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IMPLEMENTING ISO 9000  
QUALITY GUIDELINES IN MANUFACTURING

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Topic: **IMPLEMENTING ISO 9000 QUALITY GUIDELINES IN MANUFACTURING**

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# IMPLEMENTING ISO 9000 QUALITY GUIDELINES IN MANUFACTURING

## OVERVIEW OF ISO 9000

### NEED FOR A HARMONIZED QUALITY STANDARD

After World War II, Europe needed to rebuild its industry and economy. To facilitate this, all countries were concerned with developing product, quality, and regulatory standards, Unfortunately these efforts were not unified and each country proceeded to develop its own sets of standards. Until recently, European producers considered their individual, professional, industrial, or national standards more than adequate [14].

When the European Community (EC) was created, its executive body, the European Commission, chose as one of its tasks, the harmonizing (unification) of European standards. The International Organization for Standardization (ISO) has been instrumental in this effort. During the past 30 years, only a few hundred standards have been harmonized out of the tens of thousands that exist [12]. Of these, only the ISO 9000 series defines the minimum requirements that a company must meet to assure a quality product to their customers.

The publication of the ISO 9000 series in 1987, together with the accompanying terminology standard, ISO 8402, has brought harmonization on an international scale and has supported the growing impact of quality as a factor in international trade [15]. In the United States, these standards have been released through the American National Standards Institute (ANSI) as the Q90 series with the accompanying terminology standard A3 [1], [2], [3], [4], [5], [6].

As Europe moves to unify its marketplace, "Europe 1992" has come to mean freedom of movement of people, goods, and capital within the European Community. Common standards are essential in securing this freedom. The European Commission has chosen ISO 9000 as the starting point for achieving this.

### WHAT IS ISO 9000?

Whether organizations sell products or services, customer expectations are usually incorporated into a set of specifications. However, these specifications are not guarantees for the consistency of a product's quality. This need for consistent quality has resulted in a series of standards, ISO 9000. The standards are basically a set of Quality Management System (QMS) practices and guidelines. The ISO 9000 system is

not a unique "system" in itself. Implementing ISO 9000 forces a company to record its management systems such that certain specific actions and procedures are not overlooked. However, the series is not intended to standardize quality systems implemented by these companies [16].

The ISO 9000 series must be looked at as a series of minimum quality system requirements. It can be thought of as the lowest common denominator of quality system requirements meant for all industry and service groups [7]. These standards focus on establishing and maintaining controls to assure that customer requirements are continually met. The five standards in the series are described in Table 1.

### **MARKET ACCEPTANCE/DEMAND**

The European Community is pursuing many standardization initiatives to achieve a unified market by the end of 1992. Of the 76 technical directives required to create the unified market, 58 had already been adopted by spring 1990. When these directives are complete the 12 EC countries together with the 6 European Free Trade Association (EFTA) countries will represent the largest free trade market in the world. This marketplace will consist of 350 million citizens compared to Japan's 120 million and 250 million in the United States [13]. Globally, companies are preparing to compete for marketshare in this large developing marketplace.

As part of the EC's quality strategy, most European companies are certifying their quality systems to ISO 9000. The United Kingdom has led other countries with over 10,000 firms being ISO 9000 certified [13]. The ISO 9000 series has also been adopted by many other nations and regional bodies and is rapidly supplanting national and industry-based standards as companies worldwide prepare to sell to the European Community [9].

Growing worldwide acceptance of ISO 9000 shows that quality systems are becoming increasingly important both as a potential marketplace requirement and as a marketable company feature [7].

### **METHOD OF CERTIFICATION**

A third party certification scheme for quality systems registration and for auditing compliance to the requirements is employed. Under such certification schemes, a company arranges to be audited by a single accredited independent (third party) registrar organization. If the company's quality systems, documentation, and operations are found to meet the requirements of the applicable ISO 9000 series international standard, the registrar grants certification and lists the company in its

register of companies with certified quality systems. All purchasers of the company's products can then accept the third party certification as evidence that the company's quality system meets the applicable ISO 9000 series requirements [15].

Whenever a company obtains certification it will have the freedom to export to any of the EC countries without suffering any technical trade barriers [12].

### ISO 9000 STANDARDS

ISO NAME	ANSI NAME	STANDARD TITLE	DESCRIPTION AND APPLICATION EXAMPLE
ISO 9000	Q90-1987	Quality Management and Quality Assurance Standards - Guidelines for Selection and Use.	Guide for appropriate selection of standards 9001-9003. Applies to all companies.
ISO 9001	Q91-1987	Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing.	Applies to companies that design and supply product, such as, engineering, and construction companies.
ISO 9002	Q92-1987	Quality Systems - Model for Quality Assurance in Production and Installation.	Applies to companies that use processes to deliver a product, such as, manufacturers and primary contractors.
ISO 9003	Q93-1987	Quality Systems - Model for Quality Assurance in Final Inspection and Test	Applies to companies that assure product conformance through inspection and test, such as, distributors or value-added contractors.
ISO 9004	Q94-1987	Quality Management and Quality System Elements - Guidelines	Guide for the application of the elements used in developing and implementing Quality Management Systems. Applies to all companies.

TABLE 1

## PURPOSE

The purpose of this project is to examine why companies are implementing ISO 9000 guidelines, the problems they are encountering during implementation, and the methods used to overcome these problems.

## BACKGROUND

### WHY IMPLEMENT ISO 9000?

The trend of increasing customer expectations for products and services has resulted in the establishment of standards dedicated strictly to quality in many countries. While this assures that a company adhering to these standards would be involved in a quality program, it does not solve the problems of companies in different countries trying to equate different aspects of their countries individual standards. These concerns contributed to the development of the ISO 9000 international standards [11].

Compliance with ISO 9000 is not mandatory. However, the EC directives and standards require manufacturers to have a quality system. There also needs to be a nationally recognized organization, that audits these systems, approves the design of devices, and institutes a continuing surveillance of the approved quality system. The quality system described in ISO 9000 is the only one currently in international use that meets these requirements [16].

With the approval of the Single European Act and the ISO 9000 quality standard, it will soon be necessary to show evidence of meeting the European quality standards in order to be competitive for business within the European Community [11].

