

THESIS REPORT

Master's Degree

**Using Systems Engineering Principles for
Developing ISO 9000 Training and
Documentation Tool**

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Using Systems Engineering
Principles for Developing ISO 9000 Training and
Documentation Tool

by

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Abstract

Title of Thesis:	Using Systems Engineering Principles for Developing ISO 9000 Training and Documentation Tool
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The globalization of markets has sparked the need for a universally recognized and accepted means of assessing quality. ISO 9000 is a series of standards issued by the International Organization for Standardization (ISO). The standards are designed to certify consistent practice and proper documentation of company procedures. Registration to ISO 9000 is awarded after a company demonstrates conformance to the ISO 9000 requirements.

Documentation is a key aspect of the registration process. The most important element of the documentation requirements is the quality manual, a collection of documented procedures reflecting the daily operations of a company. The structure, content, and control of the quality manual are critical to the ISO 9000 registration process. However, problems with documentation are the primary cause of failure of an audit.

This thesis work addresses the pressing need to reduce documentation-related problems by designing and developing a software tool that assists users in creating a quality manual. A methodology based on systems engineering principles is followed to ensure that early requirements are understood and met. The unique highlights and contributions of the software developed in support of this thesis include:

- Emphasis on early analysis activities, especially user analysis, before coding of software.
- Performance of trade-off analysis to determine the best Windows programming tool.
- Utilization of human factors and graphical user interface (GUI) principles.
- Incorporation of ISO 9000 tutorial in software.
- Formatted screens for easy creation of sections.
- Examples and Help to increase users' understanding of ISO 9000 requirements.

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1.0 Introduction

1.1 Importance of Quality

In recent years, United States (US) industry, the Department of Defense (DoD), and others have placed a great deal of emphasis on the subject of quality. The prime motivator is that of "survival" in a highly competitive international environment. In general, the availability of cost-effective, high-quality systems and products from international sources has been increasing. This has increased competition and has provided incentive for industries to do a better job in the design and production of systems. As a result, the field of "quality," although not new, is undergoing a change in emphasis. Understanding this change requires dropping outdated ways of thinking about quality and recognizing the factors that contribute to low quality.

1.2 Factors Affecting Quality

Foreign manufacturers are increasingly challenging the US's position as a world leader in developing and building quality products. American companies, universities, and governments must emphasize quality within their own organizations and develop new ways of conducting business to maintain a competitive edge in the global market. Several of the existing problems are listed below, along with changes that are taking place and suggestions for further improvement.

1.2.1 Introduction of New Products or Services

Most organizations will introduce products and services in a rush to beat the competition. Many times customers are the ones that are used to test the products and services. Later, when it becomes evident that certain changes are essential, companies will implement short-term solutions instead of looking for long-range solutions. This can result in a loss of confidence in not only the product, but in the company itself. Quality should be thoroughly tested by the company before introduction of a product to the market. Otherwise, any advantages obtained by bringing a product onto the market early can be easily outweighed by the high costs and embarrassment resulting when a company must recall that product. Intel Corporation faced these problems when a flaw was discovered in its highly touted Pentium chip. Having kept the defect secret for months, Intel tried to lessen the consumers' concerns by claiming that imperfections in the Pentium would affect only highly complex calculations. Most users, Intel maintained, would encounter an inaccurate answer just once in 27,000 years. Intel was unwilling to replace the chip even after tens of thousands of customers expressed outrage at the company's poor handling of the situation. Intel finally agreed to replace the chip only after IBM announced that it would stop shipments of all its products containing the Pentium chip. With 80 percent of the world's personal computers (PCs) having "Intel Inside," Intel should have taken

more care to ensure the flaw was corrected before 4 million Pentium-based computers were sold.¹

1.2.2 Basic Research

There are two opposing views in the debate over basic university research.² The President of Exxon Research and Engineering Company, remarked, "There is a fine science and technique created in academia which is not effectively coupled with the nation's commercial innovated system, and research as an autonomous function will tend to fade."

Equally outspoken on the same subject is the California Institute and Technology Provost and President. He advocates, "State universities are regarded as tools of people, and they have to respond where people want something. But there is a need to have scientists. We have to have scientists who are free to look at the future without being battered by the hurly-burly of current events."

In general, many believe that basic research is not useful for industries. Funds allotted to basic research are utilized to maintain the research and development lab. However, it is now well established that basic research actually pays a large dividend in the long run. Basic research directly supports new

¹ Castro, Janice, "When the Chips are Down," p.26.

² Ingle, Sud, In Search of Perfection, How to Create/Maintain/Improve Quality, p. 5.

technology development and technology utilization, which are essential for industry to improve the quality of a product.

1.2.3 National Emphasis on Quality Improvement

Any nation interested in improving its quality and productivity needs to understand that there must be nationwide commitment working towards that common goal. It is of very little use for a few to try organizing to improve quality when major industries are working in the old-fashioned way. The US has recognized this and in response to the need, established the Malcolm Baldrige National Quality Award to recognize US companies for business excellence and quality achievements. Recipients of the award are required to share information about their successful performance strategies with other US organizations. To ensure the repositioning of American goods and services in the international marketplace, emphasis must continue to be given on the national level, with a specific commitment from the government to nationwide quality improvement. Building active partnerships in the private sector, and between the private sector and government is fundamental to the success of any program to improve quality.

1.2.4 Management Styles - Participative Versus Top Down

With top-down management, decisions are only made by a few people while the majority of people are excluded. Decisions are generally made in a short

time, but their implementation takes a long time. Another type of management style is participative management. In this type of management, various committees are formed to get more input from the employees on how to run the business more effectively. Such committees consist of members ranking from the executive to the ground-level worker, thereby representing a full cross section of the company. This gives every employee the feeling that he or she is responsible for the ups and downs in the company.

1.2.5 Quality Training in Schools and Colleges

Compared to many countries in the world, American education standards are significantly more liberal. Math and science are often viewed by students to be too difficult and many shun away from these subjects in college. One can graduate from an educational institution without learning much more than basic math or science. In today's high-tech environment, personnel skilled in these areas are essential. Technology and quality improvements in the future rely on the schools and colleges in our country to provide early encouragement and training of students in math, science, and engineering. Emphasis should also be placed on teaching students statistical quality control or other quality aspects. In Japan, all these subjects are mandatory in schools and colleges.³

³ Ingle, Sud, In Search of Perfection, How to Create/Maintain/Improve Quality, p.10.

1.2.6 Ongoing Training Programs in Various Skills

As science progresses, new equipment, methods, and technologies are being introduced into various industries, rendering old technologies obsolete. Due to this rapid progress in the scientific field, workers face tremendous pressure and are often reluctant to work in technologies equipped with modern methods. Ongoing training programs in various skills is essential to give workers the confidence they need to handle new techniques.

1.3 Future Challenges

To regain our leadership in the quality arena, changes must be made with many of our current business practices. As competition in the world market increases, new challenges will also be generated. Today's worldwide economic competition requires all businesses to take immediate and effective action to meet these new and existing challenges. To compete in a global market, many companies have chosen to emphasize quality improvement as one of their main objectives.

1.4 Emergence of ISO 9000

The problems of competing in today's international business environment are not just unique to the US. Countries all over the world have needed to find ways of improving the quality of products while at the same time, lowering costs.

Working together to find solutions to these common problems, the International Organization for Standardization (ISO) developed a series of standards known as ISO 9000. Founded in 1947, the ISO is a nonprofit group comprised of industrial standard setting bodies from 100 countries. The group's mission is to develop industrial standards that facilitate international trade. The organization sets, but does not enforce, international standards for everything from paper sizes to screw threads to film speeds. The US is represented in ISO by the American National Standards Institute (ANSI).

The ISO 9000 quality system standards were written with the goals of facilitating international trade and increasing customer satisfaction through a process of continuous quality improvement. As the ISO 9000 *Guidelines for Selection and Use* states, ISO 9000 objectives affect competitiveness as well as quality:

"In both these situations, the supplier's organization wants to install and maintain a quality system that will strengthen its own competitiveness and achieve the needed product quality in a cost-effective way."⁴

1.5 What is ISO 9000?

ISO 9000 is not a product standard, but a quality system standard. It applies to the process that creates the products or services. Designed to apply generically to virtually any product or service manufactured by any process

⁴ Johnson, Perry, ISO 9000, Meeting The New International Standards, p. 22.

anywhere in the world, ISO 9000 tries to refrain from mandating specific methods, practices, and techniques.

Fifty-nine countries have now adopted ISO 9000 as their national standard. Today, more than 50,000 organizations worldwide, including about 3,600 in the US, have had their quality system evaluated and registered to the ISO 9000 requirements by an independent, accredited third-party registrar.⁵ Registration is awarded by the registrar after it verifies (by reviewing documentation and conducting on-site assessments) that the facility:

- Has a quality system that meets the ISO 9000 standard.
- Uses that system actively in its daily course of activities.

ISO 9000, which is extremely popular in Europe, is gaining popularity in the US as well. The trend for ISO 9000 certification in the US began with the requirement that any company exporting to the European Community (EC) would have to meet the same regulations and standards that the European industry itself met.

ISO 9000 emphasizes the principles, goals, and objectives of a business, with the main objective being: meeting customer expectations and requirements. To meet this objective, ISO 9000 requires that every business activity affecting

⁵ Rothmeier, Craig, "The Quest for ISO 9000 Certification Pays Off," p. 43-45.

quality be conducted in a three part, continual cycle of: planning, control, and documentation.

1.6 The Importance of Documentation in the ISO 9000 Registration Process

Documentation is central to the ISO 9000 registration process because it provides objective evidence of the status of a facility's quality system. However, documentation is usually the most common area of nonconformance among American facilities wishing to implement ISO 9000.⁶ In fact, according to one technical writing specialist, ISO 9000 auditors are keeping a "hawk's eye" on documentation, so much so that "when they see muddy documentation it turns them off." Poor documentation can derail the often grueling and expensive preparation for ISO 9000 accreditation, so companies must ensure that the documentation itself is of "high quality."

Three major problems associated with the development of ISO 9000-compliant documentation have been identified.⁷ Many companies were found to be guilty of:

- Improperly organizing procedures on paper.
- Making documentation unreadable.

⁶ Johnson, Perry, ISO 9000, Meeting The New International Standards, p. 124.

⁷ McKenna, Joseph F., "The 'Write Way' to ISO 9000," p. 36.

- Disregarding standard rules of grammar and spelling.

For many facilities, the documentation process can become nightmarish. As a representative of Strahman Valves observes: "One of hardest things to do is to get shop people to become what they think of as bookkeepers. They don't like paperwork. To many of them it's a dirty word."

But the process of creating and using documentation is central to the effectiveness of quality system implementation. Quality system documentation does not need to be exhaustive or redundant, but the process of creating the needed documentation is still usually arduous because the documentation that already exists is usually inadequate. According to consultants at SGS Yardely and AT&T Quality Registrars, there are several reasons for this.⁸ They include:

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

⁸ Hutchins, Gregory, ISO 9000: A Comprehensive Guide to Registration.

In the ISO 9000 documentation hierarchy, the "top tier" of documentation is usually a **quality manual**. Of all the elements that make up the ISO 9000 quality system, none is as central and important as the quality manual.⁹ The quality manual is a collection of documented procedures that provides a one-to-one reflection of a facility's quality system as it is operated every day. The structure, content, and completeness of the quality manual is critical to the ISO 9000 registration process because facilities are expected to demonstrate that the documented procedures are, in fact, utilized in practice.

The problems identified with the development of ISO 9000-compliant documentation, and the importance of the quality manual in particular, have pointed to the need for a simpler, more effective way of organizing, creating, and maintaining quality system documentation. Another major factor to consider is cost. The cost of pursuing registration to ISO 9000 can get as high as \$200,000 per site.¹⁰ With ISO 9000 essentially being a set of generally accepted principles for documenting quality procedures, a system that saves time and increases efficiency will translate into significant cost savings. This thesis addresses these needs by using system engineering methods to develop a software package that:

- a) Provides a tutorial on the structure and requirements of ISO 9000;

⁹ Johnson, Perry, ISO 9000, Meeting The New International Standards, p. 61.

¹⁰ Henkoff, Ronald, "The Hot New Seal of Quality," p. 116-120.

- b) Walks the user through the elements and procedures necessary in development of an ISO 9000-compliant quality manual; and
- c) Incorporates graphical user interface (GUI) design principles to allow the user to perform tasks efficiently, without spending too much time thinking about the application itself.

1.7 Thesis Organization

The following chapters will address the development of a software program created to assist users in developing an effective ISO 9000 quality manual. The components of the software are designed through the use of systems engineering and GUI principles. In addition, a study of the role and requirements of ISO 9000 is performed to determine the specific structure and necessary elements of the software. Specifically, Chapter 2 examines the need for ISO 9000 and the benefits associated with registration to ISO 9000. Chapter 3 discusses the structure of the ISO 9000 Quality System Standards and the steps required for registration. Chapter 4 defines the system engineering methodology followed in the development of the quality manual software. Chapter 5 discusses the importance of emphasizing GUIs in the development of user software. Finally, Chapter 6 summarizes and highlights the unique contribution of this thesis work. Recommendations based on the results of this work are presented as well.

2.0 ISO 9000: Origin, Need, and Benefits

2.1 Origination of Quality Standards

Throughout history, technological advancements and the development of standards seem to have gone hand in hand. Standardization itself originated with the birth of the Industrial Age. Eli Whitney's use of standard, interchangeable parts in the making of rifles was in itself a major achievement.

By the start of this century, quality standards were being institutionalized and documented. As far back as 1912, the British government created an office to ensure the quality of British military aircraft.

Quality standards have existed in the US since WW II, when the DoD established its MIL STD series of standards. These standards were significant to the development of today's international quality standards. MIL-Q-9858, a quality management program adopted in 1959 by the DoD, is the most significant documented military standard.¹¹ A parallel development was the creation of supplier quality standards imposed by major manufacturers such as the Big 3 automakers and first-tier suppliers to the DoD. These organizations, which relied heavily on subsidiary suppliers for subassemblies and components, realized that meeting imposed quality standards required them to impose quality standards upon their own suppliers.

