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ABSTRACT

AN INTEGRATED APPROACH TO IMPLEMENT ISO 9000 SERIES STANDARDS TO UNITED STATES MANUFACTURING INDUSTRY

by
Jatin Amin

Implementation of ISO 9000 series quality system standards to the U.S. manufacturing industry is discussed by developing a generic model for implementation. In recent past, quality became a prime performance issue to formulate strategy to improve market share and profit for U.S. manufacturing industry. Many companies seeks for ISO 9000 registration. Manufacturing industry and other industries as well, are facing numerous problems in implementing ISO 9000 quality system standards. At present, about 400 U.S. companies have gained certification under this standard.

In this work an attempt has been made, to highlight problems which are most likely to be critical to most organizations. Also implementation procedure and guidelines are developed for quick and easy certification or registration to ISO 9000 series standards. Standards are discussed for its proper use and shortcoming of the standard narrated for future research and development of the standards.

AN INTEGRATED APPROACH TO IMPLEMENT ISO 9000 SERIES STANDARDS TO UNITED STATES MANUFACTURING INDUSTRY

by
Jatin N. Amin

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APPROVAL PAGE

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This Thesis is dedicated to
my Grandfather

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CHAPTER 1

INTRODUCTION

1.1 Quality

During late 1980's quality became a global performance issue and recently lot of companies are marketing their products as quality products to win the market shares. U.S. industries were not aware of the quality till recently.

At present lot of companies are formulating their business strategy on the grounds of quality, to improve market share and profit. U.S. manufacturing companies are making their efforts to improve product quality and services. It is important to improve quality continuously to remain competitive. The overall program of this continuous improvement of quality and services and to manage quality is known as Total Quality Management (TQM).

Quality revolution occurred because companies could not exist, prosper and grow by putting up with the inefficiencies that come from the price of nonconformance, rework and warranties. One has to get the cost down by learning to do things right. It is important for growth of any company.

Quality has different definitions like:

Do it right the first time.

To meet design specifications and requirements.

According to Juran, fitness for purpose or use.

Global competition, continuous pressure for better products at lower price, and scientific and technical development lead to consider the issue of quality.

According to ISO 8402 Quality is defined as " The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs"[1]. In last few years the concept of quality has evolved to recognize

the importance of satisfying an organization's many stakeholders, including community, suppliers, shareholders, employees and management.

1.2 Global Competitiveness

Competitiveness means - how companies regain, ensure, and improve market share. In other words it is company's ability to compete in world markets. In 1983, President Reagan established the President's Commission on Industrial Competitiveness, to study ways to improve competitiveness, the commission's 1985 report states that : "America's competitive preeminence in world commerce has eroded over past decade. We are being challenged in the trading arena by our European trading partners and industrializing nations in Asia and Latin America. Sustaining America's competitiveness is important for maintaining our standard of living, our foreign aims and our national security." Competitiveness is the basis for a nation's standard of living. A company can be defined as competitive if, it can produce products or services of superior quality at lower costs than its domestic and international competitors.

1.3 Standard Practices to Improve Quality

There are some standard practices used by the industries to improve quality and to gain market share are :

1. ISO 9000 registration.
2. Department of Defence Guidelines. (DOD)
3. Deming's Program.
4. Juran's Philosophy.
5. Crosby's zero defect program.

From these ISO 9000 is most widely and internationally accepted tool for the quality assurance.

ISO 9000 is international conformity standard for quality systems established by the International Organization for Standardization (ISO, Geneva). It has became a major focus in the U.S. industries.

1.4 ISO 9000 Series Standards

The objective of this thesis is to study various aspects of ISO 9000 standard and develop an implenetation procedure for U.S. manufacturing industry. Main focus is on manufacturing industry in business of design, production and services.

The objectives to promote the standards are to facilitate international exchange of goods and services, develop co-operation in intellectual, scientific, technical and economic activities. ISO 9000 was first published in 1987 and is non-perspective, generic and largely based on BSI 5750; CSA Z 1.15; ASQC Z 299 and MIL Q 9858 A, standards.

It is set of five individual but related standards on quality management and assurance.

A company which wants to implement the quality program under ISO 9000 has to register by completing application form. A third party registration is done by registrar approved by Registrar Accreditation Board (RAB), Milwaukee.

Third Party Registration: It requires preparation of documentation, initial assessment, implementation and registration. There are several benefits of the registration such as reduction in second party audits by customers, use of registration as a marketing tool to demonstrate commitment to quality, and access to European market that requires quality system registration.

In order to be a certified manufacturer, a manufacturing system must get registered for ISO 9002 for production and installation. Recently more numbers of manufacturing companies are going for registration largely driven by customer demand.

1.5 Definition of ISO 9000 Series Standards

ISO 9000: Quality management and quality assurance standards - A guideline for selection and use [2]. Explains fundamental quality concepts; defines key terms; and provides guidance on selecting, using and tailoring ISO 9001, 9002 and 9003. ISO 9000 is series of standards that provides basic definition and concepts and summarize how to select and use other standards in the series.

ISO 9001: Quality Systems - model for quality assurance in design development, production, installation and servicing [3]. It is used to ensure conformance to specified requirements during design and development, production, installation and servicing. The most comprehensive standard in the series, ISO 9001 covers all elements listed in 9002 and 9003. In addition, it addresses design, development and servicing capabilities.

ISO 9002: Quality Systems - model for quality assurance in production and installation [4]. It is used when only production and installation conformance is to be ensured. It addresses the prevention, detection and correction of problems during production and installation. Most registrations in the industries are for ISO 9002.

ISO 9003: Quality Systems - model for quality assurance in final inspection and testing [5]. The least comprehensive standard; ISO 9003 addresses requirements for the detection and control of problems during final inspection and testing. It is the least detailed standard and requires only that conformance in final testing and inspection to be ensured.

ISO 9004: Quality Management and Quality System Elements Guidelines [6]. Provides guidance for the supplier to use, in developing and implementing a quality system and in determining the extent to which each quality system element is applicable. ISO 9004 examines each of the quality system element in greater detail and can be used for internal and external auditing purpose. It contains guidance on the technical, administrative and human factors affecting the quality

of products and services.

The other definitions of the terms used are as under:

Organization: A company, corporation, firm or enterprise whether incorporated or not, public or private.

Company: Term used primarily to refer to a business first party and purpose of which is to supply a product or service.

Customer: Ultimate consumer, client, beneficiary or second party.

1.6 Roots of ISO 9000

British Standards Institute (BSI) produced BS 5750 specifically for the defence equipment sector in 1979. The U.K. government, concerned with industries' lack of international competitiveness, supported further development of the standards, which were initially popular in Engineering. The U.K. Chemical Industries Association and British Standards Institute Quality Assurance (BSIQA) adapted the standard so that, it could be used by industries. The resulting document, Chemical Industry Guidelines 2, BS 5750 was published in 1987. The same year, International Office of Standardization (ISO; Geneva) published the ISO 9000 series. In 1990 the European Community issued EN 29000 quality standard and EN45000 certification and testing standard to support its global approach to quality. EN 29000 is equivalent to ISO 9000 series and EN 45000 is equivalent to ISO 10010 series. ISO 9000 series standards were developed by ISO Technical Committee (TC) 176, which includes ISO 9000, 9001, 9002, 9003 and 9004. The standards were intended to be advisory in nature, primarily for use in internal auditing under two party contractual agreements.

Also, it can be traced back to the initial military quality standard MIL-Q 9858A. Almost all quality system standards in the world can be traced to MIL-Q ; since, it became the template of many commercial standards in regulated industries like safety, health and other core industries. It was used to evaluate

internal as well as supplier's quality systems. ANSI (American National Standards Institute) a private sector organization coordinates much of the voluntary standards development in the U.S. It developed Q 90 series standards which are the actual base of the ISO 9000 series standards and most of the definition in Q 90 standards are replaced with British English in ISO 9000 series.

CHAPTER 2

DEVELOPMENT OF STANDARDS

2.1 Historical Background

ISO is the International Organization for Standardization, and its objective is to promote the development of standards, testing and certification in order to encourage the trade of goods and services. The organization consist of representatives from 90 countries. Each country is represented by a standards body. ANSI (American National Standards Institute) is U.S. representative to ISO. It provides structure and mechanism for industry or product groups to come together to establish consensus and develop a standard.

ISO comprises more than 180 technical committees, covering many industry sectors and products . ISO Technical Committee 176 consist of quality experts that work with the international committee to draft, revise and word ISO 9000 quality assurance and quality management documents [16].

U.K. has BSI (British Standards Institute) for national standards development. BSI produced BS 5750 specifically for the defence equipment sector in 1979. The U.K. government, concerned with lack of international competitiveness, supported further development of the standards, which were initially popular in Engineering. ISO 9000 evolved from existing and widely used military quality standards such as MIL-Q 9858A, NATO quality standard, AQAP 1 and BS 5750. Almost all quality standards in the world can be traced back to these roots. MIL-Q also became the template of many commercial standards, especially in regulated industries such as safety, health, aerospace and nuclear. It was used to evaluate internal as well as supplier's quality systems. An important point is that MIL-Q evaluation was periodic quality auditing.

In 1987 ISO: Geneva published ISO 9000 series for quality system standards. The standards were intended to be advisory in nature, primarily for use in internal auditing under two party contractual agreements.

2.2 Importance of Standards

2.2.1 Basic Concepts

The standards have been used for years to communicate requirements, establish common units of measurement, facilitate interchangeability and interoperability, enhance product reliability and simplify products. The Aztecs, Egyptians, Romans, Assyrians, Greeks, Mayans, Aryans and others used standards to constructs temples, boats and aqueducts etc., many of which still exist today. The basic principle behind these early developments were common and consistent method for design, construction and measurement. Standards are basic element of society's economic and technological development. A standard can be defined as : "A prescribed set of rules, conditions, or requirements concerning definition of terms, classification of components, specification of materials; performance; or operations, delineation of procedures, or measurement of quality in describing materials, products, systems, services and practices" [12]. The important element of the standard is accepted set of rules, which are often developed in the area that deals with public safety and health. The trend was started in nineteenth century when fire, boiler and fastener standards were developed to prevent catastrophic failures and to preserve the well being of the society. The post war era consumer safety and product liability and environmental issues have come in to light. Chernobyl, Ozone depletion, Three mile island, Food carcinogens and product failure and other disasters had frightened people and prompted government surveillance and regulation. Thus, goodwill of public interest and safety of environment has served the purpose of development of standards.

2.2.2 Standard as Communication Tool

Apart from safety and health, the technical standards also serve other purposes like:

- improving product and process quality
- reducing product liability and litigation
- communicating requirement to stakeholders
- establishing common objectives
- communicating complex information in a simple, structured manner
- promoting compatible methods for testing products
- standardizing parts for production

Standardization of parts is essential for maintaining product interchangeability. When part is designed there is an iterative process to ensure that part can be manufactured. This becomes more complicated when parts are purchased from distant supplier whose quality is unknown and difficult to monitor. Therefore, engineers are designing new products with existing components to minimize iterations. Different types of standards such as policies, procedures and drawings are also means to communicate needs and requirements to manufacturing and external suppliers. Procedures communicate approved or suggested forms of behavior.

2.2.3 Standards - Tools for Development and Protection

Today people are more aware of customized requirements, due to global competition and some what due to media. No one knows the future trend in trade whether it will be free trade or managed or there will be trade war. However, many countries are creating trade barrier through tariffs, technical barrier or political barrier to protect the industry in the country. This can be done through duty or tariff on specific products to give added advantage to domestic producer. On the other hand, national standards or specifications become technical barrier,

by outlining type of material, dimensions, physical and chemical properties and other product performance characteristics. This also includes the type of required processes with which a manufacturer must comply before securing approval to sell its products in a certain country. Some economists see technical standards such as ISO 9000 as a potential non tariff barrier to global free trade. In other words countries and companies will require ISO registration as a condition of business. If all European countries put this as condition then it will create a closed European market. Which is not realistic, because about 25 % of EC's GDP (gross domestic product) is being exported. If this is the case then other developed nation will retaliate, resulting in trade war. Obviously no country will like to do that, so governments are trying to downplaying this scenario to maintain free trade. Many countries want to use ISO 9000 to defuse tension and criticism that, it is not playing fair by trying to restrict entry of imported products and goods. Also many countries wants to use it to maintain the free flow of products. Such trade war may put the world in recession. However, near future challenge is that rising trading blocs may promote free trade within the bloc and manage inter bloc trade. In free trade country like U.S. overseas manufacturer are dumping the goods at lower cost than the domestic manufacturer, as a result more and more U.S. companies are looking for options. On the other hand it is equally beneficial to U.S. companies to improve their product quality to regain the market share. One such example is U.S. automobile industry which is coming up again due to healthy competition.

2.2.4 Competitive Importance of Standards

Consensus among standards stakeholders has been key concept driving U.S. and EC standards development. Consensus is reached when most of the concerned individuals agree on the major issues and good-faith efforts are made to resolve differences. The voluntary consensus process of standards development works good for longer period but, in a highly competitive global economy problems

arise. U.S. alone can not dominate the rest of the world on this issue. Regional trading blocs, such as EC are developing their own standards that favor indigenous national companies. As the technology is advancing faster, the problems with consensual standards are becoming a major trade and competitiveness issue. Leadership and consensus is not coming out of the U.S. standards development community, so it is being used as a rationale for U.S. government involvement through the National Institute of Standards and Technology (NIST) and other agencies. The danger that U.S. faces is a loss of the competitive edge over their counterparts due to failure of leadership in the international standards development process. In the recent study of the Office of Technology Assessment (OTA) for U.S. congress, on what extent standards developments support the growth and competitiveness of U.S. economy in changing global environment. The report states that, [12]:

- Standards help determine the efficiency and effectiveness of the economy; cost, quality and availability of products and services; and the state of the nation's health, safety and quality of life.
- In an information-based global economy, standards are employed strategically as marketing tools and also to interconnect economic activities.
- U.S. voluntary consensus standards development process is not working because of a lack of cooperation and trust.
- Failure to bring American standards-setting organizations together and to work out their relationship with government is a very serious problem in dealing with other nations in the world where economic welfare through economic warfare are dominant policy issues.
- Paralleling the lack of unity in the private-sector standards community is a lack of coordination and policy making at the federal level.
- U.S. government has tended to disregard or underestimate other governments' efforts to use standards as a means to expand business, create market opportuni-

ties, or to enhance trade opportunities.

- Due to the process of accounting for all stakeholder views will become a global issue because of the rapid advance of technology, shift to a global economy, the rise of user groups and government involvement.

Thus, we can say that U.S. government has to initiate the formulation and development of rationale of standards and more involvement towards the development of the technical standards like other countries of Europe and Japan.

2.3 EC Standards Development

As the cold war with communism no longer exists due to fall of USSR, the EC countries are not concerned with their military security. Instead they are pursuing economic destiny and having realized the importance of the technical standards, they are now forming common economic market for competitive success. Often companies doing overseas business confront special or unusual marketing, manufacturing, design, performance, labeling, or packaging standards that are technically biased in their own favor. If offshore producers wanted to sell products in the U.S., they have to follow U.S. standards and technology. But now EC has emerged as the world's largest market and they are expecting to accommodate their standards. So its up to EC to adopt or defer to international standards as much as possible. The European perceive that U.S. companies are whining about the need to level the battle field. To lessen these tension, countries on both sides are trying to adopt international standards as acceptable means to assure their conformance. The European countries dominate the international standards groups. In fact they administer more than 70% of the ISO technical committee secretariats. Also many U.S. companies are concerned that EC will not allow access to CEN/CENELEC standards development.

Also EC dominates the ISO and regional standards committee, so with this influence, EC officials can defer to or accept ISO standards.

EC wants to create a harmonized system of regional standards that replaces many existing national standards. The idea is to have a company comply with one European or international standard in lieu of each country's national standards. This is known as New Approach Directives. EC directives are not technical processes and product standards, but they are policy documents [16]. Conformity Assessment is made for checking and assuring conformity to standards and specification and to get knowledge of the company's compliance to the standards. If this type of thinking is enlarged to encompass the world, a manufacturer will have to conform to only one globally accepted technical standard and be approved through a conformity assessment mechanism which includes ISO 9000 quality system audits.

2.4 U.S. Standards Development

Today approximately four hundred U.S. organizations have developed and adopted more than thirty thousand voluntary standards. These groups include trade association, professional societies, general membership organizations, third party certifiers and consortia of standards developers. U.S. government standards involvement has traditionally focused on areas of safety, health, environment, consumer protection, and in general areas that affect public welfare. Thus to large extent U.S. standards development reflects the cultural and political biases. U.S. standards development has also strong market and user focus. Standards were developed by experts and employees of the organization that wanted to input a standard's development. The goal of the U.S. standards activity was to develop consensual standards that would be widely understood, adopted and used. U.S. standards development in the last hundred years was managed by technocrats. These U.S. standards-making efforts were usually represented by the state of the art companies, so rest of the world reluctantly or happily adopted them and designed products consistent with U.S. standards. This unilateral approach and

practice was restricted when EC and other countries started developing their own technical standards with little input from the U.S.

2.5 ISO 9000 Standards Development

ISO 9000 evolved directly from market need to obtain greater assurance that products conform to technical requirements. Customer requirements are not consistently met by technical specifications which details dimensions, materials, test, performance, reliability etc. If there are deficiencies in upstream system, like in design, manufacturing, or in service specifications then it may may cause deficiency in the output. ISO 9000 can be traced to military quality standard MIL-Q 9858A. By the late 1970s many European countries developed quality standards that followed the NATO AQAP 1. In 1979 BSI published BS 5750. Each countries has its own designation as under:

Table 1 Equivalant Standards for different countries compare to ISO 9000

International	ISO 9001	ISO 9002	ISO 9003	ISO 9004
European	EN 29001	EN 29002	EN 29003	EN 29004
United States	(ANSI / ASQC) Q 91	Q 92	Q 93	Q 94
Netherlands	NEN 2646	NEN 2647	NEN 2648	NEN 2650
United Kingdom	BS 5750 Part 1	BS 5750 Part 2	BS 5750 Part 3	BS 5750 Part 0, Sec. 0.2

Due to changes in political and economical scenario and need for global market place as well as harmonized quality standards, ISO formed a technical committee, TC 176 to develop an international series of standards. TC 176 comprises of 29 active participating countries and 29 countries as observer. The designations of the standards are problematic and result in confusion among

laypeople who must understand, use and comply with the standard.

The reality is that ISO 9000 needs lots of interpretation by the user and assessor. It should not be considered as final solution, but just as basic concept for given situation to which it is being applied.