It is obvious that compliance with the ISO 9000 standards has become a market driven requirement for companies that want to export products and services to the European Community. However, some Asian countries, such as Japan, do not appear to be making any rapid moves toward ISO 9000 certification. Given its present world position in quality achievement, Japan probably can afford to take its time [11].

Primary reasons [10],[12],[13], for implementing ISO 9000 guidelines include:

- Selling in the European Community marketplace
- Gaining competitive advantage
- Quality improvement
- Management policy



The secondary benefits [7],[17] of certification include:

- Worldwide recognition by potential customers as a viable supplier
- Technical trade barriers will become obsolete and company will gain access to European Community marketplace
- Company gains a quality management system that can be used for continuous product and organization improvement
- Overall cost-reduction due to proactive quality management
- Creates confidence between customer and supplier
- Third party auditing protects confidential technology and promotes objectivity and consistency
- Facilitates the preparation of an approved supplier list

#### **ELEMENTS OF ISO 9000**

In order to implement the ISO 9000 system, a company needs to observe each of the elements described in the applicable standard. Each of these elements needs to be established, documented, and maintained as a minimum requirement for compliance, for example, if a manufacturing company chooses to be certified to ISO 9002, a careful implementation of the elements [3] summarized in Table 2 would be necessary.

ISO 9002 ELEMENT SUMMARY

ELEMENT	DESCRIPTION
Management Responsibility	Requires that quality policy be defined, documented, and communicated throughout the organization, responsibilities be defined, resources available for verification and that a management representative ensures these requirements are met.
Quality System	Requires a quality system that meets the criteria of this ISO standard be established, documented, and maintained as a means of ensuring product conformance.
Contract Review	Requires review of contracts to ensure defined requirements and capability to meet requirements.
Document Control	Requires establishing and maintaining procedures for controlling documentation through approval, issue, change, and modification.
Purchasing	Requires that purchased product conform to specified requirements ensured through subcontractor verification.
Customer Supplied Product	Requires procedures for verification, storage, and maintenance of customer supplied product.
Product Identification and Traceability	Requires procedures for identifying product during all stages of production, delivery, and installation.
Process Control	Requires procedures to ensure control of production and installation processes, includes documentation and monitoring.
Inspection and Testing	Requires procedures for inspection/testing at receiving, in-process and final stations, includes disposition of material.
Inspection, Measuring, and Test Equipment	Requires procedure for selection, control, maintenance, and calibration of all test and measuring equipment.
Inspection and Test Status	Requires marking of product throughout production to show conformance or nonconformance to tests and inspectors.
Control of Nonconforming Product	Requires control of nonconforming product to ensure that it is not inadvertently used; identify, segregate, and evaluate.
Corrective Action	Requires procedures for investigating cause of nonconformance, includes actions taken to rectify and prevent future problems.
Handling, Storage, Packaging, Delivery	Requires procedures for handling, storage, packaging, and delivery of product.
Quality Records	Requires procedures for identification, collection, indexing, filing, and storage of quality records.
Internal Quality Audits	Requires a system of internal audits to verify that quality activities comply with requirements.
Training	Requires procedures for identifying needs and providing training.
Statistical Techniques	Requires procedures to identify the use of statistics in plant.

TABLE 2

## METHODOLOGY

The research project began with an exploratory phase that included interviews and a literature search. The informal interviews helped in our basic understanding of ISO 9000 and how it applies to industry. The literature search yielded many articles, 11 of which are listed as references.

From this work we were better able to focus the project's theme. Once the theme was defined, we decided that we needed some specific data. Therefore, we created the questionnaire which is shown in Appendix I. The group's members contacted companies that they knew were involved in implementing ISO 9000. Additionally, Washington State University had held a conference on ISO 9000 in July, 1991, and had issued a list of attendees. These people were also contacted and asked to respond to the questionnaire.

Twenty five companies were contacted and 19 have responded at this time. This gives a response rate of 76%. Not every question of every questionnaire was completed, therefore the results will sometimes show less than 19 responses. Most companies are located in the Northwest U.S., with others located in California, Illinois, Texas, New Hampshire, and France. Most companies are electronic product manufacturers, but others are manufacturers of semiconductors, materials, industrial equipment, and printed circuit boards.

Although the number of responses were better than expected, the sample is too small to generalize the results through statistical analysis. Therefore, the results are presented as general indicators and not as absolute certainties of how industries are managing the implementation of ISO 9000.

## RESULTS

The results of the questionnaire are summarized in the following paragraphs and are graphically depicted on the following pages.

### HOW IS ISO BEING IMPLEMENTED?

In the questionnaire, respondents were asked how their companies are implementing ISO 9000 guidelines. Was it on a company wide basis, specific factory locations or certain products and processes? Most are implementing it on a company wide basis, (Figure 1). There were 11 out of 16 companies using this method, 3 by product and process, and 2 by factory location.

### CURRENT STAGE OF IMPLEMENTATION

Of the 19 companies surveyed, 13 are in the planning phase, 5 in the execution phase and 1 has completed the process, (Figure 2).

### STATE OF QUALITY SYSTEM

The respondents were asked to rate their companies' quality systems before the process of implementing ISO 9000 guidelines began. A 13 point rating system is used, where 1 is "no quality system" and 13 is a "world class quality system". Of the 18 companies which responded to this question, 8 rate themselves a 6, which is better than "Military Standards", but less than "ISO 9000 Guidelines", (Figure 3).

### REASON FOR IMPLEMENTING ISO 9000

The respondents were asked to rate the importance of several factors as to why their companies were implementing ISO 9000 guidelines. A 3 point scale is used, where 1 is "not important" and 3 is "very important". The highest average rating is for "Selling in Europe", (Figure 4). The second highest rating is "Customer Requirements". The lowest rated factor is "Selling In The Asian Market".

### DEGREE OF DIFFICULTY

The respondents were asked to rate the degree of difficulty of 13 areas which are important to the implementation of ISO 9000 guidelines. A 5 point scale is used, where 1 is "not difficult" and 5 is "very difficult". The averages of all the responses are plotted on a Pareto chart, (Figure 5). Two areas tie for the

most difficult; "Documenting ongoing work activity and relevant data", and "Establishing and maintaining procedures". The least difficult area is "Maintaining and controlling inspection, test and measurement equipment".

