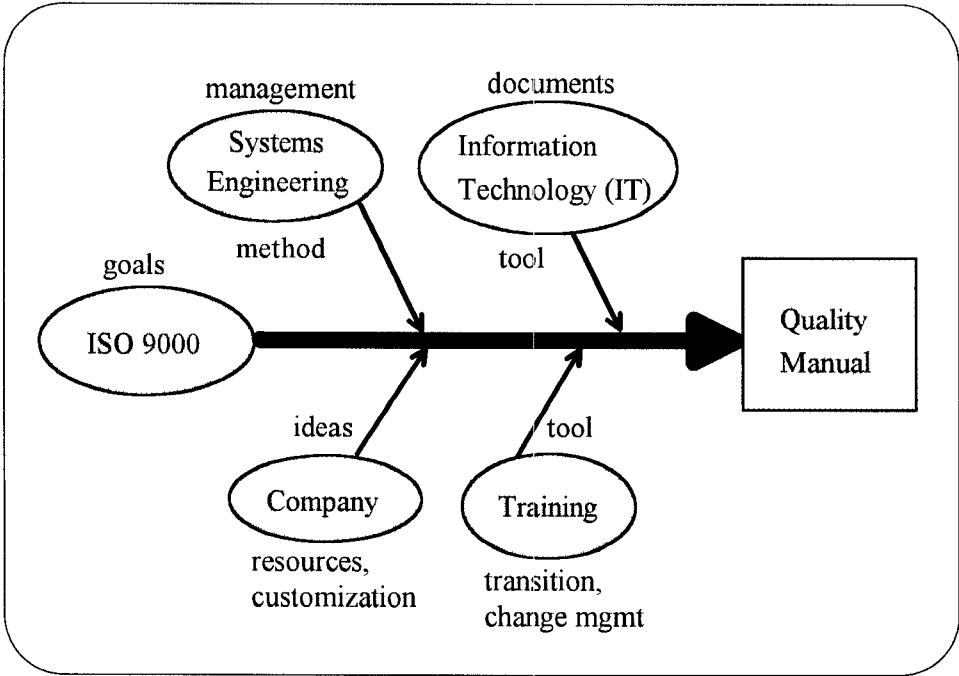


FIGURE 4.1: Focus on Information Technology

## 4.2 Globalization and the Need for Quality

The traditional market is expanding beyond national borders and becoming a

global marketplace. This transition was aided by banking deregulation, which made the flow of different currency through different countries possible, and by the increased and rapid flow of information through the development and application of information technology. Examples of this transition to global market competition:

1. The size of the U.S. economy is approximately three times the size of the Japanese economy and twice as large as the combined economies of France, Germany, and Britain. Needless to say, the American people are still the most significant economic force in the world.
2. The U.S. domestic manufacturers have lost, and are continuously losing, market shares to foreign countries such as Japan, Germany, Korea, etc. U.S. companies are laying off workers and managers. The center of the financial world is moving from New York city to Tokyo.
3. American consumers have developed a taste for foreign products because of the quality and value of foreign goods. The trade imbalance is one indication that the ability of the U.S. to participate in the world market has eroded and that the U.S. has lost its competitiveness.

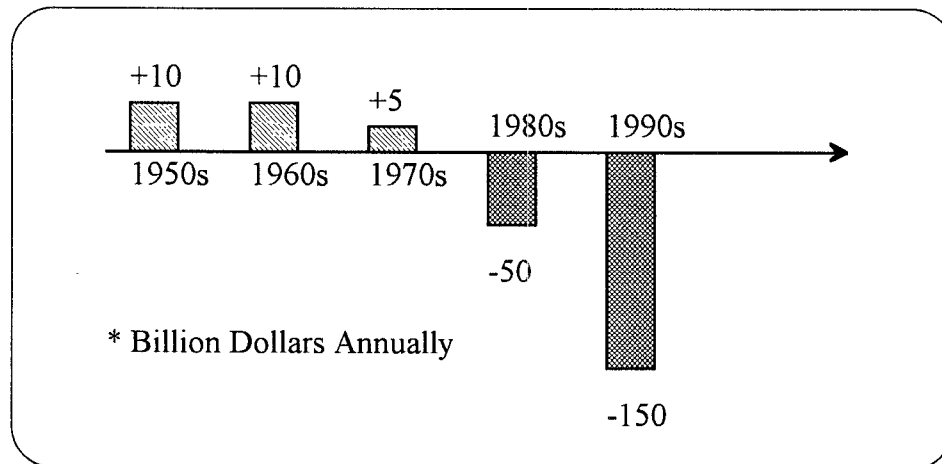


FIGURE 4.2: United States Trade Balance

4. Loss of economic leadership and transfer of wealth have alerted the American people, especially the politicians. The focus of the 1992 presidential election was "the U.S. economy". American people want to create jobs and to regain its competitiveness in the world market. U.S. business leaders are realizing that they must take decisive action to improve their management styles and manufacturing processes, and to meet the needs and expectations of customers. In fact, some companies are doing very well.

To reach out to this global market, companies have begun to alter their traditional functional hierarchy for a more global company structure. These structures can be one of three types:

1. Multinational -- investment in other companies
2. Global -- supply resources and knowledge to other companies
3. Transnational -- network of headquarters and subsidiaries

The result of these restructuring efforts is the creation of:

1. Virtual corporations -- no boundaries, different entities that come together temporarily to generate a product.
2. Value-added partnerships -- parts of a value-added chain that work together as one to compete.

Due to worldwide economic competition and the advances of computers and communication, traditional hierarchical structures of a company are being reexamined, and in some cases replaced by more specialized team-oriented structures, such as virtual corporations [15] or value-added partnerships. Companies are moving away

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15 Davidson, William, "The Virtual Corporation".

from vertical integration to specialization in one or two areas of the value-added chain. A value-added chain is made up of the steps that a product or service goes through from raw material to final consumption. Traditionally, each entity in each step has operated independently, or several entities have been part of one company hierarchy. Below is an example of a value-added chain in a generic product industry, and includes the following components:

1. Raw material supplier
2. Raw material distributor
3. Manufacturing/production
4. Packaging and shipping
5. Final product distributor
6. Retailer
7. Consumer

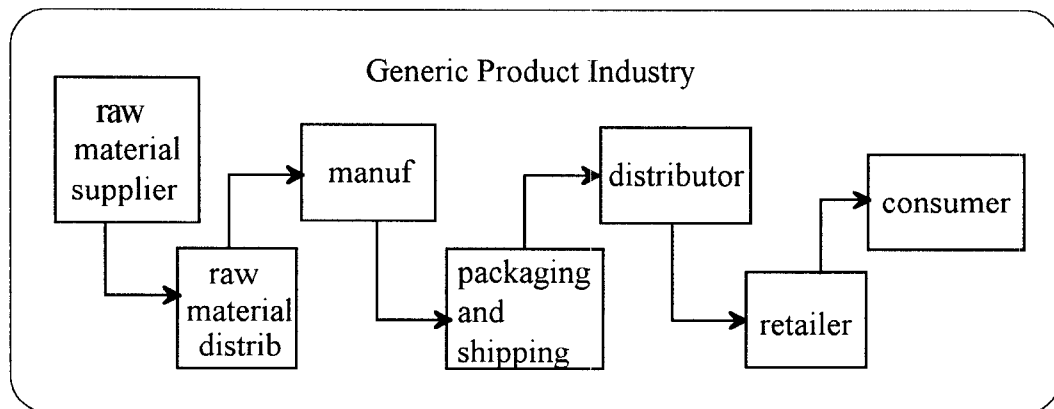


FIGURE 4.3: Value-Added Chain

By definition, value-added partnerships are a set of independent companies that

work closely together to manage the flow of goods and services along the entire value-added chain. Some value-added partnerships have come about as a result of the disintegration of large companies towards specialization in value chain. Partnerships usually develop first between organizations that perform adjacent steps in the chain. Partnerships, not the individual functions, compete as one unit. The ultimate goal is to improve the response time in meeting customer requirements and changing market needs.

Companies who are moving towards more specialization may ask, "Why not hire a contractor to take care of the quality issues?" Due to constraints of time, limited resources, and limited personnel, this may sound like a good alternative. However, these are the companies who will not succeed in their quality efforts because they do not fully understand the fundamental quality concepts. By definition, quality involves active participation of entire company. Consultants can be hired to suggest changes in a business process, but it is up to the company employees to actual carry out those changes.

Also, the nature of competition is changing due to the global competition. These new corporate structures, such as the VAP, now require competing companies to share data about their customers. The new competition now is not in the data collection area, but rather in the data analysis. The winner will be the one who analyzes

the data better to get superior knowledge about the consumer and changing market demands.

### **4.3 The Importance of Information Systems in a Quality System**

Why should a information system be considered in a quality system development framework? Deriving from the definition of an information system, a quality information system (QIS) is one that is a well-planned system for the collection, storage, analysis, reporting, and distribution of information needed by the quality system to meet quality objectives. The roles of the QIS include being a facilitator, a tool provider, a support function in the areas of document management, version control, database management, and process analyst.

The following is a list of functions usually performed by the quality information system:

1. Partial Systems Overhaul -- update interfaces, fine-tune overall operations, provide training and support to ensure that system provides proper information to support quality efforts.
2. Full System Overhaul -- replace old system with new one that is more transparent as a tool in collecting, storing, and reporting information.
3. Training -- make sure personnel understand how to use system, and how to properly enter information in database.
4. Oversight -- set quality goals for the information systems use and verify that everyone understands these goals. [16]

A quality information system does not necessarily include computers. It can be as simple as paper, index cards, and a filing system. However, competitive advantage can be gained by applying information technology to the quality information system. Information technology (IT) is the integration of computer, communication, and software. In the past, its use has been mainly in the area of office automation. Currently, IT is being studied for application under new organization structures such as the virtual corporation, and business teams. Components of IT include hardware such as PC's, dumb terminals, workstations, network interface cards, and cables, software such as network operating system, graphical user interface (GUI) builders, and a single shared database. The application of IT involves the integration of these components.

There are several advantages to a computerized document control system.