CHAPTER 3

EXPLANATION OF ISO 9000 SERIES QUALITY SYSTEM STANDARDS

3.1 Analysis of Standards

3.1.1 Existing Standards

ISO 8402 : Quality Management and Quality Assurance - Vocabulary

ISO 9000 : Quality Management and Quality Assurance Standards - Guidelines for Selection and Use

ISO 9001 : Quality Systems - Model for Quality Assurance in Design, Development, Production, Installation and Servicing

ISO 9002 : Quality Systems - Model for Quality Assurance in Production and Installation

ISO 9003 : Quality Systems - Model for Quality Assurance in Final Inspection and Test

ISO 9004 : Quality Management and Quality System Elements - Guidelines

3.1.2 New Standards

ISO 9004-2 : Quality Management and Quality System Elements - Part 2; Guidelines for Services

ISO 9000-3 : Quality Management and Quality Assurance Standards - Part 3; Guidelines for the Application of ISO 9001 to the Development, Supply and Maintenance of Software

ISO 10011-1 : Guidelines for Auditing Quality Systems - Part 1; Auditing

ISO 10011-2 : Guidelines for Auditing Quality systems - Part 2; Qualification Criteria for Quality System Auditors

ISO 10011-3 : Guidelines for Auditing Quality Systems - Part 3; Management Auditing Programs

3.1.3 Work in Progress

ISO 9000-1 : Revision to ISO 9000

ISO 9000-2 : Quality Management and Quality System Elements- Part 2; Guidelines for Implementing ISO 9001, ISO 9002 and ISO 9003

ISO 9000-4 : Quality Management and Quality Assurance Standards - Part 4; Application for Dependability Management

ISO 9004-1 : Revision of ISO 9004

ISO 9004-2 : Quality Management and Quality Systems Elements - Part 2; Guidelines for Services

ISO 9004-3 : Quality Management and Quality Systems Elements - Part 3; Guidelines for Processed Materials

ISO 9004-4 : Quality Management and Quality Systems Elements - Part 4; Guidelines for Quality Improvement

ISO 9004-5 : Quality Management and Quality Systems Elements - Part 5; Guidelines for Quality Plans

ISO 9004-6 : Quality Management and Quality Systems Elements - Part 6; Guidelines for Configuration Management

ISO 10012-1 : Quality Assurance Requirement for Measuring Equipment - Part 1; Metrological Conformation System for Measuring Equipment

ISO 10012-2 : Quality Assurance Requirements for Measuring Equipment - Part 2; Measurement Assurance [11].

3.1.4 Overview of ISO 9000 Series Standards

As ISO 9000 series stresses quality documentation, it becomes foundation for total quality and continuous improvement effort. ISO 9000 certification rests on

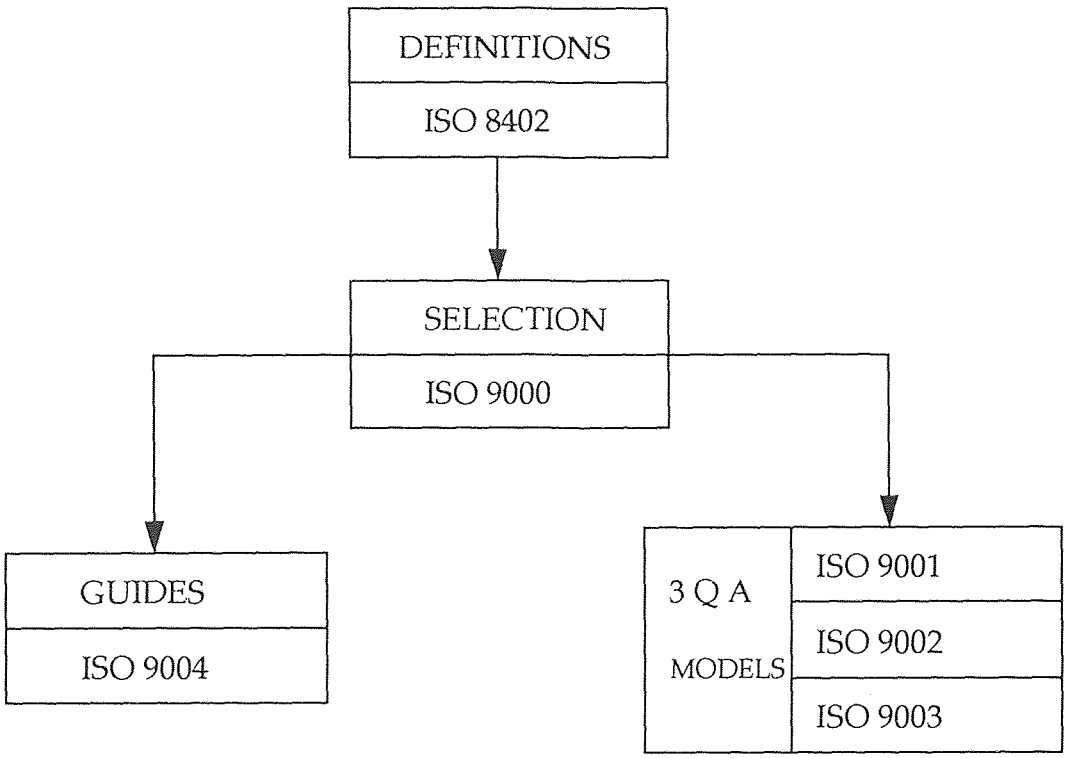

Figure 1 Selection of ISO 9000 Series Standard.

conforming or complying with particular ISO 9001/9002/9003 series requirement. The two major level of requirements are, organizational policies and procedures. Documentation regarding operation called as workmanship standards is also required as third level of requirement. The quality auditor checks these documents to ensure that policies and procedures are being followed correctly. ISO 9001/9002/9003 facilitate customer-supplier communication, co-ordination and cooperation. The quality systems documents provide "shall" instructions to external suppliers in ISO 9001/9002/9003, and indicate "should" instructions for internal quality assessments in ISO 9004. The ISO 9000 series is written generically so, it can be applied to a wide number of industries. Therefore, each standard is open to interpretation. ISO 9000 is for guidance purpose only and to assist companies in the selection and use of the other standards in the series.

Figure 1 shows the general outline of the standards. A major difference between ISO 9000 and other standards is its range of application. A relationship diagram is shown in figure 2.

In the series all the standards are mutually related. It can be seen from the figure that ISO 9003 is subset of the 9002 and 9002 is the subset of the 9003. In other words ISO 9001 incorporates all the requirements contained within ISO 9002 and ISO 9003. Many grey areas exist in choosing the correct standards, ISO 9000 provides the guidance for correct selection of the standards.

3.2 Requirements for ISO 9000

3.2.1 Registration Requirements

Registration may be demanded by customers, competition, for business improvement or may become necessary due to global trade compliance. If the supplier is audited for ISO 9000, then it is easier for the customer as well as

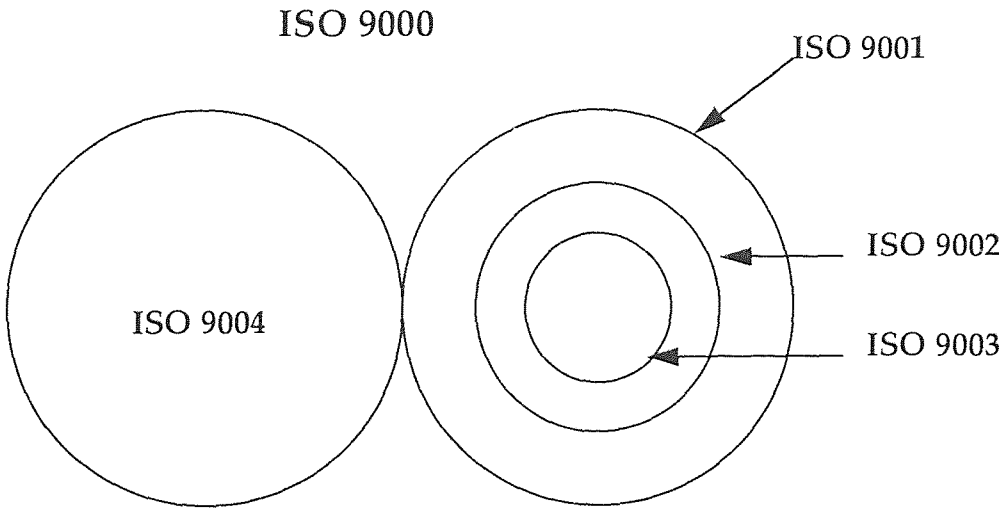

Figure 2 Relation between the standards.

supplier to provide desired quality products and to save time. ISO registration is the major assurance mechanism for assessing conformance to the customer's requirements. Materials from certified suppliers do not require inspection of all incoming material. This also encourages subcontractors to get certification for their organization so as to ensure that products meet requirement. The basic necessity is commitment of customer and supplier towards achieving their respective goals through registration, which is important factor to condition for partnering for quality.

3.2.2 Systems Requirements

There are three major requirements for the quality system registration and are as under:

Self Certification : The supplier shall attest the product quality that, it will be universally accepted and will be faultfree as well as meets specifications and customer needs. Usually supplier supplies subassembly to customer and in that case requirements and design are provided by customer. Then it becomes supplier's responsibility to deliver quality product which will not require any inspection or testing at customer's facility.

Product Certification : It is based on inspection of products at the customer's facility for the trial batch or lot of the first run off the product line for the evaluation purpose only. This is generally carried out to ensure that the quality systems are in place. This enhances the interchangeability of the product in global market.

Quality System Registration : Suppliers are responsible for the quality of their products. Also, they have to maintain the quality all the time and once the quality system is documented then, it is supplier's responsibility to keep the system working properly. Subsequent quality audits are only for the

verification process and once the quality is documented it is no longer inspected. Generally quality audits are performed periodically to ensure it satisfies customer's needs and serves purpose of quality assurance in the system. It also enhances organization's efficiency and productivity.

3.3 Explanation of ISO 9000 Standards

In ISO series ISO 9000 and ISO 9004 are guidelines for the selection and use of the other standards in the series. It does not contain any specific requirements with which supplier has to comply.

ISO 9000 provides guidelines for quality management and quality assurance standards. It serves purpose of the selection of standard in the series for which supplier would like to have registration depending on type of business of a company.

ISO 9004 provides guidelines for the quality management and quality systems elements. It shows what the organization's goals are?; what are customers needs and expectations?; what are risk considerations and cost benefits to company and customers? etc.. Further, it also provides guidance for what are management responsibilities to observe quality systems principles, how to structure quality systems and organization, indicates the usage of resources and personnel. It also provides the outline for the documentation required to operate quality system effectively and to maintain quality records. The guidelines also include usage of each system element in the quality system such as selection of suppliers, quality in procurement, quality in production, product verification, control of measuring and testing equipments, nonconformity and corrective actions, and usage of SQC techniques.

3.4 ISO 9001 Quality Systems Standard

Model for Quality Assurance in Design, Development, Production, Installation

and Servicing. This standard is used for external quality assurance. It is used generally in normal form but under special condition and requirement it is tailored to contractual situations. Quality system elements of ISO 9001 are as follows:

3.4.1 Management Responsibility

3.4.1.1 Quality Policy

Quality policy must define objectives for quality system and state commitment to quality. It should also define objectives pertaining to quality, quality policy as decided by the management and be implemented to entire quality system at all possible levels. The quality policy must be understood throughout supplier's organization. Commitment is made in the form of a pledge to pursue quality objectives for continuous improvement. Objectives and commitment constitute minimum requirement for the quality policy such as, improvement of performance, customer satisfaction, continuous improvement of quality and safety.

3.4.1.2 Organization

Responsibility and authority : An organization diagram (Chart) showing key personnel and their responsibilities and interrelation is most effective way to define organization structure including detailed quality assurance and quality control activities. Procedure dealing with specific actions should define the authority and responsibility of personnel concerned with these actions. These responsibilities can be documented directly in the procedures to avoid any conflicts. Personnel responsible for verifying system and product compliance to management policies and procedures are also responsible for verification of resources. Suppliers can define their own verification methods and needs. Quality systems auditing shall be supported by an independent individual.

3.4.1.3 Management Representative

Management representative is responsible for maintaining and ensuring ISO 9001 quality system registration. Representative may be a quality assurance Vice President, Director or Manager. However standards do not require a full time quality assurance (QA) person. Main role of the representative is to acheive quality system compliance under registration. One of the main reasons for requiring management representative is to satisfy customer that supplier's facility is equipped with quality personnel who are responsible for the quality organization. If there is a management representative appointed in the organization then, his/her responsibilities must be defined and properly documented.

3.4.1.4 Management Reviews

Management must be obligated to periodic review of quality policies, procedures and overall quality system for the effectiveness of the quality system. These reviews should be totally different from internal audits. Besides review of quality audit results, the primary objective is to revise system in response to changing markets, technology and other conditions. Records of results shall be maintained for future use. The review covers complete current and accurate specifications, application of procedure, quality manual completeness and corrective action effectiveness. Management reviews quality plans, tactical plans, procedures and benchmarking to improve operational effectiveness of the organization.

3.4.2 Quality System

Quality system must comply with the standard and be documented and implemented. Organization should keep records and maintain personnel of quality system to ensure external and internal customer satisfaction through

cost competitive quality products and services. Compliance is achieved when requirements of other sections of the standard are addressed. Implementation is assessed against the system documentation, which includes quality policies, procedure, work instructions and regulating quality system in accordance with requirements of the standard. ISO 9000 should be used as a base to accommodate any specific requirements of other quality system standards to ensure operational consistency and prevent nonconformances. The goal of quality system planning is to satisfy customer through delivery of quality products and services.

3.4.3 Contract Review

Supplier must assure himself that, the purchaser's requirements have been well understood and defined. To ensure contractual quality, documentation shall be periodically reviewed for things such as purchase order, process and product specifications, quality plans, control and capabilities requirements. New and modified products should be reviewed to assure requirements are defined and understood and new requirements can be complied. Verification can be made by inventory and delivery schedule, financial capacity, material availability etc. Contract review must be planned, documented and recorded.

3.4.4 Design Control

3.4.4.1 General

Majority of quality features of a product are determined in the design stage. Designs should be controlled and planned throughout product development to ensure that specified requirements and needs are satisfied.

3.4.4.2 Design and Development Planning

Design activities shall be planned and documented. The design plan should

include design input and output variable, identification, interfacing, monitoring and measurement to support the product development activities. Since design is an evolving process, the standard requires, to review the plan and update the design progress periodically

3.4.4.3 Design Input

Product requirements shall be identified and documented. Groups with specific expertise shall be identified. Design input requirements define the desired features and characteristics of a product.

The standard mandates that all, input requirements be reviewed and that any conflicting, incomplete or ambiguous requirements be resolved.

3.4.4.4 Design Output

Design output shall define the product, instructions for how to manufacture it and provide evidence of compliance with customer requirements by defining process and product requirements, classifying and prioritizing product attributes and acceptance criteria.

3.4.4.5 Design Verification

Design verification addresses the design input requirements. It involves design reviews, reliability testing, alternative calculations and comparison with similar design of competitor. Demonstration and independent analysis should also represent other issues of interests such as safety, health, marketing, production and services. All design activities shall be planned and documented for reviews and assessment purpose.

3.4.4.6 Design Changes

Design modifications, changes or revisions shall be initiated and approved

through proper channels and same may be described in relevant procedures in subsequent documentation. Thus, system of design changes should be closed loop for identification, documentation and verification purpose.

3.4.5 Document Control

3.4.5.1 Document Approval and Issue

Documents must be authorized and made available at locations of their use. Quality system should include issue, approval, distribution and modification.

3.4.5.2 Document Changes / Modifications

Documentation changes and modifications shall be recorded to ensure prompt action. This can be achieved by decentralizing the system. It is pertinent to mention here that, no one should change the documents without prior approval of the appropriate authority. A change brief shall be included in new revision and identify new revision and distribution.

3.4.6 Purchasing

3.4.6.1 General

This requirement emphases on product description and contractor's qualification. This implies that, subcontractor should also have quality system in operation equivalent to the purchaser.

3.4.6.2 Assessment of Subcontractor

Subcontractor selection criteria shall be based on product type, past history, self assessment, process control, product inspection and testing. Quality system auditors will look in to the process of selection by reviewing and deliberating that, selection was made on the basis of acceptability criteria, methods, and assessment of product and processes.

Approved list of vendor (subcontractor) shall be available in the purchasing department. Supplier shall be responsible for effectiveness of its vendor's control.

3.4.6.3 Purchasing Data

Product shall be clearly described and all quality verification related to requirements should be stated on purchase order. Purchasing information and documentation should be encouraged to implement ISO 9000 systems. Also, purchasing documents should be approved prior to their issue.

3.4.6.4 Verification of Purchased Products

Quality system representative must review and approve all customer and supplier documentation throughout product development and product life cycle. Customer's requirements shall be described in documentation specifying type of service, type of material and level required, delivery requirements, cost, performance requirements, corrective actions and other related data.

3.4.7 Purchaser Supplied Product

Purchaser must be notified of any damage, defect or loss of his product. Procedures shall be established for specifying, identifying, transporting and storing purchased materials. Materials shall be stored and handled according to standard approved procedures. Statement addressing requirements of any section should be included in the procedures dealing with inspection, product identification and nonconformity.

3.4.8 Product Identification and Traceability

Identification of material and product and its design shall be established throughout the production, installation and product life cycle. The

identification required is in the form of drawings and specifications. Identification procedure must be documented. Traceability is required for in-house and purchased material, which are needed to be traced during product development. It is also required that, if unique identification is specified by customer or third party, it should be included in the documentation. At documentation and implementation levels, identification of product is required from drawing and during all stages of production.

3.4.9 Process Control

3.4.9.1 General

All general processes including any production, manufacturing, service activity or organizational process shall be controlled. Thus meaning of processes is very wide and can be applied to particular process when it is documented specifically. Process control also applies to engineering, purchasing, marketing activities, documentation, processes, statistically controlled equipments, work instructions and product characteristics etc. Production plans must be documented, which include inputs, components, manufacturing processes, inspection points and product flow. It is advisable to post traveller (tag) accompanying the product for documenting and communicating the production plan. The plan must define, document and communicate all manufacturing processes and inspection points to ensure proper flow of material and processes. Production environment is often a problem due to rapid change in technology so, production must be carried out in suitable and controlled environment by monitoring processes and instruments. This leads to checking, calibration and proper maintenance of the process equipments and machines. Other important aspect of this section is workmanship; if required and applicable, criteria for workmanship standard should be defined.

Workmanship standard helps in achieving required quality and consistency. This may be available in written standards, specimens and samples. It requires to issue work instructions and process procedures and same must be followed during production.

This section addresses important area of the production but, it is brief and general. This may be a weakness of the standard.

3.4.9.2 Special Processes

Special processes must be monitored and performed in accordance with written procedures. Special processes are those that are operator dependent. Process control requirements shall be defined for all process variables. Output of special processes must be monitored to ensure that it complies with specifications and instructions. Records of the special processes shall be maintained for future use.

3.4.10 Inspection and Testing

3.4.10.1 Receiving Inspection and Testing

All received materials and components as well as final product must be inspected according to documented procedures to ensure conformance to specifications. All materials and components that are to be incorporated in final product must be verified. If material is not inspected then, certification of compliance shall be required from the supplier. Also material from certified supplier need not be inspected. Supplier can define special verification needs and same should be documented in procedures or quality plans, if required. Quality personnel shall be responsible for generating inspection reports and quality documentation.

Reports of evaluated products from quality and engineering departments shall be communicated to purchasing department for supplier's approval. Engineering, Manufacturing, Quality and Purchasing departments

must sign off first evaluated product results and on acceptance, an approval document shall be generated.

A joint waiver from all these departments is required in case of emergency requirement of material. There must be a provision for preventive measures in the system to eliminate entry of nonconforming items or rejected product in to the production line. Uninspected material may pass in the production with exception, if product recall is possible.

3.4.10.2 Inprocess Inspection and Testing

Inprocess inspection points must be identified in a flow chart or similar document. The standard does not mandate any intermediate inspections nor provides any guidelines for it. Inprocess inspection must be credited to the mandatory final inspection. Inprocess inspection shall be identified and purpose must be documented. Document also identifies type of inspection, product characteristics, methods and equipments.