#### **PROBLEM CATEGORIES**

The respondents were asked to categorize the primary type of problem for each of the problem areas. The categories are personalities, technical, budgetary, time/scheduling, facilities/site and performance. The problem categories for each area are shown in Figure 6. For the top two problems, the number one problem category is time/scheduling.

#### **TYPES OF PROBLEMS**

Figure 7 shows the sum of each of the individual problem categories. Time/scheduling is shown to be the number one problem in the implementation of ISO 9000 guidelines.

#### **INITIAL QUALITY SYSTEM RATING VS. DIFFICULTY FACTOR**

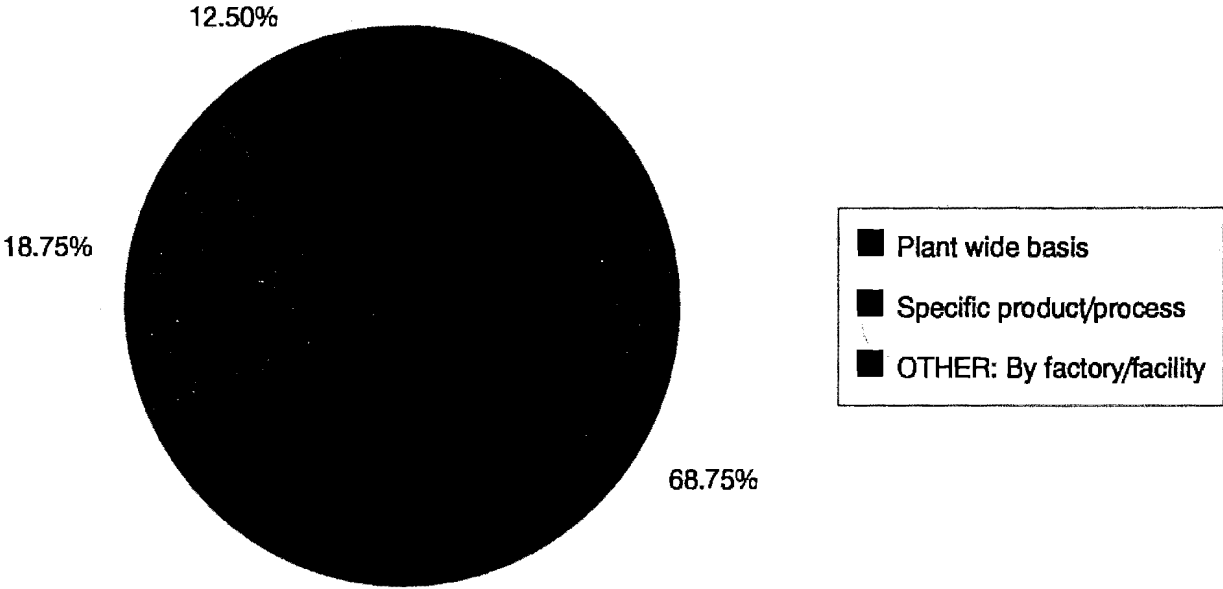
Figure 8 shows the average difficulty ratings for each company versus the quality system rating of the company.

#### **COMPANY SOLUTIONS**

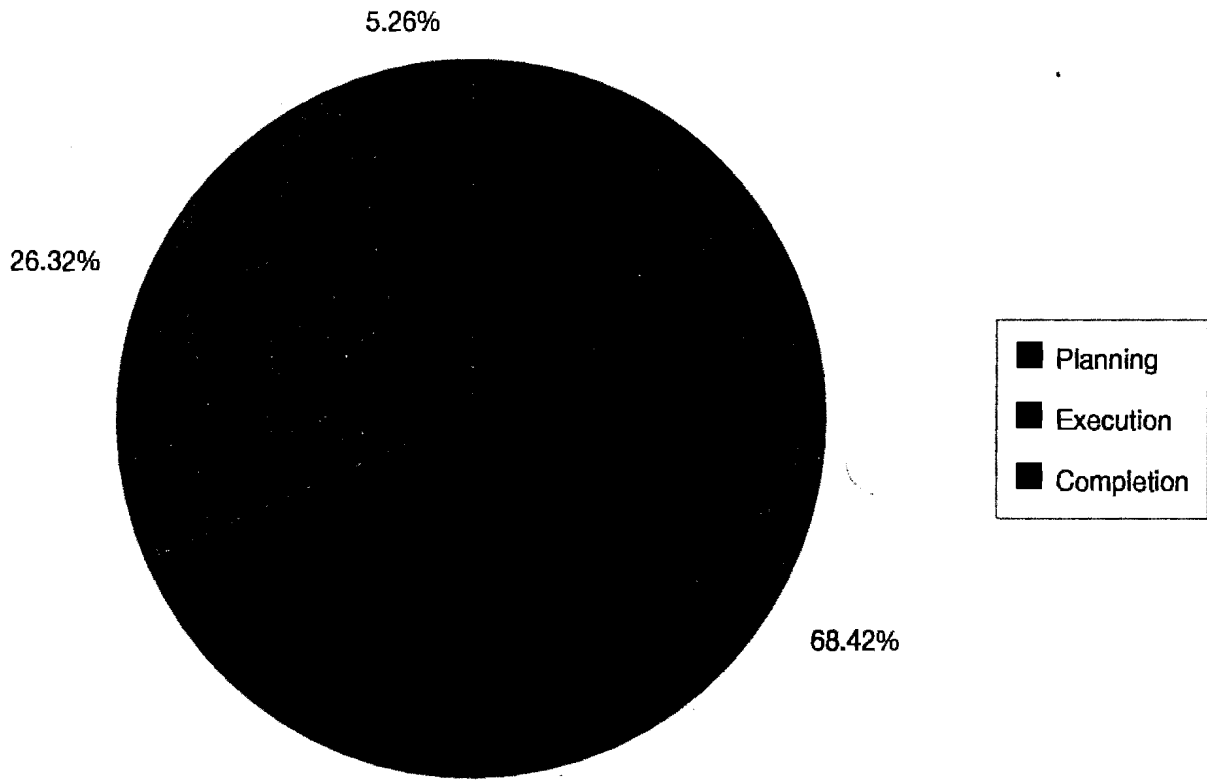
The respondents were asked to describe in detail their company solutions to their three most difficult problems. Table 3 and Table 4 show their responses.