They include:

1. Immediate Access -- on-line documents are quickly retrieved if the system has a user-friendly retrieval system and if users are properly trained.
2. Authenticity -- document changes are controlled by managing the read/write attributes of final documents, as well as any other passwords or network security.
3. Completeness -- on-line access allows all involved to easily retrieve, check, edit, and sign-off on the document before it is approved and released.
4. Integration -- on-line document editing and review that requires other information can be integrated with other computer information sources such as spreadsheets and databases.
5. Better control and coordination -- review process

Information technology will become a necessity to compete rather than a

competitive advantage due to the globalization of the market and competition. An example is McKesson corporation, a value-added partnership. Before it became a partner with retailers in the value-added chain, McKesson was the average distributor of drugs, health care products, and other consumer goods. After discovering that the retailers they were supporting were losing market share, McKesson decided to connect suppliers with a computer-to-computer ordering system so that the suppliers' order-entry costs, number of shipments, and inventory costs could be reduced. The result was that suppliers improved customer service, provided lower prices, remained responsiveness to local tastes with product mix, and provided faster reordering.

To maintain or increase both market share and customer satisfaction, companies are beginning to create electronic links between customers and retailers. An example is United Airlines' APOLLO airline reservation system, or American Hospital Supply Corporation's ASAP order entry system. The main idea behind both systems was to supply customers with a direct access to an electronic catalogue of products and services available for sale by the single vendor. The customer would browse through a list of items, and electronically place an order if the price was right. Customers appreciated these systems because it reduced their total procurement cycle, and less people were needed to perform procurements.

However, after customers became familiar with the system, they wanted a multivendor system instead of the single source products and prices. This demand

created the electronic markets, and an example is American Airlines' SABRE airline reservation system. This system, like APOLLO, allows customers to browse through available flights and make airline reservations. The main difference was that they could browse through flights of many airlines, not just American Airlines. Many feel that these multivendor electronic links, or electronic markets, is the future for commodity products [17].

There can be no doubt that the collection and analysis of company data would be difficult if there did not exist a quality information system. Even though the information system department has been treated as an independent non-entity in the past, the information and analysis should actually be considered the backbone of a company. Data, documentation, and records are all present in any quality system, so there is a need for the information system to create a smooth flow of information between each group inside a company. This integration of data and the information system is the key to a solid quality system. An example would be the requirements documents. Good leadership would insist on a well-defined requirements document as the first step in systems development. All subsequent work and design would have to be accomplished to meet this document. A verification document after each design phase would be a good way to ensure that the requirements are being met.

Besides documents, other forms of information and analysis include storage of

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17 Hopper, Max, "Rattling SABRE -- New Ways to Compete on Information".

measurements, benchmarking, problem solutions, and prevention of problems. To help leadership manage using statistical analysis, measurements from some form of metrics procedure must be taken and analyzed using the appropriate statistical equations. To help a company assess itself, data must be collected about competitors and competing products so that benchmarking analysis can be performed. It would be difficult to set a vision of improving without knowing what has already been done, and what needs to be done. There are many ways to perform a benchmark test, including the Baldrige award criteria, the 12-step approach by AT&T, and the 6-step approach used by ALCOA [18]. Also, analysis of customer data may show relationships between customer negative or positive responses to product features and the competition's products.

In quality information systems, a key component of the analysis function is statistical quality control, which is used to find solutions and preventions. Many statistical applications that make up SQC, such as Shewhart's control charts, were developed many years ago. The important point is that these ideas are now being researched for incorporation in real business practices. Information technology can produce faster response times in these graphical representations of quality control. In applying statistics to the business world, Deming has found the following charts to be very useful:

a. Cause-and-effect charts

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18 Bemowski, Karen, "The Benchmarking Bandwagon", p. 19.

- b. Pareto charts
- c. Histograms
- d. Control charts

The cause-and-effect chart, also called the "fishbone" diagram, was created by Kaoru Ishikawa. It charts a good or bad effect produced by a group of causes. This chart is used to determine the cause of an event, such as large manufacturing errors, always missing lunch, getting to class late, etc...

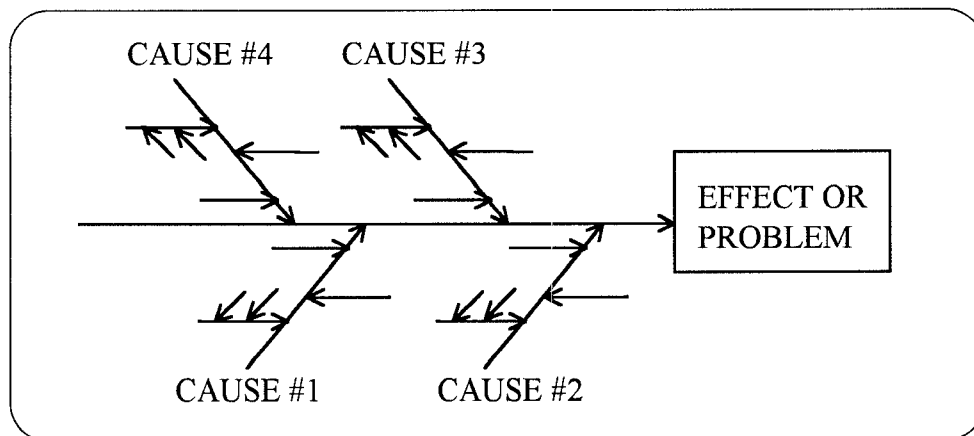


FIGURE 4.4: Cause-and-Effect Chart

Once all causes of effects, such as sources of errors, have been found, the pareto chart can be created to determine which cause to fix first. This chart is a graph of the types of causes and the frequency of these causes.

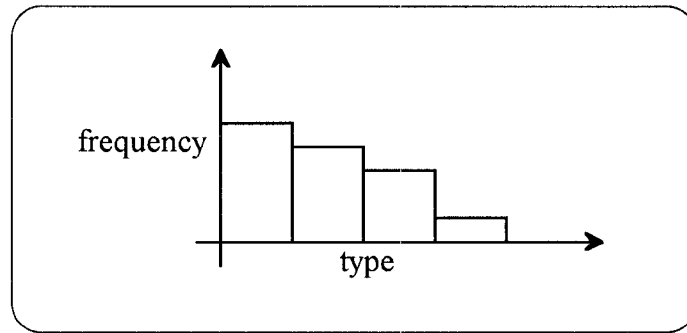


FIGURE 4.5: Pareto Chart

A histogram is a plot of the frequency of events in time. There are certain pitfalls to be aware of when using histograms. Too few measurements can lead to wrong decisions. Usually 50 or more data points will produce useful results. One weakness of histograms is that it doesn't say anything about data trends.

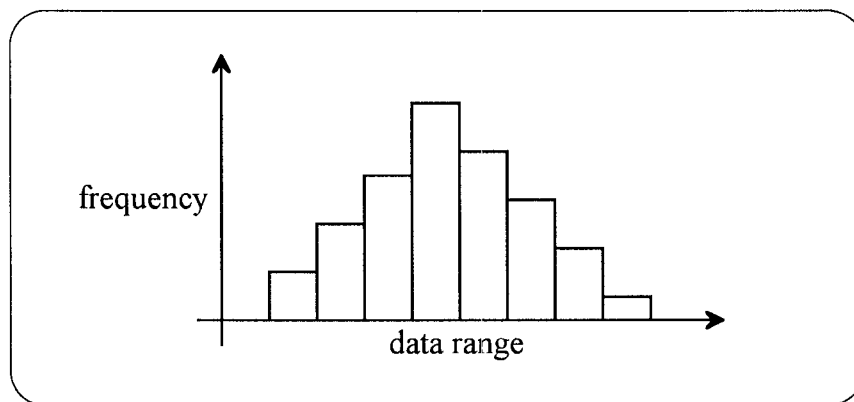


FIGURE 4.6: Histogram

Control charts, which were first developed by Walter A. Shewhart, is a graph

used to determine whether a process is under statistical control. There are many different types of control charts with the variations relating mostly to how the limits are calculated. The original X-bar control chart is based on the normal distribution, a fixed sample rate, and assumes that samples taken are independent events. It is very important to remember these underlying concepts and assumptions when applying control charts.

Control charts are used to identify "special causes" of variation. The term "special causes" was defined by Deming as causes of variation that can be found and eliminated. Examples of special causes include, machine malfunction, unsuitable worker, and poor quality material. "Common causes", on the other hand, are variations due to natural variations, such as worker's ability, procedures, and machines limitations. These causes are much harder to find so usually it is good enough to find and solve the special causes to bring a process under control. The main pitfall of control charts is not understanding assumptions. This could lead to false determinations of special causes, whose elimination costs money and time. For example, if the skewness and kurtosis values of data set's frequency distribution is greater than that of normal distribution, then the nonconforming parts will be falsely accepted (Type II errors).

A process is under statistical control when its output has normal distribution with acceptable mean and standard deviation.

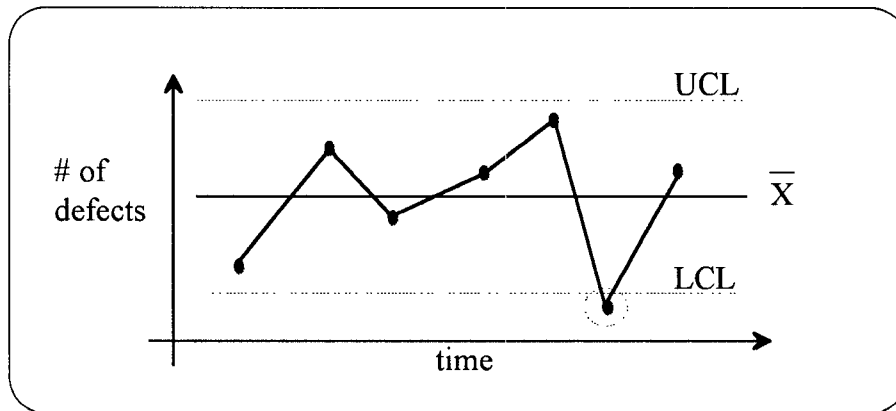


FIGURE 4.7: Control Chart

Research is continuing in the area of statistics applications. The latest developments include efforts to develop a model for creating control charts based small production sampling, zone control charts [19], extending exponentially weighted moving average (EWMA) for process variation control, and extending cumulated sums (CUSUM) to monitor process variation. Control charts has historically been used for mass production industries. With the increasing popularity of statistical quality control, most of the research has concentrated its efforts to apply control charts to processes whose yields produced are small. Any new methods found could help the software industry in its search to measure software development processes and bring software under statistical control.

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19 Jaehn, Alfred H., "The Zone Control Chart", p. 65.