¹¹ Johnson, Perry, ISO 9000. Meeting The New International Standards, p. 14.

This resulted in proprietary quality standards, such as Ford Motor company's Q1 and General Motors' Targets for Excellence (TFE). Over the past decade, the requirements of such standards have tightened. They have become more demanding and more specific as to the types of quality tools, techniques, and reporting systems that suppliers are expected to use. However, suppliers to these firms are often subjected to as many as a dozen competing or contradictory quality standards. These suppliers are often virtually under constant audit by one customer or another.

Recently, the Big 3 automakers began work to bring consistency to their various standards. This would allow their suppliers to adhere to one automotive quality standard instead of three.

In 1968, NATO adopted MIL-Q-9858A as its own quality system standard, calling it AQAP-1. The British Department of Defence incorporated most of AQAP's provision two years later in its own quality system standard called DEF/STAN 05-8. The British, however, were the first to go beyond implementing official quality standards for defense alone. In 1979, Britain officially adopted a quality system standard for its commercial establishment. The British Standards Institute developed BS 5750, a quality system standard evolved from DEF/STAN, AQAP, and MIL-Q. The British government vigorously promoted BS 5750 throughout the private sector. It actively encouraged firms to register and

publicized BS 5750 to increase consumer awareness and acceptance of the standard.

In 1987, ISO created the ISO 9000 quality system standard, drawing upon the British standard 5750. The British modified BS 5750 and DEF/STAN 05-8 to harmonize it with ISO 9000. The European Community (EC) adopted a quality standard virtually identical to ISO 9000 called EN 29000.

2.2 Quality Programs in the United States

Several organizations within the US are dedicated to the cause of bringing about quality improvement. The American Society for Quality Control (ASQC), a private industry trade group, publishes a harmonized version of the ISO 9000 standard under the name Q9000. The US government promotes the concept of total quality management (TQM) through the Federal Quality Institute. The government, in partnership with the private sector, also sponsors the Malcolm Baldrige National Quality Award. The Baldrige Award, which has set standards for world-class quality, rewards business excellence and the quality achievements of American companies. The Baldrige Award criteria, which demand quality products, satisfied customers, and continuous improvement, could have become the international quality standard. However, the extremely competitive nature of the award seems to be discouraging companies from even applying for the award. Only 76 companies applied for the 1993 award, down from a peak of 106 in

1991.¹² As a result, ISO 9000 has gained more popularity because the number of companies that can achieve ISO 9000 registration is not limited to a few slots per year.

Although efforts are being made to promote improved quality, US quality programs and standards are almost unknown to the general public. The US government does not mandate quality systems, sponsor training and accreditation organizations, or promote quality awareness to the public.¹³

In addition, according to a poll taken by management consultants, nearly two-thirds of executives at midsize manufacturing firms have either never heard of ISO 9000 or think it will have no impact on their companies.¹⁴

In Europe, however, ISO 9000 enjoys high public awareness and acceptance. ISO 9000 is the recognized and, for certain products, mandated quality system standard in Europe.

Major corporations companies such as DuPont, General Electric, Eastman Kodak, and Philips Electronics are among the US businesses that are beginning to recognize that ISO 9000 provides a very practical opportunity to obtain significant and far-reaching benefits. ISO 9000 will most likely be the rule by which the quality game is played in the global marketplace.

¹² Henkoff, Ronald, "The Hot New Seal of Quality", p. 116-120.

¹³ Johnson, Perry, ISO 9000, Meeting The New International Standards, p. 18.

¹⁴ Henkoff, Ronald, "The Hot New Seal of Quality", p. 116-120.

2.3 Current Need for ISO Registration

A facility may decide to implement ISO 9000 for quality management purposes, however, most companies that get involved with ISO 9000 aim for registration to the standard. A facility may seek registration to ISO 9000 for one or more of the following reasons:

- One or more customers require it by contract.
- The facility expects such contractual requirements to be imposed at some point.
- The facility views the registration approach as the most logical and effective way to implement and manage the quality system.

Some firms seek registration for competitive reasons or because they hope ISO registration will reduce the number of supplier quality assurance (SQA) audits they must undergo. Others register because theirs is a "regulated product" as defined by the product directive of the EC. But according to a study by Britain's authoritative Institute for Quality Assurance, most firms seek ISO 9000 registration because of pressure from customers.¹⁵

A well designed, well implemented, and carefully managed ISO 9000 quality system provides confidence that the output of the process will meet

¹⁵ Johnson, Perry, ISO 9000, Meeting The New International Standards, p. 7.

customer expectations and requirements. It is aimed at providing that confidence to three audiences:

- The customers directly.
- The customers indirectly (via third party assessments and quality system registration).
- Company management and staff.

2.4 Registration Process

Registration is awarded by an accredited third-party registration body after it verifies (by reviewing documentation and conducting on-site assessments) that the facility:

- Has a quality system that meets the ISO 9000 standard
- Uses that system actively in its daily course of activities

The facility becomes certified to one of three "parts" of the ISO 9000 standard. These parts, called ISO 9001, 9002, and 9003, are actually quality system models. The facility becomes certified to the model that most closely fits the scope of its operations, as described in detail in the next chapter.

Certification, once awarded, is reinforced through semiannual on-site audits. These "surveillance visits" review any changes to the quality system and

ensure that corrective actions called for under previous assessments have been carried out.

2.5 Benefits of ISO 9000 Registration

The benefits of registration can be substantial. One benefit of registration is that the facility regularly undergoes objective assessment by outside quality professionals. This alone is a powerful argument for registration. There are many other compelling reasons as well, including: access to markets, competitive issues, process and product improvements and potential net reduction in audits.

2.5.1 Access to Markets

Access to markets is the most critical benefit of ISO 9000 certification. It enables facilities to maintain or create new business in situations in which ISO 9000 certification is required.

As noted earlier, the EC Council of Ministers now mandates ISO 9000 certification for makers of certain types of products. These include commercial scales, construction products, gas appliances, industrial safety equipment, medical devices, and telecommunications terminal equipment. More products may be added to this list via additional product directives. This is especially likely for products and services that are potentially hazardous, that involve personal safety, or that are otherwise affected by product liability or similar regulations.

But at this time such "mandated" ISO 9000 registrations are rare. Today, the pressure for ISO registration is almost purely driven by nongovernment forces. Some major firms in Europe and elsewhere are moving toward mandating ISO 9000 registration by their suppliers. For example, companies such as Adhesives Research, which has a major commercial presence in the EC, felt the pressure for ISO 9000 registration several years: "Our customers started asking for it as far back as late 1990, early 1991." Adhesives Research has since been registered to ISO 9001. For firms like Adhesives Research, the "benefit" of certification is that it enables them to retain their existing markets.

2.5.2 Competitive Issues

Other firms are moving toward ISO 9000 registration because of competitive threats. For example, Menasha Corporation, which was in the process of implementing an ISO 9001 quality system, felt pressured into speeding up the implementation process when one of their competitors revealed that they were going to be registered within the year. Menasha Corporation feared losing their customer who was asking very specific questions about whether they would get ISO 9000 registration.

2.5.3 Standardized Processes and Process Improvements

In the quest to conform to ISO standards, many practices are streamlined or eliminated. ISO documentation of operating practices, work procedures and functional processes increases customer confidence in the systems.

While other systems may exist to monitor quality performance, ISO provides for an effective quality system and opportunities for quality process improvement.

2.5.4 Streamlined Training

For many companies, ISO 9000 ensures easier, faster and more comprehensive training. A well-established ISO 9000 quality system provides clear guidelines for all employees. In the past, an employee may have calibrated a system to X while another did it to Y. ISO standards leave no doubt about which process is correct. The customer is thereby assured of uniformity and consistency in the delivery of products and services.

2.5.5 Increased Productivity and Improved Product

As awareness of the company's quality objectives becomes instilled within the entire organization, the productivity of the employees increases while they embrace the new standards and procedures. This increased employee commitment translates into improved products and services, which naturally enhances customer satisfaction.

2.5.6 Potential Audit Reduction

The final benefit of ISO 9000 registration is the potential for fewer audits. Many facilities in certain industry segments undergo dozens of customer quality audits each year - as many as 30 per month! As ISO 9000 registration becomes understood and accepted in the US, it is possible that many customers will accept current ISO 9000 registration instead of site audits, mail-in audits, or other redundant "supplier quality assurance" programs.¹⁶

2.6 Distinction of ISO 9000 Registration

At this time, most of the pressure for ISO 9000 registration is from commercial pressure arising simply from stiffening international competition and the needs of firms everywhere to differentiate among their suppliers.

Certified facilities are authorized to display a special mark, or logo. EC firms understand and value the significance of that mark. As quality becomes an increasingly vital differentiator in the marketplace, ISO-certified facilities will enjoy a clear competitive advantage.

The benefits of registration are real and have translated into success for many businesses. It has also been shown to enhance business health. The Institute

¹⁶ Johnson, Perry, ISO 9000. Meeting The New International Standards, p. 28.

for Quality Assurance has found that the annual bankruptcy rate for nonregistered British firms is 7.1 percent, while the rate for registered firms is a mere 0.2 percent.¹⁷

2.7 ISO 9000 Compared With Other Quality Schemes

ISO 9000 has strong commonalities with other quality schemes, such as MIL-Q, Deming's 14 Points, TQM, and the Malcolm Baldrige National Quality Award criteria. All these quality schemes promote the awareness of quality as an increasingly important element in competitiveness. The primary difference is that a firm can register to ISO 9000. There are other differences as well. ISO focuses very closely on a company's internal processes, especially manufacturing, sales, administration, and technical support and services. Deming's 14 points are heavily oriented toward the use of statistical thinking and methods to identify opportunities for quality and productivity improvement. Deming's 14 points are a plan for management to follow to enhance its company's competitive edge over the long run. The Baldrige criteria places more emphasis on customer satisfaction and business results. ISO 9000 is an elemental tool while the Baldrige Award criteria evaluates how many tools are integrated into a cohesive program that results in customer satisfaction and business results.

¹⁷ Johnson, Perry, ISO 9000. Meeting The New International Standards, p. 8.

President Bill Clinton, who strongly supports the Baldrige Award, stated: "Through the Baldrige Award and the principles of quality management it embraces, countless businesses have found new and stronger life."

The rewards of winning the Malcolm Baldrige National Quality Award can be quite substantial. Examples of this "new and stronger life" can be observed on the stock market. Stock of Baldrige winners that are traded on the New York Stock Exchange have been especially good investments. According to *Business Week* magazine, \$1,000 invested in the stock of award winners on the days their awards were announced would have shown a gain of 89.2 percent, excluding dividends, by the fall of 1993. The same theoretical investment in shares in an accepted stock index would have grown only 33.1 percent. for both the company and its stockholders.¹⁸

ISO 9000 is the tool that ensures a structured working environment that captures improvements and integrates them into a stable and structured operation. Achieving ISO 9000 certification will help a company prepare for the Baldrige Award by providing a framework for reviewing and complying with customer expectations, training employees, and keeping records. ISO 9000 also fits in well with a company's TQM program that incorporates management structure derived from Deming's 14 points and other established management principles.

¹⁸ Hutchins, Gregory, ISO 9000: A Comprehensive Guide to Registration.

3.0 Implementing a Quality System

3.1 Structure of the ISO 9000 Standard

The ISO 9000 standard is not a single standard; it is actually a series of standards. The basic ISO 9000 series is comprised of five standards: ISO 9000, ISO 9001, ISO 9002, ISO 9003, and ISO 9004. The standards are subdivided into two types: guidance standards and conformance standards. Refer to Figure 3.1.

ISO 9000 and ISO 9004 are guidance standards. Companies do not register to either of these guidance standards. Instead, they register to one of the conformance standards, ISO 9001, ISO 9002, or ISO 9003. These conformance standards are called **models for quality systems**. Facilities seek registration to the model that most closely fits the scope of its operations.

3.2 What is a Quality System?

A quality system consists of the organizational structure, responsibilities, procedures, processes, and resources used for managing and implementing a company's quality policy. The aim of a quality system is to ensure that the facility's product or service (generically referred to as output) meets the customer's quality requirements. The quality system incorporates both quality assurance and quality control.

Quality, as ISO 9000 interprets it, is an integration of the features and characteristics that determine the extent to which output satisfies the customer's

needs. The definition of "quality" is judged by the customer. Customers determine what features and characteristics are important. Customers judge the extent to which the features and characteristics of the output satisfy their needs.