3.4.10.3 Final Inspection and Testing

The purpose of final inspection is to verify all previous inspections. The inspection points must be identified in a flow chart. Whenever extensive inprocess inspections are implemented, the final inspection shall be carried out. This should be part of the quality plan and must be defined and properly documented including scope of inspection. Since, final inspection is mandatory, finished products awaiting for final inspection shall not be dispatched.

3.4.10.4 Inspection and Test Records

Every inspection must be recorded and test records shall be maintained indicating conformance or nonconformance. The format used for record should be authorized and used consistently.

3.4.11 Inspection, Measuring and Test Equipments

All equipments for verification or inspection of material or product should be controlled, calibrated and kept in working condition. During product development, characteristics shall be identified and documented for inspection and testing purpose, also equipments used therein must indicate the characteristic of product accurately and precisely. Verification instruments used should ensure consistency in measurement capability. Required accuracy of the measurement must be known and selected equipment should be capable of achieving it. Accuracy checks must be made concurrently with calibration. Also any calibration performed on equipment shall be recorded and documented.

This section also addresses to specific requirements of the equipment, there should be proper identification of equipment; documentation of calibration date, frequency, authority and accuracy; and evaluation of calibration process. Absence of such document may lead to noncompliance of standard. The most common noncompliance found in the industries is lack of checking and certifying jigs and fixture, templets and patterns used for inspection.

3.4.12 Inspection and Test Status

Identification of inspection and test status must be carried out throughout the process to inform next processing station about the authorization of subsequent processing. Identification system used should include, segregation of nonconforming products and proper tagging of the nonconforming products. Identification system must be documented properly. Inspection status identification may include tags, color labels or marks as a record and proof of inspection.

Release authority for conforming products should sign and date products, lots and shipments.

3.4.13 Control of Nonconforming Products

Identification of nonconforming products in the production is important, as it can cause either misuse or contamination (in case of hazardous material) of production area. Nonconforming products must be identified, evaluated and disposed off according to the procedure, to avoid misuse of product or installation.

Thus handling of nonconforming product must be regulated and controlled and if required documented in procedures. Procedures relating to this section must demonstrate that nonconforming products are being prevented from subsequent processing once nonconformity is observed or recorded.

3.4.13.1 Nonconformity Review and Disposition

Responsibility of reviewing and authority for disposition must be defined and documented for nonconforming products. This is a must to avoid any safety related problem by detecting the defect. It is useful to divide possible types of nonconformities in different groups, to assign it to respective level of authority for easy and quick disposition. Nonconformity reviews must be regulated by procedures and nonconformities may be scrapped, reworked, returned to vendor (supplier) or regraded. The review system must be documented.

3.4.14 Corrective Action

The purpose of corrective action is to focus on root cause, eliminating the symptom and preventing reoccurrence. Corrective action must be initiated if, a nonconforming product, customer complaint or noncompliance is noted or

identified. Level of corrective action must be evaluated by considering risk potential associated with particular condition or problem. Thus corrective action system consists of detecting cause of defect, implementation of action and verification of its effectiveness. This may include correction of system, modification of design (product), change in equipment, revision of procedures or/and training of personnel. The corrective action system from initiation to result must be documented properly.

3.4.15 Handling, Storage, Packaging and Delivery

3.4.15.1 General

Procedures must be developed for handling and processing of products after final inspection and must be documented. Processing of product includes storage, packaging, shipping and delivery of materials or products. This is not a typical quality assurance operation or procedure but, purpose for defining is to provide protection of product during transportation.

3.4.15.2 Handling

Handling procedures ensure that material should not get damaged during production cycle. It enhances personnel and product safety by detailing special handling requirements. Each department responsible for the various handling processes should be encouraged to write and maintain its own procedures.

3.4.15.3 Storage

Storage areas should be adequate, secured and designated properly to control movement of materials and to prevent misuse and damage to the material and products. Material in storage must be periodically checked and assessed for deterioration. Storage procedures should also instruct personnel on maintaining proper environmental conditions.

3.4.15.4 Packaging

Packaging specification must be documented and designed to meet customer requirements, type of transportation and other factors. Packaging procedures must be approved and authorized.

3.4.15.4 Delivery

When delivery is specified as requirement in the contract then it must be audited against all the subsection of 3.4.15. Delivery applies to service organization. Delivery procedures ensure that material or products should not get damaged during internal as well as external transit.

3.4.16 Quality Records

Quality records of the product quality should be generated and maintained throughout the quality system. Major requirements of this section are, records must be identifiable, easily retrievable, correct and accurate, should be stored appropriately and secured. Also it should be retained for specific period of time. Compliance to these must be documented. Thus, it states that records are important to achieve and maintain product quality.

3.4.17 Internal Quality Audits

Effectiveness of quality system can be achieved by correct thorough internal audit of quality system requirements. Auditing of quality system leads to more effective and profitable operation. Quality audits should be prioritized based on the importance, cost and internal requirements. Auditing system should be comprehensive thus, all activities in the system should be checked for its effectiveness and compliance as per standard or documented system. This also includes product and material compliance. Frequency of internal audit should be specified in the plan for implementation and effectiveness of the system and

important activities. Quality audits must be conducted by independent, trained and qualified personnel.

Audit reports should be distributed to specified personnel as prescribed in the procedures. Audited areas may be reaudited, if required to evaluate efficiency, effectiveness and corrective actions. Audits must be concluded with written reports and any noncompliance should be followed up with corrective actions. Personnel responsible for nonconforming conditions should analyze the cause and must suggest proper corrective action.

3.4.18 Training

All training needs - education, seminars, in-class instructions, practical training, etc. must be identified and required training be provided to personnel involved in quality activities. Thus every employee should have education and training record. Training in respect to technological change should also be provided to all personnel. Training efforts should be evaluated and updated periodically. Operational heads are responsible for ensuring that training objectives are attained. System and activities related to training must be documented in procedures.

3.4.19 Servicing

As ISO 9001 is applicable to design, production and servicing it becomes important to interpret the servicing requirements. Service processes, systems and documentation should address to all service requirements such as, after sales services to meet customer satisfaction. Whereas normal activities include maintenance, change of worn out parts and items. Production of a service is required and desired while process is individual activity or function. If inspection and testing is a service then, it should comply in respect to specified requirements to meet customer satisfaction.

3.4.20 Statistical Techniques

Statistical techniques should be established for appropriate processes. Any use of statistical methods or sampling plans should be used to evaluate supplier's capabilities, costs and risks. Records of all such activities must be maintained to note the results of analysis and to pursue continuous improvement.

3.5 Other Standards of the Series ISO 9002, 9003

ISO 9001, ISO 9002 and ISO 9003 are successive subset of each other. ISO 9002 is applicable to production and installation thus, out of 20 requirements of 9001 only 18 elements are required to comply. Design Control and Servicing are excluded and rest are same as ISO 9001. This standard is widely used in the industries, in fact majority of the registration in the industries are for ISO 9002. It addresses to prevention, correction and detection of defects or problems during production and installation [4].

ISO 9003 is applicable to final inspection and testing and requires only 12 system elements. In other words it is subset of ISO 9002 as well as ISO 9001. In addition to Design Control and Servicing, other six elements excluded are Internal Auditing, Contract Review, Purchasing, Process Control, Purchaser Supplied Product and Corrective Action [5]. This standard addresses to detection and control of problems during final inspection and testing. It is least detailed standard and requires conformance in final testing and inspection.

3.6 ISO 9004 - Guidelines for Standards

It provides guidelines for the supplier, how to develop and implement quality system and also helps in determining the extent to which each element of system is applicable. It examines each of the elements in detail and can be used for internal and external auditing purpose. It focuses on key issues like management responsibilities, quality system principles, documentation of the

system, auditing of the quality system, selection of qualified supplier, product verification, control of production, how to achieve quality in design; production, procurement, personnel participation and motivation influencing quality [6].

In short it gives comprehensive guidance on the technical, administrative and human factors affecting the quality of products and services. It also addresses the goals of company, customer needs and expectation, cost and risk considerations benefits of participating in quality system.

3.7 Use of Standards

The standards are very generic in nature ("one size fits to all ") so, it is very important to select appropriate standard by analyzing functional criteria, type of production or services (See Table 2). Also standards are not easy to implement in to specific process or system. However, it can be applied broadly and fine tuned to specific application easily if company already has quality program, as quality terms and concepts are widely accepted in quality domain. The main purpose of the quality series standards is for a company to be able to establish quality system, maintain product integrity and satisfy customer. Over and above the functional criteria for selecting standard other criteria to be considered in selecting appropriate standard are design capability, production and process capability, product safety, service safety, cost benefits and economics.

Driving forces for U.S. companies to register for ISO 9000 are global competitiveness, emphasis on quality, emerging market of EC, universal acceptance of the standard itself, documentation of the quality system, continuous improvement of quality and commitment to the quality. All this

Table 2 Use of Standards

	USE OF STANDARDS		
	ISO 9003 12 Elements Requirements It is used for quality assurance in final inspection and testing.	ISO 9002 18 Elements Requirements It is used for quality assurance in production and installation.	ISO 9001 20 Elements Requirements It is used for quality assurance in design, development, production, installation and servicing.
1.	Management Responsibility		
2.	Quality System		
3.	Document Control		
4.	Inspection and Testing		
5.	Inspection, Measuring and Test Equipments		
6.	Inspection and Test Status		
7.	Control of Nonconforming Products		
8.	Handling, Storage, Packaging and Delivery		
9.	Quality Records		
10.	Training		
11.	Statistical Techniques		
12.	Product Identification and Traceability		
13.		Internal Auditing	
14.		Purchasing	
15.		Corrective Action	
16.		Contract Review	
17.		Purchaser Supplied Product	
18.		Process Control	
19.			Design Control
20.			Servicing

leads to registration of companies under ISO 9000. Two main considerations for registration are external and internal. Internal issues which affect the decision on registrations are improvement of efficiency, economy, coordination, effectiveness, customer involvement in ISO implementation. Whereas, external issues are customer requirements, competitor's program to meet the quality and design, and manufacturing of regulated products. These play important role to design and implement quality system that comply with ISO standards.

3.7.1 Types of Companies Seeks for Registration

Generally speaking there can be three types of companies who seeks registration for ISO 9000 :

First group consists of companies producing or involved with safety and health related products must meet ISO 9000 requirements if, they are in business with EC countries. Second group consist of exporting companies and their customers currently require or eventually could require ISO certification as a condition of doing business. Third group consists of companies that see ISO certification as a way to enhancing marketing strategies, if they like to enter in global markets.

3.7.2 List of Documents and Records

From the above discussion in 3.4, 3.5, and 3.6 we can outline list of records and documentation required under ISO 9001 for the certification.

List of documents required is as under :

1. Management policy statement - it should define and communicate all quality policies and goals of the company.
2. Organization charts defining authority responsibility and relation with personnel.
3. A written appointment of quality representative authorized by management.

4. Procedure defining review frequency and management reviews.
5. Procedure regulating contract review activities. It should also define customer requirements and needs.
6. Design and development plans showing; design activities, personnel assignment, design input and output requirements, organizational and technical interface and design verification.
7. Procedures to control and verify design.
8. Procedures for document issue, approval, placement and changes.
9. List of approved subcontractors, if any.
10. List of current revisions of all documents.
11. Procedures for verification of storage, and maintenance of purchaser supplied products.
12. Procedures for product identification and traceability during all stages of production, delivery and installation.
13. Production plan specifying all material, processes and assembly.
14. Equipment manuals, process producers, work instructions, workmanship standards.
15. Special process procedures.
16. Quality plan showing all inspection and testing .
17. Inspection and testing procedures and points of inspection.
18. Calibration procedures of equipments.
19. Status list of all equipments under calibration system.
20. Procedures regulating handling of nonconforming product including identification, documentation, evaluation, segregation and disposition.
21. Procedures for investigating causes for nonconforming conditions and initiating corrective actions.
22. Procedures for handling, storage, package and delivery.

23. Procedures for identification, collection, indexing, filing, storage, maintenance and disposition of quality records.
24. Internal quality audit plans and procedures of internal quality audits
25. Procedure for identifying training needs and providing training.
26. Procedures for performing and verifying services.
27. Procedures for use of statistical techniques to verify process capabilities and product characteristics.

List of records required is as under :

1. Record of management reviews.
2. Record of contract reviews.
3. Record of approved subcontractors and suppliers.
4. Record of damaged, deteriorated or unsuitable purchaser supplied products.
5. Unique product identification record when traceability is required and specified.
6. Records pertaining to qualified processes.
7. Inspection and testing records.
8. Calibration records.
9. Nonconforming product documentation (reports).
10. Documentation of nonconforming product disposition decisions.
11. Storage receipt and dispatch records.
12. Internal quality audit reports.
13. Personnel qualification and training records.

CHAPTER 4

REGISTRATION OR CERTIFICATION PROCESS

4.1 Chapter Synopsis

Once management decides or approves to implement ISO 9000 standard,it is not beginning of the process, actually it is only a decision. The actual work starts with pursuing for registration when quality system representative or person fully responsible for the implementation of standard is selected by management. Registration process is in three parts namely, preregistration or preparation, registration and postregistration. Preregistration and registration are deciding factors for certification. Postregistration is necassary to maintain the registration or certification once the process of registration and system audit are finalized.

Preregistration is like getting started or preparation work for scope of compliance and organizing team for the work to be carried out for assessment, audit and documentation. This is key point of preparation otherwise, efforts put in will not get desired level of output and satisfaction. Registration includes implementation of changes in the existing system then, reassessing by second or third party assessment to obtain registration. Whereas, postregistration includes implementation of recommended improvements, meeting postregistration requirements, correcting deficiencies to maintain registration. Since quality auditors can check the system under surveillance checking, it is utmost necessary to keep quality system monitored continuously. This also includes reregistration, if registration is suspended for some reason.

4.2 Preregistration / Preparation

The first step is to determine the scope of compliance, whether all sites or only one site is to be applied for registration. Similarly for one product or all of the products registration is required and under which standard. What type of the business company is doing? The selection of standard depends on type of business whether it is servicing, manufacturing or inspection and testing or all of these. Other part of preparation is to organize implementation team and training of team members/participants. And finally, using guidelines in ISO 9000 and ISO 9004, device the plan for initial assessment and implementation of system elements. The team so organized shall have to carry out preassessment or assessment of the existing quality system to identify gaps and develop plans to close or bridge these gaps. Other function of the implementation team is to implement changes in the existing system and reassessment of the quality system.

4.2.1 Scope of Compliance

It is important for organization to study and understand trends and areas in conformity assessment of standardization, specific to the organization or industry or businesses. A simple approach is by studying; whether countries are adopting ISO 9000 exclusively?; condition to entry, standard development and their validity to the future market.

The EC countries and others are developing the regulations, laws and standards that affects many industries such as environmental, packaging, labeling, product disposal and health and safety related products. So, it is obvious that any organization dealing with these countries must adapt ISO 9000 standards. In other areas of trend, it is likely that customer or their customer provides initial impetus or drive for ISO 9000 certification as

requirement in the contract or purchase order. If this is the case then registration becomes a condition for doing business.

Sometimes in supplier chain if manufacturer requires that all of its suppliers should be registered then also there is little choice. But, it is important to check the plans of successive supplier in the chain to avert any business loss. Here, it is important for company to check government agency's interest in industry or field whether, any comments are made on proposed rule making. This is also an early sign indicating to build up infrastructure for the quality system under ISO 9000. In the competitive world as well as domestic market, it is utmost necessary to understand the competition for conformity assessment and to get an edge or advantage over the competitor. In other words, it is being used as " from a market advantage to market necessity, domestically as well as internationally"[12]. Study of market growth and strategy should incorporate any future registration of ISO 9000 and possibility to improve business for competitive advantage. This early action leads to selfpromotion of quality and customer satisfaction.

Simultaneously, it is equally important to study and understand ISO 9000 standards and guidelines for proper application of the standards. Study of trends in the industry can be done by participation in group seminars, consulting registrars, auditors, customers, governmental agencies and trade/ industry groups. This gives better idea about the current trends in the industry and what other competitors are doing for achieving certification. This also helps to track conformity assessment and current developments in the standards which may affect the company.

For scope of compliance company should see [9]:

- Current trends in the industries
- Customer requirement and their customer's requirement if in suppliers' chain

- Competitors approach to deal with the issue
- Is it used as trade barrier, especially in EC?
- Industry requirement for doing business in certain countries
- Foresee need of requirement for registration
- Part of strategic planning for competitive advantage
- Government agency's initiative towards mandatory requirement

4.2.2 Organizing Implementation Team

Establishing a interdepartmental and multidisciplinary team to direct and implement the ISO 9000 series standards is important function. The pursuit of registration affects many organizational areas, processes, products and systems. The best way to prepare for registration is through a team. A multifunctional team can monitor all product check points from purchasing to distribution to customer service. Thus it should include quality, manufacturing, purchasing, marketing and engineering professionals. As need arises people from specific area, process or product with specific knowledge should be included. Apart from supervisors and managers in the team, people from lowest level, those who actually apply and use the procedures and system should be included to form a complete team.

As a whole functions of team or committee are [14]:

1. Support development of necessary documentation
2. Monitor implementation
3. Provide resources
4. Report periodically to management
5. Share learning experience with others
6. Participate in internal quality audits.

All the team members should be trained and educated for ISO 9000. If

required they should attend a lead assessor's or lead auditor's seminar. The advantage of attending seminar is that, it shows how quality system works and audits are conducted. It is important while selfassessment or initial assessment is carried out for the organization. Primary objective of the team is to assess existing quality system and identifying gaps in the system for ISO 9000 registration by developing plan. To evaluate different elements in the system a team within the team should be formed. This helps in carrying out evaluation simultaneously and independently. All these teams should also be responsible for respective implementation of changes and documentation of the systems' elements.

4.2.3. Developing Plan for Initial Assessment and Documentation

Registration requires organizational commitment, resources and efforts. Like any project, it follows a project plan. The plan should define objectives, timeliness, responsibilities, costs, constraints to overcome, resources and schedule requirements. It should also emphasize on the registration, direct auditor, consultation, registration cost and opportunity costs. Although it is difficult to derive estimated internal and external costs of ISO certification, it should give an idea about what changes and implementations are required about external and internal quality system.

The initial preassessment compares what is being done against what should be as specified by the ISO standards. It compares existing quality documentation and quality system against the specific requirements of ISO 9000.

Initial assessment can be carried out to :

- Compare ISO 9000 with what is written.
- Compare what is written with what is done.

- Compare the ISO 9000 with what is done.

The results or outcome of these assessment give an idea about how far one should proceed in implementing system and processes to satisfy requirements.

In general initial assessment identifies :

- Where the quality systems stand - identifying baselines
- Where to go - identifying benchmarks
- How much will it cost? - identifying time lines

The result of assessment identifies the gaps and deficiencies in the system. These deficiencies and gaps should be listed and corrective action should be devised to eliminate both. Quality documentation should be provided for the compliance purpose to the auditor if available, and if not, then quality system documents should be written and upgraded to meet ISO 9000 requirements and criteria. This provides opportunity for the organization to evaluate and modify quality system without major expense of audit at supplier's facility.