#### **4.4 Information Technology Capabilities for the Framework**

Before procedures are designed or refined in each section of the quality manual, information technology should be considered. Information technology often can provide unique solutions that would otherwise not be considered using traditional tools. For example, if a bank wanted to increase customer satisfaction by starting 24-hour banking services, the solution would be to either hire many more people, or automate banking functions using IT. There are many advantages of IT. If applied to a business process that is designed or redesigned with information technology in mind, IT has following the capabilities that can benefit an organization:

1. Communication and Coordination
2. Data Access
3. Analysis Power
4. Structure
5. Automation
6. Multitasking
7. Competitive Advantage

Organizations can and have used information technology to transcend time and space barriers to improve communication and coordination and support the globalization trend of market competition. Through IT processes become independent of geography for those companies that are either spread out all over the world, or have global partners in business.

Information technology's informational capability allows management to control access of data, and at the same time, distribute data to more people and locations. Since power is defined by the level of access to information in the database, IT can provide more empowerment to lower levels while also keeping control at the management level by providing more monitoring information.

Traditionally, the analytical power of IT has played a major role in business processes. IT provides more powerful complex analytical methods for a processes such as statistical data analysis, modeling, process control, or tracking. The goal ultimately is to convert data to information, and analyze the information to gain superior knowledge. IT supports the business process of knowledge management by allowing the capture and dissemination of knowledge and expertise to improve the process. Detailed tracking of task status, inputs, and outputs is also facilitated by the analytical capabilities.

In process management, functions and tasks are examined carefully and weak processes are redesigned. With IT in mind, the unstructured processes can be transformed into routine transactions based on new design ideas that are unique to information technology.

Another IT capability that has been used a great deal in the past is the automation of business processes. When carefully planned, information technology can be applied to perform certain tasks more quickly or with less errors through process

automation. The result is often the replacement or reduction in routine human labor.

The multitasking capability of information technology introduces the possibility of changing the sequence of tasks in business processes to increase effectiveness. The software development process is one that has gained much benefit from the multitasking features of IT.

In the past, information technology was used to gain a competitive advantage. However, as it becomes more powerful and less expensive, IT is slowly becoming a necessity for a company to remain competitive. In terms of the quality manual development, IT can provide competitive advantage if it is used to take shared data such as customer sales and market demands, convert it to information, and analyze information to get superior knowledge.

While there are many advantages to apply information technology to the development of a quality manual, there are also a few common pitfalls. The danger of applying information technology to the business process is to interpret IT as more than a tool. Alone, IT cannot change or improve a process. The process must be examined to determine if IT can be effective. Also, IT cannot be implemented unless management wants it because IT often demands management and workers to leave the comfort of traditional work habits and adopt new processes with different power distribution and new control mechanisms.

## **Chapter 5. Quality Manual Development Framework**

### **5.1 Introduction**

The developed framework resulted from the definition of the ISO 9000 as the framework's quality guideline, the tailoring of the Systems Engineering method into a quality effort chain, the expansion of this chain to cover the 20 elements of the ISO 9000, which is illustrated in Table 5.1, and the integration of information technology, company efforts, and training into this expanded chain. In this life cycle form, the ISO 9000 standard itself can be implemented more easily into a company's unique business process. The resulting quality manual development framework, which is illustrated in figure 5.1, is made up of the documented procedures grouped in following components:

1. Management
2. Information Systems
3. Internal Audit
4. Corrective Action
5. Training
6. Customer Interface
7. Product Design
8. Procurement
9. Manufacturing and Process Control
10. Inspection, Testing, and Calibration
11. Handling, Storage, Packaging, Delivery
12. Service

The quality manual is the result of documenting the quality system. The quality

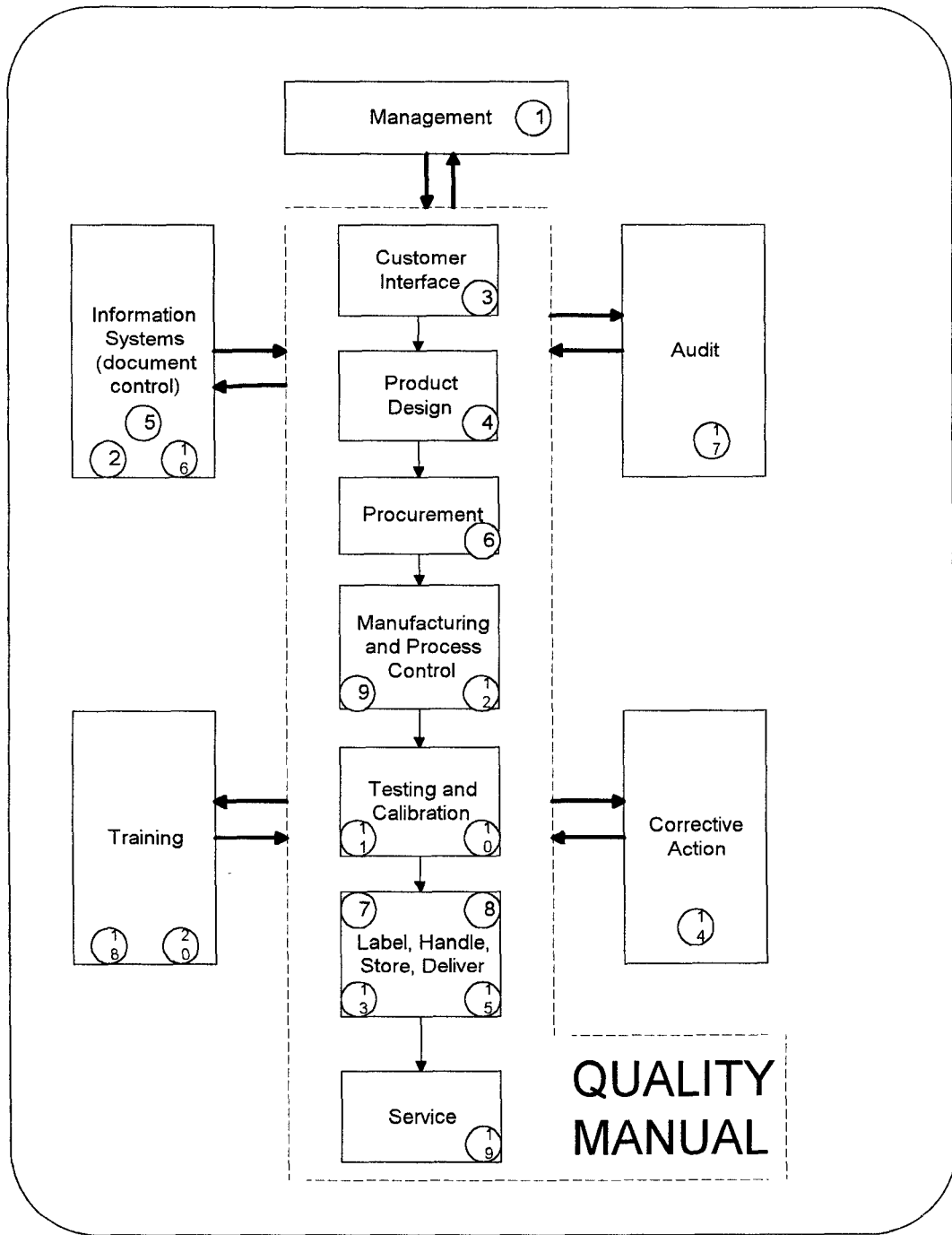


FIGURE 5.1: Quality Manual Development Framework

TABLE 5.1: Framework to ISO 9001 Mapping			
Quality Manual Framework Components	ISO 9001 Element	Systems Engineering Process	Database
1. Management	#1	--	management
2. Audit	#17	--	audit
3. Quality Information Systems	#2, 5, 16	--	n/a
4. Training	#18, 20	--	training
5. Corrective Action	#14	Testing	fix
6. Customer Interface	#3	Requirements	customer
7. Design	#4	Design	design
8. Procurement	#6	Production	parts
9. Manufacturing and Process Control	#9, 12	Production	manf
10. Test Equipment Test and Calibration	#10, 11	Testing	test
11. Handling, Storage, Delivery	#7, 8, 13, 15	Installation	handle
12. Service	#19	Maintenance	service

manual should be clear, concise, and easy to read. It should describe only those procedures that a company will use in its quality system. It should not be padded with fancy sentences or complex procedures that will not be used. For example, one company's quality manual was made up of a set of index cards that documented each procedure! The quality manual is a document that new employees can quickly read to understand how to assure quality in the company. It can also be a reference for those employees who are forgetful. Of course, the quality manual is not a collection of statements etched in stone forever. It also follows the spirit of continuous

improvement. The quality manual must be used, and revised whenever the results of audits see any problems with any documented or undocumented procedure.

## **5.2 Management**

A quality system's success starts at the top with management involvement. This is a point that is common to TQM, Deming, ISO 9000, and all other quality standards. Therefore, the quality manual must start with a description the management function in the quality system. The management function involves the following:

- a. Setting a vision
- b. Organizing company structure for the quality system
- c. Provide necessary resources
- d. Making decisions
- e. Communicating decisions

The quality manual must state the objective of the quality system in the form of a quality policy statement. This statement represents the management's vision and goal for the company in terms of quality. Such a statement should be brief. In two or three sentences, the company should be able to express what they intend to achieve and with how much dedication.

In their feasibility analysis, CTEL's management is considering both the ISO 9001 and 9002 models to become certified under. Creating a quality system that was

certified under the ISO 9001 or 9002 would solve their needs for both a quality system and to meet European contract obligations.

The goals of the quality system should be linked to other company goals such as increasing customer satisfaction, or reducing operating costs. Otherwise, conflicts will occur. For example, if the company's business goal is to reduce overall costs, but the quality policy states that product performance must reach a very high level regardless of cost, then the result is a fight over the financial resources. All employees should be involved in discussing the objective for the company's quality system. Suggestions are then summarized in a few sentences, and the management makes the final decision on the exact wording of the quality policy. By linking quality to existing company goals, the quality policy becomes more tangible, employees better understand why they should create, modify, document, and implement the quality procedures, and these procedure do not conflict with other company goals.

Based on this understanding, CTEL came up with the following policy:

"We here at CTEL are constantly refining our procedures to satisfy the needs of the telecommunications world through the our employees commitment to the spirit of continuous improvement as well as a well-defined and efficient working environment for employees."