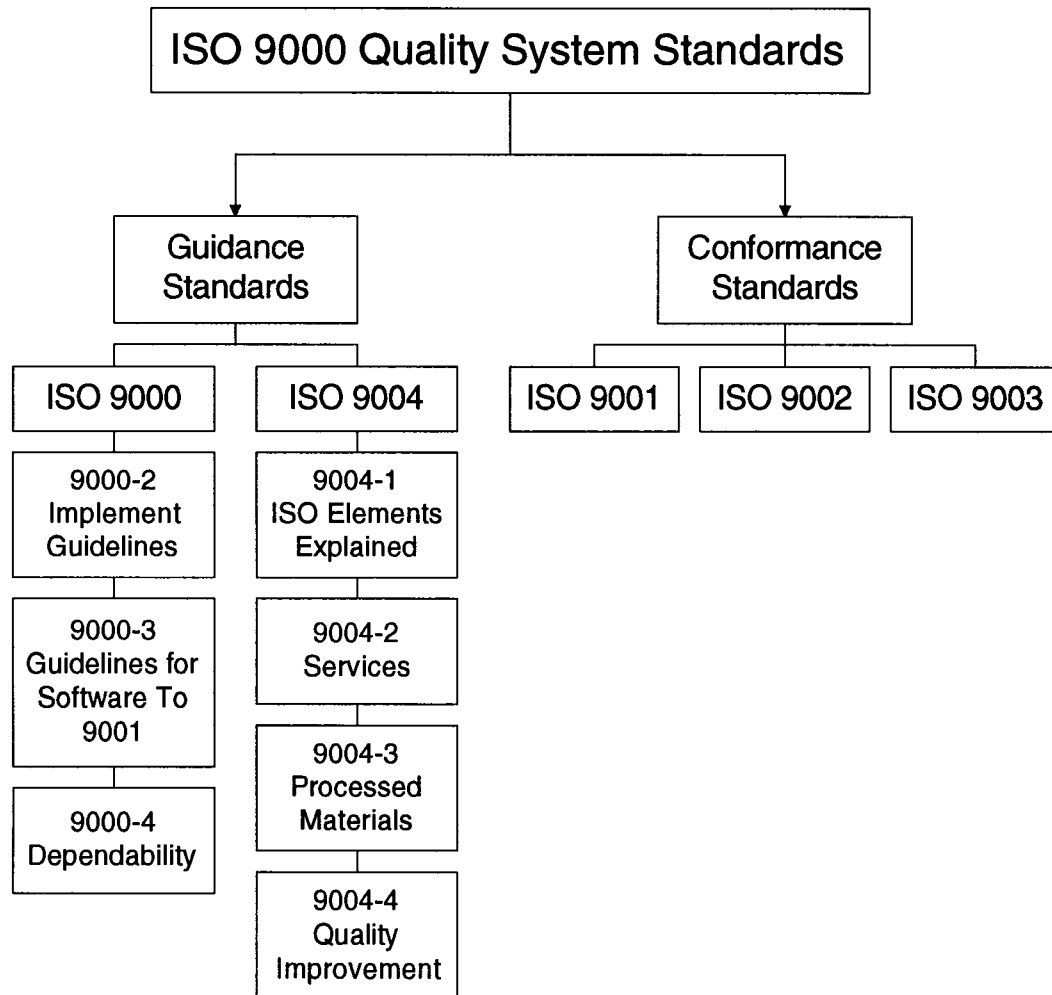


Figure 3.1 - The ISO 9000 Quality System Standards

Quality assurance is the collective term for planned, formalized activities intended to provide confidence that the output will meet required quality levels. In addition to in-process activities, quality assurance includes an array of activities external to the process, including activities undertaken to determine customer needs.

Quality control is the collective term for in-process activities and techniques intended to create specific quality characteristics. These activities include monitoring, reduction of variation, elimination of known causes, and efforts to increase economic effectiveness.

3.3 Quality Pyramid

A quality pyramid is the suggested method to use in organizing a quality system, although there are other ways of achieving the same result.¹⁹

A quality pyramid has four tiers (or layers) of documents. Each layer develops a steadily increasing level of detail about the company's operations and methods. Refer to Figure 3.2.

¹⁹ Lamprecht, James L., ISO 9000, Preparing for Registration, p. 62.

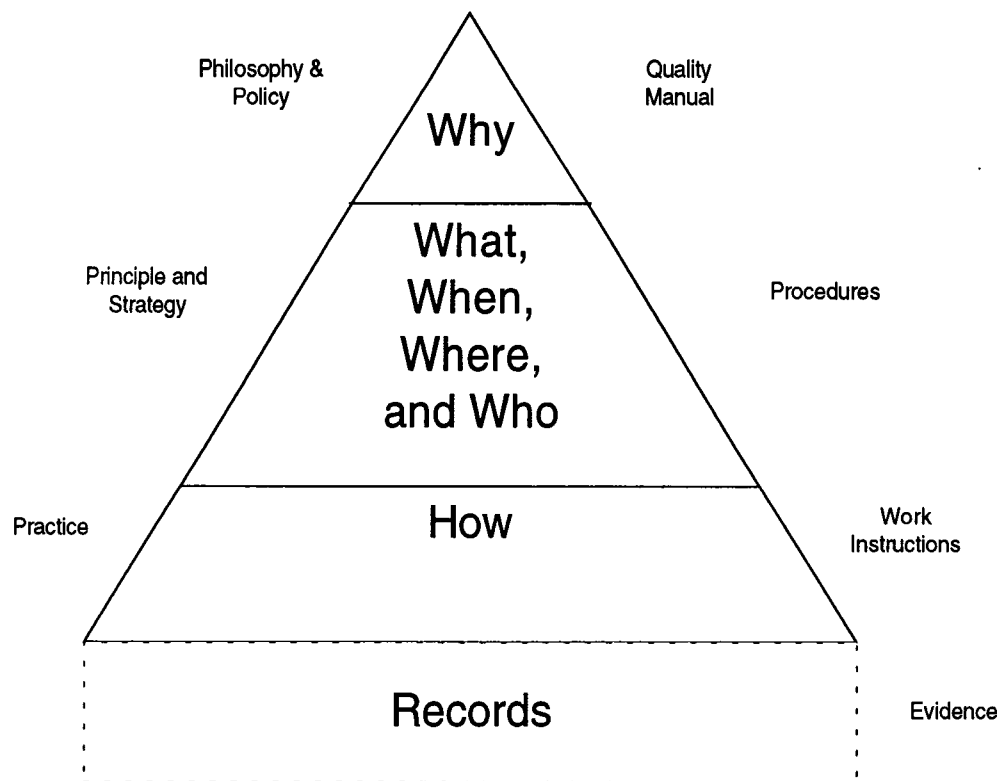


Figure 3.2 - The Quality Pyramid

The quality manual, the top tier of the quality pyramid, represents the core of a quality system. The quality manual must address each section of either ISO 9001, 9002 or 9003. Its purpose is to assure the reader/assessor that the company in question has addressed all of the relevant ISO paragraphs.

3.4 Quality System Elements

The ISO 9000 standard focuses on twenty aspects of a quality program that are subject to rigorous audit during the certification process. Each section relates to a specific aspect aimed at satisfying customers. The following 20 elements are contained in Section 4 of the ISO 9000 standard document:

1. Management Responsibility
2. Quality System
3. Contract Review
4. Design Control
5. Document Control
6. Purchasing
7. Purchaser Supplied Product
8. Product Identification and Traceability
9. Process Control
10. Inspection and Testing
11. Inspection, Measuring, and Test Equipment
12. Inspection and Test Status
13. Control of Non-Conforming Product
14. Corrective Action
15. Handling, Storage, Packaging, and Delivery
16. Quality Records

17. Internal Quality Audits
18. Training
19. Servicing
20. Statistical Techniques

3.5 Conformance Standards

ISO 9001: *Quality systems - Model for quality assurance in design/development, production, installation and servicing* is the most comprehensive of the conformance standards. It includes all the elements listed in ISO 9002 and ISO 9003. In addition, it addresses the design, development and servicing capabilities not addressed in the other models. Table 3.1 provides a cross reference of the quality elements found in each quality system model.

ISO 9001 is used when:

- The supplier must ensure product conformance to specified needs throughout the entire product life cycle.
- The contract specifically requires a design effort.
- Product requirements are stated principally in performance terms.

ISO 9000 Quality System Element	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
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 Inspection, Measuring, and Test Equipment	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

Table 3.1 - ISO 9001-9003 Cross Reference

ISO 9001 commonly applies to manufacturing or processing industries, but it can also be applied to services like construction, or to professional services, such as architecture and engineering.²⁰

²⁰ Gault, Roderick, The ISO 9000 Handbook.

ISO 9002: *Quality systems - Model for quality assurance in production and installation* addresses the prevention, detection, and correction of problems during production and installation. The main distinction between ISO 9001 and ISO 9002 is that ISO 9002 does not include the design function.

ISO 9002 applies to a wide range of industries whose work is based on technical designs and specifications provided by their customer. It is relevant for products that do not involve a design aspect and is used when the specified product requirements are stated in terms of an already-established design or specification.²¹

ISO 9003: *Quality systems - Model for quality assurance in final inspection and test* is the least comprehensive standard. It only addresses the requirements for detection and control of problems during final inspection and testing. ISO 9003 applies to organizations whose products or services can be adequately assessed by testing and inspection. Generally, this refers to less complex products or services.²² Refer to Figure 3.3 for the scope of the ISO 9000 conformance standards.

²¹ Goult, Roderick, The ISO 9000 Handbook.

²² Goult, Roderick, Ibid.

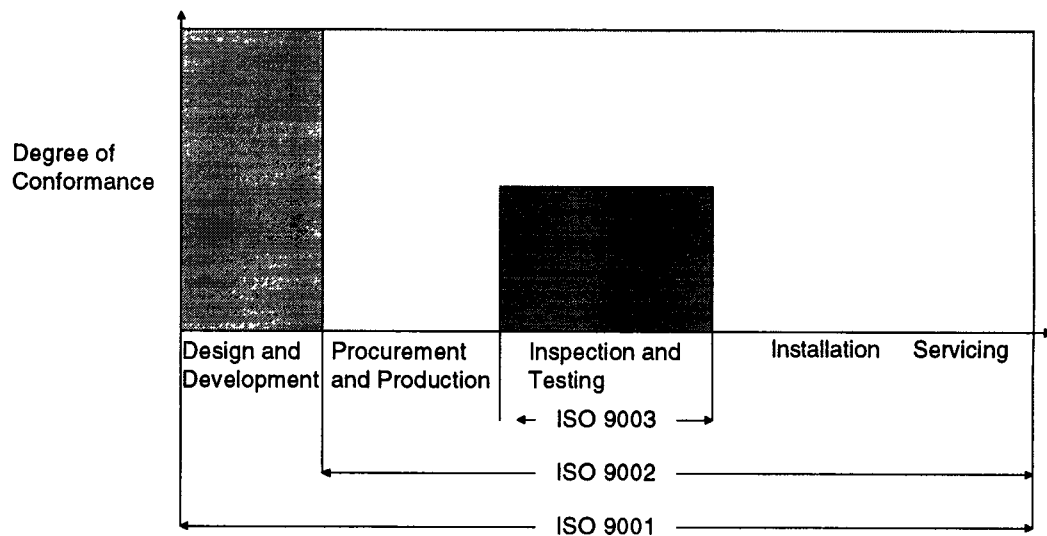


Figure 3.3 - Scope of ISO 9000 Conformance Standards

3.6 Guidance Standards

The choice of which model to select depends on the functional or organizational capability required of a supplier. ISO 9000, Section 8.0, offers guidance in selecting the appropriate model for quality assurance. ISO 9000 lists six factors to be considered when choosing to become registered to ISO 9001, ISO 9002, or ISO 9003. The six factors include:

- Complexity and difficulty of the design process.
- Design maturity.
- Production process complexity.

- Product or service characteristics (complexity, number, criticality).
- Product or service safety.
- Economic costs of the preceding factors versus the costs due to nonconformities.

After a company consults ISO 9000, it should consult 9004 "in order to develop and implement a quality system and to determine the extent to which each quality system element is applicable." ISO 9004 can help every company develop a thorough internal quality assurance system.

ISO 9004: *Quality management and quality system elements - Guidelines*, provides guidance to all organizations for internal quality management purposes, without regard to external contractual requirements of quality assurance. ISO 9004 examines most of the quality system elements contained in ISO 9001, ISO 9002, and ISO 9003 in greater detail. It can help organizations determine the extent to which each quality system is applicable to them.

Throughout ISO 9004, "emphasis is placed on the satisfaction of the customer's need, the establishment of functional responsibilities, and the importance of assessing, as far as possible, the potential risks and benefits."²³

²³ Gault, Roderick, The ISO 9000 Handbook

3.7 Implementing ISO 9000

3.7.1 Top Management Commitment

The absolute prerequisite before implementing ISO 9000 is top management commitment. Most quality consultants and company managers agree that without it no quality initiative can succeed; with it no quality initiative, including ISO 9000 implementation, can fail. That is how important top management commitment is.

The first phase of implementation calls for the commitment of top management - the CEO and perhaps a handful of other key people. The next step is to create a personnel structure to plan and oversee implementation. The first component of this personnel structure-and the most important one, after the CEO-is the management representative (MR).

In the context of the standard, the MR is the person within the facility who acts as the interface between facility management and the ISO 9000 registrar. In reality, the MR's role is much broader than that. The MR should also act as the facility's "quality system champion," the protector of the vision. The MR must be a person with:

- Access to and total backing of the CEO.
- Genuine and passionate commitment to quality in general and the ISO 9000 quality system in particular.

- The clout-resulting from rank, seniority, or both-to influence managers and others of all levels and functions.
- Detailed knowledge of quality methods in general and ISO 9000 in particular.

Next, a top-level implementation team is created. In some firms this is called the Quality Action Council. In others it is known as the Quality Steering Committee. The team is usually chaired by the MR and consists of:

- The CEO
- Top managers
- Key functional managers
- Top union representative (if applicable)

The Quality Action Council is mainly a policy group. It sets objectives for quality system implementation, approves plans, evaluates reports, and recommends changes as needed. The Council also makes critical decisions about the quality system documentation. Its members should decide early on who (1) is responsible for writing, editing, and approving the facility's quality manual and (2) who is responsible for second-tier and (if utilized) third-tier documentation.

Next comes a network of Quality Action Teams. In small to midsize facilities, these teams are organized by department or function. Each team is headed by the functional manager or department head, who in turn is a member of

the Quality Action Council. Larger facilities have more elaborate action networks, but the objective remains the same: to have a team of people representing each critical facility function and process element. Whatever organization is created, there must be a clear and visible reporting and communication network extending up to the MR and the Quality Action Council.

All members of the Quality Action Teams are knowledgeable about the process elements with which they work. That is the main criterion for membership. Advanced familiarity with ISO 9000 quality systems should be provided by an ensuing training cycle.

The Quality Action Teams comprise the hands-on element of the ISO 9000 implementation effort. They execute the policy developed by the Council. In short, the teams make the quality system happen.

3.7.2 Assessment of Current Quality System Status

There is actually very little that is new or novel about the ISO 9000 quality system. Most of its elements are a combination of good common sense as well as generally accepted quality methods, techniques, and philosophies that have been around for years.