A second audit, identifies process cycle or loops such as product development process, production process, and product life cycle etc., and for each cycle following questions should be addressed :

- Are external customers requirements identified?
- Are requirements consistently followed?
- Are internal customers satisfied?
- Are internal processes benchmarked, measured and improved?
- Are requirements proceduralized and operationalized?

4.2.3.1 Advantages of Preassessment

Initial assessment will : 1. Verify if the organization is ready for the audit

2. Increase confidence in passing of the audit
3. Establish baselines from which to measure improvement
4. Identify resources to pass audit
5. Identify benchmarks for continuous improvements
6. Cost less than a formal auditor pre-certification audit
7. Provide time to design system and process changes

4.2.3.2 Documentation

Good quality system documentation is one of the key elements to pass the quality audit. Quality system should be detailed in quality documents. Since, ISO 9000 audits are unique in nature, the auditor requires documentation, to know whether it is quality document or manual. Main aim of the auditor is to corroborate and verify what is documented is really done. If there is no documentation then there will not be any audit. Main purpose of the documentation is to ensure customer concerns are defined and conveyed internally and quality systems are developed and operationalized. The challenge is to develop sufficient procedures so that ISO 9000 quality system elements are addressed. It is important that documentation should be worded carefully. Catch phrase is " Document what you do and do what you document"[10].

According to Les Schnoll of Dow Corning: " when you document your quality system, you should never use the words 'all' or 'never'"[10]. Hence, it is important that procedures should be developed and written by quality staff, line personnel or consultant, with interdisciplinary teams from affected areas. Also this helps in overcoming cynical attitudes. An outside consultant also advises the team in writing internal procedures that conform to ISO 9000 specifications. The task of the team should be to adapt what is currently done

and what is required by ISO 9000. It is easy to write down procedures which are already in use and then fill up the gaps to make them ISO proof. There are possibilities that some of the ISO 9000 systems' requirements may be already in practice, under different names and procedures if so, the same should be adapted. This speeds up the process by eliminating the need to train personnel in new system.

Following are tips or points for developing a good quality documentation [12] :

- Key the documentation in the manual to the specific ISO 9000 section
- Do what you say you are doing
- Develop documentation for what is required in the ISO standard and for ensuring process quality
- Develop levels of documentation in a large facility

A three tire document system should be adapted

A three tire system essentially answers the questions what?, who? and how?

- Use standard documentation forms as often as possible
- Use existing procedures as much as possible
- Write concise, accurate, and complete procedures and documentation which are easy to understand and to use

Table 3 A three tire quality system documentation

Company Quality System Manual (WHAT ?)	Broad Quality Policy Statement
Facility Manual (WHO ?)	What needs to be done by whom and Procedures
Work Instructions (HOW ?)	How to do it ?

4.2.4 Evaluating Current Stage of Quality and Quality System

4.2.4.1 Quality Stages and Level

In the competitive global market, to survive in the business is the most important issue. However there are many reasons to lose business. In last decade lot of industries have lost business because they were lacking in quality such as, U.S. automobile industry, U.S. chemical industry, electronic appliance industry and many more. Till recently foreign manufacturers or companies were dumping their products in U.S. market at low price and better quality than their counterparts in U.S. This is the key issue. Many think that, to improve quality or to get some sort of quality stamping on the product is costly but, in long run it is not. Though in the initial stage investment is there, in long run the payoffs are higher. In many cases the potential increase in profit from the application of a well planned quality system are considerably greater than, those realized from doubling the size of the enterprise at current profit levels. Quality system implementation requires lot of efforts and money. Therefore, it is essential to check what is current stage of quality of the product before going to make any change in the system.

Quality of the product starts from the raw material. Raw material should meet specified requirements in order to achieve desired quality level in the final product. It may range from type of raw material e.g. plastic, metal, alloys etc. to characteristics of the material e.g. strength, elasticity, corrosive action, color, and recyclability.

Correct procedure and application of the process adds to the material to get final product which meets the requirements. Sometimes material may require to undergo special processes to get desired characteristics.

All these stages should be checked to find out, by comparing competitors' product, what extra advantage can be achieved. It is part of

benchmarking the product. After benchmarking the product, at what level changes are required can be evaluated and plan should be developed to implement these changes.

4.2.4.2 Evaluating Quality System

After checking quality level, next step should be evaluation and modification of operational systems and controls. One of the way is, use of statistical process control techniques, (see sect. 3.4.20). A company can stabilize operations and ensure that, it is capable of meeting requirements and specifications. This will lead to consistent operations, quality procedures will be kept accurate and updated, personnel will be trained and processes will be continuously observed and improved. It is essential to ensure that all processes are in control, capable, and improving. All these can be achieved by implementing S. Q. C. (Statistical Quality Control) techniques. Here, control means no unusual or abnormal process deviation, capable means the process is meeting requirements, and improving means process is continuously on target and becoming more uniform and showing less variation and control limits are getting closer to the mean. Whereever necessary and required, modify the internal quality systems and controls to increase chances for registration. This may include, modifying internal operations, procedures, controls, systems and even personnel to ensure uniform quality operation.

4.3 Registration

Registration process includes selection of registrar, auditors, application for certification, quality audit, planning and scheduling. The important point is in selection of registrar, as it is at the center of process so selection has to be made very carefully. After selection, the next step is to apply for certification in prescribed form so as to facilitate quality system audit by the auditor. Auditors,

basically check the procedures which are documented and see if they are being followed or not and whether requirement of the standards are met. Following the submission of application a comprehensive selfaudit should be conducted and discrepancies should be corrected. This helps in speeding up evaluation by accrediting agency and hence registration itself. A general flow chart of registration process including preparation is shown in the figure 3, [14].

4.3.1 Selection of Registrar

Selection of registrar should be done very carefully and in a nutshell one should look for :

- Background, reputation and creditability - check whether registrar had successfully certified the companies in the industry or not. If so, get report from these companies. Registrar should also understand and fulfill needs of the company.
- Registrar must be accredited or certified by the accreditors. Registrar Accreditation Board (RAB) or other European accreditor. This way one can know his competence and reliability [18].

Like any purchase decision, registrar should satisfy quality, performance, cost and service requirements and ability to obtain registration as well.

Like any contract, terms and condition should be finalized before entering in to agreement. Concerning issues are scope of services, level of registration, consultation, availability contract terms, cost escalation, and confidentiality.

Scope consists of the type of services to the customer a registrar can provide and should include preassessment consulting, auditing and postassessment consulting, surveillance auditing and recertification.

General Flow Chart of The Registration Process

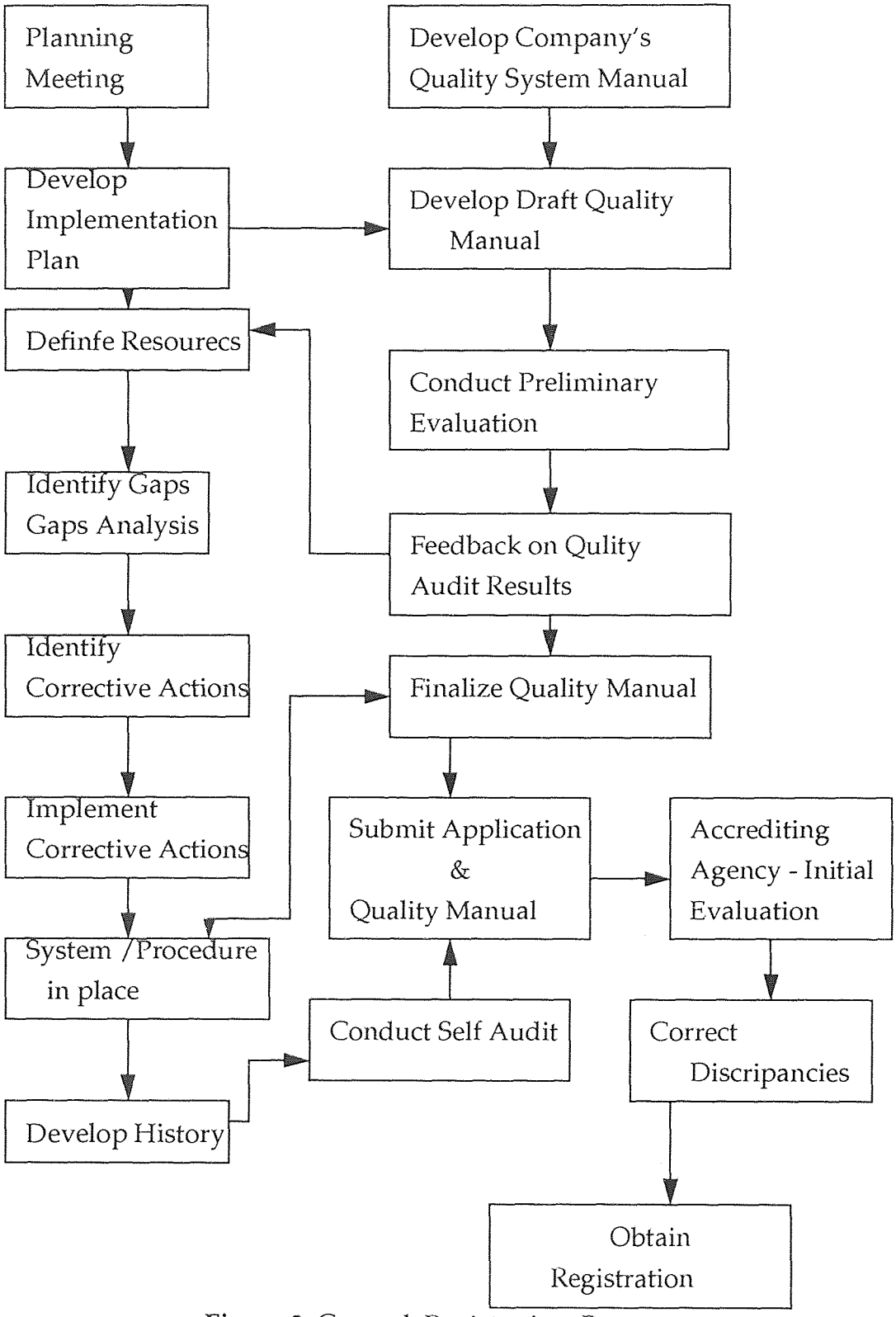

Figure 3 General Registration Process

U.S. Accredition Process

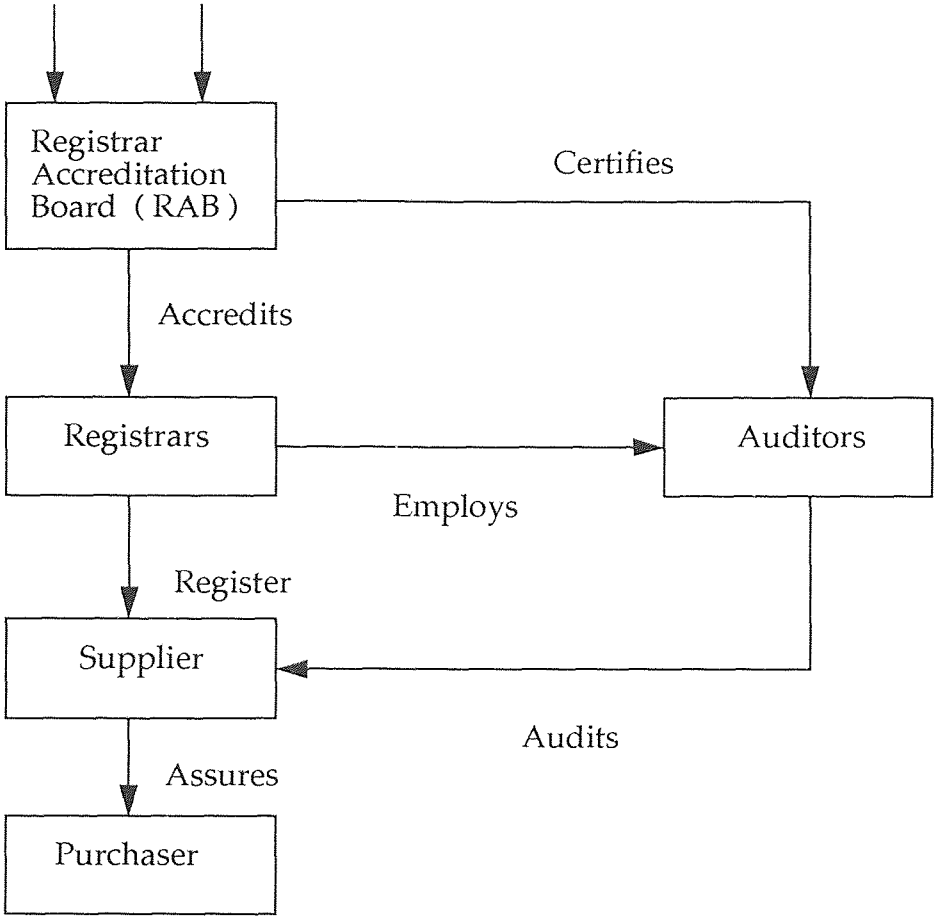

Figure 4 U.S. Accredition Process

Availability is another factor, at present, with some registrars there is queue of customers. This is because demand is higher than the supply of trained auditors and registrars. So, it is important for company to plan for registration in advance. Another factor is confidentiality. Confidentiality issue arises when auditor visits a facility as they have access to confidential information. The customer should ask the auditors to sign a nondisclosure paper.

Cost criteria is involved with fee structure. At present, because of demand and supply gap, fees are not competitive. Fees can be negotiated if, the work contains multiple sites, consulting, periodic surveillance. Generally fees should cover application, preregistration assessment or initial assessment, quality document assessment, annual registration, periodic surveillance, audit, corrective action, follow-up audit, multiple site audit (if applicable) off shore audit (if required), travel time and cost, audit recertification, analysis and reports, consulting service, post audit corrective action analysis and other services like mailing, faxing, copying. Consulting is one of the difficult issues in ISO registration. Generally in operational and financial auditing, auditor provides consulting services to the area being audited. But for ISO registration purpose it is recommended that, auditors and registrar/consultants should come from different organizations.

4.3.2 Selection of Internal Auditors

Internal audit is not a requisite by ISO standard but company applying for registration should carry out internal audit to evaluate the system and to get accustomed with actual audit. This enables the employees who are actually implementing or following system requirement to get experienced to audit. Also any deficiency in the system may show up and can be rectified before the actual audit. For this purpose, a team of interdepartmental employees should

be selected and trained for the purpose of system audit. Of course, this can also be included in the preparation or preregistration but the work of audit may be carried out after preparation to detect deficiencies in the system.

4.3.3 Auditing Quality and Quality Auditors

One of the requirements of ISO series standard is quality auditing. Most of the consultants consider this as major and important element because, it serves the purpose of ensuring that quality systems are effectively and efficiently working to achieve objectives of organization. ISO 10011-1,2,3 provides guidelines for auditing quality systems with ISO 9000 series standards. These standards are general and can be applied to any industry, sector, system, process or product. These guidelines have to be interpreted and tailored to the specific application.

Quality system audit, or quality audit means quality evaluation of the company, authorities, processes, procedures, products, personnel and resources. Definition of quality audit as per ISO 8402 is " A systematic and independent examination to determine whether quality activities and related results comply with plan arrangements and whether these arrangements are implemented effectively and are suitable to achieve objective."[1].

There are three major forms of verification and certification,

1. *First-party* : It means supplier conducts self audit against ISO 9000 standards and releases a conformance certification.

2. *Second-party* : It is common in U.S. where customer audits the supplier [16]. There is much duplication of work as most companies have similar requirements of supplier.

3. *Third-party* : A certified agency, audits the supplier, upon the approval the third party places the supplier on register. This is the type of certification most widely accepted in the industries. The importance of third-party

verification is, more and more work is outworked to often a single "world class" supplier.

ISO 9000 quality audits are conducted to:

- Evaluate compliance or conformance to customer's contractual requirements
- Evaluate the effectiveness, efficiency and economy of a company's operations.
- Pinpoint documentation problems
- Meet regulatory and other agency requirements
- Determine corrective action or quality system effectiveness
- Increase operational understanding
- Monitor continuous improvement
- Identify areas for corrective action

Quality auditor is the person who conducts the audit and if, team is performing audit then lead person is called lead auditor. Many of the auditors come from regulated industries in which they have conducted military, aerospace, or pharmaceutical industry quality audits, where similar to ISO 9000 compliance audits were conducted. Functions of lead auditor are, selecting of the audit team; organizing the audit team; being responsible for final report; examination of quality documentation; planning and scheduling the audit; managing the audit and presentation of audit results to the customers.

During the visit of audit team at company or facility to audit and evaluate quality system, it may disrupt the operations, therefore it is essential that the lead auditor and customer should jointly organize and schedule the audit. It should also include providing all quality documentation to auditor, arrangement of space, resources, tools and equipments to the audit team. During audit the auditor or team gathers and evaluates data, hence there should be sufficient information for them to arrive at an audit opinion of conformance.

4.4 Postregistration

At the conclusion of the audit, auditor documents the report and submits to the customer. Report may contain detection of deficiencies often called as nonconformances. Nonconformances may be minor or major, auditor will issue corrective action request for all, those the auditor believes are critical, major or recurring. All such nonconformances should be rectified by appropriate corrective actions. Post registration generally includes, correcting deficiencies, assessment of quality system for maintaining registration and post registration requirements [14].

4.4.1 Postregistration Requirements

The audit report communicates auditor's findings and opinion derived from the audit. It also communicates state of conformance of existing quality system to ISO 9000 series standards requirements. This may result in registration or corrective action requests. Upon implementation of these corrective actions, certification will be granted. Auditor may detect nonconformance which may be major or minor or recurring. The function of auditor in a compliance audit is to note the area and the deficiency and then convey it to auditee to determine the "fix". The fix eliminates the symptom and the correction eliminates the root cause.

Registration is often just a step in the continuous improvement process. It requires day to day attention to the quality process and operations. ISO 9000 registration is not a certificate awarded for passing inspection on an initial set of written procedures. In essence, it is an ongoing process at the root of total quality management.

To maintain certification it requires:

- Maintaining and controlling quality documentation and specifically the

quality manual in compliance to the specific ISO 9000 standard

- Developing and maintaining an approved supplier procedure or similar documentation
- Providing access to the registrars auditors
- Appointing a management representative to be responsible for all certification requirements.
- Notifying the registrar of major quality system changes
- This may require chance in documentation

Registration maintenance requires more surveillance visits. These visits may be unscheduled or scheduled. Purpose of scheduled or planned visit or audits is conformity certificate. Whereas, unscheduled or surveillance audit is to verify that quality conducted as a result of a complaint, major publicity, litigation, product failure or some other major incident.

A registrar can suspend the registration under following conditions [12]:

- Fraud, negligence or other actions that may impugn the registrar's reputation
- Requested corrective actions not being completed by the timeline
- Improper use of logo, mark or symbol
- Company not informing the registrar of changes to the certified quality system

The registration of certificate holder can be canceled under:

- Does not pay fees
- Acts in a fraudulent or highly negligent manner
- Does not correct the conditions that led to the suspension

ISO 9000 series doesn't specify how often should a company be completely recertified. There are international requirements for periodic or surveillance audits to ensure quality systems are working properly. But, there is no international requirement for a complete recertification audit.

Some registrars and auditors are of the opinion that recertification audits should be a requirement of ongoing and improving quality.