**How ISO is Being Implemented**

**Figure 1**



**Stage Of Implementation**  
**Figure 2**



### State Of Quality System

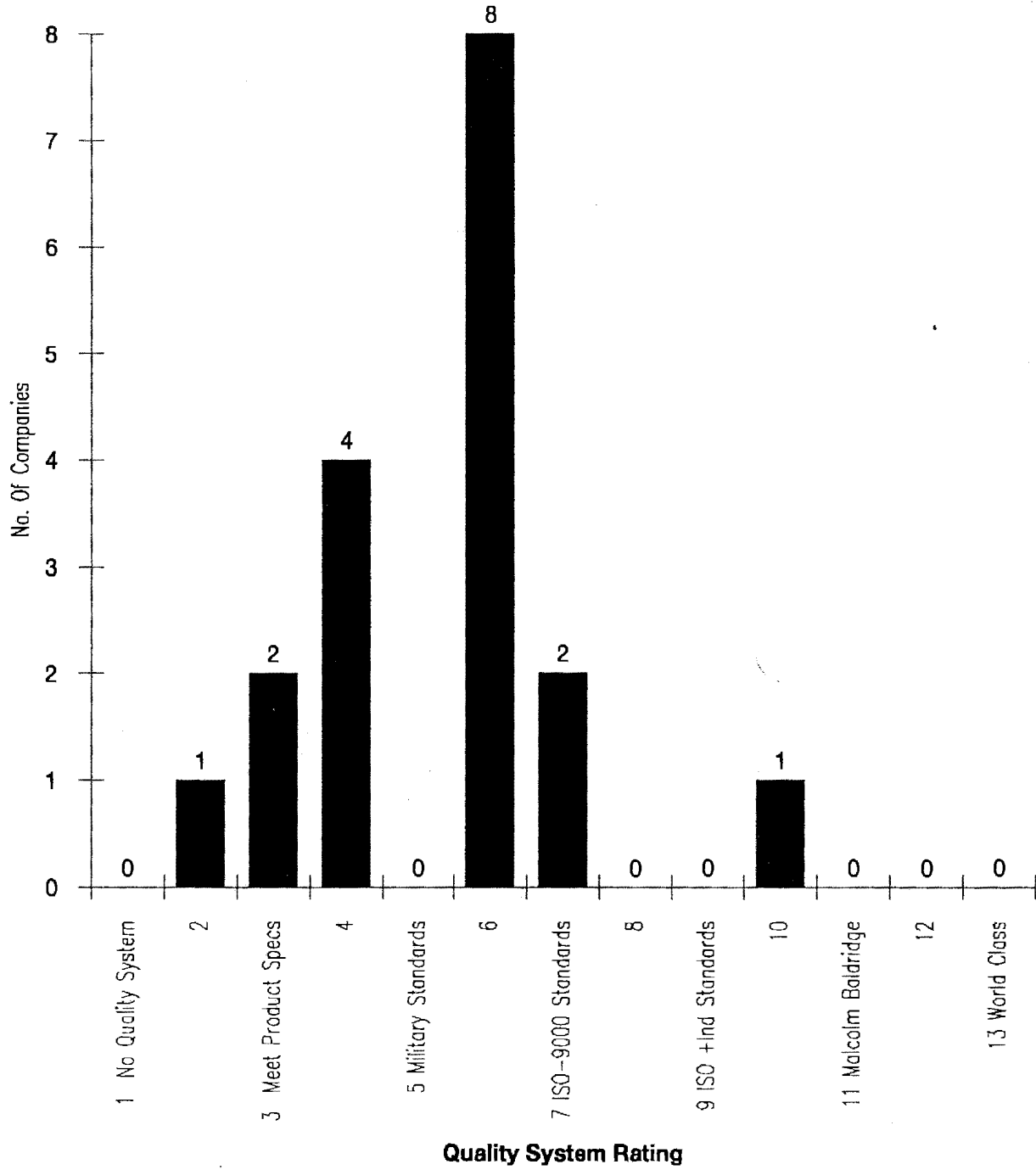
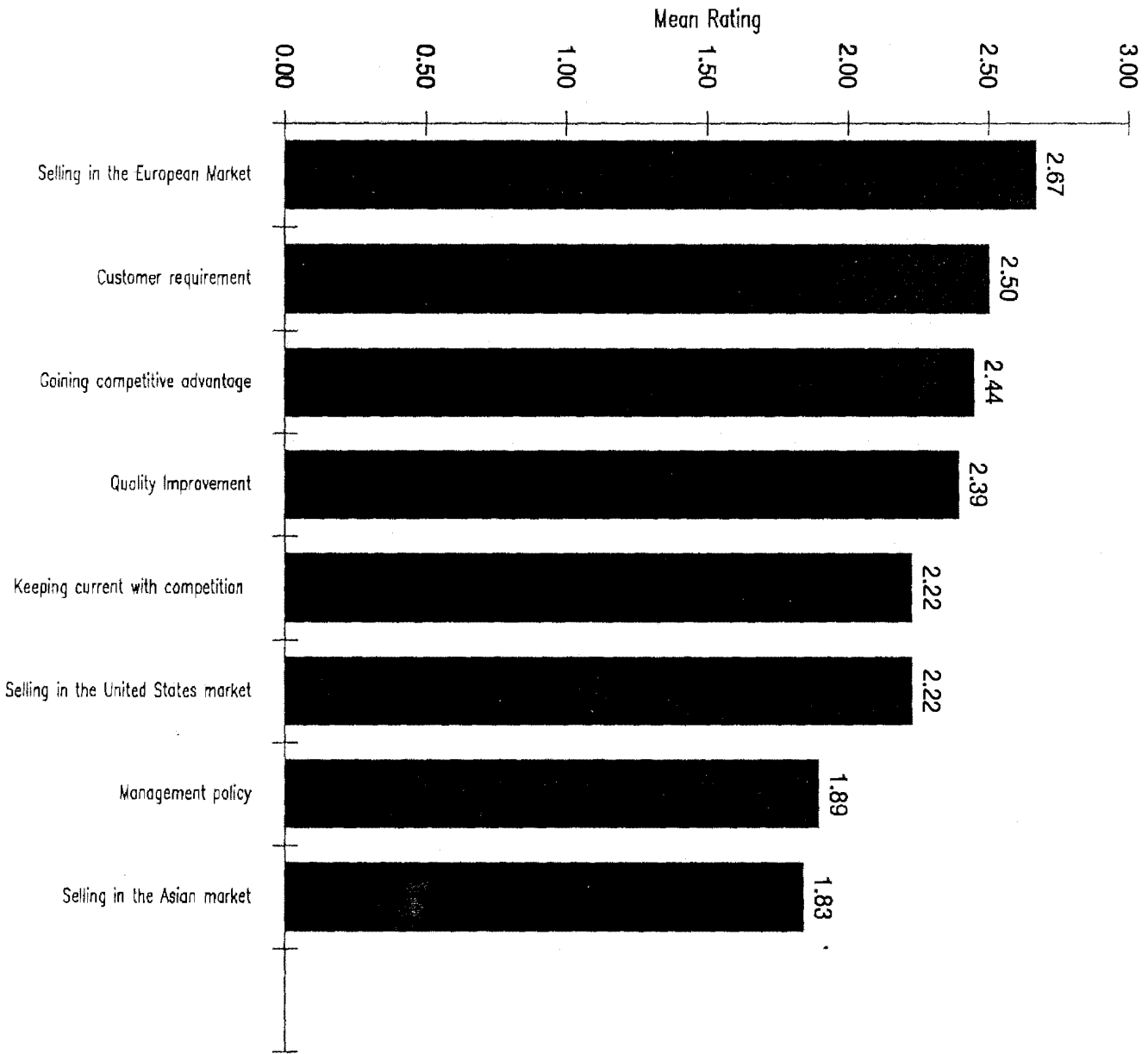