Nothing in the ISO 9000 standard requires duplication of effort, redundant systems, or make-work. On the contrary: the goal of ISO 9000 is to create a quality system that conforms to the standard. This does not preclude

incorporating, adapting, and adding onto existing quality programs. In fact, the standard encourages facilities to do just that.

The next step in the implementation process is to compare the facility's existing quality program and quality system (if one exists) with the requirements of the standard. Program assessment can be done internally, if the knowledge level exists. Or a formal preassessment can be obtained from any one of a large number of ISO 9000 consulting, implementing, and registration firms.

Ideally, the assessment is conducted at several levels. The Quality Action Council focuses on the larger elements of the ISO 9000 standard, including: Management Responsibility, Quality System, Quality Costs, Quality Audits, and Personnel and Training. Quality Action Teams compare the standard's requirements with systems and procedures in their own functional areas.

The main purpose of these assessments is to get a clear picture of the state of the facility's quality program as it compares with the ISO 9000 standard. The teams should pinpoint systems that conform, systems that can be adapted, and, most critically, areas of non-conformance.

Facilities that are already subject to customer quality audits often find that their existing system meets a substantial number of the ISO requirements. This is especially true of facilities conforming to the various military standards. Some companies recognized that MIL STD 45208 and 45662 had many elements found in ISO. Phillips Circuit Assembly, which conforms to MIL-Q9858, finds that the

MIL standard is parallel to ISO in many ways. "The intent is the same except for two or three different areas. They share many of the section titles, groupings, and wording of the various subsections."²⁴

The same is true for other customer-mandated quality standards such as General Motors' Targets for Excellence (TFE). A representative of TRW states: "If you interpret it broadly, TFE has everything that ISO has. It's not as explicit in its documentation requirements and does not require the quality that ISO has. Also, TFE does not require quality manual approval."

Facilities that have subscribed to the Malcolm Baldrige National Quality Award criteria also find their ISO 9000 implementation path easier than others. "GE Automation," according to Managing Automation magazine, "had an easier time than many in winning ISO 9001 registration ... because the company had previously applied for the Malcolm Baldrige National Quality Award. It already had extensive outside comment on its quality procedures."

Unfortunately, there are many companies that do not have a quality system of any type in place. These companies face a much more difficult task of ISO 9000 implementation.

3.7.3 Creation of a Documented Implementation Plan

²⁴ Johnson, Perry, ISO 9000, Meeting The New International Standards, p. 120.

Once the facility has obtained a clear picture of how its quality system compares with the ISO 9000 standard, all nonconformances are addressed with a documented implementation plan. This plan is usually created by an ad hoc committee under the authority of the Quality Action Council. The purpose of the plan is to set up procedures to make the facility's quality system fully compliant with the standard.

The implementation plan should be detailed and thorough and should contain the following:

- Procedures to be developed.
- Objective of the system.
- Pertinent ISO 9000 section.
- Person or team responsible.
- Approval required.
- Training required.
- Resources required.
- Estimated completion date.

These elements should be organized into a detailed Gantt chart, to be reviewed and approved by the Quality Action Council. Once approved, the plan

and its Gantt chart should be controlled by the MR. The chart should be reviewed and updated at each council meeting as the implementation process proceeds.

Areas requiring implementation can vary significantly from facility to facility depending upon the existing type and level of quality system elements. Some facilities, with long-standing TQM or other quality systems, may only need rudimentary implementation measures to deal with nonconformances. Others may require the development of complete quality systems, a process that can take months, if not years.

3.7.4 Creation of Documentation

As noted earlier, documentation is the most common area of nonconformance among American facilities wishing to implement ISO 9000 quality systems. When beginning their implementation, many companies find that documentation is inadequate or even absent in some areas.²⁵

Documentation is a mandatory element for ISO 9000 compliance. It is essential to the registration process because it provides objective evidence of the status of the quality system. Furthermore, documentation demonstrates that companies have documented their operations and actually perform what they have documented. Written documentation is also:

- Evidence that thought has been given to the procedures.

²⁵ Rabbitt, John and Peter Bergh, The ISO 9000 Book.

- An irreplaceable reference resource for outside assessors.
- An invaluable training and improvement tool.

ISO 9000 Documentation Requirements

Under the ISO 9000 quality system, all work that affects quality must be planned, controlled, and documented. Every employee whose work affects quality should know how to work in a way that maximizes quality. Detailed written procedures and work instructions must be created where, as the standard states, "the absence of same would adversely affect quality."

To ensure success, these procedures and work instructions should be created by the people who actually do the work. They are the ones who understand the procedures to the lowest detail and also tend to benefit the most from actually writing down the procedures.

Many facilities that find the creation of work procedures and instructions to be a difficult process are facilities that have never properly documented their procedures before. It is not uncommon to find that important process work, even work with a serious impact on quality, is done in an unplanned, inconsistent manner.

Benefits of the Documentation Process

Quality system documentation forces the facility, at all levels, to think through exactly what is being done and how it is being done. Most firms find this task to be an arduous but positive learning experience. Documentation allows process knowledge and expertise to be collected and then disseminated. In addition, the entire process creates a positive, proactive environment that fosters teamwork and an understanding of quality. Specifically, employees learn how to work together better, understand the expected roles of other employees, and establish communication channels that result in positive improvement.

The Quality Manual

The final link in the documentation chain is the facility's quality manual. From an implementation standpoint, creation of the quality manual is driven by the top-level Quality Action Council, which draws upon the systems, procedures, and documentation created and implemented by the Quality Action Teams. The quality manual must address, on an individual point-by-point basis, the components of the ISO 9000 quality system being implemented. Ultimately, the quality manual will serve as the expression of the facility's quality commitment.

3.8 Summary

Facilities with a well-established quality system tend to exhibit the following attributes:

- A philosophy of prevention rather than detection.
- Continuous review of critical process points, corrective actions, and outcomes.
- Consistent communication within the process, and among facility, suppliers, and customers.
- Thorough recordkeeping and efficient control of critical documents.
- Total quality awareness by all employees.
- High level of management confidence.

Having quality documentation that is organized and properly maintained is essential to the success of ISO 9000 implementation. The benefits of high quality documentation are tangible and will lead to improvements in the control of quality costs, reduction of waste, increased productivity. Furthermore, quality documentation allows management to make more informed and competent decisions.

Overall, the facility with a well-designed and well-implemented quality system has a process which tends to be lean, sensitive to customer needs, highly reactive, efficient, and positioned at the leading edge of its marketplace. These are

goals that any company would strive to achieve. The creation of effective documentation is critical to achieving these goals.

4.0 Systems Engineering Approach to Software Design and Development

4.1 Introduction

While preparing for ISO 9000 registration, many companies find that although using a simple word processing software package is adequate to write their quality documentation, there is no easy way to develop, display, change and distribute the documentation.²⁶ "We suddenly realized we would have been creating a large, inflexible paper trail in attempting to get all the documentation out to people, " says a quality assurance manager at Air Products and Chemicals. "We discovered we needed some sort of system to manage all that."

4.2 Systems Engineering

Recognition of need is the first step in the orderly process of creating a new system. This orderly process is known as **systems engineering**. A systems engineering approach provides the methodology to effectively develop any simple or complex system.

The systems engineering process, which begins with the identification of a need, extends through planning, research, design, production or construction, evaluation, consumer use, maintenance and support, and ultimate retirement

²⁶

Moad, Jeff, "How ISO 9000 Quality Programs Affect IS," p. 65.

(phaseout) of a system. These activities may vary from one system to the next, and should be individually tailored to the type of system being developed.

Figure 4.1 shows a simplified system life cycle. Program activities have been classified in two basic phases, the system acquisition phase and the system utilization phase. Referring to the figure, systems progress from the identified need through conceptual and preliminary design, detail design and development, and so on.

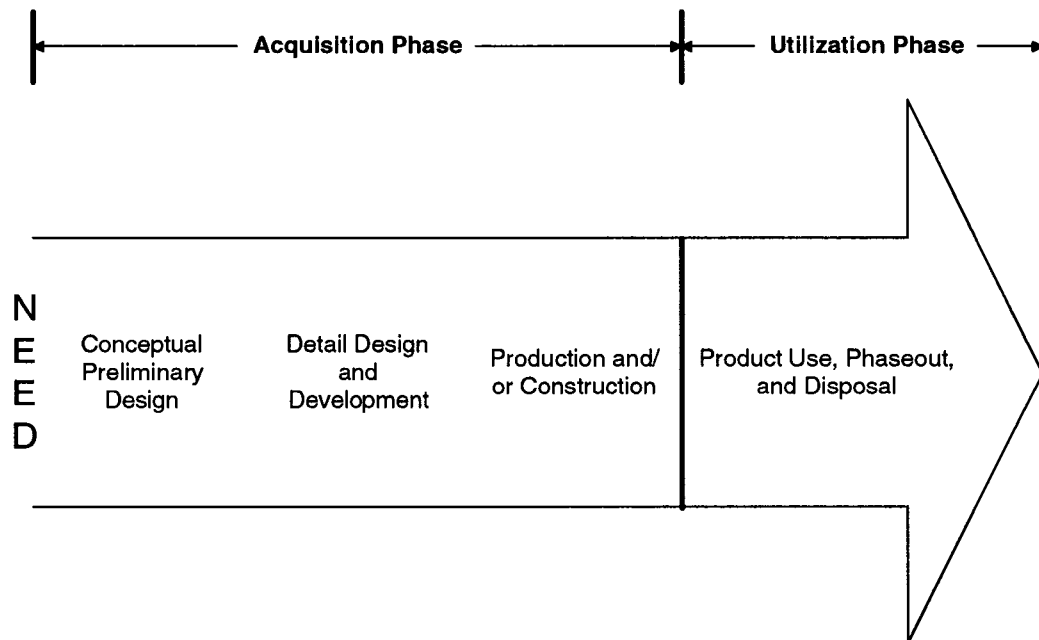


Figure 4.1 Systems Engineering Process in Simple Form

4.3 Why Systems Engineering?

Systems engineering is a process that has only recently been recognized as essential to the orderly evolution of man-made systems. Throughout history, the development of more sophisticated tools has resulted in a decrease in dependence on human physical energy. Often, the development of these automated tools involves the application of intellectual and cognitive effort. The Industrial Revolution represented a major thrust in this direction.

In most cases, a new tool or machine makes it possible to perform a familiar task in a somewhat new and different way. Enhanced efficiency and effectiveness is usually the goal. In a few cases, a new tool has made it possible to perform new tasks that could not be accomplished before. The process of designing tools to increase the efficiency and effectiveness of certain tasks has often been done on a "trial and error" basis. When tool designers were also users - the case for the simple tools and machines of the past - initial designs were often good or soon evolved into good designs.

The increasing complexity of physical tools, machines, and systems has led to the necessity for larger design teams. This, in turn, has created problems that continue to affect system development efforts. To cope with these problems, a number of methodologies associated with systems design engineering have evolved. Through these methodologies, it has been possible to decompose large design issues into smaller, subsystem-level design issues. These subsystem could

then be designed and built to form the complete system as a collection of these smaller systems.

However, simply connecting the individual subsystems together does not result in a system that performs acceptably, either from a technological efficiency perspective or from an effectiveness perspective. This has led to the realization that systems integration engineering and systems management throughout an entire system life cycle are necessary. Therefore, recent efforts in systems engineering have focused on tools and methods and on the system design methodology that promotes appropriate use of these tools. Also, emphasis is placed on systems management approaches that allow for the integration of various design approaches within a system or organizations. The use of appropriate tools, as well as systems engineering methodology and management, enables the design of systems that results in more efficient and effective human interaction.

4.4 Importance of Systems Engineering in Early Design Stage

The systems engineering approach emphasizes the significance of understanding the problem and planning before designing solutions. In the past, engineers focused mainly on the acquisition phase of the life cycle and were involved mainly in early design and analysis activities alone. Product performance was the main objective, rather than the development of an overall system with economic factors in mind. However, experience in recent decades indicates that a

properly functioning system that is competitive in the marketplace cannot be achieved through efforts applied largely after it comes into being.²⁷ It is essential that engineers be sensitive to operational outcomes during the early stages of system development, and that they assume responsibility for life-cycle engineering.

4.5 Design and Development of ISO 9000 Documentation Software

This thesis work involves the application of systems engineering principles to the development of a quality manual information system. The steps involved in the analysis, design, and development of this system are depicted in Figure 4.2.

4.6 Systems Analysis

The systems analysis phase includes: a determination of the need for a new system, an assessment of the users' characteristics, a trade-off analysis, a high-level breakdown of the required tasks, and a functional analysis. Several of these activities involve frequent iteration to achieve a satisfactory result.

Even after recognizing the importance of the analysis phase, most developers still want to get past this phase quickly to begin on the process they understand better, such as design or evaluation. However, early emphasis on the systems analysis activities can provide an enormous impact on the quality of the

²⁷ Sage, Andrew P., Systems Engineering.