4.5 Benefits of Registration

Benefits are varying from company to company but major benefits to all the organizations under ISO 9000 registration are:

1. Customers are more receptive to implementing a supplier partnering relationship with companies with whom they have developed well defined and mutually agreed upon requirements. This can result in to competitive advantage to the registered supplier of products or services.
2. A prevention attitude can be implemented throughout the company, accompanied by early detection and corrective action systems, providing evidence not only of a quality management system, but also of positive quality attitudes and management's commitment to continuous improvement [8].
3. Adequate quality training is available for all members of the organization.
4. There is greater focus on the needs of the customer and customer satisfaction.
5. To ensure company's product will be produced at the same level of quality even if all the employees were replaced by new set of workers.
6. It provides the processes that locate and deal with problems.
7. Clear and well documented procedures are established and maintained.
8. Registration enhances the ability to compete in global markets.
9. Reduction in number of costly and time consuming customer audits.
10. Compliance with international quality standards provides its customers an adequate level of assurance of product quality and consistency.
11. Enhanced marketability through the use of recognizable logo and inclusion in registered supplies listing.

4.6 Disadvantages of Registration

Following are constraints and disadvantages of ISO 9000 Registration.

1. ISO 9000 registration involves costs, risks and uncertainty and confusion among countries about the acceptance of registrars as well.

2. EC countries are providing mixed signals and mixed messages about recognition of other countries' conformity assessment.

3. Registration sometimes follows a hard mentality.

4. There is poor understanding about the nature of European directives requiring registration.

5. Auditor and registrar quality may vary.

6. ISO 9000 is not universally accepted.

7. Interpretation of ISO and other standards is inconsistent since, the standards are generic in nature.

8. ISO 9000 has different levels of certification and companies don't know exactly which to pursue.

9. Registration is expensive because it has to be continuously maintained.

10. Consultants warning that ISO registration is necessary for all products creates incorrect and mixed signals.

CHAPTER 5

ISO 9000 - NEW CHALLENGE TO UNITED STATES MANUFACTURING INDUSTRY

5.1 Chapter Synopsis

Till recently U.S. industries were not emphasizing on quality. However in late 80's quality became a prime performance issue globally. Lots of companies are formulating their strategy on the basis of quality to regain or improve market share and profit.

On the political front in Europe, formation of E.C., put Europeans as world's largest market, instead of America. New business avenues have been formed and global competition has become more competitive. This leads to the need for global quality standards. Adoption of ISO 9000 has become popular in Europe as well as other countries. Thus more and more companies are seeking registration under ISO 9000.

Due to erosion of U.S. competitive preeminence in the world market, many U.S. industries were challenged by companies from Europe, Asia and other developing countries. This in fact forced U.S. industries to look for alternative to compete again in the domestic as well as world markets.

Many U.S. industries are seeeking for ISO 9000 registration. A survey shows that most of the U.S. companies which are already registered or preparing for registration has to go for ISO 9002 registration. As number of U.S. manufacturing companies registered under ISO 9000 standards are growing, management is shifting their focus from achieving initial registration to managing issues that have emerged afterwards.

Though there are teething problems initially during development of quality systems and when processing starts, same can be streamlined as work progresses.

5.2 Background

At present, about 400 U.S. companies have gained ISO 9000 certification and many more are seeking for it. There are about 30 registrar available who can provide the certification required by European and other international customer of U.S. exporters. Main problem is lack of recognition of U.S. agencies to certify registrar with same standing as the European certified registrars. Currently, U.S. registrars who want their work recognized oversees have gained their status through arrangement with European agencies authorized to approve registrars.

U.S. manufacturing industry and other as well, are facing numerous problems in implementing ISO 9000. In general, industries are facing management, process and material, employee, customer, registration, and registrar related problems. An attempt has been made, to highlight those problems most likely to be critical to most organization.

5.3 Management Related Problems

Not committed to quality system implementation - it is most important factor affecting the registration of ISO 9000.

Management must be committed to the quality policy and must be responsible for overall management function through which quality policy has been implemented.

Major problem in this area is management's commitment. In most of the organizations, management is not committed to quality policy, once the decision of implementation of quality system is taken. Not reviewing and

monitoring the progress to change with changing market and needs. This may lead to failure of the system which in then leads to suspension or termination of the registration.

Another major problem is lack of management time during the process of gaining certification/registration. Management shall have commitment for the registration once the decision was taken for registration.

Another difficulty encountered by management is interpretation of ISO 9000. Standards are generic in nature so most of the people are finding it difficult , how to apply to their organization. This can be overcome by appointing consultant who is reasonably good in the respective industry. Management have only a minimal commitment to the principals of quality assurance, and install the system in response to customer pressure. If this is the case then sooner or later company may lose registration. Lack of commitment on part of management, can cause lack in product quality. This may result in to loss of market, customers and in turn profit. Also in subsequent audit if quality of the product is not meeting the requirement as documented, in may cause suspension of registration. Thus management had to be committed to continuous quality and ISO 9000 standards. They have to monitor the system periodically in order to keep it working through out the organization.

In most of the U.S. firms, managements are relatively more interested in the financial aspects and give more weightage to it, compared to other area. This is the major obstacle. Managements have to revise their corporate strategy or strategies to include response of foreign competition which in turn calls for greater investment in people and equipment to improve manufacturing capability and product quality. Focus should be shifted to product quality and quality systems relative to other functional areas to sustain competitive manufacturing capability. Emphasis on product quality is the area where

manufacturer can improve upon significantly to gain advantage over the competitor. Generally management supports the quality system in regards to implementation, however they are not familiar with it. This sometime makes problem during the auditing because familiarity of management on quality policy is one of the checkpoint of auditor. Management tends to rely on the quality representative and assumes that it is not their but QA's responsibility. In such case, QA should continuously feedback the progress, improvements and decisions to the management.

Once quality system is implemented management is not reviewing and checking preformance of system, rather they are more interested in, are there any improvements in "Balance Sheet" by adopting quality system?

In nutshell management related problems are-

- lack of management time
- interpretation of ISO 9000
- minimal commitment to quality assurance principals
- not right level of management commitment to create proper quality system and integrating with their operation.
- without justifying the needs, management going for ISO 9000 registration
- lack in knowledge about global technical standardization related to respective industry.
- quick decision for registration (may be due to customer demand) for short term gain without benchmarking product and understanding competition.
- not aligning quality strategies with business strategies in order to work it.

5.4 Process - Material Related Problems

Today in the industries, customers are dictating the market. Previously market were governed by the manufacturers but, this is not the case due to global trade

and competition, and excessive supply. Companies are investing billions of dollars in research and development for new products to meet the customer's requirements and needs. Technology is changing rapidly than the products. New methods and approaches are developed to make things in better way, right away. In most of the U.S. manufacturing companies it is observed that generally they lack in planning, i.e., process planning, documenting process and production plans, also not quick in to response, market needs and change. This leads to failure of any system whether organizational or quality system. Special processes are generally not documented in the manual and this causes inconsistency process parameters and products by any new employee. Most common deficiencies observed in U.S. firms are document control and design control i.e. not having all relevant documents like, workmanship standards, use of outdated standards and regulations. ISO 9000 standards do specify about document control but does not indicate about role of documentation which is important to specify or identify quality improvement efforts and support for efforts. Similarly U.S. manufacturing companies are facing problems in proceduralizing operations mainly because personnel have not been encultured to these expectation and have got a bad reputation because they were seen unchangeable. However proceduralizing is critical in many regulated industries, like, nuclear power, aerospace and power system.

Other major problem faced by the companies is lack of consistency in operations which is the root cause for unwanted variation. It can be easily handled by proper documentation of procedures and proceduralizing the operation.

Most of manufacturing companies purchase material from other suppliers or vendor. Almost all of them have to rely on the supplier surveys to provide a measure of the supplier's potential to satisfy the requirement. This is

mainly due to information purchaser needs, about the demonstrated performance of the material is often not available. In such case material needed for production arrives late or is rejectable for quality reasons, it is too late to find out that the supplier is incapable of doing the job satisfactorily.

A small portion of other U.S. manufacturing companies face problems arising from lack of agreement between organization and field equipment, methods, and standards of inspection and test, and these are due to appraisal incompatibilities. When products requires field erection, installation, or service for customer use, opportunities frequently come up for errors to be made and for disagreement to arise because field people do not have the same kind of equipments or performance standards as used in the factory for control of production. Thus factory and field organizations should cooperate to ensure the compatibility. Proper calibration and maintenance of field equipments, as integral part of sec. 10 of ISO 9002 (Inspection, Measuring, and Testing Equipment).

Most of the companies have varying degrees to the same problem- often heavily dependent on their supplies for their own capability to perform satisfactorily in the marketplace. This is partially depended on (manufacturer's) organizationing ability to meet due dates and volume, adherence to quality and safety requirement and effect of any lapses on the operations of the organization itself.

5.5 Employee Related Problems

Employees are the strength of the any organization and it is the biggest resource of any industry. Therefore, it should be nurtured properly.

Majority of the companies are facing difficulties in the implementation of the ISO 9000 techniques due to employees. People accept the requirement for

self-discipline in direct relation to their personal involvement in the process. Average employee sees the "new thought" or "new speak" as another imposition or indoctrination and this leads to doubts, resistance and sometime hostility towards management and organization. The main reason for this is not developing common language in quality environment that every one can understand and communicate. This is also true when any company tries to modify a business culture, direction or objective.

For firms undergoing ISO 9000 registration, it is necessary to device quality training and inculcate common language. Training should also provide developing skills, objectives, common language, team building and ethos. Sometime it is observed that, even training is not sufficient to implement quality system successfully. The emphasis on empowerment and quality improvement should be focused. Employee should be asked, what they could do for themselves to improve work area. Self-satisfaction that came out these efforts immeasurable because it reflects direct effect of employees on what they are doing on daily basis. This also helps to be more open and talking with each other to figure out to do things in better way.

Another employee related problem is to follow the written procedure on day to day basis. Its easy to write procedures and hard to ensure they are being followed day after day. "It is easy to develop procedures and relatively easy to initially implement them, but more difficult to carry them out day to day once the initial excitement wears off "[12]. Sometime employee resists the response of the management by asking person how to do the job which he or she is doing for long time or by imposing on him or her through a procedure of how it should be done. This is general picture in the industry. This requires complete training of qualified employees and their training needs should be periodically assessed.

Another problem in U.S. manufacturing industry is ISO 9000 quality system procedures that may be imposed on worker as the "approved" operating method, the best solution to this is let the worker write their own procedure. This helps because they are the best acquainted with how the work is actually done. However this has another obstacle in form of natural suspicion, "management want to find out what I do so they can find someone cheaper." Another, challenge is that many people don't know how to write procedures, and finally, building consensus for a team or work area to write procedures takes time.

5.6 Registrar and Auditor Related Problems

Most critical part of the registration is how well and organized, the registrar is? And other important question, is U.S. registration acceptable in Europe? Any firm seeking for registration or certification due to import requirement in the respective industry has to check whether registrar is acceptable in Europe and other trading countries. Whether customer requires specific mark of the registrar due to credibility and trust of the registrar over other. Since, U.S. registration efforts are relatively new, selection of the registrar involves ethical consideration.

Other problems industries are facing is auditor's inconsistency in conducting audits or interpreting ISO 9000 and high variation in auditor's quality. Sometimes auditor imposes conditions which are not required for manufacturers and this may result in add cost and little value to customer supplier relationship. Auditor lacks in education and does not have specific process or product background which may cause an auditor focusing on the trivial questions and missing the critical factors during an audit. Another factor affecting registration is appearance of conflict of interest with some registrar.

Registration audits are supposed to be conducted by independent third parties. However, the third parties are in the business to generate revenue, and registrar compete and advertise for auditing and consulting service. It is difficult to maintain independence and impartiality for registrar by separating both functions. Eventually, the loser is the supplier or company.

5.7 Government Involvement

U.S. mechanism of conformity assessment and standard development depends purely on societies and organizations formed by industries. Government has no direct control over it. Also it is classified as private sector activity. However E.C. and other countries want to negotiate with national level counterparts to ensure credibility for consumers, environmental, safety or health conformity assessment products entering in their country. The gist is E.C. and government of other trading partners want to deal with government entity which can provide assurance of the validity of U.S. conformity assessment activities. Thus, U.S. manufacturer doing business in the E.C. countries has to under go double conformity assessment or registrar notified by the E.C. countries. This is again difficult for U.S. manufacturer to select particular registrar, whose certification is acceptable by customer. Because of variation in the E.C. countries itself, some registrars' mark are not transferable or not recognized across the border. Therefore, it is essential for U.S. government to interfere to safeguard U.S. manufacturer's interest.

5.8 Implementation of ISO 9000 Standards in U.S. Manufacturing Industry

Purpose of implementation of quality system offers specific guideline for applying general concepts discussed in the chapter 3. It identifies activities required to implement quality system and resources available. Also it characterizes the work process in each of the element and their respective areas.

A good system can run for longer period if, it is properly implemented and regularly maintained. In this study, design aspect of the product is also considered to control quality of the product. This is only required when manufacturer is designing and manufacturing the product, otherwise it can be excluded.

5.8.1 Product Development

It is series of activities within product life cycle which includes customer needs, market analysis, and product planning. Customer needs are identified to define product characteristics. Next, market analysis predicts acceptable product prices and customer demands. From these information, product planning defines the product and offers guideline for the subsequent product phases. Product development generates and verifies the product design. Process design identifies required manufacturing practices and equipments. Procurement provides the needed raw materials. Production makes the physical product, distribution transfers the product to customers, and customer operation provides product maintenance and customer services.

Planning: Initial and ongoing planning activities are necessary to define, implement and manage the process.

Detailed design: Production of design information needed to manufacture the product, based on the functional product definition and objectives.

Manufacturing process: Work done to define and implement process to manufacture the product in volume. Selection and procurement of necessary components and raw material for cost effective manufacture.

Production: Work done to establish objectives and strategies for making smooth transition from prototype production to targeted volume manufacturing.

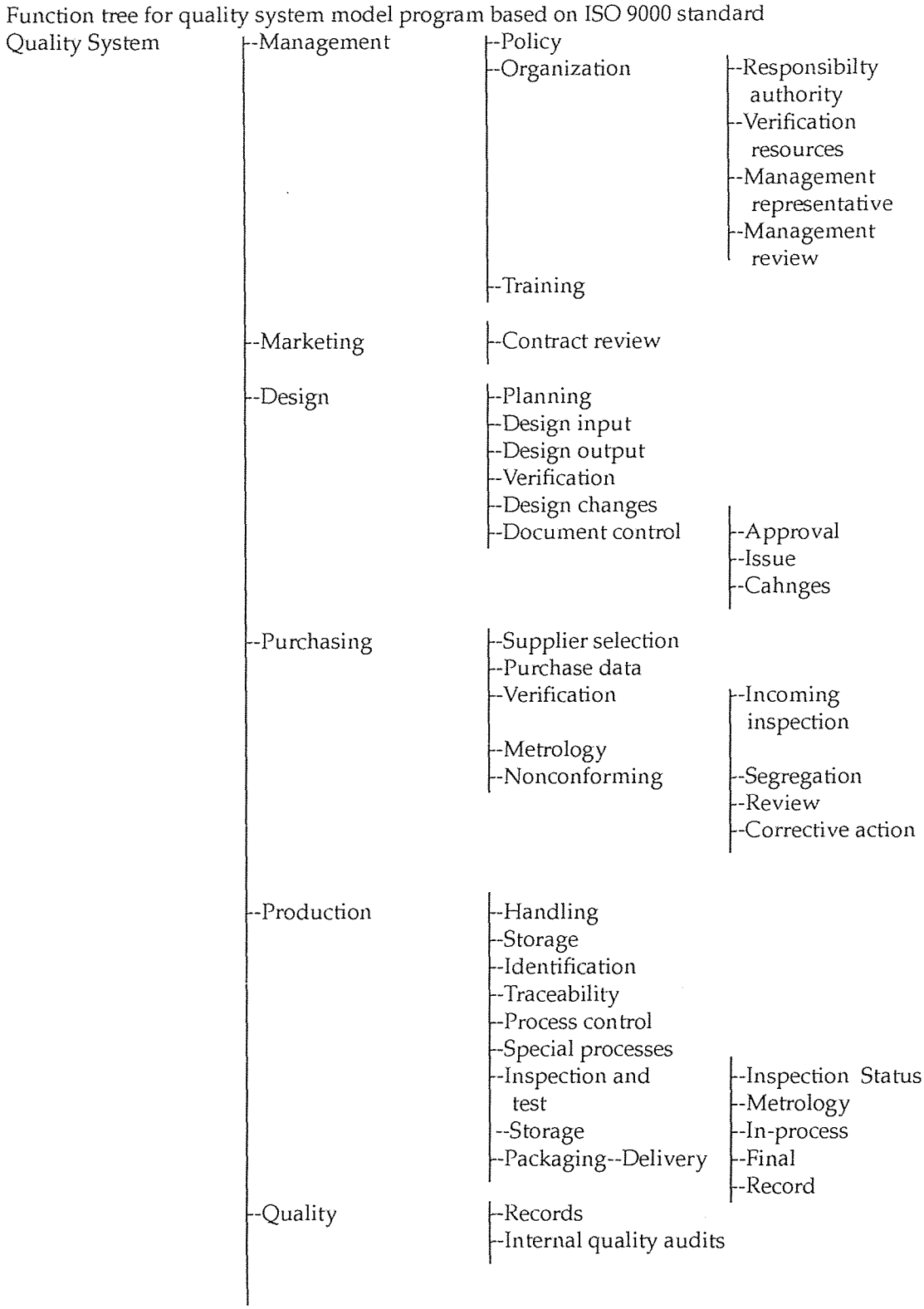

Figure 5 Function tree for quality system model program based on ISO 9000 standard