This policy was a combination of statements from each employee at CTEL. The quality policy is well understood by each person because it came from each employee.

This policy will be placed in each department as a constant reminder of their commitment.

Once a decision has been made regarding a policy, or later a course of action, management is responsible for communicating this continuously to the company. According to Vaskevitch, "Rather than being generators of words and numbers, managers focus primarily on the three C's: communication, coordination, and control" [20]. The communication function is one of information technology's inherent features by definition, and therefore, provides direct benefits to the management. Examples of communication through information technology includes networks, e-mail software, video conferencing, group decision support systems, and groupware. Networks are made up of computers that are interconnected using network interface cards, cables, gateways, network operating software, and software applications. This technology enables management to quickly distribute information across long distances through many time zones. E-mail is a software application that makes this communication across many hardware platforms possible.

Another software application that is quickly gaining more recognition as an effective communication technology is groupware. Groupware is a network application that allows a group of people in one room to discuss ideas anonymously by using a computer to type in their thoughts to a question. This can be especially helpful in converting those typical time-consuming but wasteful meetings into more effective

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20 Vaskevitch, David, "Why Business Managers Are Empty-Handed", p.93.

discussions that reach more definite conclusions. These groupware applications have been implemented in the AT&T and IBM teaching theaters at the University of Maryland at College Park. In the corporate environment, research by Dr. Maryam Alavi has shown that groupware can help companies in the following ways [21]:

1. requires less time to generate ideas
2. generates more ideas in each meeting
3. generates better quality ideas
4. needs less time to prioritize ideas
5. results in higher perceived group cohesiveness
6. makes meeting participants feel more comfortable in offering ideas

The capabilities of information technology can impact the coordination responsibility of management. Examples of this include the value-added partnerships, and Singapore's TradeNet system [22]. Examples of VAPs that have coordinated well using information technology include the Menichetti company in the Italian textile industry, and the McKesson Corporation in the drug and health care industry [23]. In similar fashion, Singapore's Tradenet system electronically linked many different agencies in the trading and shipping process to decrease time to pass customs, verify quantity and location, and reduce paperwork.

This idea of value-added partnerships is based on the value-added chain concepts. As part of the value-added chain, both McKesson and Menichetti use

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- 21 Alavi, Maryam, "An Assessment of Electronic Meeting Systems in a Corporate Setting", p145  
22 King, John, "Singapore TradeNet (A): A Tale of One City".  
23 Johnston, Russell, "Beyond Vertical Integration -- the Rise of the Value-Adding Partnership", p. 94-101.

information technology to electronically link each part of the chain together to share information regarding customer sales and local market preferences to generate a quick response system. Such a system has the ability to respond quickly to changing market demands. It uses IT to compete on scale as well as local responsiveness. Advantage shifting to retailers who take advantage of being the channel entity that is closest to the consumer by collecting and analyzing data about customer tastes and expectations. Companies such as Toys 'R Us, Walmart, The Limited, Benetton, and Home Depot implemented this quick response system to successfully coordinate. The advantages of quick response systems using IT are:

1. Reduced inventory loads
2. Increased inventory turnover
3. Replenishment on actual data instead of forecasted sales data
4. Enhanced profitability
5. Tight coordination leads to competitive advantage for all those in the value chain
6. Rapid flow of product and information
7. Provides integrated information pipeline throughout channel
8. Shortened product development cycle
9. Creation and analysis of databases

Besides linking quality goals to company goals, management needs to clearly define the company structure, roles of each employee, skills and resources required, and authority level in the quality system. To manage people in the quality system, a company can decide to use either a centralized hierarchical structure, or a more decentralized one. Since quality involves the entire company, quality teams are a very

important part of the system. The goal of quality circles or teams is to get feedback from employees about company and to promote both communication and empowerment. IT can enhance team performance by providing support to group coordination and group task execution. The communication and coordination capabilities of IT discussed earlier applies here equally. The team approach enabled by IT promotes empowerment as indicated in the management section. This combination of teamwork and IT gives some authority, as recommended by the ISO 9000 and rightfully so, to those the lower level workers, who are "closest to the customer, and therefore, know best what changes are needed to improve customer satisfaction" [24].

For this framework, there should be two types of teams depending on its function. To carry out quality procedures within each department, quality teams should be formed using only those employees within each department. To audit the quality system, a verification team should be formed using members from each department. A cross-functional team will ensure that the audit results reported to management are objective and fair. Information technology can be effectively applied to the quality team structure to improve the communication between teams as well as team members. In CTEL's case, one member from each department was chosen to be part of the quality team. They are Eric Yam, Teresa Willard, Dave Brobst, Bhupendra Patel, and Cindy Holm.

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24 Cortada, James W., "Implementing Quality in a Sales Organization", p.67.

Each team needs a team leader whose responsibility is to make sure that the team understands its role and carries out its assigned quality procedures well. Also, management must assign one employee as the representative who will be the interface between management and employees. This management representative's role is to make sure that the quality teams meet defined milestones, and to keep management informed about the quality system.

Another important function of management is to determine whether man or machine will perform a task, what skill level is needed, and how many are required to successfully carry out the tasks in a quality system. This human factors issue will help determine the procedures are absolutely necessary, and those that can wait. It also will help management determine the resources, such as time, test equipment, or more personnel, that are needed to support the required personnel. This section should reference the training section.

It is important for top management to give the team leaders and management representative enough power to make decisions on their own. The management representative should be given authority to do whatever is necessary to make the quality system work as designed. In this way, the management representative's function can add more value to the quality system. Also, by allowing the quality teams to make changes to their processes, each employee feels a greater sense of

responsibility when doing their job. This empowerment of the team is enabled by the application of information technology.

TABLE 5.2: MANAGEMENT				
Company X Quality Manual				
DATE	VERSION	AUTHOR	DOCUMENT NUMBER	DATABASE
mm/dd/yy	1	John Doe	22.33	management
<p>Management Procedures:</p> <ol style="list-style-type: none"> <li>1. Create a quality policy</li> <li>2. Organization structure definitions:               <ol style="list-style-type: none"> <li>a. structure: quality teams, verification team</li> <li>b. role: team leaders, management rep</li> <li>c. skill: auditing, human factors. <b>Refer to human resource analysis in training section.</b></li> <li>d. authority: management representative</li> </ol> </li> <li>3. Provide necessary resources: equipment, time, money, personnel, training</li> <li>4. Review the quality system audit report: corrective action decision, communicate corrective action to company</li> </ol> <p>Management Data:            quality policy, personnel roles, level of authority, review date, suggestion ID, reviewer name (mgmt), response, course of action  <b>Link to audit database.</b></p>				
	#1			page x of y

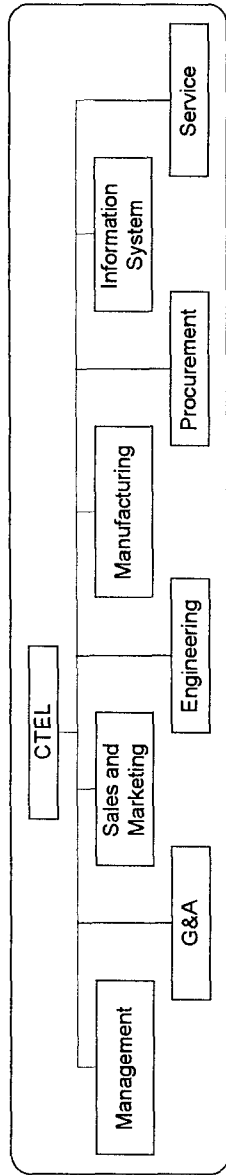
Once the company is organized to begin fulfilling their quality policy, management must set a schedule for periodic verifications of the quality system. Management will then evaluate the audit results, decide on the best corrective action,

and then communicate both the results and recommendations to appropriate personnel. The management representative should make sure that the corrective action is implemented quickly. Then, another audit will determine the effectiveness of the solution. This review will help the system constantly improve. The procedures and data needed in the management component of the framework are summarized in Table 5.2. References to other components and links to other databases are cited in this table also.

### **5.3 Internal Audit/Verification**

Once the management function has been outlined, the next step in the quality manual development framework is to define the audit tool. Internal audits, or verifications, are very useful tools to continuously improve every component of the documented quality system. The basic processes in an audit involve following the flow of the data. This data includes customer inquiries, product status, and billing. The goal of auditing is to determine how well the documented quality procedures are being executed, and find any existing or potential problems.

Audits in this framework can be facilitated here also by the combination of teamwork and IT. Singapore TradeNet system used IT in the form of databases, networks, and document management software to reduce the paperwork for approving



NAME	MGT	G&A	S&M	ENG	MAN	PRC	IS	SER
Teresa Keplinger	--	☺	☺	--	--	--	--	☺
Missy Littrell	--	☺	☺	--	--	--	--	☺
Cindy Holm	--	☺	☺	--	--	--	--	☺
Eric Yam	☺	--	--	☺	☺	☺	--	☺
Teresa Willard	--	--	--	--	☺	☺	☺	--
Kevin Sung	--	--	--	☺	--	--	☺	☺
Dao Tran	--	--	--	--	☺	--	--	--
Ash Q.	--	--	--	☺	--	--	--	☺
Bhupendra Patel	--	--	--	--	☺	--	--	--
Hausting Hong	☺	--	--	☺	--	☺	--	☺
David Brobst	--	--	--	☺	--	--	--	☺
D.P. Patel	☺	--	--	☺	--	☺	--	☺
Jerry Hartanto	☺	--	☺	--	--	--	--	☺
Vaikunth Gupta	☺	☺	☺	☺	--	☺	--	--
Sujata Gupta	☺	☺	--	--	--	--	--	--

FIGURE 5.2: CTEL Company Structure

transported were correct in quantity and type. On a smaller scale, the total time to audit a quality system can be shortened by designing automated processes to simplify the comparison of requirements in computerized checklist format to computerized quality results.

Audits serve two functions in the development of the quality manual depending on what stage the quality system is at. First, in the early development stages, it is used to model the current company processes. The data flow analysis should follow a bottom-up approach to determine and document what the company is currently doing. Employees in a company know the procedures to follow to do their job, but these procedures are usually undocumented. During this initial audit of the company, employees should document their procedures in detail. Once each job is documented, a high-level flowchart should be created to represent all the departmental processes. Interfaces between and interactions among processes and resulting documents from each process should also be shown. The result is a documented model of the current company process.