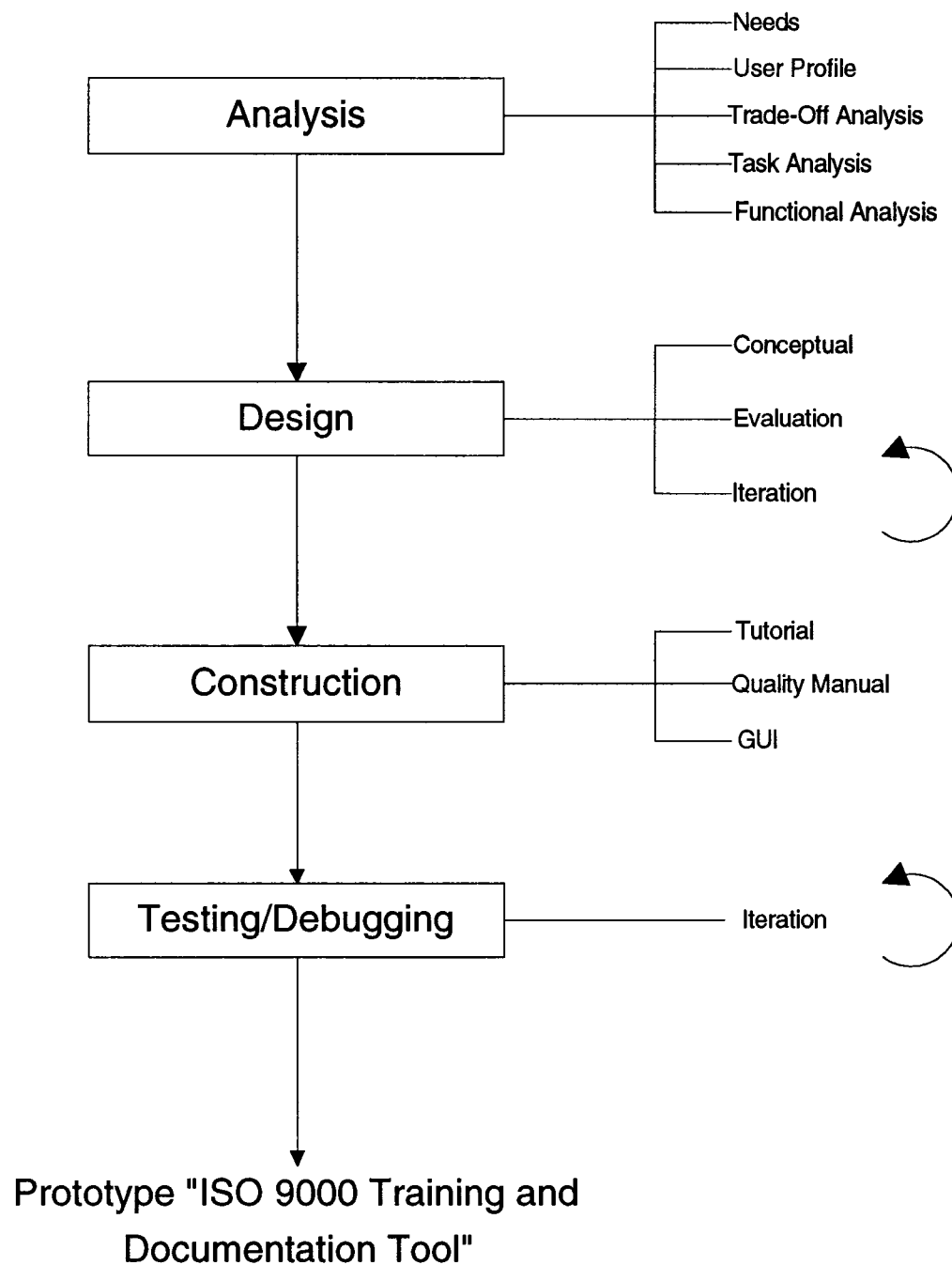


Figure 4.2 - Systems Engineering Methodology for Development of ISO 9000 Quality Manual

final product, including the ease and cost of producing it.²⁸ Much of the design rework that occurs during the iterative phases of development can be avoided if the goals of the design, the characteristics of the users, and the tasks to be performed are more thoroughly considered early in the design process.

4.6.1 Needs Analysis

This phase establishes the need for a new system, based on the overall objectives of the organization and demands of the marketplace. Also, the needs analysis determines the basic goals, purpose, and features desired for the application.

The need for an information system to assist in the development, display, modification, and distribution of documentation required for ISO 9000 compliance was summarized in Section 4.1. As explained in Chapter 1 and Chapter 3 of this thesis, documentation is central to ISO 9000. It is also the most unpopular aspect of the ISO 9000 requirements, with many firms viewing ISO 9000 as unnecessarily paper-heavy and bureaucratic.²⁹

This aversion to documentation, in fact, is the primary cause of ISO 9000 nonconformance. Nearly 20 percent of all noncompliance, according to registrars, is in the area of creating and using documentation.³⁰ See Figure 4.3

²⁸ Hix, Deborah and H. Rex Hartson, Developing User Interfaces.

²⁹ Johnson, Perry, ISO 9000, Meeting the New International Standards.

³⁰ Rabbitt, John T., Peter A. Bergh, The ISO 9000 Book.

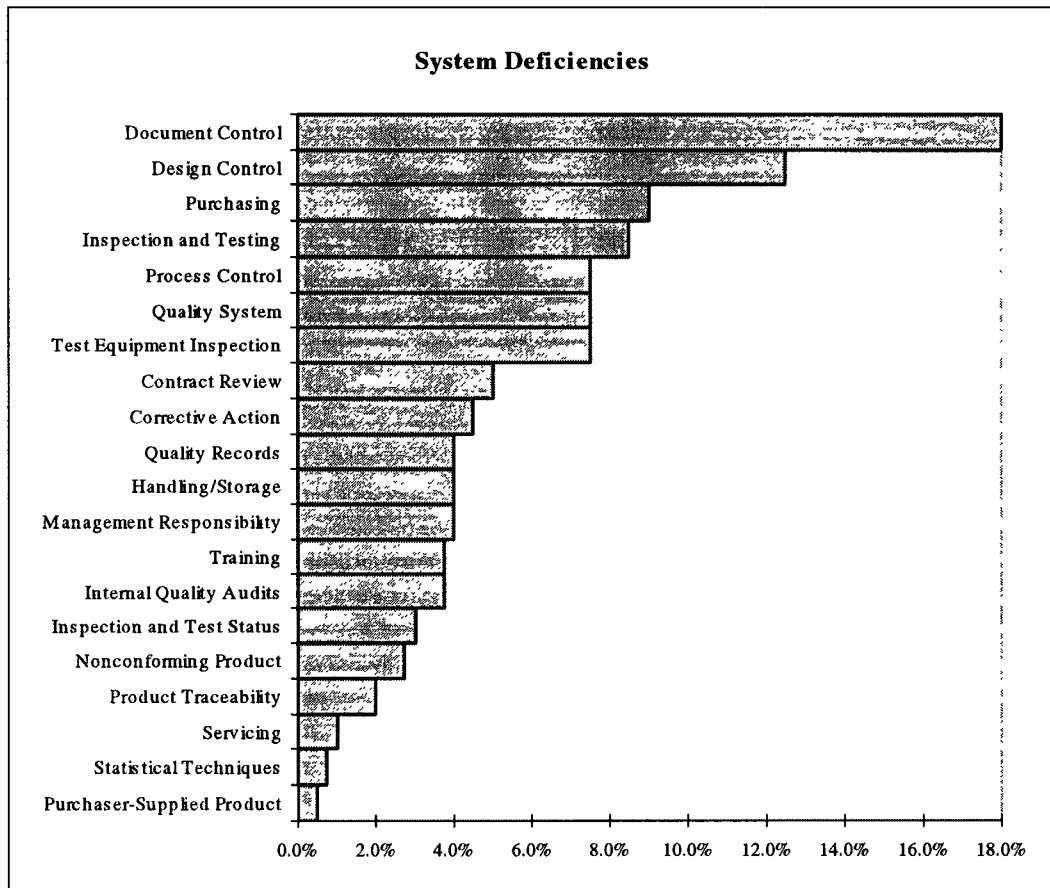


Figure 4.3 - Areas of ISO 9000 Noncompliance

Several registrars pointed out that having a greater understanding of the standards and directing more effort and resources into the preparation of the quality manual would assist users in the documentation process.³¹ Since lower

³¹ Rabbitt, John T., Peter A. Bergh, The ISO 9000 Book.

level documentation expands into greater detail from one layer to the next, having a well-organized, highly accessible quality manual would provide strong support for the development of these more detailed documents.

Having an effective quality manual is the first step to performing well during an audit, and more importantly, it demonstrates that a company thoroughly understands its business. The structure, content, and completeness of the quality manual is critical to the ISO 9000 registration process because facilities are expected to prove that their documented procedures are, in fact, utilized in practice. It is for these reasons that the quality manual was selected as the focus of this thesis work.

4.6.2 User Analysis

This phase combines cognitive theory of human users, specific information about job functions and tasks of potential users. The result of this analysis is a set of user class definitions, also called "user profiles," which consist of the user characteristics and skills.

User Characteristics:

Several issues should be addressed in defining user characteristics. First, all employees ranging from those in management positions to those in technical positions need to be considered. Second, all workers should be knowledgeable

about their work processes. Third, each user should have easy access to the quality manual. Finally, within a company, several users should have input to the quality manual. In general, users should have high skill levels. Specifically, the users should have general knowledge of computers and possess keyboard mouse skills.

Conclusions

Overall, the developed program must be simple, allowing users of varying skill levels to get accustomed to the program more quickly and easily. Usability of the software is as important as functionality. The functionality of the program must be greater than that of a quality manual developed manually, or by a word-processing software package.

4.6.3 Trade-Off Analysis

Before beginning the design phase of the systems engineering process, the Windows development tool that best meets the requirements of the needed system must be selected. The objective of this phase is to select the best tool possible through the iterative process of systems analysis using various analytical methods.

Figure 4.4 illustrates the steps involved in performing trade-offs and evaluating alternative approaches. These steps are an integral part of the systems engineering process shown in Figure 4.2. Alternatives are identified, evaluation

criteria are established, analytical methods are selected, input data is collected, and the various alternatives are evaluated relative to one another.

Identification of Alternatives

Three possible alternatives were identified as possible Windows development tools. These alternatives, as shown in Figure 4.4, are: Visual Basic, Visual C++, and the C programming language. Alternatives were chosen based upon the assumptions that: (a) the program must be executable on a PC; and (b) the tool must be capable of generating graphical elements, such as text boxes, command buttons, and the like.

Evaluation Criteria Establishment

When selecting evaluation criteria, the factors used may vary considerably, depending on the stated problem and the constraints (e.g., time) placed upon the system development. For the quality manual information system, criteria were developed by accounting for factors such as schedule, level of performance required, complexity of the programming language, and ability to maintain and upgrade.

A set of five high level criteria were established based upon these factors, including: lines of code/complexity, development environment, performance, learning curve, and maintenance.

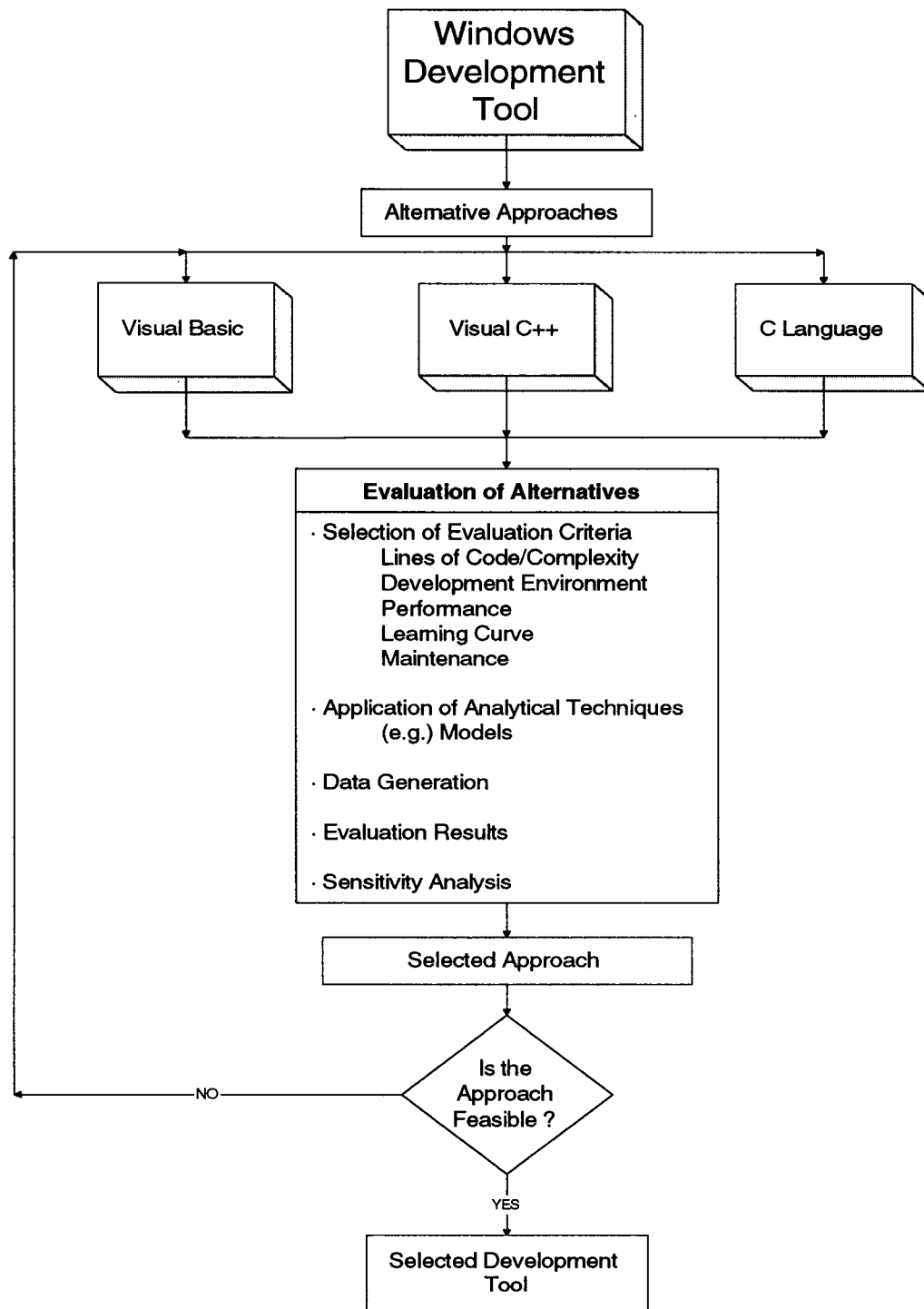


Figure 4.4 - Evaluation of Alternative Window Development Tools

Evaluation Using Expert Choice

The determination of the weighting factors and the evaluation of the alternative development tools was performed by using the Expert Choice software from Expert Choice, Incorporated. Expert Choice is based on the Analytic Hierarchy Process (AHP), a multi-objective decision making process developed by the mathematician T. L. Saaty of the Wharton School at the University of Pennsylvania. AHP, which is one method of dealing with both tangible and intangible factors, accommodates uncertainty and allows for revision enabling individuals and groups to grapple with various concerns. The results of AHP are easily tested for sensitivities to changes in data, assumptions, or judgments.