Figure 3



Reason For Implementing ISO 9000



Reasons

Figure 4

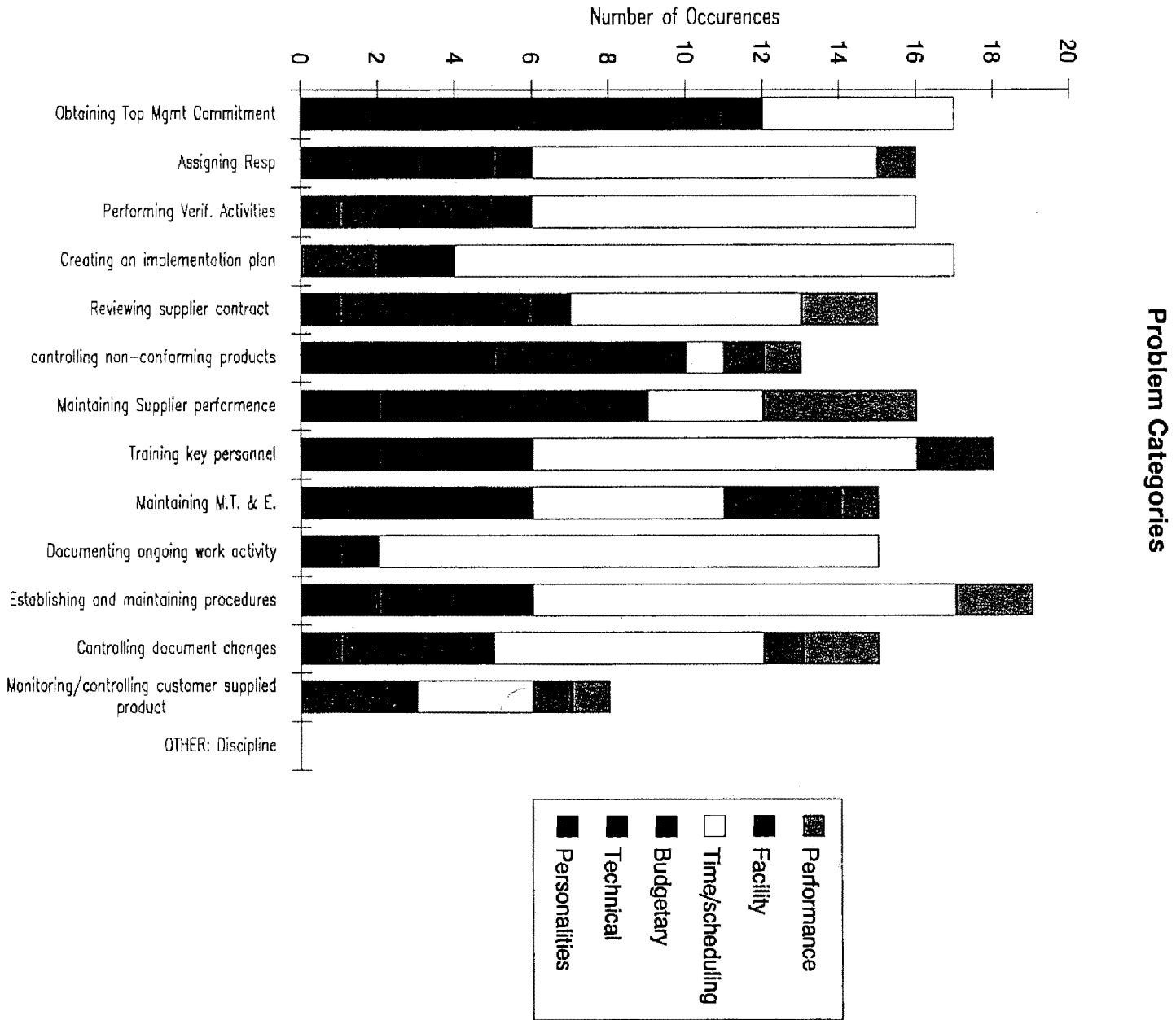
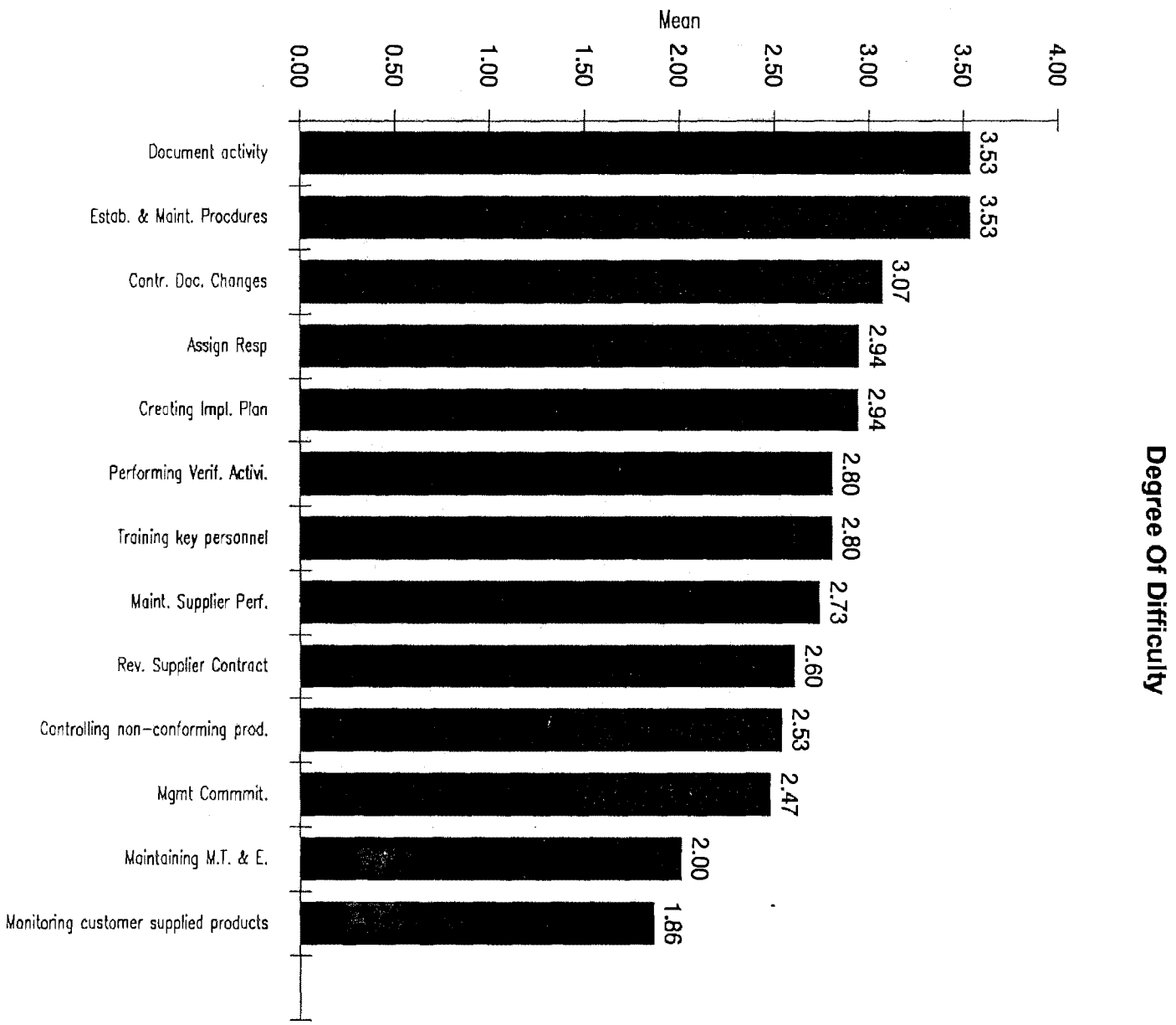