At this point, the company has both a model of current processes and a set of goals to reach as defined by the quality policy and the ISO 9000. By comparing the model with the goals, the company can determine what procedures and documents need to be created or modified. This gap analysis in the initial audit of the current

company process usually yields a long list of problems and omissions that need to be addressed when creating the quality manual.

The second function, which is used once the quality system is up and running, is to find and correct problems in the manual once it has been created. After the initial quality manual has been created and implemented, periodic audits are necessary to measure the quality system, and improve those functions that do not satisfy the goals set forth by management. This second function usually involves using a checklist document and can be referred to as a verification. The model is necessary because a company needs to understand their current status before they can decide what needs to be improved. This periodic audit can start at any point in the overall company process to analyze the flow of information. For example, if management sets the after-sales service department as high priority, the verification team pick out a customer complaint from the quality records, and follow the paper trail to determine if the complaint was handled as described and if this response meets the company's quality policy. If not, then it is noted on the audit report and a corrective action is recommended to management for review.

Verification may also involve evaluating parts or suppliers compliance to company standards. This will involve taking the data collected by the information system and statistically analyzing and compared against the established company standards.

To accomplish the goals of this element, several steps need to be taken. First, all elements of the quality system need to be defined. This includes management objectives, organizational structures, operational procedures, required personnel and equipment resources, and necessary documentation. Then audit procedures need to be created and documented. Personnel skills and quantity required to perform the review of each of the quality system elements need to be determined. Next, the reason for the audit should be documented and recorded in the audit database. Possible reasons include:

- a. Routine check
- b. Investigate possible deficiencies
- c. Corrective actions
- d. Evaluate effectiveness of corrective actions

Once all procedures and personnel are understood, the review procedures should be implemented by the verification team, and the results need to be documented in the quality information system. The output of internal audits is a verification report for management that should include:

- a. Audit date
- b. Document ID number
- c. Documented process that was violated or is causing problems
- d. Description of the problem found
- e. Name of auditor
- f. Recommended solution
- g. Solution auditor
- h. Date to finish implementing changes

- i. Assess effectiveness of implementing corrective actions based on previous audits.

This report summarizing any problems in the quality system is sent to management for review. Reference should be made to the management section.

TABLE 5.3: AUDIT/VERIFICATION				
DATE	VERSION	AUTHOR	DOCUMENT NUMBER	DATABASE
				audit
<p>Audit/Verification Procedures:</p> <ol style="list-style-type: none"> <li>1. Create checklist of processes (based on requirements and goals) to audit.</li> <li>2. Determine personnel skill and quantity to perform verification. <b>Refer to human resource analysis in training section.</b></li> <li>3. Document reason for audit.</li> <li>4. Implement verification procedures.</li> <li>5. Summarize audit findings in a report.</li> <li>6. Give report to management for review. <b>Refer to management section.</b></li> </ol> <p>Audit/Verification Data:            audit date, document ID number, auditor name, quality manual section or process that was violated or is causing problems, description of the problem found, recommended solution, solution project leader, date to finish implementing changes, report id  <b>Link to management database</b></p>				
	#17			page x of y

#### 5.4 Quality Information System

A quality information system is a well-planned system for the collection, storage, analysis, and reporting of information related to quality to assist in making

decisions. It should be integrated with the company's management information system (MIS). A QIS, supported by information technology, such as computers connected as a network, is a very useful tool in this document-intensive effort of developing the quality manual. The most important function of the QIS is in the area of document management and version control. The editing, data sharing, and security features of such a tool allow all assigned personnel to communicate and interact when editing the same document over the network during reviews, and then quickly modify the quality manual once agreement is reached.

Also, this computerized tool allows the collection of documented procedures and relevant records resulting from activities such as equipment calibration, human resource analysis, and training. This data can then be placed on-line to provide faster distribution of data to more people, and easier access for all employees. The quality information system adds better control and coordination to the development of the quality manual. In terms of the quality system, the QIS also facilitates the collection of data for quality records.

The quality information system can be developed using the Systems Engineering approach also. These steps include:

1. Analyze and document customer requirements: this requires understanding the data needed, understanding documentation processes, and modeling both the data and processes.
2. Create a design specification
3. Review with management and negotiate for approval
4. Develop

5. Test
6. Implement
7. Review system performance
8. Maintenance, training, support
9. Upgrades based on reviews

To manage risk, companies should consider integrating existing off-the-shelf IT applications. Information technology is literally changing and progressing every day. There are decisions to be made in the areas of hardware and software. Today, you have a choice of a PC-compatible, RISC workstation, or the mainframe for the hardware platform. Within each of those domains, there is a choice for features such as processor type and speed, system memory, disk storage space, screen size and resolution, bus architecture, and disk interfaces. The addition of each feature will affect the speed, cost, and security of the overall quality information system. For software, there are choices for operating system, word processors, spreadsheets, databases, and communications. If integration is considered separately, there are options for networking computers, client-server applications, groupware, and e-mail.

During the design of the QIS, many issues need to be considered. Standards should be adopted for any document that goes into the system to maintain consistency and reduce errors. These standards may be in the form of blank forms, a computer text file format, a graphic file format, or a report format. Data formats can apply to a wide range of data including telephone calls, forms, letters, ascii files, word processor files, spreadsheet files, and database files. Besides data format, expandability is another

design consideration. This involves functions such as edit capability, field additions, and deletions. Audits to remove unused or old data and reports should be a regular part of the final QIS. Of course, costs in terms of time, labor, materials, and software of the QIS must be weighted against the value of information generated.

Another major design consideration of the QIS is reports, an aid in data retrieval. The purpose of reports is to aid in investigations and corrective actions, and provide early warning of potential problems. There are two types of reports -- executive reports and operational reports. An executive report is a high-level summary of performance specifications, costs, design tests, manufacturing data, plan of corrective action, and maintenance and support data. The following are reports presenting information in high-level views:

1. factory quality deficiencies (rework and waste costs relative to sales)
2. finished goods quality (defective parts per million, demerits per \$1000 sales)
3. field performance quality (maintenance hours per 1000 operating hours)
4. field performance deficiencies (warranty repair costs relative to sales)
5. supplier quality (defects as percentage of purchases)
6. top 10 quality problems
7. promptness of service (response time in days)
8. quality benchmarking against top three competitors
9. avoidable changes
10. document quality (percentage of defective pages)
11. software quality
12. invoicing errors (correction costs, percentage errors)
13. quality improvement

The following is an example of subjects covered by a typical executive report at

General Dynamics Corp.:

1. Avoidable engineering changes
2. Deviations/waivers
3. First-time yield
4. Scrap (labor hour)
5. Scrap (material value)
6. Repair and/or rework (labor hour)
7. On-time delivery
8. Purchase item acceptance
9. Service response time
10. Material review actions
11. Inspection escapes
12. Overtime

Another example of an executive report is Texas Instruments' (TI) quality reporting system. This system has some powerful data analysis functions to monitor their quality efforts. The TI reporting system is made up of three types of reports that summarize different types of data. The first type of report looks for leading indicators to predict quality. These indicators are in the form of raw material data, market research, design review, and product audit. The second type of report examines concurrent indicators in the form of internal in-process manufacturing data to get quality of in-process procedures. The third type of report looks at lagging indicators to obtain the actual quality level of their products and services. This requires getting responses directly from customers in the form of material rejection, product returns, customer feedback, and audit of product use.

Besides executive reports, data can be retrieved in the form of operational reports, which decompose high-level summary into lower level details for daily operation improvement analysis (pareto analysis) by managers and engineers. Operational reports provide daily views in the form of product specification requirements, technical measurements, individual personnel summary, and process correction. The following is a list of data that should be recorded to manage a quality system:

1. Inspection data
2. Test data
3. Qualification data
4. Validation data
5. Audit data
6. Material review
7. Calibration data
8. Quality cost
9. Mechanical drawings
10. Circuit schematics
11. Process flow charts

This data can then be analyzed to get information to:

1. Assess quality of subcontractor
2. Assess effectiveness of corrective action
3. Analyze quality trends
4. Verify that the final product meets defined customer requirements

Another design consideration is the use of generic forms and formats that contain an identification system, and information to link a document to related

documents preceding it and those proceeding after it. An example of a number system for each document is DDDD.AAA#.XXXXR, where

DDDD = four-digit department number

AAA# = three character initials of author plus a number

XXXX = unique four-digit number to identify the document

R = revision or version number

The following information should be included in each document:

- a. Title
- b. Page #
- c. Date
- d. Version
- e. Author

Also, a master list should be kept to track all current documents. This will make it easier for the quality system audits. Under certain situations, the hypertext and hypermedia concepts can be used to present reports and their links to other reports or data.

For their quality information system, CTEL looked mainly at the PC-compatible hardware because most of their development tools, customer base, and products are based on this platform. By staying with the same type of hardware CTEL assured that it would be able to easily integrate the quality system computer hardware with the existing company information technology. The applications examined were DOS-based and MS Windows-based. CTEL also considered a database program to manage and

analyze the quality system data. For all the applications, the network version was also considered to provide easier access to the necessary data.

TABLE 5.4: QUALITY INFORMATION SYSTEM				
DATE	VERSION	AUTHOR	DOCUMENT NUMBER	DATABASE
				n/a
<p>Quality Information System Procedures:</p> <ol style="list-style-type: none"> <li>1. Model company documentation process and determine if application of IT is potentially useful.</li> <li>2. Determine type of data to be collected.</li> <li>3. Determine personnel skill level and quantity requirements. <b>Refer to human resource analysis in training section.</b></li> <li>4. Determine standard format for data storage, retrieval, and sharing.</li> <li>5. Create numbering system for document id.</li> <li>6. Create master list for version control.</li> <li>7. Create procedures for retrieving document, filling out document, and getting approval.</li> <li>8. Define personnel with authority to approve document for storage into quality information system.</li> <li>9. Create procedures for data analysis. <b>Refer to statistical analysis in training section.</b></li> </ol> <p>Quality Information System Data:            title, document #, data, version, author, inspection data, test data, qualification data, validation data, audit data, material review, calibration data, quality cost, mechanical drawings, circuit schematics, process flow charts</p>				
	#2. 5. 16			Page x of y

**5.5 Training**

The development of the quality manual requires knowledge of several key concepts that may be new to some companies, or some employees of a company. This

includes the ISO 9000 standard, computer word processors, operating system commands, and databases. Without a basic understanding of these concepts in this framework, a company cannot get all their employees involved in the quality system. This problem is handled by the use of training.