Determination of Criteria Weighting Factors

The criteria weighting factors are determined by comparing each possible combination of criteria based on its relative importance. For example, the importance of the complexity/lines of code required criterion is compared to the importance of the development environment criterion. This is termed "pairwise comparison." Each possible combination of pairwise comparisons are made within Expert Choice, which produces the final weighting factors based on the results of the comparison. A description of each criterion is provided below.

1. **Lines of Code/Complexity.** An important aspect in the evaluation of a Windows development tool is the number of software lines of code required to write an actual, useful application. The greater the number of lines, the more complex and time-consuming the programming becomes. The number lines of code in a program is also proportional to the difficulty in debugging. With schedule constraints as a major factor, a Windows development tool that provides the needed functionality with less complexity and lines of code is preferable.
2. **Development Environment.** The development environment refers to the programming tools provided to assist in the development of the application. This may refer to features, such as, graphical capabilities, the quality of the debugger, availability of useful help, and the ability to interface with other applications, such as spreadsheets, word-processors, or clip art galleries.
3. **Performance.** Performance primarily refers to the speed at which the program executes the developed code. Users want to see immediate feedback for their actions, therefore, there should be minimal delay between the initiation and performance of an action.

4. **Learning Curve.** The time required to learn the development tool is a significant factor, because of the overall time constraints placed on the development of the software. Assuming that the programmer has general familiarity with programming, the selection of the best Windows development tool depends on the length of the time spent learning about the tool. Obviously, tools with shorter learning times are more desirable than their counterparts.

5. **Maintenance.** Maintenance generally refers to the capability of adding new features, customizing existing features, or reusing code to develop similar applications. The ease of performing these tasks provides users with a greater return on the initial development effort, since they will be more apt to allow designers to modify or reuse the existing application instead of creating new ones.

Based upon a comparison of the relative importance of the given criteria, Expert Choice generated the weighting factors provided in Figure 4.5. As can be interpreted by the results, the lines of code/complexity criterion and the learning curve criterion were deemed most significant in determining the best Windows development tool.

Evaluation of the Alternatives

Evaluation was performed by comparing the preference of each alternative to the every other alternative, within the context of the criteria. In some cases judgments were based on intuition and experience. In others, the comparison was based on hard data and analysis.

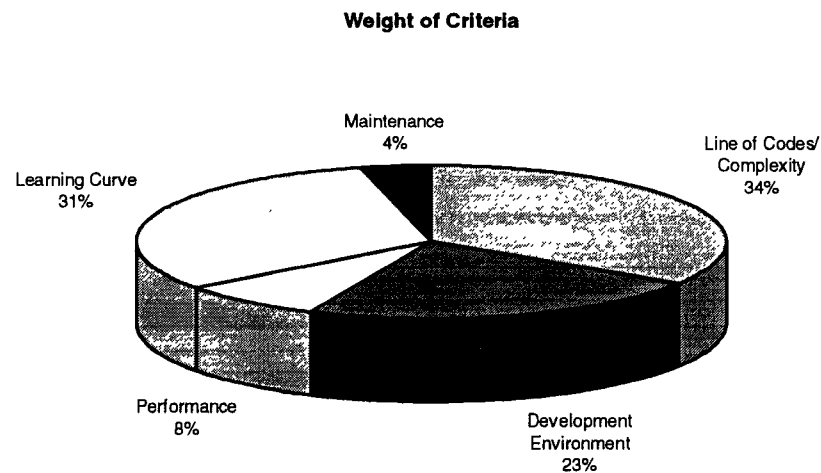


Figure 4.5 - Weighting Factors

A brief description of each programming tool is presented below:

1. **C** is a powerful and flexible programming language. **C** programs are commonly used for producing word processing programs, spreadsheets, compilers, and other products. For example, most of the UNIX operating system is written in **C**. **C** programs tend to run quickly, but are difficult and

time-consuming to develop, especially for inexperienced programmers. C is a compiled language, which means that a compiler checks the program for errors and provides warning to the programmer if any exist.

2. **Visual C++** is based on the C programming language, however, there are many significant differences. Visual C++ runs on Windows, which allows access to a full set of Windows-based tools to help create and manage applications in Windows. C++ is also an object-oriented programming (OOP) language, a new approach to programming. OOP provides explicit support for active, intelligent objects that are inherently built to operate on themselves. These objects provide easy reuse of code among various Visual C++ applications. Learning OOP is difficult because a programmer must adapt to the unique OOP environment.

3. **Visual Basic** is a development tool created specifically for Windows programming. Unlike C, which is difficult and time consuming to program in the Windows environment, Visual Basic is designed especially for the type of task with its straightforward graphical design capabilities. For example, a simple screen that pops up with a few line of text can require about five pages of C code and four separate files. On the other hand, to perform the same task using Visual Basic, the programmer only has to draw the window to the

desired size and draw the text box there. After the window screen is completed, a few lines of Basic code is usually all that required to activate the screen. Visual Basic automatically creates the working executable files for the programmer. However, a noticeable disadvantage of Visual Basic is its slow execution speed when compared to the C and Visual C++ programming languages.

Expert Choice provides a means of comparing these alternatives in verbal, graphical or numerical ways. In making verbal comparisons, the most common method for this task, the evaluator is asked questions such as: "With respect to the selected evaluation criteria, which architecture alternative is better, A or B, and how much better?" To quantify semantics, a verbal scale with which to rate the alternatives may be used. See Table 4.1.

Numerical Scale	Verbal Scale	Explanation
1.0	Equal importance of both elements.	Two elements contribute equally.
3.0	Moderate importance of one element over another.	Experience and judgment favor one element over another.
5.0	Strong importance of one element over another.	An element is strongly favored over another.
7.0	Very strong importance of one element over another.	An element is strongly dominant.
9.0	Extreme importance of one element over another.	An element is favored by at least one order of magnitude of difference.
2.0, 4.0, 6.0, 8.0	Intermediate values between two adjacent judgments.	Used for compromise between two judgments.

Numerical Scale	Verbal Scale	Explanation
Increments of 0.1	N/A	Intermediate values in increments of 0.1 (Example: 6.3 is a permissible entry in the Numerical Mode)

Table 4.1 - Verbal Comparison Scale

Once pairwise comparisons were completed for every combination of alternatives for a single evaluation criteria, a score was calculated for each alternative. The Expert Choice software uses the AHP method to generate a positive reciprocal matrix from the pairwise comparison rankings. The eigenvalues of this matrix are used to check for consistency in the rankings. If there is an appropriate level of consistency, the matrix is used to generate a score for each alternative relative to the criteria being evaluated.

When this evaluation is completed for every criteria, overall scores for each building block alternative are calculated. The score at each criteria level was multiplied by a weighting factor, and then summed together to obtain the overall score for each alternative. The overall scores for the criteria and alternatives are presented in Figure 4.6.

Once the evaluation process is complete, sensitivity analysis can be performed to determine the impact of the weighting values in selecting the preferred alternative.

Sensitivity Analysis

A sensitivity analysis may be performed to determine how the weighting of each criteria affects the score of each alternative. The initial weighting factors are used as a starting point for the sensitivity analysis.

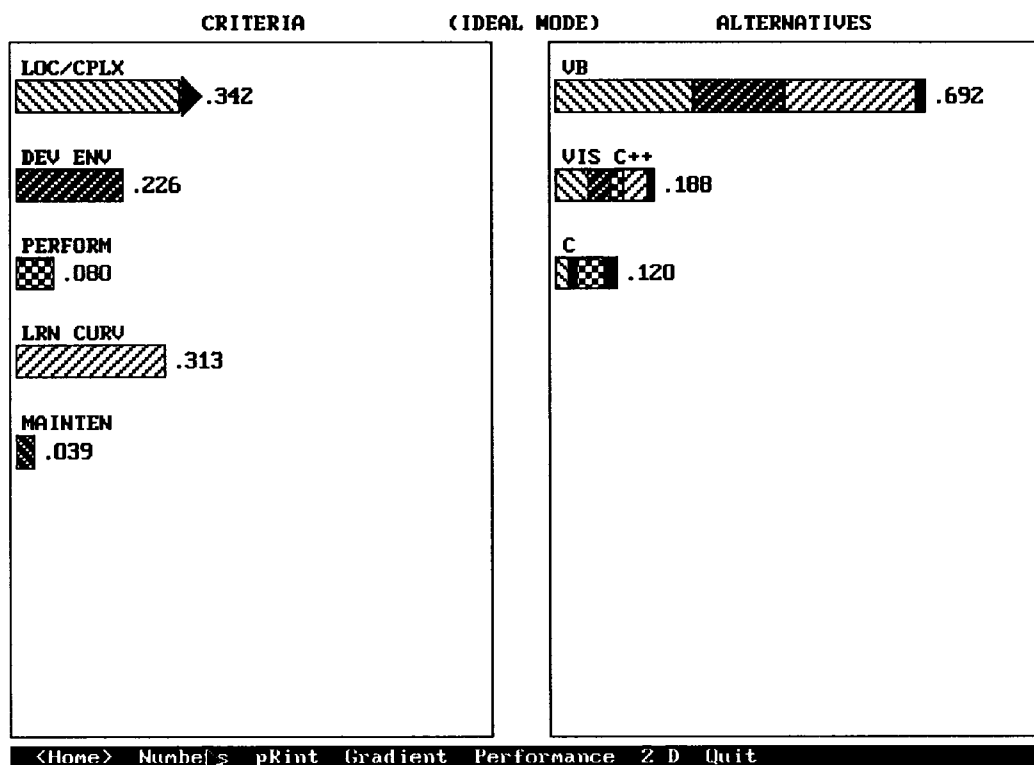


Figure 4.6 - Criteria and Alternative Scores

During the sensitivity analysis, weight values are shifted to observe any changes in the rankings of the alternatives. This type of analysis is useful in

identifying any dominating solutions, which are independent of the criteria weights, if present. This analysis is also useful in determining the degree to which a particular alternative is preferred overall.

Figure 4.6 provides a graphical presentation of the sensitivity analysis results of the programming tool evaluation. These analyses demonstrate that Visual Basic is a clear dominating or advantages solution. Varying the values of the weighting factors does little to counter the strong dominance of Visual Basic over C and Visual C++.

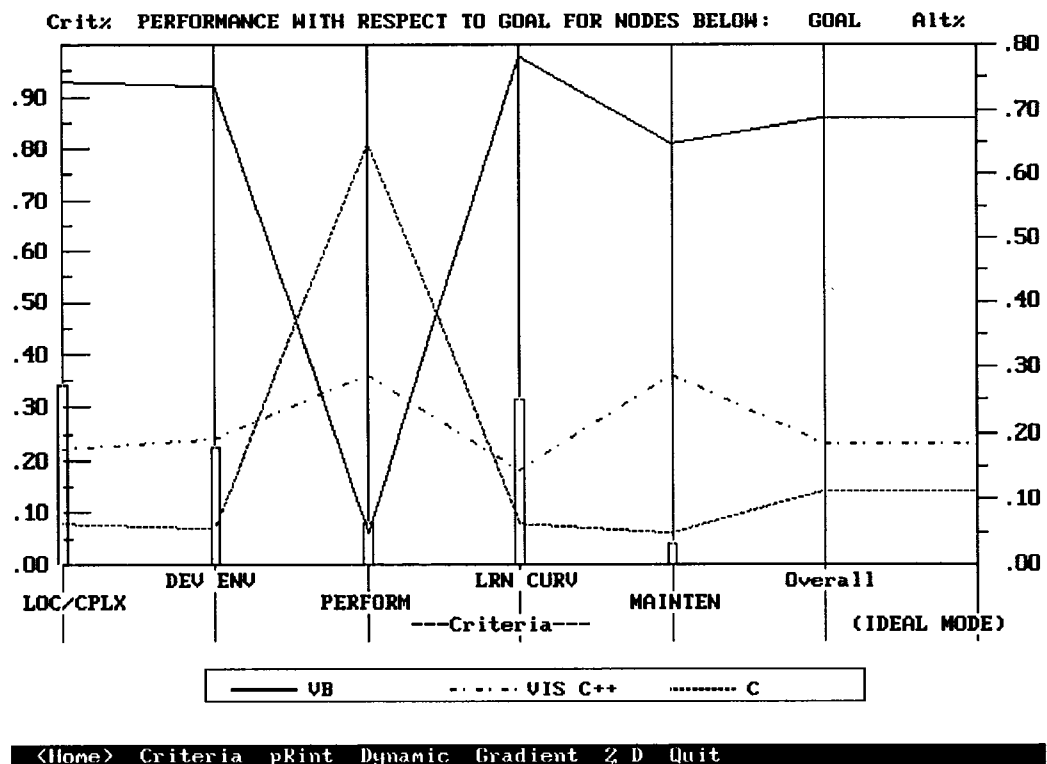


Figure 4.7 - Sensitivity Analysis

4.6.4 Task Analysis

This analysis provides a description of the tasks, subtasks, and methods involved in using the new system. This analysis uses information derived from the needs analysis to define how the user will use the system. One can produce a high-level task description of the quality manual information system directly from the goal statement provided by needs analysis. This is "assist users in the development, display, modification, and distribution of the quality manual." Major subtasks are also produced from the needs analysis. These include:

- Learning about the ISO 9000 requirements that drive the development of the quality manual.
- Understanding the need for a quality manual.
- Learning tasks that must be completed before creating the quality manual.
- Choosing the appropriate conformance standard.
- Adding (new) quality manual procedures for each section.
- Adding preparer name.
- Indicating the status of the quality manual before exiting section.
- Modifying (existing) status of the quality manual.
- Modifying (existing) quality manual sections.
- Obtaining access to Help.
- Obtaining access to conformance information.
- Saving quality manual.