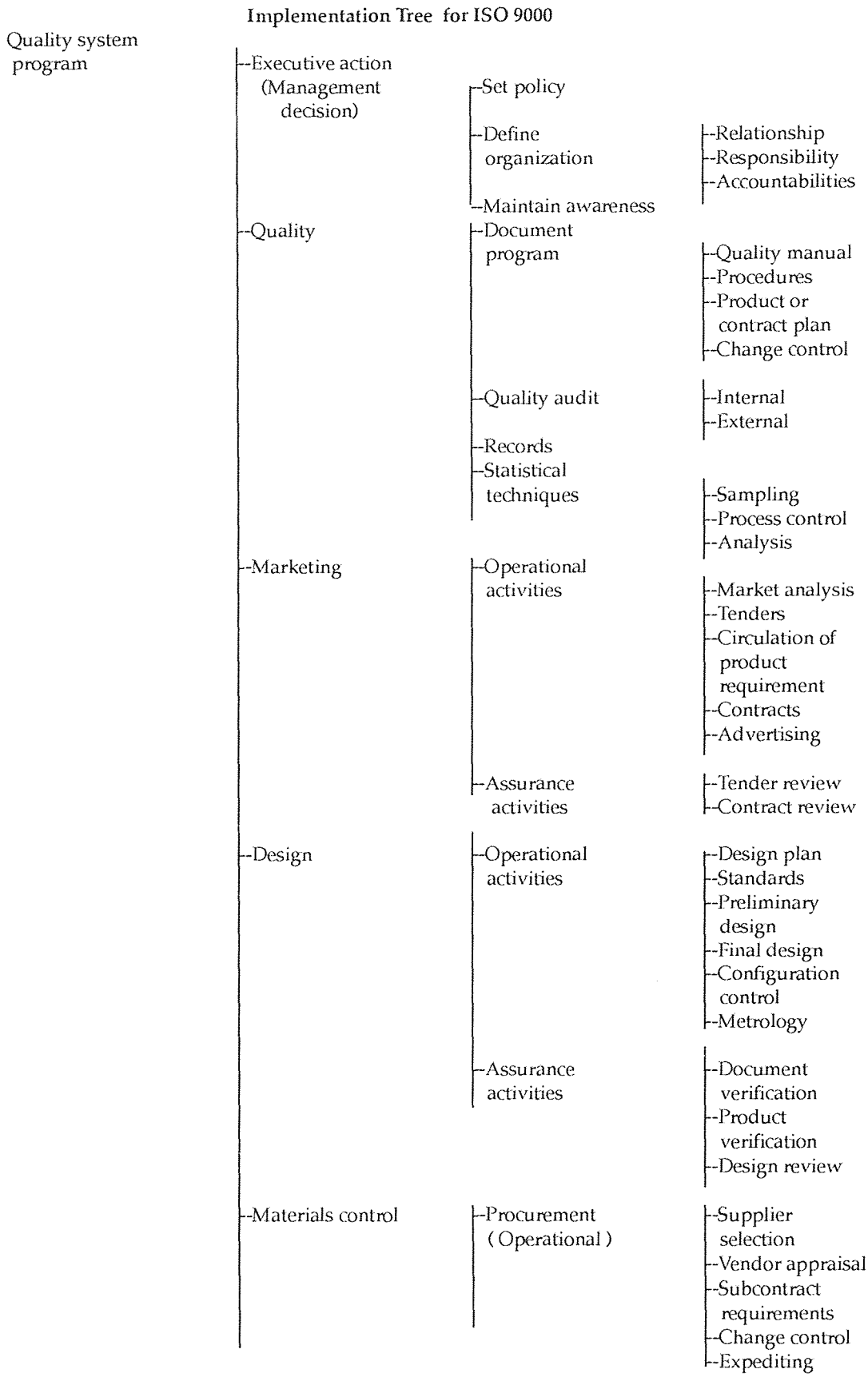

Figure 6 Implementation Tree

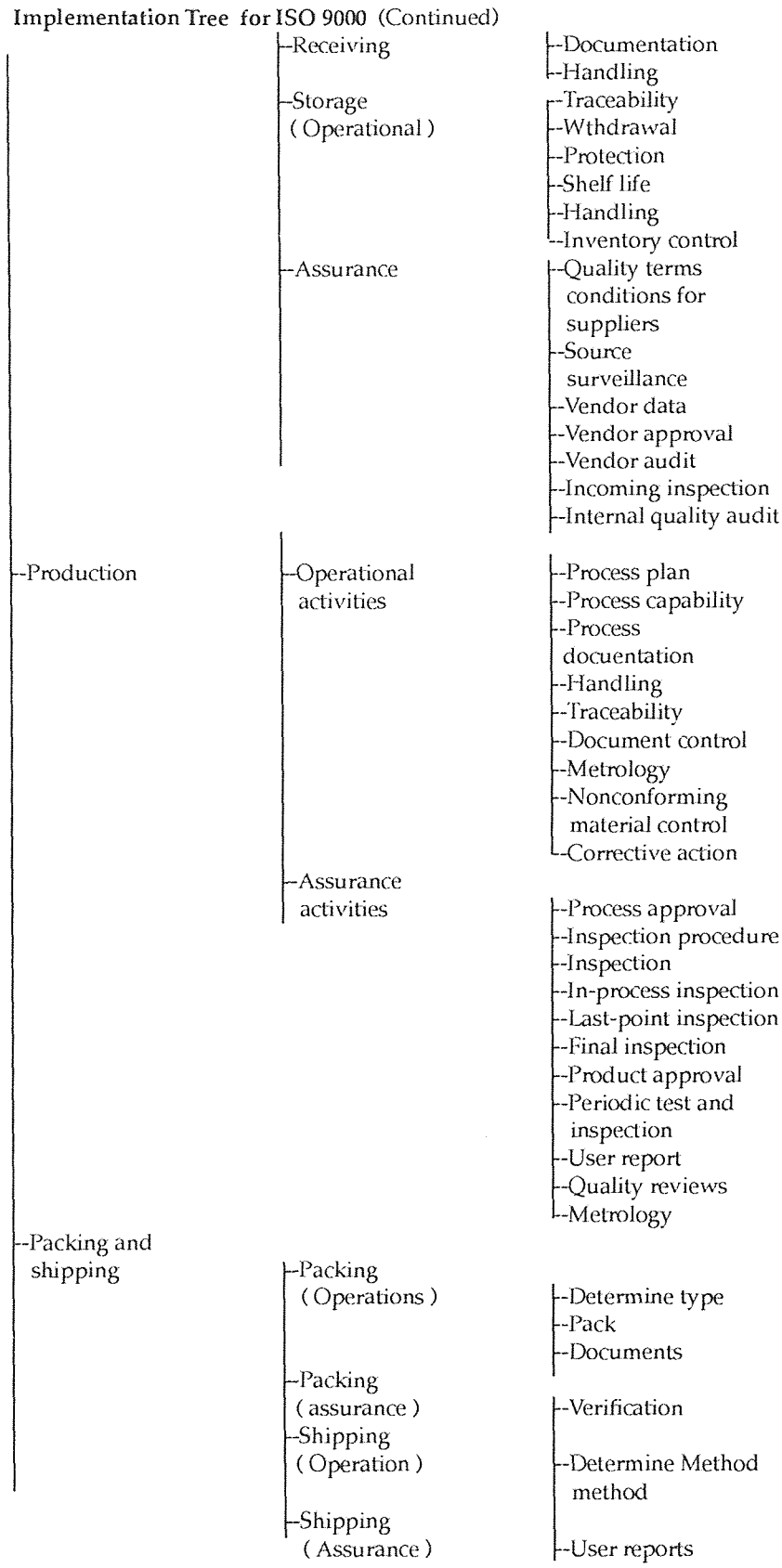

Figure 6 Implementation Tree

Deployment support: Continued work needed to establish processes and systems to manage and support interface between organization and customers.

5.8.2 Functional Tree

The ISO 9000 standard defines elements comprising a quality system and tend to ignore overall objectives of those elements. This concentration on techniques has a tendency which inhibits the development of new or improved system. It is necessary to define desired functions for the implementation of the standard. Implementation of ISO 9000 series standard through functional approach is discussed in this section. The functional tree of the ISO 9000 is shown in the figure 5.

For an organization desiring implementation of quality system, it is essential to analysis major functions fall within the scope of standard. Thus for design and manufacturing organization, the analysis might address all functions shown in the figure 5.

5.8.3 Implementation Procedures and Tree

After defining functional aspect, next phase is of implementation of the standard by proceduralizing the system elements. System elemets are grouped in the production activities and a document level chart can be prepared as shown in the figure 6. This identifies the important procedures which are to be developed in order to implement the standard. Important procedures are generalized and flow charted in order to make complete model for any manufacturing company. (see Appendix A). All these procedures must be determined by the quality assurance representative and properly defined as per requirement or need of the processes involved and services rendered by the company.

Overall manufacturing process is shown in the figure 8. The activities involved are process definition, process measurement, process improvement,

Grouping of ISO 9000 Elements in to Basic Production Activities

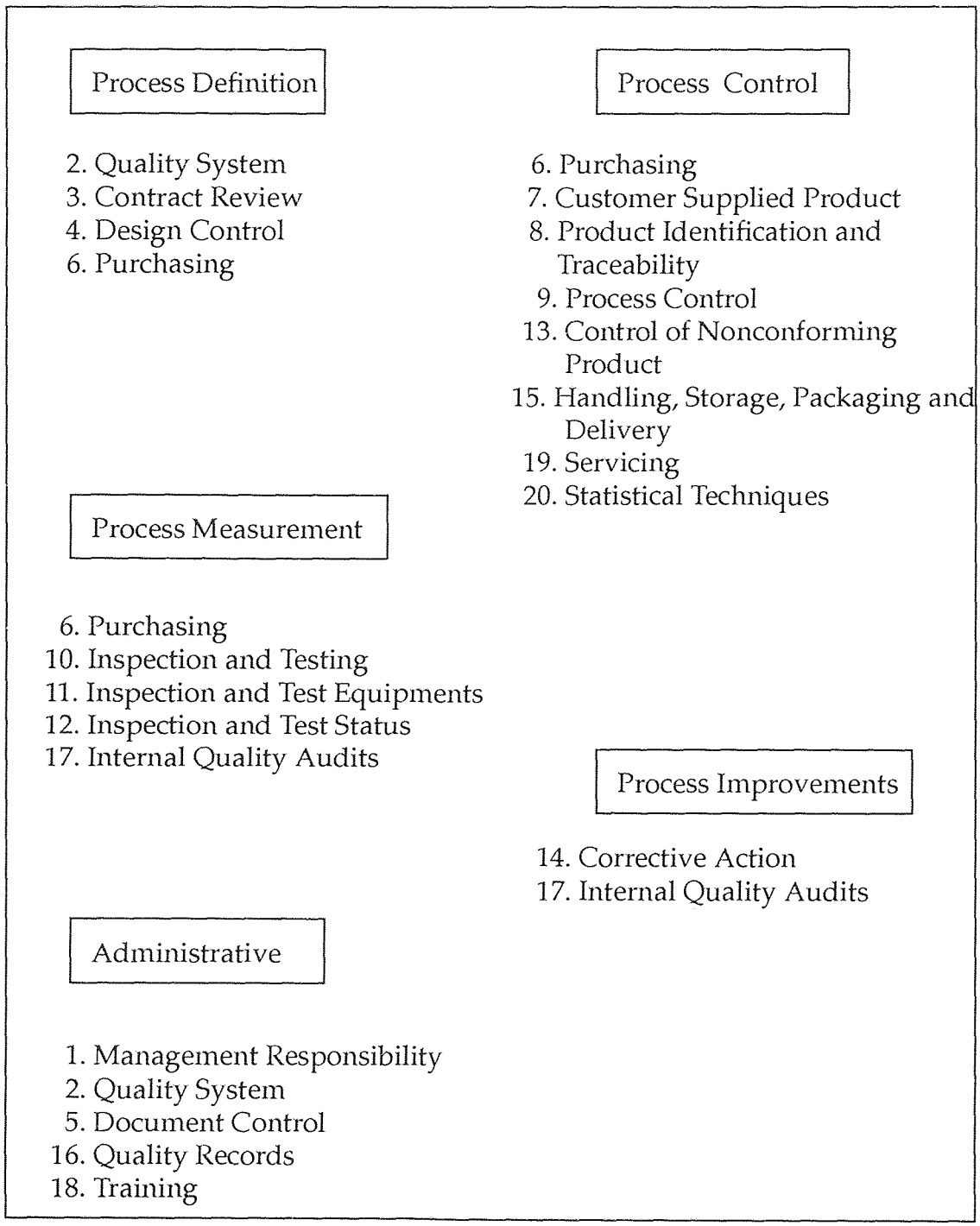

Figure 7 Grouping of Basic Production Activities

Over View of Manufacturing Procedure

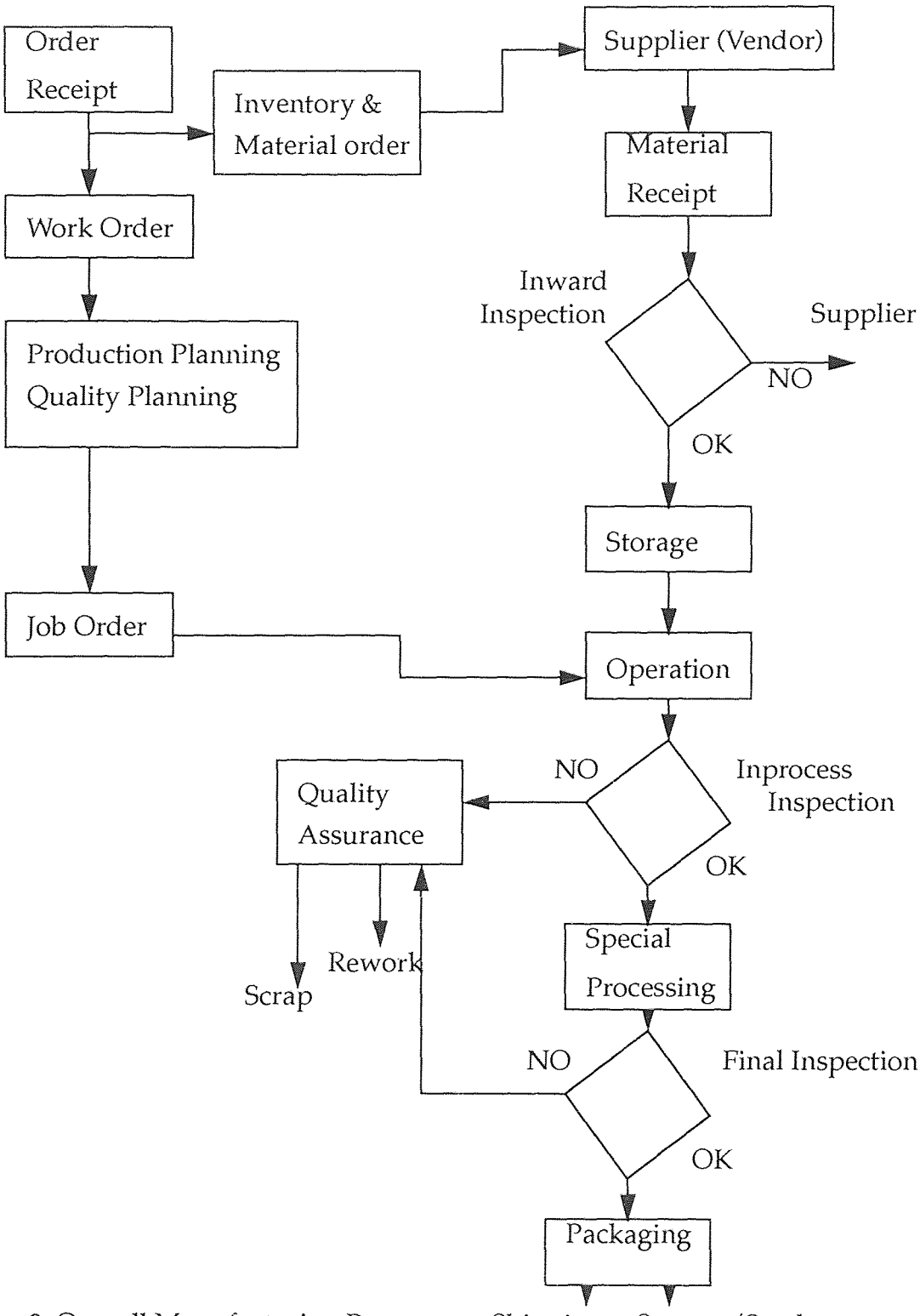

Figure 8 Overall Manufacturing Process

and administrative. This basic activities of production are grouped together based on ISO 9000 system elements are shown in figure 7. By grouping the system elements it is easier to define the implementation activities.

Process Definition: It includes important quality system elements. Design control and contract review as well as quality system. It analysis technical feasibility of design, creates functional definition of the product, captures design and defines plan for testing and design of product.

Process control: it includes customer supplied product, verification, control of nonconforming product, handling, storage and use of statistical techniques to establish control over process.

Process measurement: Process measurement performs inspection and calibration of instruments, inspection of product, use of S.Q.C. techniques, inprocess track of the product. It also analysis process parameters and root cause for variation.

Process improvements: Main functions are investigation of causes, data analysis, internal quality system audit and corrective action.

Administrative: It is basically not a production activity however, it is directly related to production. It involves training of employees, motivation to improve quality decision and actions on quality of product and process. And main responsibility is to monitor documentation of the quality system.

For all of these five activites, outputs are to be identified by listing input required and activities or efforts put in (see Appendix B). Thus all quality system elements are addressed for the need of complete quality system as required by the standards. This implemtation phase is very sensitive because, if any element is not properly addressed then it may lead to noncompliance of the standard.

CHAPTER 6

CONCLUSION

6.1 Conclusion

The ISO 9000 series standards are applied to wide spectrum of the industry but implementation of these standards has many grey areas. Almost all industries in U.S. to seek registration for ISO 9000 due to precondition of doing business with European countries.

The standards can be used as foundation for the quality system independant of the registration. Many factors affect the decision of ISO 9000 registration for a U.S. company as discussed in Chapter 4. Implementation of quality system based on ISO 9000 can bring lot of advantages to company. In general it can improve overall competitiveness, provide accesss to the global markets, enhance marketing credibility, improve supplier base quality, create uniform quality system, improve internal operation and can develope self discipline. Further it controls risks and exposure i.e. mainly risk associated with litigation and minimizes damage claims.

Both standards and registration process has some discrepancies. Since whole process of assessment is very subjective, shortcoming of the standards are: adding cost but not value to the system, no guarantee of customer satisfaction, appearance of conflict of intrest between customer and supplier, variation in auditor quality, difference of opinion in interpreting ISO 9000 standards. No emphasis on continuous improvement, overpromise and underdelivered.

ISO 9000 series of standards for quality assurance in general is very generic. There is lot of much documentation in the whole process for getting

certified. The documentation is absolutely important for getting quality products for a company but it has to be seen that the procedures documented are followed in real life. Quality systems thinking, to some, implies documentation and paperwork thinking. Documentation is an outgrowth of quality systems control, but is not an end in itself. It is also seen that auditors that are accredited by the RAB in U.S. have different opinion in auditing their firm.

Regardless of what quality experts say, the future of ISO 9000 and conformity assessment is still uncertain mainly due to valunerability of assurance mechanism; as it is a political and socioeconomic instrument. ISO 9000 can be used to serve multiple economic and political purposes. Similarly it can be used for inflictive purpose or as a trade barrier. Much thinking in regards to future trade with EC and other Asian countries is required as future of ISO 9000 itself is unclear. At national level future of ISO 9000 can be described in three words, credibility, value, and trust.

To study the effect of registration and problems encountered during the registration a survey was conducted for U.S. manufacturing companies. A questionnaire (see Appendix C) was circulated to the firms which are certified for ISO 9000. However only six companies come forward to share experience and provide detatils out of 200 surveyed companies. This is mainly due to sensitivity of the issue and competition. This also gives fairly good idea about sensitivity of subject that lot of companies are serious about registration and competition.

Finally at national level it can be summed up that quality system required for intenational trade and business by using ISO 9000 is still in premature stage in context of conformity assessment process. It requires to earn credibility and trust.