Figure 6

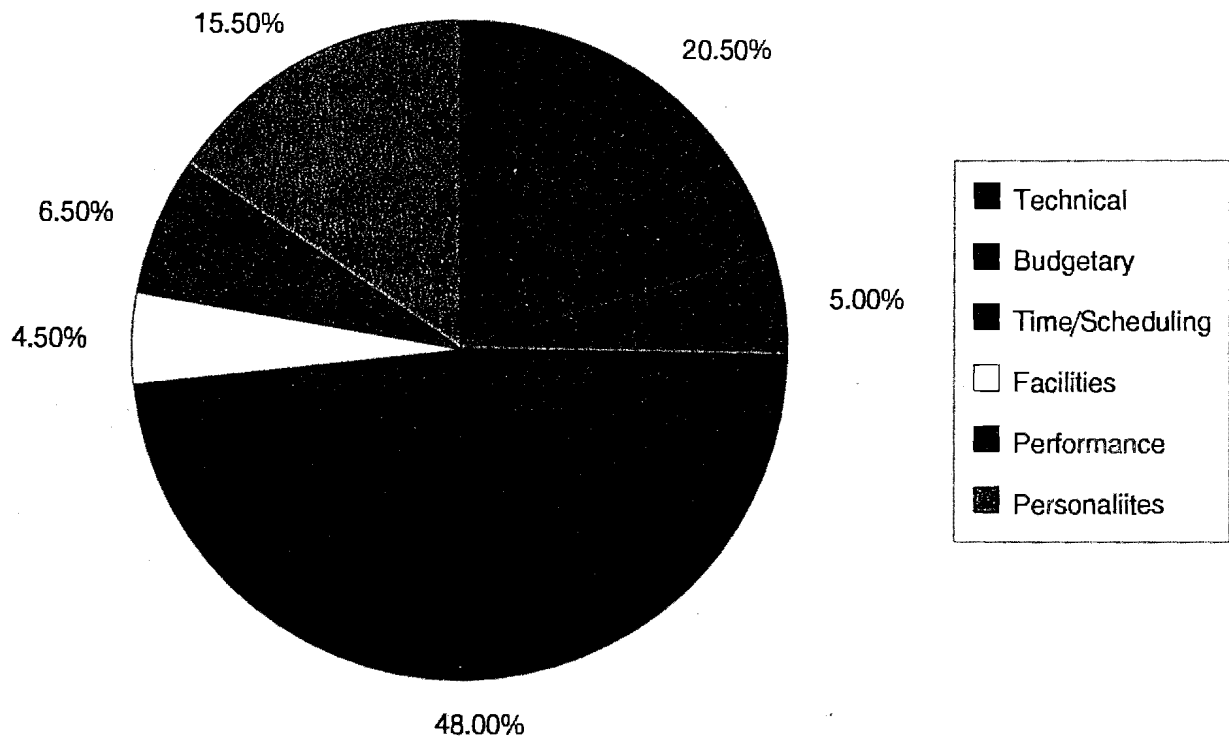


**ISO 9000 Elements**

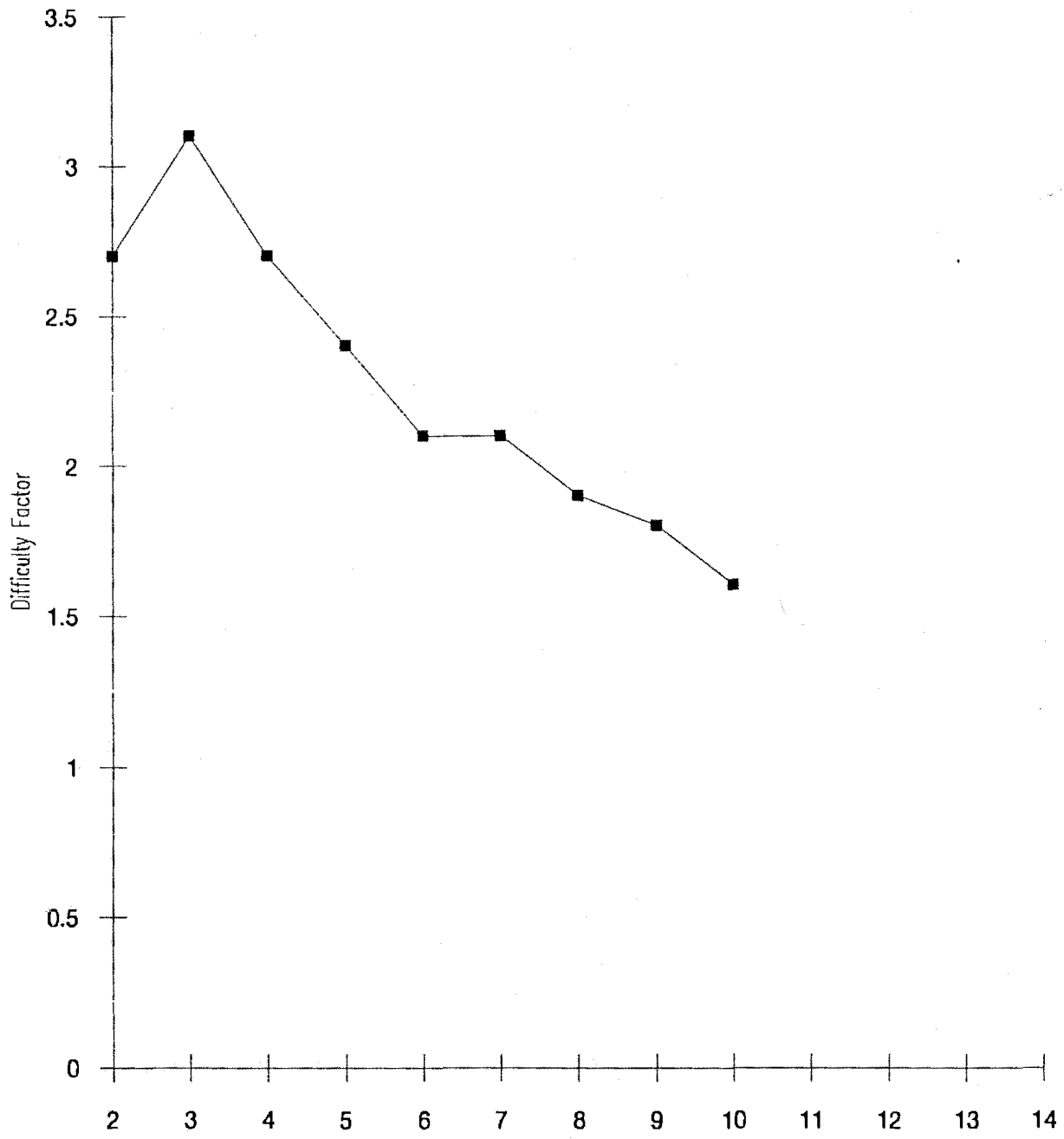
**Figure 5**

# Types Of Problems

## Figure 7



### Initial Quality System Rating vs. Difficulty Factor



Quality System Rating  
Figure 8

COMPANY SOLUTIONS I

PROBLEM	COMPANY RESPONSES
Documenting ongoing work activity and relevant data	<p>A. Provide training to participating employees.</p> <p>B. Define roles and duties then identify additional staffing requirements.</p> <p>C. Implement on-going internal audits with results going to top management.</p>
Establishing and maintaining procedures	<p>A. Decentralized management of procedure system.</p> <p>B. Increase staffing and have each person document the procedures for the job they are doing.</p> <p>C. Assign procedures to various individuals with due dates and monitor compliance to plan.</p> <p>D. Evaluate for proper staffing and assigned responsibilities.</p>
Controlling document changes	<p>A. Documentation department needs to be trained in configuration management.</p> <p>B. A Quality Assurance Technician performed a daily procedure audit.</p> <p>C. Sensitized staff to the importance of procedure conformity.</p> <p>D. Set up a panel to follow modifications.</p>
Assigning responsibilities	<p>A. Get top management to communicate the responsibilities and commitment.</p>