Task analysis usually results in a top-down decomposition of detailed task descriptions. The ultimate goal is designing a better (more productive, more efficient, higher quality, more capable) procedure. Task analysis, although one of the more important up-front analysis activities, is most frequently overlooked. Many user interaction developers claim that insufficient or inaccurate task analysis is responsible for many poor designs.

4.6.5 Functional Analysis

The functional analysis phase requires description of the program code functions that must be written to implement the users tasks. These functions, when combined with the user interface, will provide the features promised in the needs analysis phase. At this point, a duality exists for each operation that will be performed together by the user and system.

For example, in the developed software a user task was identified for selecting a conformance standard (ISO 9001, ISO 9002, or ISO 9003). The program must provide the user with the correct set of elements to be adhered to for registration. For ISO 9001, all twenty quality system elements are used. For ISO 9002, eighteen of the twenty are used, and for ISO 9003, twelve are used. If the user fails to choose a standard, the user cannot begin to develop the quality manual. The program must notify the user of this. Some tasks may be manual

(and will be performed by the user), while others are automated (and will be performed by the system).

4.7 Design Phase

Having completed the task analysis and determined the various features of the quality manual information system, the next major phase in the development is the design phase. Design is a complex activity with infinite alternatives. It is the most creative and individualized activity in the life cycle.

The design phase can be broken down into two major types of activity: conceptual design and detailed design. Conceptual design is a higher level activity and involves synthesizing objects and operations. Detailed design pertains to activities such as determining the wording of messages, labels, and menu choices. It also includes determining the appearance of objects on the screen, navigation among screens, and much more.

4.7.1 Conceptual Design

The ISO 9000 standards do not specify exactly what the format or contents of the quality manual should be. However, since the purpose of the quality manual is to demonstrate adherence to the ISO 9000 quality system elements, it follows that the quality manual should address each section of the ISO 9000 model that the facility adopts. The concept of a quality manual provides a set of hierarchically

nested subsections. These subsections can follow the same general format for each section and may include: scope, responsibility and authority, quality activity, and related documentation.

Text boxes should be provided to allow the user to enter text into each subsection. The preparer of each section must enter his or her name in the appropriate location before exiting. In addition, each subsection must be completed for every given quality system element in order to be considered complete. An indication of the status of the section when the user exits that particular section should be provided. This allows the editor and approver to determine if the section is ready for their review.

Examples and/or help should be provided to users. Also, information that cross-references the section of the quality manual to the standards would be beneficial to the user.

The system should also contain a tutorial section that introduces new users to the ISO 9000 quality system requirements. Viewing this section should be optional, but encouraged for new users. A "Main Menu" will show the users what the various sections of the program contain and should be the first item to appear on the screen during execution.

During the conceptual design phase, initial designs of the screens were sketched, including menus, buttons, and icons. At this stage of the design phase, it

is not necessary to perfect the icon appearances or menu wording, since much of the design will be subject to change.

Because of the ease of using Visual Basic to create screen sketches relatively quickly and more neatly than using a paper-and-pencil approach, screen sketches were also made on the computer.

4.7.2 Detailed Design

During the detailed design phase, the initial design approaches are fully reproduced using Visual Basic. The design activity becomes much more iterative as the designs are tested on users and their comments are incorporated. During this iterative phase, the screens are improved considerably. The goal is to develop a better layout and visual design for the system based on results of early usability evaluation and the study of human factor/user interface principles. These principles are described in detail in Chapter 5 of this thesis.

The design process is very iterative and usually requires many revisions before satisfaction is achieved. The steps during this process basically follow those of the conceptual design, but involve the refinement of the screens to finally achieve the interfaces that provide the most favorable responses from users.

5.0 Importance of Graphical User Interfaces

5.1 Use of Graphical User Interfaces

In this thesis work, efforts are devoted to designing and developing the ISO 9000 quality manual software detailed in Chapter 4. Heavy emphasis has been placed on the design of the graphical user interfaces (GUIs). A user interface basically provides a connection between a human and a computer (application). A graphical user interface is unique in that it provides the following features: bit-mapped graphics, windowing, and direct manipulation. These features have been deliberately incorporated into the quality manual software developed in this thesis work. The principles and benefits of a GUI design are presented in the following sections.

5.2 Need for Understanding the User

A GUI is more than just "pretty pictures." It actually supports the user's tasks and goals by:

- Putting the user in control of the interface.
- Providing an efficient and effective interface.

Elements of a productive GUI fall into three categories: using good design judgment; nurturing a process to support the design; and recognizing the area where most design failures occur - understanding the user. For any system to be complete, the human being and the interfaces between the human and the other

elements of the system must be considered. The field of human factors helps to address this issue within the scope of systems engineering. Human factors is gaining increasing popularity because of the recent shift from the so-called "technocentric model of corporate application design" (in which technologists force people to adapt to their technology) to a human-centered design, in which tools are designed to fit people.

By emphasizing the user in the design of technology, corporations hope to achieve the following goals:

- Optimize user productivity
- Minimize user errors
- Reduce training requirements
- Increase user satisfaction

These goals are largely obtainable if one understands what the user wants and likes.³² A user analysis serves to define the characteristics of users in terms of:

- Their general computer literacy.
- Their expertise level (novice, intermediate, or advanced user).

³² Hix, Deborah and H. Rex Hartson, Developing User Interfaces.

- The hardware they are most familiar with (e.g., Macintosh, PC, workstation, mainframe).
- The software they are most familiar with (e.g., word processors, spreadsheets, databases).
- General experience with similar or related applications.
- Skill base (e.g., typing).
- General education level.
- Organization-specific knowledge and/or experience.

5.3 Elements of a "Good" GUI

In software development, the issue of human factors is mainly emphasized in the design of the GUI. In fact, GUI design is rapidly entering the realm of engineering and, although natural creativity helps, steps to designing an effective GUI can be learned.

Learning about the elements of a "good GUI" requires an understanding of a few basic and sometimes scientific principles. In 1982, H.E. Dunsmore showed that screen clarity and readability could be improved by making screens less crowded.³³ He showed that splitting items on one long line into two improved productivity by 20%. Recently, R.S. Keister and G.R. Gallaway showed that

³³ Sarna, David E.Y. and George J. Febish, "What Makes a GUI Work?," p. 29.

"good design principles" improved productivity 25% while simultaneously reducing errors by 25%.³⁴

Poor design is literally painful. In 1989, Michael L. Matthews, John V. Lovisak, and Karen Martins reported that 60% of individuals who viewed CRTs for extended periods reported eye-focusing problems and 40% reported pain in the eye area.³⁵ The reasons for the problems can be described by physics. At normal viewing distances (19 inches), visual acuity is sharpest within a circle with diameter of 1.7 inches. At the edges of this circle, visual acuity is reduced by half. Therefore, if a user focuses at a point on the screen, the area that is in sharp focus is a circle around that point with a diameter of 1.7 inches. This constitutes a single chunk of information that the user observes at a glance. This is called the Rule of 1.7. A person who constantly needs to move his or her eyes to read a chunk of information requires a lot of unnecessary and tiring eye movements - a violation of the Rule of 1.7.

In fact, many other rules of good design derive (unconsciously or not) from this physical reality. Some common design rules, such as: "limit the use of option buttons to no more than six, arranged in two columns of three each" or "limit the number of list boxes to six to eight lines" are just specific ways of following the fundamental Rule of 1.7.

³⁴ Sarna, David E.Y. and George J. Febish, "What Makes a GUI Work?," p. 29.

³⁵ Sarna, David E.Y. and George J. Febish, Ibid, p. 29.

Other general principles of a good GUI design include:

- Arranging the screen into logical chunks of data (one task, one chunk).
- Grouping chunks within frames.
- Aligning the chunks neatly in rows or columns or squares, rather than leaving them at haphazard locations.

Books, such as *The Design of Everyday Things* and *Turn Signals are the Facial Expressions of Automobiles*, are often used as texts in the field of technology design.

5.4 The Microsoft Windows Approach

GUIs, pull-down menus, icons, and mice almost seem like the sole accepted method of application design ever since Microsoft Corporation's Windows endorsed the Apple Macintosh/Xerox Star approach to user interfaces. To even be considered, every other platform has had to follow suit.

The superiority of the Microsoft approach has not really been examined closely and yet appears to be almost universally accepted. However, not everyone believes in the Microsoft/Macintosh approach.

According to both researchers and practitioners, the decision to use a GUI environment should be based on business needs. Creating a design that is

appropriate for a specific user's task is the single most important element in the creation of good GUIs.

Every application has a different set of "most important" rules. For Will Wright, cofounder of Maxis, the developer of award-winning simulation applications Sim City, Sim Earth, and Sim Life, a few general rules are worth applying.³⁶ Initially, users should only be provided with information that will allow them to determine how to begin using the system. This is a relatively easy task to accomplish for a simple program; however, complications arise for more complex programs. Issues, such as screen size, physical location of the computer system on the desk, frequency of software use, and even job turnover rate need to be closely examined. In addition, the designed interface should allow users to further explore the software as they become more acclimated to it. This can be readily accomplished by designing screens in which the primary buttons are layered on top of secondary buttons. Overall, development of a software product can be summarized as an iterative process, which usually requires several revisions before arrival at a satisfactory final product.

In designing a screen, it is useful to actually take graph paper and physically draw the screens. Putting common elements on a grid allows the designer, for example, to always put the OK button in the same place. It is also an

³⁶ Allen, Dennis, "Beyond the GUI," p. 10.

inexpensive way to demonstrate an initial approach to the user, before spending hours of coding the screens.

5.5 Basic Principles of GUI Design

There are many acceptable ways of designing a GUI. In this thesis work, the following ten basic principles of a GUI are applied:

1. Understand the actual usage of the product at a very detailed level.

During the design phase, designers need to ensure that they understand the basic infrastructure of the system and how the information will be presented (output) or received (input). For example, in designing the quality manual software, one must first understand the requirements of an ISO 9000 quality manual. This may not be so straightforward because the standards do not specify exactly how the quality manual should be written. The designer needs to determine the most effective way of organizing the quality manual input screens without making them too cluttered and complicated. During an initial design, the designer closely interacts with users to gain better insight into their learning styles and personalities. This helps the design to flow logically, although the process itself is very iterative.

2. Introduce interface design at the beginning of the project development.

Another basic principle that managers tend to ignore is the incorporation of interface design in the early stages of software development. "Most project managers wait until the end of the project to introduce interface design, which makes about as much sense as hiring the building architect after the superstructure of the building is finished."³⁷ Interface design should go hand-in-hand with the coding. One key advantage of using Microsoft Visual Basic to develop the program, is the application's capability of allowing the designer to create and insert objects on the screen before writing a single line of code!

3. Put the user in control of the application.

It is crucial that the user feel in control most of the time, however, there are times when the user appreciates having reminders or notifications of the implications of his or her actions. This prevents frustrating mistakes (like exiting before saving material). In the software developed for this thesis work, default examples were included in the user's data entry boxes. The user can either type right over this information or delete it completely. Help, which is available if required, is non-obtrusive and appears only when requested by the user. The user has a less control when he or she attempts to exit a section

³⁷ Angus, Jeffrey Gordon, "Coding a Masterpiece," *Infoworld*, pp. 85, 88.

without first completing the necessary information to proceed. The user is notified that the information is essential to continuing with the quality manual development; if this notification is ignored, there will be insufficient information, hence the user cannot continue before providing this information. See Figure 5.1.

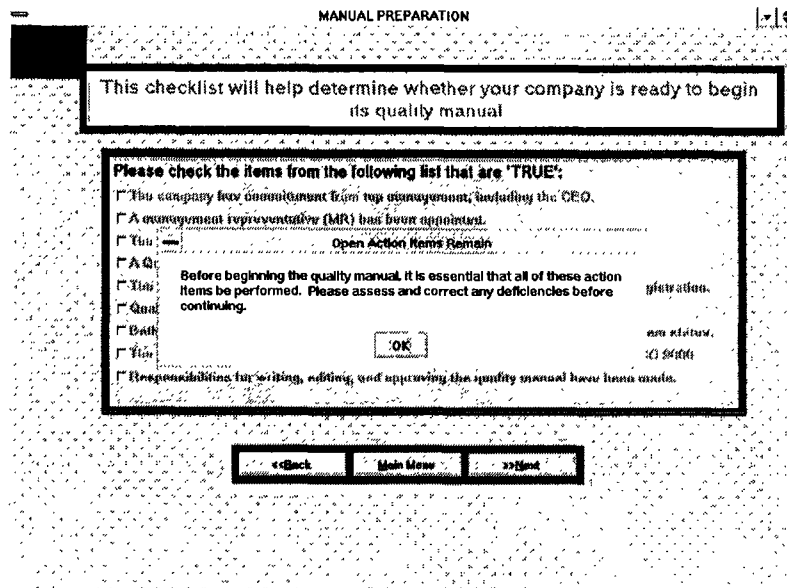


Figure 5.1 - Example of Pop-Up Screen for Notification

4. **Consistency within and across applications.** Objects should have consistent meanings. A command button should always be something that activates an action when clicked. Some recent designers have forgotten this guideline and have designed objects that are only activated when other objects are dragged

and dropped on top of them. Scroll bars should always scroll, and icons, when used must be carefully chosen to prevent confusion. Consistency is also necessary when placing common elements on a screen. For example, in the quality manual software, the **Back**, **Main Menu**, and **Next** buttons always have the same placement relative to each other, and appear in the same location on every screen. See Figure 5.2.