What procedures are required to determine the training needed? First, the work to be done needs to be documented. This may be as simple as entering data into the computer database, or as complex as building a car. Once the mission is known, a functional analysis is performed to determine what functions are needed to successfully complete the mission. Then a task analysis is done to breakdown the work into smaller, more manageable pieces. At this point, there may be certain tasks that may be performed by either man or machine, such as data analysis. The person with the authority to decide who does what must have some experience in human factors studies. Human factors is concerned with improving the work and living environments applying human cognitive theory and an understanding of human physical limitations to the man-machine interface. Once the task is delegated, a human resource analysis is performed to determine what type of skills and how many people are needed to do the task. Afterwards, it is up to management to satisfy the requirements by matching existing personnel, hiring new people, or providing training to new or existing personnel.

Based on the training experience of CTEL, there are several guidelines to make

training effective. They include:

1. Timeliness -- provide training when it is needed immediately, not months later
2. Manager participation in training design
3. Interactive style of training
4. Communicate well during training
5. Documents of training material

Documents should be required of subcontractor who will supply the training. This will be a useful reference to refresh the memory when certain subjects are forgotten. Also, records should show who has received what type of training. Training may be provided in-house or by an outside subcontractor. This will depend on the expertise available and costs determination.

When planned out carefully, information technology can automate the training process. Different subjects can be created using hypermedia or multimedia development tools to educate employees. The advantage of this IT application is that provides flexibility. Employees can obtain training at their own time and pace. Also, the costs of seminars and teachers are avoided.

The subjects of training sessions will depend on the knowledge needed to complete a task. Subjects can vary from a general understanding of quality to specific statistical analysis techniques. The following is a list of common training subjects:

1. General understanding of quality engineering
2. Understanding of a quality standard or an award criteria
3. Economics of Quality

4. Auditing techniques
5. Basic statistical techniques
6. Quantifying quality efforts
7. Certification in specialized skills
8. Proper operation of equipment
9. Computer skills
10. Ability to read and understand documentation

Since documents would be created on computer, stored on the network for access to everyone, and managed by setting network rights, CTEL had a definite need for training in basic computer applications such as DOS, Windows, spreadsheets, databases, and network operations to transfer the information technology into their business environment. As far as information technology needed, CTEL already had a local area network (LAN) and a people-to-computer ratio that was close to one. The only problem was that there were very few employees who understood the installed computer technology well enough to use it to streamline business processes. Based on an analysis of their existing resources, CTEL management decided that outside training would be needed for ISO 9000, but training in computer and test concepts would be provided in-house.

An effective training program must not only follow the procedures outlined above, but also require knowledge in the area of human factors.

#### **5.5.1 Human Factors and Quality**

One day a professor decided to go to an appliance store to buy a washing

machine for his apartment. Being a smart shopper, he checked several stores, brands, and features before deciding on a Whirlpool machine that had wheels for portability. The professor paid \$500 and brought the machine home. When he tried to open the box, he found wood braces surrounding the machine for protection from possible damage due to shipping. After spending many hours and all his strength, the professor still could not pull the braces apart. He became a very unhappy customer! So the professor made a few calls to the appliance store, and finally managed to free his machine. It took several years of error-free operation before the professor became satisfied with this purchase.

Was quality considered in the design of this washing machine? Well, the machine was well-designed and manufactured because there were no problems after several years of operation. However, in the design of the shipping and handling of the machine, the engineers had failed to consider that the strength of the average human has a limit. The engineers did not consider human factors in their design of the braces.

So what is human factors? Human factors involves the design of machines, tools, systems, and jobs using knowledge about human behavior, capabilities, and limitations. Its goals are to improve the way work is done, and to increase the product safety, job satisfaction, and quality of life. These goals are accomplished by looking mainly at the man-machine interaction. Human factors emphasizes the human being in

the design of systems, especially in the conceptual phase. Other terms used in place of human factors include ergonomics, human engineering, and engineering psychology.

When machine products are designed for use by humans, anthropomorphic data such as height, weight, posture, frequency range of ears, and image detection limits of eyes, must be used. Besides the Whirlpool example above, another classic application of human factors in man-machine interaction is the automobile. Information about humans is needed to design seat heights and widths, as well as placement of accessories. The requirement for the red safety light in the back window was a result of human factors studies.

The human relationship in the workplace and its effect on quality have become more emphasized recently. People are the key to quality. In other words, employees must understand the need for quality and actively participate in the quality effort. This is accomplished through motivation and disciplined work ethic. Effective motivation of employees is needed to keep the human bond strong and vibrant so company goals can be achieved. Also, management's fundamental objectives in developing good human relations center around the creation of an environment that makes the satisfaction of human needs compatible with company goals.

When we talk of an organization and its people, the human dimension becomes a fundamental aspect. There are four requirements of successful quality design: (1) management commitment, (2) employees involvement, (3) organizational support, and

(4) reevaluation of the social systems or society. This means that throughout the system design, a human factors analysis is performed as an integral part of the overall system design. The human factors analysis constitutes a composite of individual program activities directed toward (1) the initial establishment of human factors requirements for system design, (2) the evaluation of system design to ensure that an optimum interface exists between the human and other elements of the system, and (3) the assessment of personnel number and skill level requirements for a given system design configuration.

The analysis effort employs a number of the analytical techniques, such as alternatives decisions making, optimization, and probability and statistical methods. Also, the analysis effort is closely related to the reliability analysis, maintainability analysis, logistic support analysis, and life cycle cost analysis. The human factors analysis begins with conceptual design when functions are identified, and trade-off studies are accomplished to determine whether these functions are to be performed manually using human resources, automatically with equipment, or by a combination thereof. Given the requirements for human resources, one must then ensure that these resources are used as efficiently as possible. Thus, the analysis continues through an iterative process of evaluation, system modifications for improvement, reevaluation, and so on. [25]

The application of human factors in design of systems does not completely lend itself to the formulation of a complete set of solutions. A systematic consideration of the human factors aspect in quality design should be done with human beings (employees and customers) in mind. This consideration can be fulfilled by answering questions that are related to the quality of the design system. Questions like [26]:

1. What functions need to be carried out to fulfill the system objectives?
2. For a given function, what information external to the individual is required? Of such information, what information can be adequately received directly from the environment, and what information should be presented through the use of displays (charts, graphs, SPC, etc.)?

TABLE 5.5: TRAINING				
DATE	VERSION	AUTHOR	DOCUMENT NUMBER	DATABASE
				training
<p>Training Procedures</p> <ol style="list-style-type: none"> <li>1. Work description document</li> <li>2. Functional analysis</li> <li>3. Task analysis</li> <li>4. Human resource analysis</li> <li>5. Training subjects: statistics</li> </ol> <p>Training Data: name, skill level, training received, date, source of training, project, requirement document number, project WBS document number.</p>				
	#18, 20			page x of y

3. Are the information inputs collectively within reasonable bounds of human information-receiving capacities?
4. When physical control is to be exercised by an individual, what type of control devices should be used? Is each control device easily identifiable?
5. Do the tasks which require time sharing avoid overburdening any individual or the system? Particular attention needs to be given to the possibility of overburdening emergencies.

The procedures and data needed for the training component of this framework are summarized in Table 5.5.

## **5.6 Corrective Action**

This section of the quality manual should describe a formal methodology for evaluating and fixing those products that fail inspection and testing. This includes the following steps:

1. Understand the problem.
2. Analyze the product functions to identify the problem source.
3. Determine the course of action to fix the problem.
4. Determine the skill level and quantity needed to carry out the correction. (refer to human resource analysis in the training section)
5. Collect data about the product id, defect, cause, solution, and personnel involved and record in the computerized debug database.

These procedures require some knowledge about testing, and reference should be made to the training section for test training. Note that the central repository of solutions to technical problems created in the customer interface section can also be used in the corrective action activities. The repository will definitely complement the debug

database. Ability to access this database will require some computer skills, so reference should be made to the training section regarding the subject of computer training.

Once the problem has been identified, the destination of parts and products should be decided by proper authority and handled according to procedures in component #11. Parts or products that are defective need to be evaluated by a delegated authority to determine its fate. It can either be sent back, or stored away in a place reserved for nonconforming parts and products.

TABLE 5.6: CORRECTIVE ACTION				
DATE	VERSION	AUTHOR	DOCUMENT NUMBER	DATABASE
				fix
<p>Corrective Action Procedures:</p> <ol style="list-style-type: none"> <li>1. Understand the problem first.</li> <li>2. Use debug procedures to identify source of problem.</li> <li>3. Determine personnel. <b>Refer to human analysis in training section.</b></li> <li>4. Determine best solution to problem. Record corrections made.</li> <li>5. Verify effectiveness of solution. <b>Refer to audit/verification section.</b></li> </ol> <p>Corrective Action Data:  product id, problem, cause, corrective action, solver name,  <b>Link to customer, test, and parts databases.</b></p>				
	#14			page x of y

## 5.7 Customer Interface

In this section of the quality manual, procedures should be defined and

documented regarding handling of customer inquiries, reviewing customer contracts, and understanding customer requirements. This section covers pre-sales procedures for interfacing with customers, but component #12, the last section, covers after-sales customer support. When customer call or fax, they usually complain about product malfunctions, need technical assistance, or request product information. For each inquiry, the quality manual should describe procedures to collect data immediately in a computerized customer database about the customer, the nature of the inquiry, the product affected, and then direct the call, if necessary, to a sales or service person for further assistance. Data about customers should always be collected at the point of contact regardless of the nature of the inquiry. This data may be useful later to a sales or service person who eventually will work with the customer. The combination of teamwork and IT, when applied in this section, can improve the communication and coordination that is necessary in understanding customer requirements.

Eventually, the customer database stores enough information about potential customers, which the marketing and sales departments can contact. Following the Systems Engineering approach, the quality manual must document procedures for understanding customer requirements and generating specifications based on agreed requirements. For those customers who need a new or modified solution, a contract review should be conducted to match the customer's requirements with company resources to determine if the project is feasible. On the other hand, for those customers

who are planning to buy an existing product, a contract review should be conducted to match the customer's requirements with the appropriate product configuration. At this review, differences should be worked to reach a compromise. A contract review document that has a checklist and summary of the review and compromises agreed to should be stored in the information system as a result of these processes.