Creating an implementation plan	<p>A. Assign responsible persons.</p> <p>B. Convince top management that time expenditure is required.</p> <p>C. Create interest plant wide to create enthusiastic response.</p> <p>D. Utilize a task team approach and outside consultant assistance.</p> <p>E. Need company wide goals and plans.</p> <p>F. Clearly define personnel responsibilities.</p>
Performing verification activities	<p>A. Have top managers develop process measures for their areas</p>

TABLE 3

**COMPANY SOLUTIONS II**

PROBLEM	COMPANY RESPONSES
Training key personnel	A. Must continually reinforce. B. Replace verbal on-the-job training with formal procedurealized training.
Maintaining supplier performance	A. Implemented a pro-active procurement quality program. B. Make use of external audits.
Reviewing supplier contracts	A. Use new software package to facilitate the management of contract review and compliance. B. Provide training to improve expertise.
Control of nonconforming products	A. Write policies and procedures to conform to MIL-STD-1520C.
Obtaining top management commitment	A. Convince president of need for program. Customer influence critical. B. Use customer audit results to show top management how ISO 9000 will improve satisfaction. C. Ensure CEO has a quality assurance background. Formed a top management quality council.
Maintaining and controlling measurement and test equipment	A. Create a specialist position.
Monitoring controlling customer supplied product.	No responses.