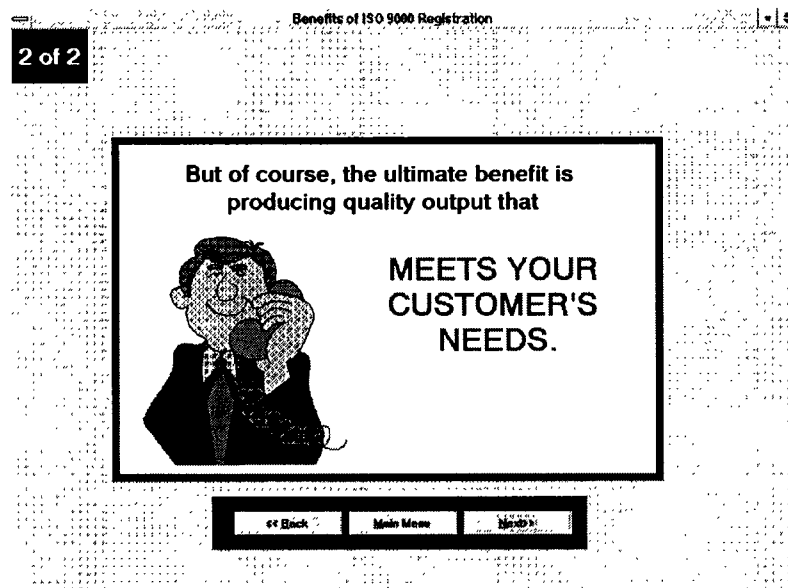


Figure 5.2 - Example of *Back*, *Main Menu*, and *Next* Button Placement

5. **Clarity.** The application should be visually, conceptually and linguistically clear. For example, elaborate menu trees should be avoided. In the quality manual software, the cognitive psychologists' Rule of Six was followed as closely as possible. This rule states that most people can only remember six

things at one time. It follows that six menus per menu bar and six choices per menu is the most users will naturally master. In the tutorial section of the program, the user was not overwhelmed with too much detail because short statements, meant to be read individually, were often used.

6. **Aesthetics.** The application should have a good graphic design. During the development of the quality manual software, users reacted much more favorably after the addition of clever cartoons and pictures in the tutorial section. See Figure 5.3.

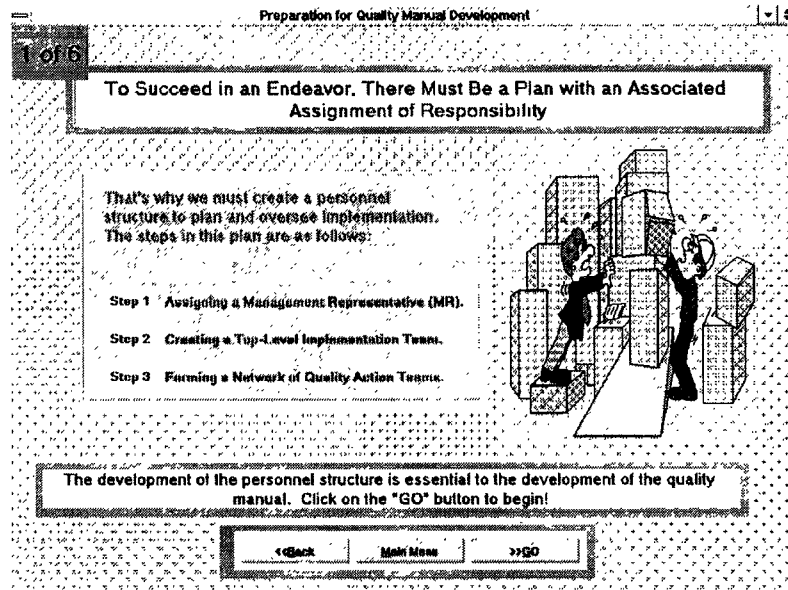
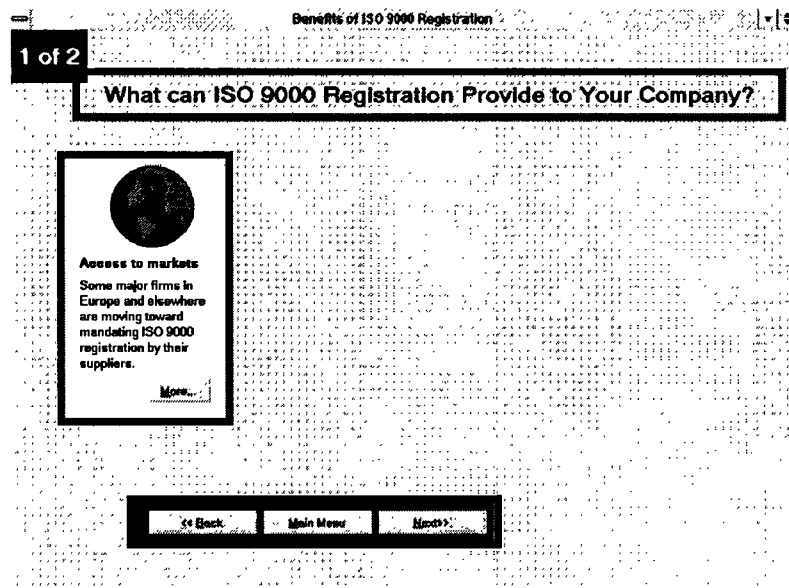
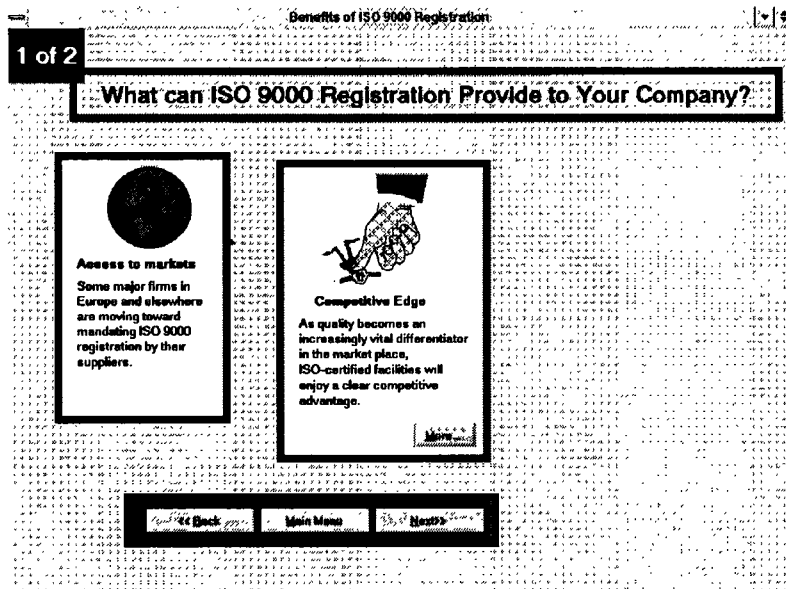


Figure 5.3 - Example of Cartoon Use

7. **Feedback.** The user always expects and should get immediate and tangible feedback for actions. For example, in the quality manual software, the user is often asked to click a **More** button to get the next chunk of information. This results in immediate addition of the new information on to the screen so as not to disrupt the flow of the information. See Figure 5.4.



Initial information presented on screen...



Immediate addition of new information after clicking *More*

Figure 5.4 - Examples of *More* Button Use

8. **Forgiveness.** The user should not be punished for exploring or making mistakes. The use of pop-up screens is often helpful in preventing the user from initiating an action he or she may not have intended.

9. **Awareness of human strengths and limitations.** The importance of the human factors issue cannot be underestimated. Understanding the strengths and limitations of the user often determines the success or failure of a particular application.

10. Test, prototype, and test again. Even if the designer knows exactly what he or she is doing, the users' needs cannot be accurately guessed in every situation. A designer should never believe that he or she will get the design "right the first time." It is essential that GUI designers realize the importance of revising and testing. Ultimately, prototyping also reduces the cost of projects by minimizing the need for upgrading and releasing new versions. The quality manual software went through many iterations of revising and testing. It was observed that even changing the background color of a particular screen had either a negative or a positive impact on the user. This aspect alone required several modifications to please most of the users. It is also realistic to expect that a single design cannot please all users, therefore, the opinion of the majority seems to be the best decision factor.

5.6 Benefits for Developers

The benefits received from applying the above ten basic principles include:

- Learning early on what users want/need from interface.
- Getting in the habit of early and continuous prototyping.
- Understanding the usability of the interface before construction.
- Potentially lowering the cost and risk of development, training, and user acceptance.
- Developing detailed blueprints for GUI construction.

A study, sponsored by Zenith Data Systems and Microsoft, demonstrated several benefits of a GUI over character-based user interfaces (CUI).³⁸ The study, which compared GUI users with CUI users, indicated that GUI users are generally more productive, less frustrated, run more software packages, and use more features within their software. In addition, the study concluded that GUIs generate:

- Higher output per work hour through higher productivity.
 - Higher output per user because of lower frustration and fatigue levels.
 - Greater return on the information technology investment than CUI, because GUI users master more capabilities and require less training and support.
- Furthermore, the study found that GUI users are better able than CUI users to self-teach, explore, and learn more capabilities within applications.

As pointed out by Dr. Rachel C. Sarna, a psycholinguist, the benefits of GUIs are related to the how the human brain works.³⁹ Humans can be thought of as having two independent brains (the left and the right), which communicate across a slow-speed network called the corpus callosum. These two independent processors respond to different stimuli.

³⁸ "GUI vs. CUI: One Picture is Worth a Thousand Words," p. 89.

³⁹ Sarna, David E.Y. and George J. Febish, "What Makes a GUI Work?," p. 29.

The left half of the brain, which can be characterized as the "thinking part", is better stimulated by words and factual information. The right half of the brain, the "sensuous part", is known to respond better to visual stimuli pertaining to beauty, design, harmony, and the like. Good visual GUIs are popular because they allow both halves of the brain to work together simultaneously on the same problem. Furthermore, the perceived productivity gains from visually attractive, well-designed GUIs are real and significant. Visually appealing, well laid out GUIs are usually more intuitive, therefore leading to improved user productivity and satisfaction.

6.0 Conclusions and Recommendations

6.1 Conclusions

In these times of intensifying international competition, companies are searching for ways to gain a sustainable competitive advantage in the marketplace. Acquisitions, mergers, or extensive advertising campaign strategies alone are not enough to prosper in today's growing global economy. Companies are now realizing more emphasis must be placed on the needs of the customers, who now face greater opportunities to purchase products and services globally. Choice elevates quality requirements and forces companies to pursue recognized quality improvement initiatives, such as ISO 9000 implementation.

Registration to ISO 9000 focuses primarily on conformance and documentation of a company's quality procedures. These procedures are documented in the quality manual, which demonstrates a company's adherence to the ISO 9000 quality system standard. The use of an information system to develop, display, modify, and distribute the quality manual provides several advantages to companies implementing ISO 9000. The creation of the quality manual is simplified through the use of pre-formatted data entry screens designed exclusively to meet the requirements of each conformance standard (ISO 9001, ISO 9002, or ISO 9003). In addition, the quality manual information system may be used as an initiation and training tool for employees to gain familiarity with ISO 9000 and the company's quality procedures.

The nature of the quality manual information system fits nicely into a plan of providing the quality manual on-line. An on-line quality manual would ease the burdens of document control personnel who are responsible for issuing revisions for several different documents. In addition, this quality manual would also allow necessary modifications to be made only in the original master copy. The quality manual could be made available to employees via the company's local area network, thereby ensuring each employee access to the most current version.

The application of human factors and GUI principles in the development of the ISO 9000 quality manual training and documentation has been shown to increase user productivity and satisfaction. Designing an interface with the user in mind, results in more efficient utilization of a person's information processing capabilities. The user is more apt to use the documentation tool and is better able to concentrate on the development of the quality manual when presented with a simple, efficient, and effective interface.

6.2 Recommendations

The purpose of applying engineering activities in the analysis and design of the information system is to exactly determine the required type of system and the best approach at developing that system within the given time and cost constraints. Although cost issues were not specifically addressed in this thesis, the importance of understanding economics within the realm of engineering cannot be ignored.

This economic concern is clearly stated in the definition of engineering adopted by the Accreditation Board for Engineering and Technology (ABET).⁴⁰

"Engineering is the profession in which a knowledge of the mathematical and natural sciences gained by study, experience, and practice is applied with judgment to develop ways to utilize, economically, the materials and forces of nature for the benefit of mankind."

Systems engineering should be thought of as a process for developing and managing technology effectively. It is only through the effective integration of technology, user requirements, and cost factors that economic competitiveness can be achieved. Systems engineering should be applied to realize and achieve an optimal balance of these elements. Economic competitiveness and the development of quality systems should set be goals of the systems engineer. Further, engineering must become coequal with other strategic business tools such as advertising, finance, production, and the like.

The growing popularity of ISO 9000 has certainly proven the need for the US to assume a very active role in the world's standards-setting process. Business and government leaders must continue to realize that understanding the new international standards is essential to compete in national and world markets in the future years. During a roundtable discussion commemorating World Standards Day, panelists made strong comments urging US businesses to take a stronger role

⁴⁰ Dieter, George E., Engineering Design, A Materials and Processing Approach.

in standardization in order to compete globally. Panelists indicated that major US competitors are using standards as strategic business tools and that the US is just waking up to that fact.⁴¹ Speaking on behalf of the government, the Director of the National Institute of Standards Technology (NIST) commented that US businesses can no longer think of standards as a limiting boundary but as an enabler.⁴² "It is clear that standards are coming to the fore as a corporate strategic tool and that standards are important to American companies, and to their ability to compete."

As the world economy changes, business practices and goals must be flexible enough to adapt to the changes. Applying the proven benefits of systems engineering methods, using information systems to improve and enhance company effectiveness and efficiency, and understanding the significance of international standards, such as ISO 9000, are critical to achieving quality improvement and strengthening US competitiveness.

⁴¹ "US Business Urged to Take Stronger Role in Standards," Quality in Manufacturing.

⁴² "US Business Urged to Take Stronger Role in Standards," Ibid.

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