TABLE 5.7: CUSTOMER INTERFACE				
DATE	VERSION	AUTHOR	DOCUMENT NUMBER	DATABASE
				customer
<p>Customer Interface Procedures:</p> <ol style="list-style-type: none"> <li>1. Determine what the customer wants, and fill out the customer requirements document.</li> <li>2. Create a checklist documenting customer requirements.</li> <li>3. Verify that the product to be developed and delivered satisfy the checklist. <b>Refer to the audit/verification section.</b></li> <li>4. If all items on the checklist are not met, then negotiate with customer to reach an agreement.</li> <li>5. Document negotiations and conclusions.</li> <li>6. Submit documents for approval. <b>Refer to the quality information system section.</b></li> </ol> <p>Customer Interface Data: customer name, address, phone, fax, inquiry, performance and costs requirements, schedule and delivery requirements, contract review checklist and report document number</p>				
	#3			page x of y

## 5.8 Design

Another section of the quality manual should be devoted to creating and documenting design-related procedures to ensure product quality. The design

procedures should consider the product's entire life cycle. To do this, designers should receive input from the marketing, engineering, manufacturing, and service people. The final product should be designed for testability, manufacturable with little sources of variation, and easily serviceable. The design procedures must not only get input from all departments, but must include procedures for communication with each other. Application of the teamwork concept with information technology, such as e-mail and groupware, fits in very well with this design section. The combination facilitates the communication between departments, and therefore, design issues can be discussed and argued to reach a consensus. For example, a product called "For-Comment" developed by Broderbund Software allows many different people on a LAN to edit a document without altering the original copy. All changes are summarized and can be compared to produce a final document that integrates the input from many different viewpoints. Also, IT tools such as computer-aided design (CAD) and computer-aided software engineering (CASE) have enable design teams to shorten the design phase of the product life cycle.

Once this consensus is reached, procedures should define how the output of the design efforts should be documented. Resulting documents to be stored in the information system include design specifications, drawings, reports, parts list, manufacturing procedures, and test procedures.

The verification procedure described in the audit section of the quality manual applies in this design section also. The design outputs must be checked against the customer requirements and system specifications to ensure that the product designed meets the customer's expectations. A design review document should summarize the verification efforts, and any mismatches should have a recommended solution.

In the design section of the quality manual, design change procedures should also be documented. This accounts for changes that need to be made following a verification recommendation for changes, or if changes need to be made later due to process control issues.

TABLE 5.8: DESIGN				
DATE	VERSION	AUTHOR	DOCUMENT NUMBER	DATABASE
				design
<p>Design Procedures:</p> <ol style="list-style-type: none"> <li>1. Plan the design and development effort.</li> <li>2. Assign roles and supply resources for project.</li> <li>3. Identify all design inputs and interface between various inputs.</li> <li>4. Document design all outputs (drawings, instructions,...)</li> <li>5. Verify that the design output meets requirements. <b>Refer to the audit/verification section.</b></li> <li>6. Establish procedures for review and approval of design changes resulting from new/modified design inputs.</li> </ol> <p>Design Data: product id, designer name, design document type, design document number</p>				
	#4			page x of y

Once all the procedures are set, the human resource analysis should be performed to determine the skill level and quantity needed to effectively carry out the design procedures. This usually requires some training in basic human factors.

## **5.9 Procurement**

Once the design procedures have been addressed in the quality manual, IT should be considered in the design or modification of the procurement system. By using IT in the form of electronic links between groups in the product development chain, a value-added partnership or quick response system is created for procurement. Procurement procedures based on such systems can improve inventory management and responsiveness. Creating procedures to work with suppliers through electronic links can also improve supplier's compliance and responsiveness. As a result, the procurement function gains all the same advantages of a quick response system.

Once the procurement system is designed, the procurement procedures should be defined and documented. Whenever parts are needed by either the design or production groups, they must follow a formal set of procurement procedures. A parts request form should be filled out and sent to the procurement department. The information needed include very specific parts number, a valid substitute in case the specified part is not available, recommended supplier, name of person requesting parts, date, and project. This information should be collected in a computerized procurement

database for use later. With this information, procedures should define the number of price quotes to get, whether potential suppliers need to be certified, and purchase approval. Once approval is given, the supplier and final price should be added to the above procurement database.

Verification applies also to the procurement function and should be referred to in this section of the quality manual. The verification process here determines a supplier's compliance to the company's parts requirements. Reference should be made to component #10 for inspection of incoming parts to make sure that the quantity and part numbers are correct. Remember to record the inspection status in the procurement database. A verification report should be filed with recommendations for any problems found. The information in the procurement database will eventually be analyzed statistically to assess suppliers and determine whether they meet the company's standards. Training will be needed to perform statistical analysis on the data. Refer to the training section.

Procedures should also deal with the proper handling, labeling, and storage of incoming parts. This section should refer to component #11. The procedures for storing parts should consider the environmental conditions such as temperature, moisture, and electrostatic discharge (ESD). Labeling procedures should be documented in the quality manual for any part that requires a unique identification, such as printed circuit boards.

In CTEL's case, an initial audit of the company discovered that the procurement function was documented well and had proper checks and balances. For example, a parts request form had to be filled out if anyone needed to order something. Approval and signatures were required depending on the dollar size of the purchase. Incoming parts were then verified against the original purchase order to determine compliance of the parts supplier.

TABLE 5.9: PROCUREMENT				
DATE	VERSION	AUTHOR	DOCUMENT NUMBER	DATABASE
				parts
<p>Procurement Procedures:</p> <ol style="list-style-type: none"> <li>1. Clearly define parts to purchase.</li> <li>2. Create checkpoints along parts procurement path. This may include parts request forms, signatures of approval, or verification of subcontractor supplying parts based on past compliance.</li> <li>3. Create procedures to handle disputes.</li> <li>4. Verify purchaser-supplied products against requirements documents.</li> </ol> <p><b>Refer to the audit/verification and handling sections.</b></p> <p>Procurement Data:  part number, product id, supplier, supplier address, supplier phone, supplier fax, quantity, price  <b>Link with fix database.</b></p>				
	#6, 7, 10			Page x of y

## 5.10 Manufacturing and Process Control

In the manufacturing and process control section of the quality manual

procedures should include a verification of a part's inspection and test status before use logical assembly sequence, sampling plan, and analysis of defect data for process control, if applicable.

Manufacturing teams and information technology can have a significant impact in this section. Communication and coordination is very important in manufacturing and process control. Designing processes that apply computer analysis and automation can provide insightful knowledge about the manufacturing process and existing level of variation. Data collection for process control and tracking of a part's inspection status are both easily enabled by the application of IT here. Once the data is collected, automatic statistical analysis of the defect data can be performed to determine the source of variations.

This computerized data collection and analysis requires training (refer to the training section) in statistical quality control. The central repository of solutions to technical problems created in the customer interface section can also be used in the process control phase of the product life cycle. It is very important to verify the inspection status of parts and components to make sure that only parts that have passed inspection are used in the final product.

This section should make reference to the human resource analysis in the training section, which should be performed to determine the skill level and quantity

needed to effectively carry out the design procedures. This usually requires some training (refer to the training section) in basic human factors.

TABLE 5.10: MANUFACTURING AND PROCESS CONTROL				
DATE	VERSION	AUTHOR	DOCUMENT NUMBER	DATABASE
				manf
<p>Manufacturing and Process Control Procedures:</p> <ol style="list-style-type: none"> <li>1. Create procedures for up-front planning.</li> <li>2. Create high level procedures that reference detailed assembly and test instructions.</li> <li>3. Create procedures for process measurements.</li> <li>4. Clearly define workmanship standards.</li> <li>5. Verify inspection and test status of parts before using. <b>Refer to audit/verification section.</b></li> </ol> <p>Manufacturing and Process Control Data:  product serial number, assembly personnel involved, skills requirements, certification of personnel  <b>Link to test and procurement database.</b></p>				
	#9, 12			page x of y

### 5.11 Inspection, Testing, and Calibration

The inspection and test section of the quality manual should cover procedures at three different stages of the production stage -- incoming, in-process, and final. Incoming parts and purchaser-supplied products should be verified (refer to the audit/verify section) by procurement. Remember the checklist and review document. For each purchase, the inspection status of a supplier should be added to the procurement database. This rating should be based on accuracy and timeliness of the

delivery, as well as quality of the parts. The inspection may be visual, or functionally verified by test equipment. Reference should be made to component #11 to properly label the inspection status of incoming parts.

In-process inspection requires taking measurements at various stages of production. A computerized inspection database should be created to collect these data points.

The third type of inspection process, verification or final inspection, is needed when the product is fully assembled. A verification against customer requirements, which are documents resulting from the customer interface section, needs to be performed before being sent to the customer. Reference should be made to the audit section of the manual. The results of this inspection should be recorded in the computerized product database. Product id, inspection status, numbering system, and any recommendations should be included in this product database. This section of the quality manual should also refer to component #11 for proper labeling of inspected products.

Incoming parts and all products, regardless of whether they pass or fail at any stage of this inspection after verification should be properly handled and stored based on procedures in reference to procedures defined in component #11 based on inspection results.

Calibration of test equipment is necessary because all the data measurements require that the test equipment is accurate. Since test equipment are tools, personnel must be trained (see training section) to use test equipment properly. They must understand the limitations, such as accuracy and tolerances, as well as proper maintenance of the equipment, such as cleaning, storage, and adjustments. If calibration and maintenance will be performed in-house, then personnel need proper training to perform these tasks, and reference should then be made to the training section.

TABLE 5.11: INSPECTION, TESTING, & CALIBRATION				
DATE	VERSION	AUTHOR	DOCUMENT NUMBER	DATABASE
				test
<p>Inspection, Testing, &amp; Calibration Procedures:</p> <ol style="list-style-type: none"> <li>1. Create procedures for inspecting incoming, purchaser-supplied, and in-process parts and components.</li> <li>2. Create procedures for inspecting final outgoing products. Refer by document number to more detailed test instructions.</li> <li>3. Determine which equipment (gauges, oscilloscopes, meters, etc...) are required in product conformance procedures.</li> <li>4. Next, determine the accuracy and limitations of each equipment on the list.</li> <li>5. Establish procedures for periodically calibrating all equipment on the list to traceable national standards. Document the results of these calibrations.</li> <li>6. Maintain an environment recommended for optimal operation of each piece of equipment. The variation of this environment should be controlled.</li> <li>7. Define procedures for the storage and handling of each piece of equipment to ensure the accuracy and function.</li> </ol> <p>Inspection, Testing, &amp; Calibration Data:            type of inspection, equipment requirements, certificate of equipment calibration, calibration date</p>				
	#10, 11			page x of y

## **5.12 Labeling, Handling, Storage, Packaging, Delivery**

The quality manual must have procedures to handle the following types of items:

1. New incoming parts
2. Partially assembled products (in-process)
3. Purchaser-supplied products
4. Final outgoing products
5. Defective parts

Once parts and products have been inspected by procedures of component #10, procedures should be defined and documented to assure the quality of the part in its labeling, handling, storage, packaging and delivery. The labeling process is required to identify and trace parts and products more easily. It affects all of the above items. The labels can be stickers for small items, or tags wrapped around a part of larger items.