APPENDIX A

PROCEDURES TO IMPLEMENT QUALITY SYSTEMS

All important procedures required to implemnt quality systems for any manufacturing setting are identified are shown in the form of flow chart in this appendix. List is as under:

1. Incoming Material Inspection Procedure (Figure A.1)
2. Inprocess Inspection Procedure (Figure A.2)
3. Final Inspection Procedure (Figure A.3)
4. Contract Review Procedure (Figure A.4)
5. Customer Reject Work Procedure (Figure A.5)
6. Inspection and Test Status Procedure (Figure A.6)
7. Process Control Procedure (Figure A.7)
8. Storage, Packaging and Delivery Procedure (Figure A.8)
9. Supplier (Vendor) Assessment Procedure (Figure A.9)
10. Design Control Procedure (Figure A.10)

APPENDIX A
(continued)

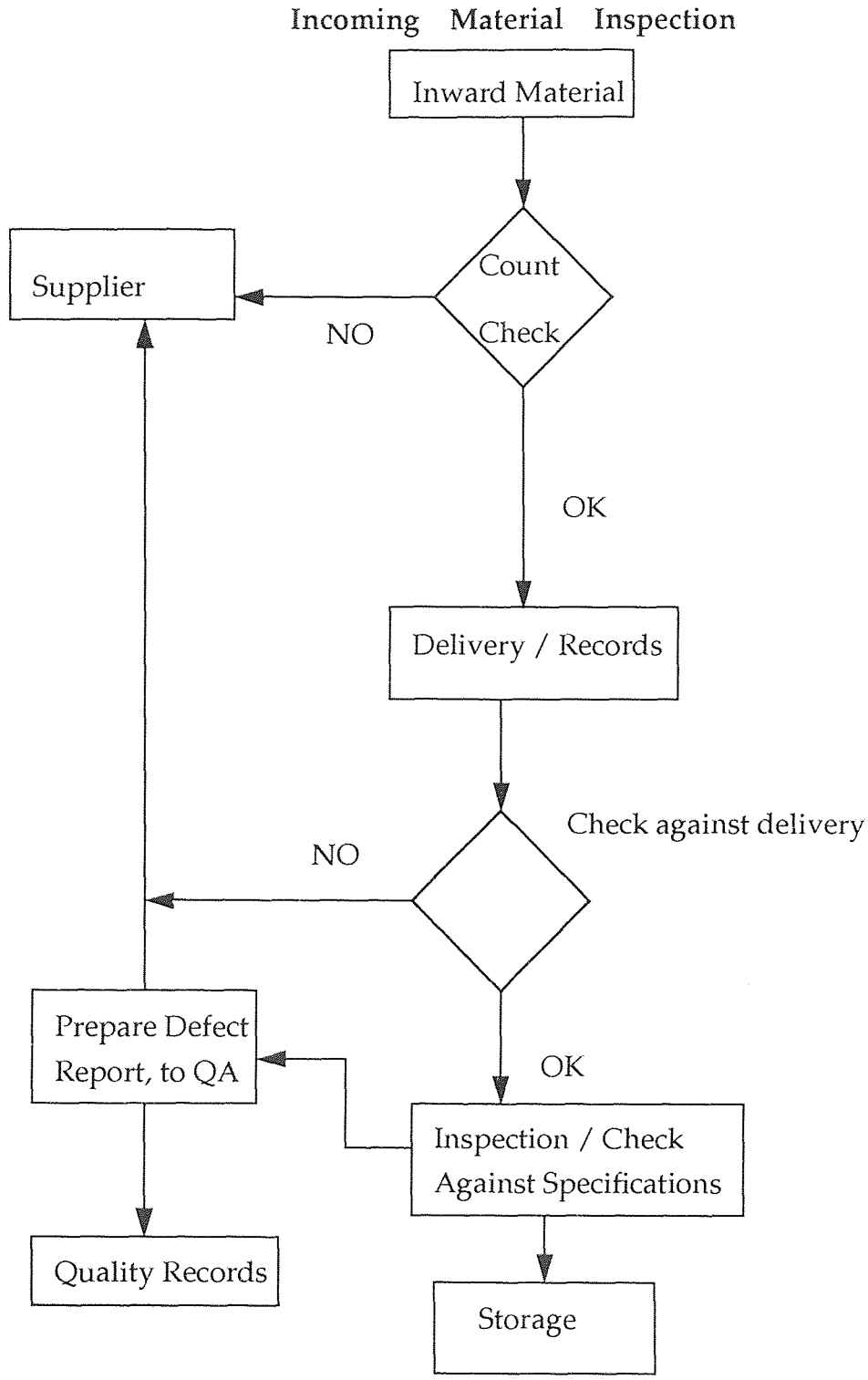

Figure A.1 Incominig Material Inspection Procedure

APPENDIX A
(continued)

Inprocess Inspection Procedure

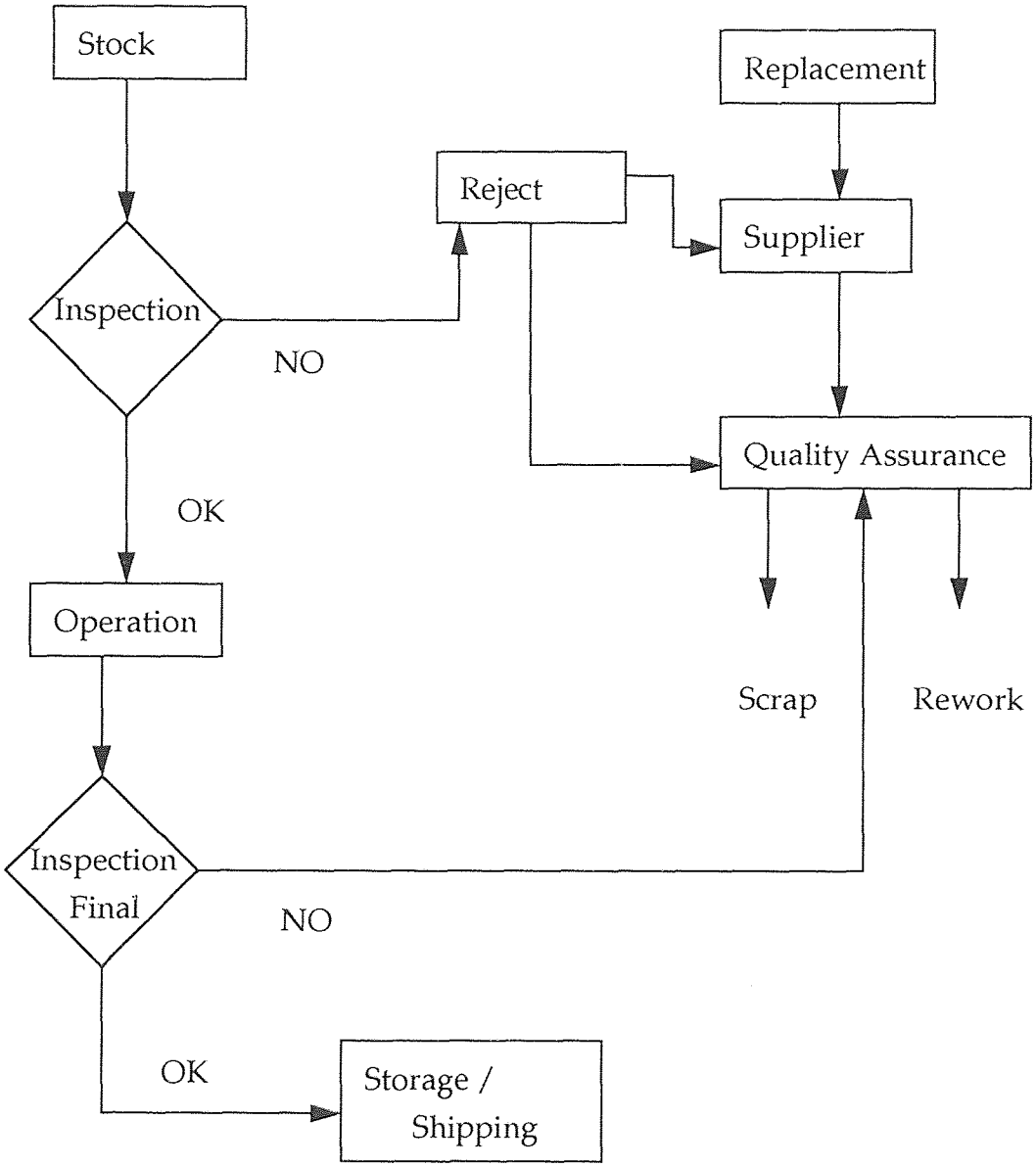

Figure A.2 Inprocess Inspection Procedure

APPENDIX A
(continued)

Final Inspection

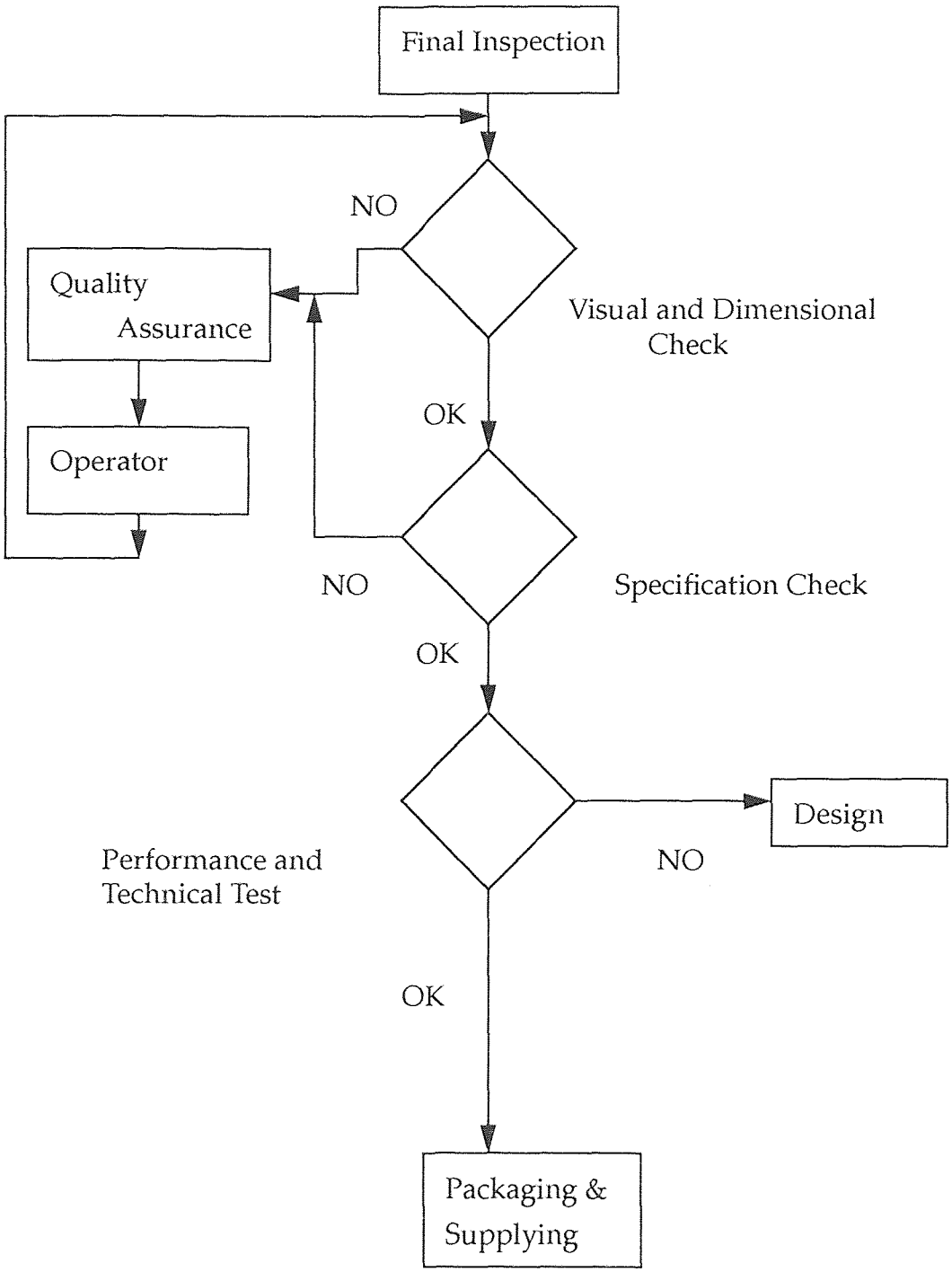

Figure A.3 Final Inspection Procedure

APPENDIX A
(continued)

Contract Review

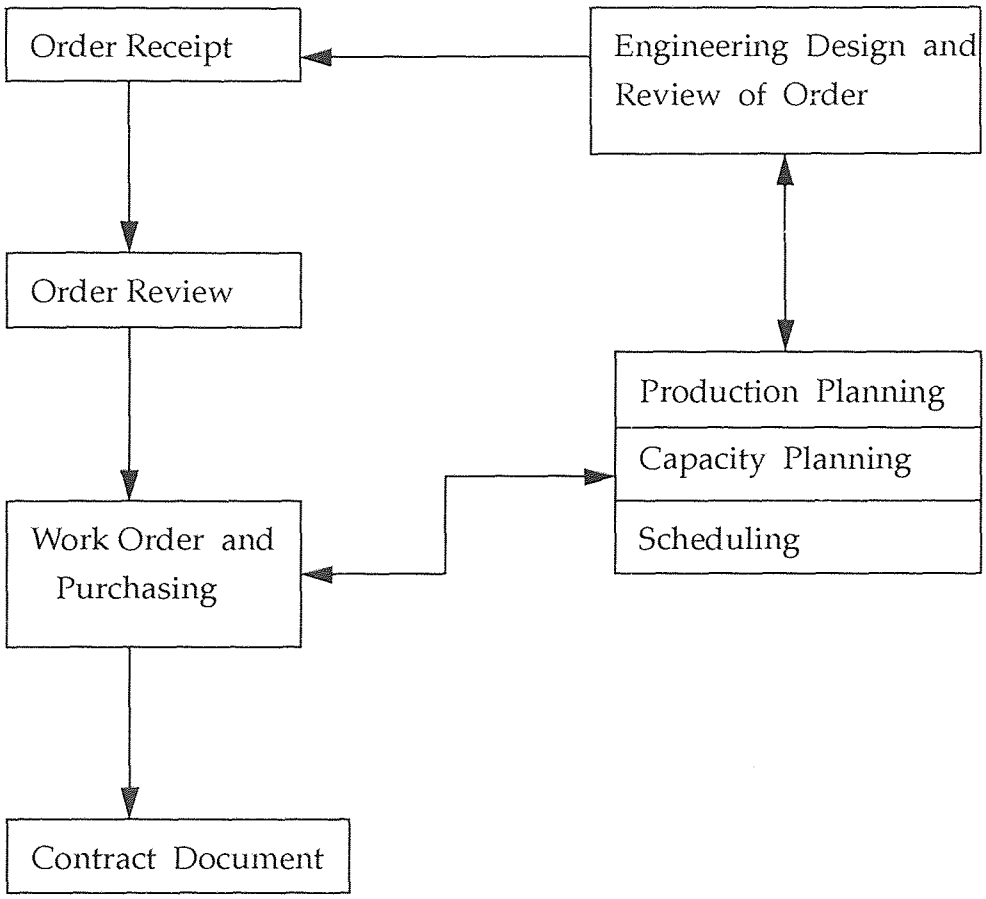

Figure A.4 Contract Review Procedure

APPENDIX A
(continued)

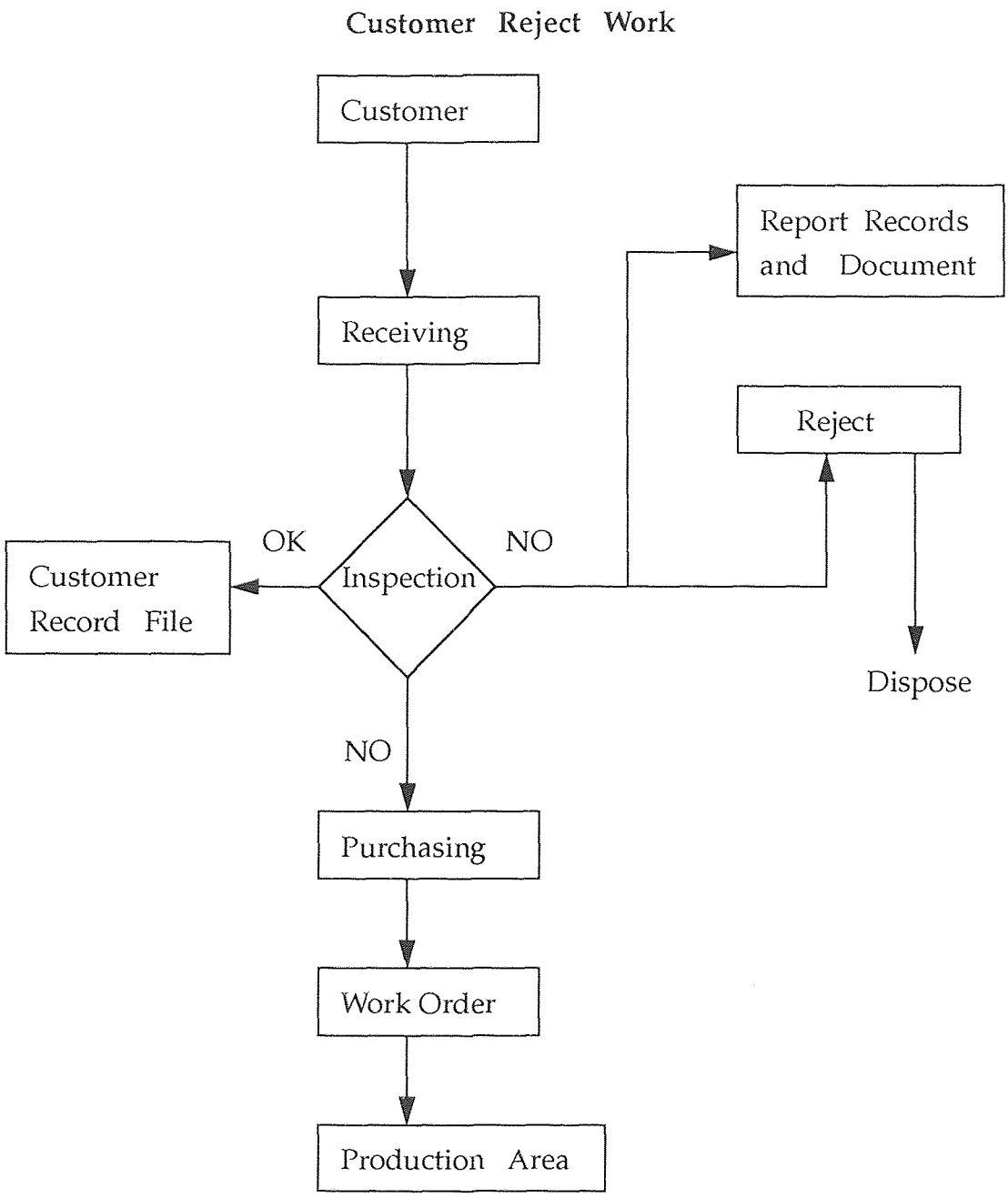

Figure A.5 Customer Reject Work Procedure

APPENDIX A
(continued)