**TABLE 4**

## DISCUSSION

### REASONS FOR IMPLEMENTING ISO 9000

The top four reasons for implementing ISO 9000 are fairly close. The companies' top reason for implementing ISO 9000 is to be able to "sell in Europe". Since the European Community is driving this movement, this is an expected result. The second top reason of being a "customer requirement" can be viewed as an extension of the first response. Some of these companies are suppliers to customers who sell in Europe. Since the customer companies will need to meet ISO 9000 guidelines, they will drive their suppliers to meet them too. These reasons along with the next two, "gain competitive advantage" and "quality improvement" agree with the primary reasons found in the literature search [10],[12],[13]. From our data, the least important reason for implementing ISO 9000 is to "sell in Asia". This reflects the fact that some Asian countries have not yet readily accepted the ISO 9000 guidelines [11].

### IMPLEMENTATION PROBLEMS AND SOLUTIONS

The top three most difficult problems are "documenting work activity", "establishing and maintaining procedures", and "controlling documentation changes". The respondents' share a common concern of many firms. Many companies that have chosen to become ISO certified, fear that they have to document and control hundreds of procedures [8]. The respondents main reason for documentation difficulties also is common to other companies in that it is difficult to find the time [10],[12] to prepare and maintain all of the necessary documentation. In fact, this is the number one reason given when explaining any problem.

In order to become certified, a company needs to accurately document both the way it does business and its approach to quality. However, companies only need to document procedures relating to the elements of the ISO 9000 standard to which they are applying. The best principle to adopt is to document what you actually do and not what you think you do, or worse, what you once did [8].

Companies are attacking the documentation problem by training individuals to be accountable for documenting their area of responsibility. Additionally, companies are using internal audits to verify compliance.

There are two items tied for the next most difficult problem, "assigning responsibilities" and "creating an implementation plan". The respondents' solution to the first one is obvious:



management must define and communicate which personnel has responsibility and authority. But it appears that managers seldom take the time to do this. Again, time is cited as the main problem in creating an implementation plan. The respondents indicate that this can be resolved by gaining management commitment to spend the necessary time and by having the planners' responsibilities clearly defined. The literature, [12], supports the need for a lot of organized teamwork and time to plan the implementation.

The next most difficult problem also has a two item tie: "performing verification activities" and "training personnel". Time is referred to as the main reason for both. But performance is also cited as a reason for "training personnel". The respondents indicate that managers need to define the necessary verification activities and means of measurement for their areas. Respondents cite the need for continual reinforcement in training. This can be expected as the initial enthusiasm of implementing a new system gradually decreases [10]. It is also consistent with the Total Quality Management concept of continuous improvement [7].

Technical problems are indicated as the main reason for difficulty in the next three items, "maintaining supplier performance", "reviewing supplier contracts", and "controlling non-conforming product". The respondents indicate that a proactive procurement program including training and supplier audits along with using innovative techniques, such as a "new" software package, can resolve these supplier issues.

Obtaining top management commitment is low on the list of difficulties. This may be explained by the fact that all of the respondents are either certified or in the process of becoming certified. Companies typically cannot undertake a large effort like this without management's prior commitment [10]. However, respondents cited the need to educate management in how implementing ISO 9000 will lead to greater customer satisfaction. Once customer oriented managers understand this, it is easier for them to make the necessary commitment.

The last two items on the list are "maintaining and controlling test and measurement equipment" and "monitoring and controlling customer supplied product". Simply assigning a responsible person can resolve the maintenance issue. Apparently, the respondents feel that if the other problems are resolved that there will be little cause for any additional monitoring of customer supplied product.

## STATE OF QUALITY SYSTEM VS. DEGREE OF DIFFICULTY

Most responding companies rate the state of their quality system before ISO 9000 as between being greater than Military Standards but less than ISO 9000 Standards. Most of the rest rate themselves below Military Standards. We wondered if there is any correlation between the state of the company's quality system and the difficulty that the company perceives in implementing ISO 9000. Exploring this further, we took an average of the degree of difficulty indicated for all items for each company and compared this to the initial state of the company's quality system. The results are as expected. The companies that rate themselves as having a better quality system think that it will be easier to implement ISO 9000 than the companies that give themselves a lower rating.

## SUMMARY AND CONCLUSION

In general, the results of the questionnaire are typical of what was discovered in the literature. The primary reasons for implementing ISO 9000 are to sell in Europe, gain competitive advantage, and to improve quality.

The point that ISO 9000 has not yet been fully accepted by Japan could give certified U.S. manufacturers an advantage in selling to Europe. It is important for U.S. manufacturers to investigate this strategy and to act quickly, since Japan could probably implement ISO 9000 rapidly if it so chooses.

The time necessary to establish and maintain documentation was the main problem cited by the respondents. Since ISO 9000 requires documenting a company's business and quality practices, this concern is easy to understand. But once implemented, companies find that the amount of work decreases dramatically [12].

The companies' responses show that while implementing ISO 9000 may require much time and effort, that implementation is nothing more than following good common business practices. That is, organize and set goals at the highest level, assign responsibilities and implement at the local level.

The results, while interesting, cannot be taken as absolute solutions to the problems of implementation. One contributing factor is that we only surveyed a small number of manufacturers and the responses may not be applicable across all industries. Another factor is that most of these manufacturers were in the planning stage. Therefore, their responses may have been more conjecture than fact. We would have had a higher confidence level in the results if we had surveyed more companies that had completed certification.

An interesting project might be to contact the responding companies in a few years, to see how many have completed ISO 9000 certification. Comparing the actual problems that they experienced during implementation to their perceived problems prior to implementation would be valuable information.

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