Labels should contain the following information:

1. Unique part id
2. Condition (ready for test, degree of completion)
3. Inspection status (untested/pass/fail)
4. Part origin
5. Product id
6. Inspection date
7. Inspector

If parts must be used before they are inspected, then they should be labeled with this information for tracking purposes later. This information should be entered in a

computerized parts database. Later, this database can be linked to the production and service databases to track desired parts and products. Identification of part should be linked to applicable drawings, specifications, and other documents during the design, development, production, and maintenance stages of the product's life cycle. Identification and traceability can be achieved by using serial number marking, tagging, inspection records, documentation of a service, or nothing if traceability is not a requirement. Identification system should also be able to account for changes during the product development. There can be many degrees of traceability.

Procedures should be clearly documented for handling parts. Sometimes handling is overlooked and damage may not be visually evident. For example, non-static gloves should be worn before handling sensitive semiconductor chips that are susceptible to damage due to electrostatic discharge (ESD). Handling should consider the nature of the product and any environmental conditions that can adversely affect it, such as temperature, moisture, or pressure. All of the above types of items must be considered when handling procedures are created.

Procedure must be developed to properly store all of the above items to maintain its quality. They must be stored in proper room conditions, using proper shelving, stacking, and spacing to avoid damage to product and people. Parts that fail should be stored in such a way that it cannot be confused or mixed up with those that have passed inspection. Then reference should be made to the corrective action section

for proper procedures on analyzing the problem and recommending some type of corrective action. Small containers that store large quantities of new small parts should be labeled properly and should not have any attributes that would damage the parts it stores.

Parts that pass should be packaged properly to maintain the quality of the final product during its shipment to customers. The packaging should consider the type of environment that the package will go through (land or sea), and should be properly labeled with warnings for the delivery (fragile, avoid electricity). The verification

TABLE 5.12: LABELING, HANDLING, STORAGE, PACKAGING, DELIVERY				
DATE	VERSION	AUTHOR	DOCUMENT NUMBER	DATABASE
				handle
<p>Labeling, Handling, Storage, and Delivery Procedures:</p> <ol style="list-style-type: none"> <li>1. Create label procedures for parts traceability. A part should be labeled with its inspection status.</li> <li>2. <b>Record</b> pertinent data such as serial number and inspection date with the part status.</li> <li>3. Identification of part should be linked to applicable drawings, specifications, and other documents throughout the product's life cycle.</li> <li>4. Consider the nature of the product when creating handling, storage, packaging, and delivery procedures.</li> <li>5. Verify handling, storage, packaging, and delivery procedures. <b>Refer to the audit/verification section.</b></li> </ol> <p>Labeling, Handling, Storage, and Delivery Data:  part id, inspection status, serial number, inspection date, status, inspector, parts release authority  <b>Link of parts database.</b></p>				
	#7, 8, 13, 15			page x of y

function should be referenced in this section to assure that all items required by the customer are packaged for shipment.

Delivery should be timely. Critical information such as product id, customer information, date, and shipping method should be collected in the computerized delivery database before the final product is shipped out. Also, data should be collected on the outcome of the delivery and stored in the delivery database. This data can later be evaluated to determine the quality of the delivery service.

### **5.13 After-Sales Service**

Finally, a section of the quality manual should be devoted to the after-sales support procedures. The main goals of this element is to maintain a high level of customer satisfaction. To do this, procedures need to be created to obtain as much customer feedback as possible, and to respond properly to customers. Companies can not increase their customer's satisfaction unless they first understand how customer feel about the company and the product. Feedback can be obtained using response cards or by calling occasionally. This information should be recorded the customer database.

There have been many success stories in the application of IT to increase customer satisfaction. The latest strategy seems to be the creation of either single source electronic links between customers and retailers, or electronic markets. If IT-based systems such as APOLLO or SABRE are developed, procedures for the this

section of the quality manual become much less complicated. Also, if customer satisfaction is achieved through a 24-hour fax back service similar to those of Borland International or Microsoft Corporation, then the only procedures needed for the service section is the maintenance of the information technology.

Besides getting feedback from customers, procedures should be created to handle customer complaints and technical questions. Interpersonal skills and a strong technical background are necessary for personnel in this area. The customer database should be updated to include the action taken to resolve any customer product complaints, or technical questions. These complaints can later be analyzed to determine if the source of the problem is in the product design and production. Also, answers to technical questions can become a central repository of knowledge that all service representatives can access to help customers. By saving the response to each customer, a history is developed of each customer, and any support personnel can access that history to help a specific customer. Anotherwords, the customer is not dependent on one specific support person to help them. The response time to their questions is much shorter because any support person has enough background information to answer an ongoing problem.

TABLE 5.13: AFTER-SALES SERVICE				
DATE	VERSION	AUTHOR	DOCUMENT NUMBER	DATABASE
				service
<p>Service procedures:</p> <ol style="list-style-type: none"> <li>1. Determine service to provide.</li> <li>2. Determine skill type and quantity needed to provide service.</li> <li>3. Define personnel responsible for support. This support may be provided internally or externally by a third party.</li> <li>4. Document service procedures such as call routing to proper service personnel.</li> <li>5. Determine type of equipment needed to provide service.</li> <li>6. Provide backup technical support and also spare parts. <b>Refer to corrective action section.</b></li> <li>7. Provide training where necessary. <b>Refer to training section.</b></li> <li>8. Use above procedures to get feedback to analyze effectiveness of corrective actions. <b>Refer to audit/verification section and statistical analysis in training section.</b></li> </ol> <p>Service Data: product, customer, service, customer feedback, date, service personnel name, equipment, skill required, number of complaints, product operation data, description of complain,</p>				
	#19			page x of y

#### 5.14 Success Stories Within the Framework

This framework integrates many parts, which themselves have many success stories. The major component of this framework is the quality guideline, which is the ISO 9000. Examples of companies who have succeeded in using the ISO 9000 standard to incorporate quality into their companies include Northern Telecom, Telecommunications Techniques Corporation, John Fluke Manufacturing Company,

Amoco Petroleum Additives Company, and BASF. Although each of these companies have used the ISO 9000 standard in different ways, all of them have seen immediate benefits from implementing the ISO 9000. These benefits include a reduction in customer audits, obliteration of procedures that do not add value, reduction in maintenance costs, improved inventory control, and streamlining of purchasing procedures.

At Compression Telecommunications Corporation, training on the ISO 9000 standards has been completed, and procedures are being created, modified, and documented for the quality system. The first draft of the quality manual has been completed. CTEL also has seen immediate benefits from going through the certification process. The training has provided the whole company with an awareness of what quality is and its importance to the business. The self-audit procedures brought out the fact that there needs to be more communication within the company. For the first time, procedures are being documented. These documents provide a starting point to analyze the strong and weak links in the companies daily business operations. Also, by being in the process of getting certified, CTEL has gained the status of accepted supplier for several companies and distributors.

## **Chapter 6. Conclusions and Recommendations**

### **6.1 Conclusions**

Companies need to implement quality into their business practice to remain competitive in worldwide market. They need to continuously improve their internal procedures to assure that their products are high quality with comparative cost. The procedures for this improvement are documented in the quality manual, which can be developed using the framework developed in this thesis research.

Several advantages can be gained by using this framework. First, the quality manual will be developed in a systematic manner. The quality manual will be developed to fit the quality guidelines into the business process rather than the other way around. This results in a better understanding of the quality procedures role in the business. A very important lesson to be learned about implementing standards and methodologies, whether it is the ISO 9000 standards, TQM, or the Systems Engineering principles, is that the method should be tailored to fit into the company's culture gradually. Reaching high quality standards takes time to implement and requires complete commitment. This commitment must come from top management.

Tools, such as SQC and information technology, must also be tailored to fit business practice. For example, a frequently-asked SQC question is how large a sample should be taken when setting up a sampling plan? The answer will depend on

costs of samples, costs of measurements, time, manpower, etc... There is no one answer. When it comes time for a company to implement a quality program, then guidelines should be followed to avoid misusing concepts in quality engineering.

Also, by using information technology as a development tool, the framework assures that the documentation developed within acceptable time, and distribution of reports and quality records is more convenient. The application of IT also causes the company to rethink and possibly redesign procedures to incorporate new solutions. Information technology is the key to succeed in this endeavor. An information-based quality system offers the following advantages:

1. Facilitate communication
2. Facilitate data sharing
3. Improve coordination process
4. Faster response
5. Flexible to globalization of organization structure

The framework developed in this thesis work is capable of not only creating the quality manual, but providing a path for the quality system to be upgraded as needed by the company. This upgrade path is available because the ISO 9000 standard is used in the framework as the baseline quality guideline, and the life cycle of the quality system is accounted for. Upgrading to meet the criteria of a more comprehensive quality guideline, such as TQM or the Balderidge Award, means adding to the current system rather than throwing it out and starting all over. The previous efforts are not wasted.

For example, if a company starts with certification under ISO 9002, then its next step may be ISO 9001, or Balderidge. Remember that the ISO 9000 is not independent of TQM. In fact, the next version of the ISO 9000 standards will move more towards TQM.

## **6.2 Recommendations**

The quality manual developed using this framework will satisfy all 20 elements of the ISO 9000. This framework can be enhanced by coding it into a software program. Such a program would be very useful as a management, document development, and training tool.

Besides a quality manual, an economic model or predictive mathematical models could be developed using this framework. These models would benefit the planning stages of a quality program. For example, in most companies, many valuable resources are lost to excessive and unplanned rework, scrap and wasted material, return of defects, and customer audits. All these costs can be determined with the help of economic models.

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