Inspection and Test Status Procedure

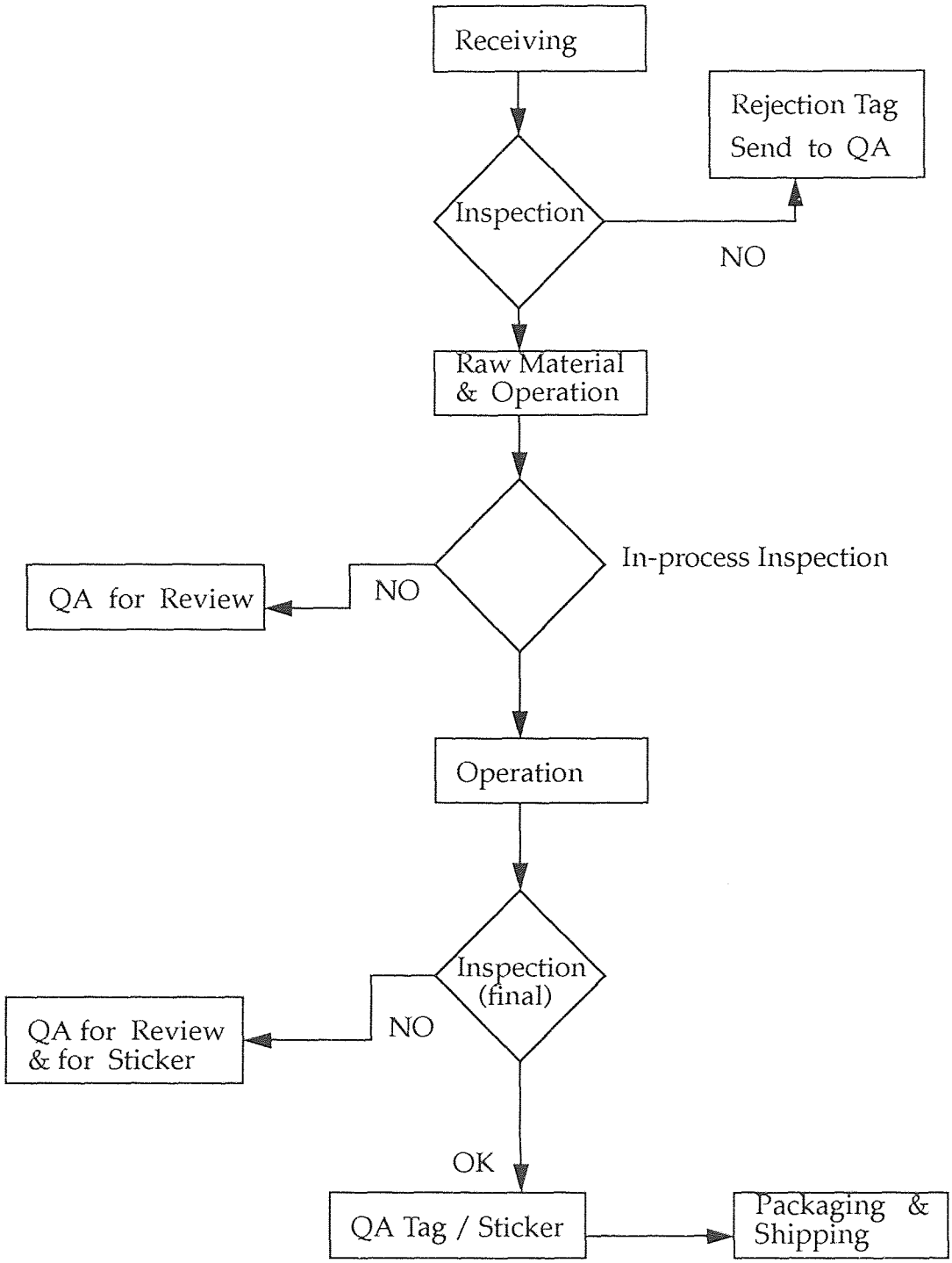

Figure A.6 Inspection and Test Status procedure

APPENDIX A
(continued)

Process Control

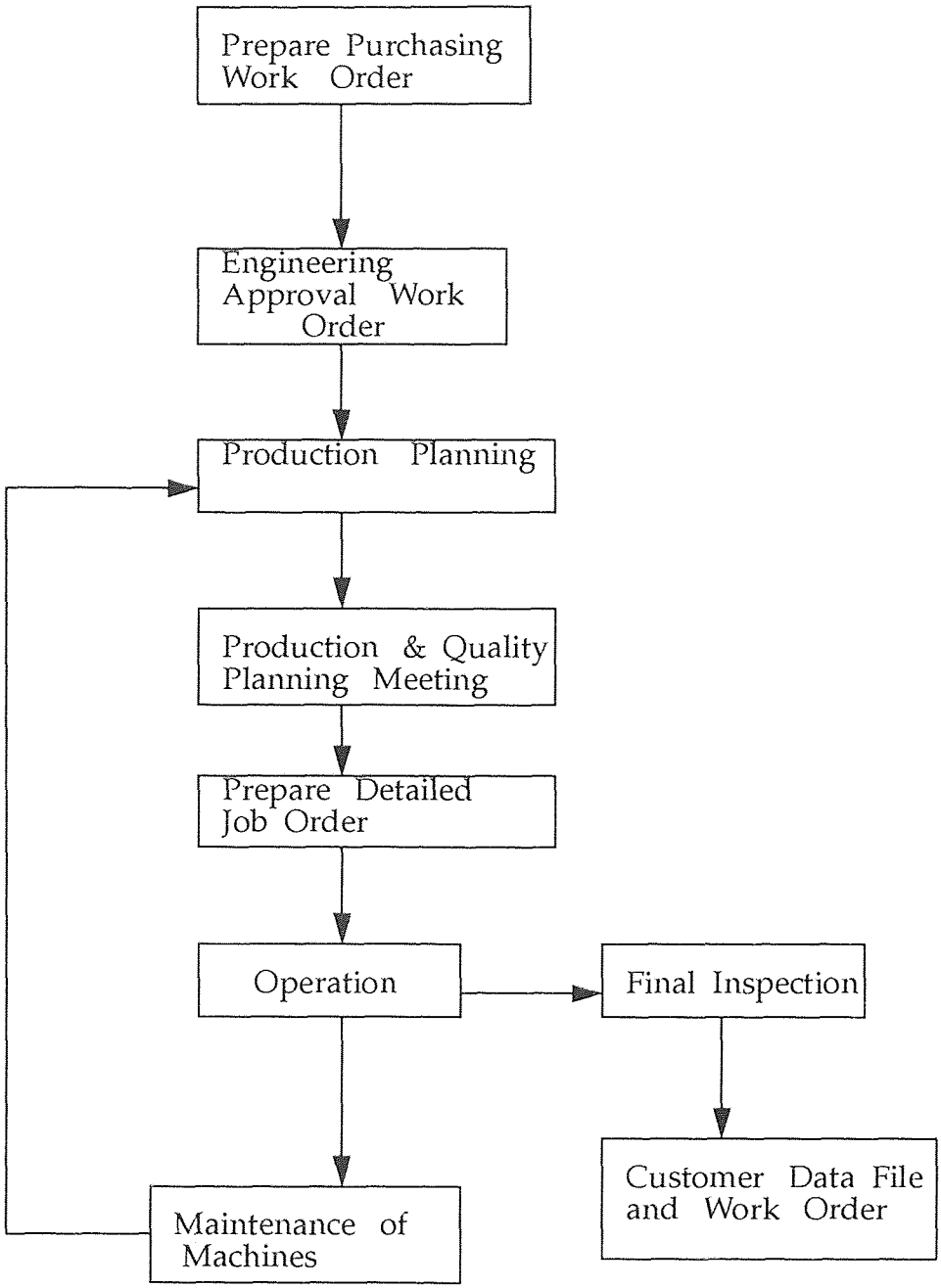

Figure A.7 Process Control Procedure

APPENDIX A
(continued)

Storage Packaging and Delivery

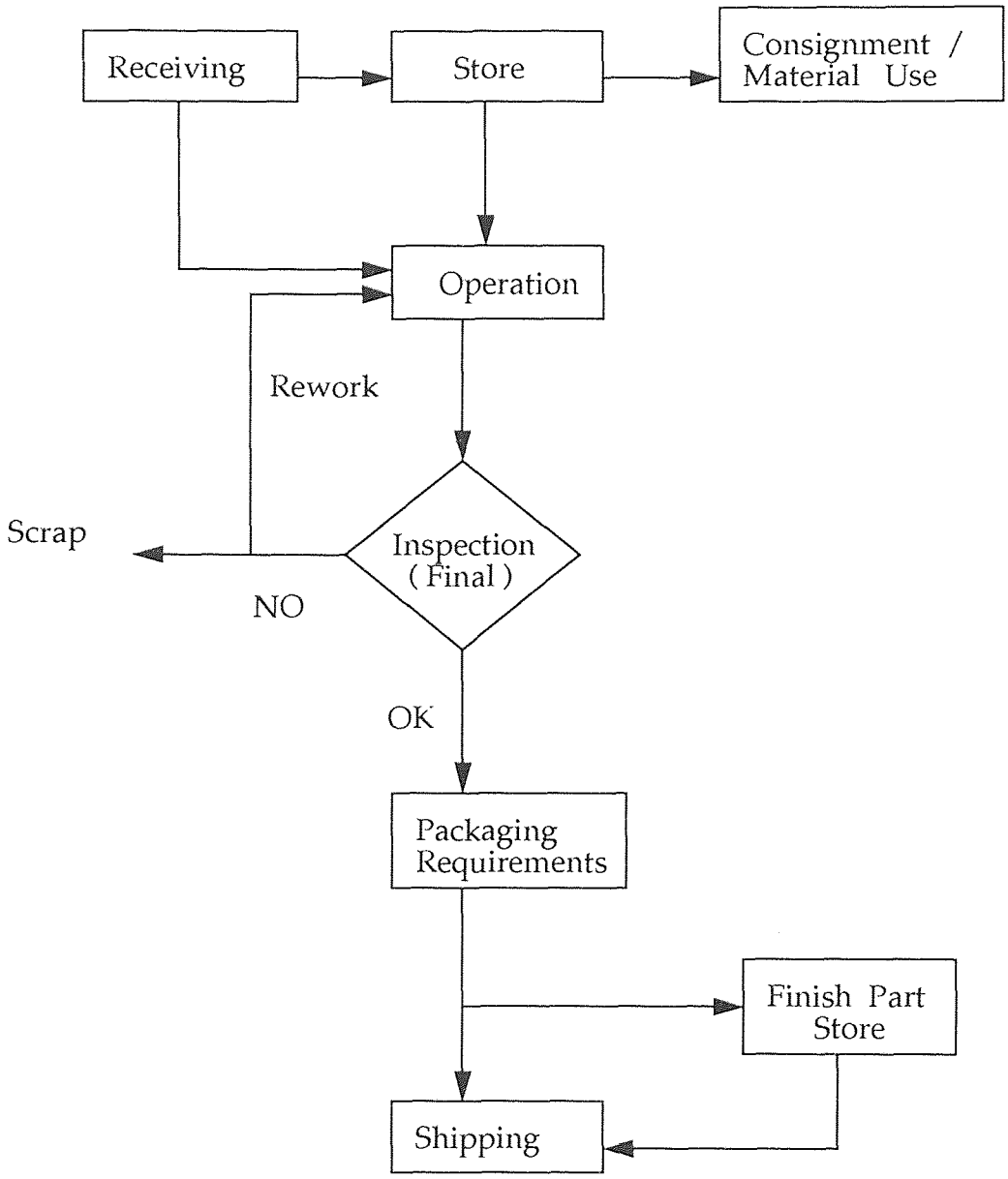

Figure A.8 Storage, Packaging and Delivery Procedure

APPENDIX A
(continued)

Supplier (Vendor) Assessment Procedure

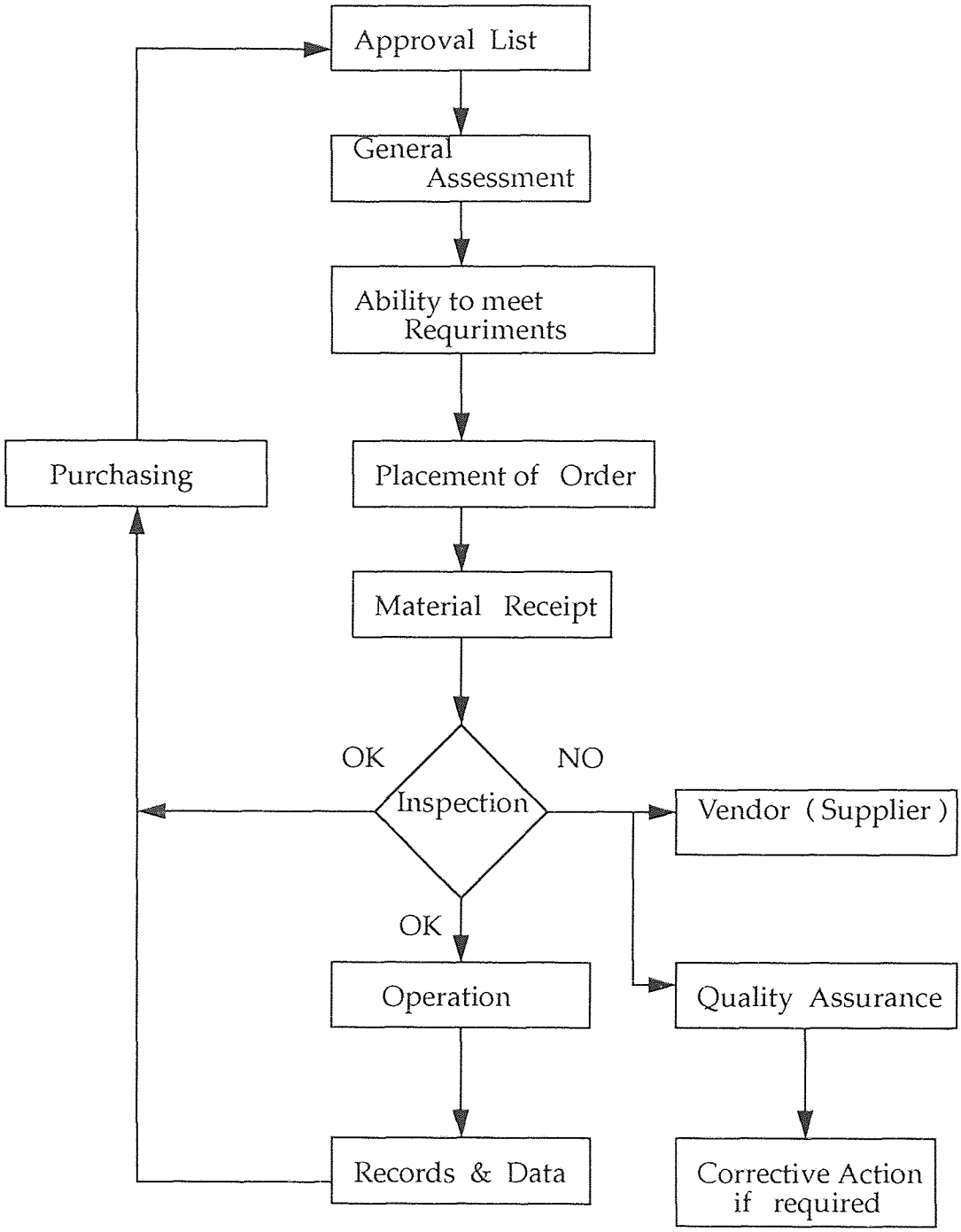

Figure A.9 Supplier (Vendor) Assessment Procedure

APPENDIX A
(continued)

Design Control

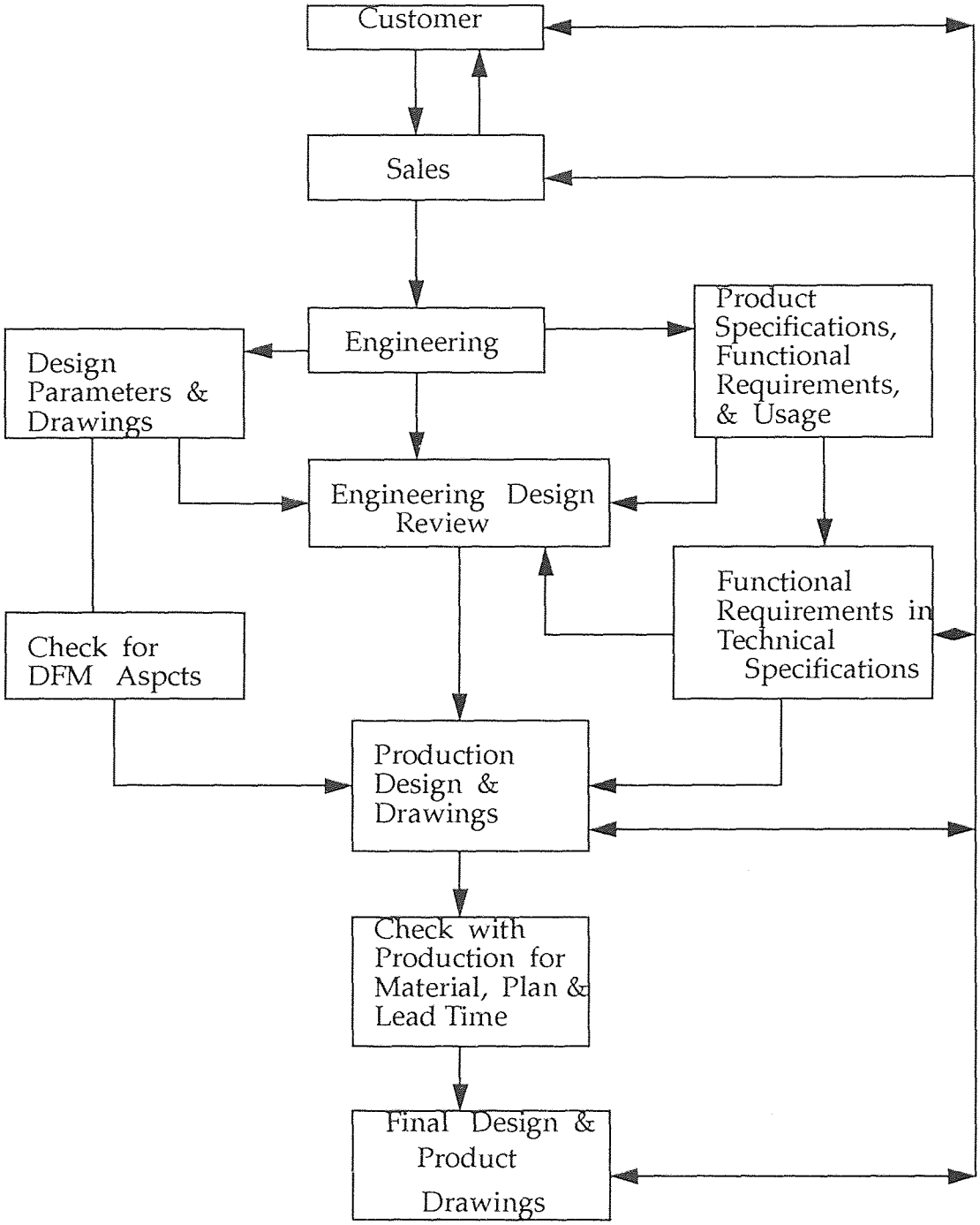

Figure A.10 Design Control procedure

APPENDIX B

INPUT and OUTPUT and ACTIVITY IDENTIFICATION

Input, activities and output are identified for each of the above group are listed here under :

APPENDIX B
(Continued)

1. Process Definition

Input	Activities	Output
* Customer requirements * Field support requirement * Product requirements * Manufacturing constraints * Specifications * Design standards * DFM guidelines * Available technology * Information from market analysis, forecast, quality and reliability yield * Documentation * Development plans * Customer contract requirement	* Analyze / clarify user needs * Analyze technical feasibility * Partition design & determine interface * Create functional definition * Capture design * Control changes * Build prototype or model * Technical feasibility and specify requirements * Plan development * Review plan * Define plan for customer needs and testing	* Product requirements includes - function - performance - quality and reliability - cost * product architecture * Specifications - interface - technology * Guidelines and standards * Drawing informations, codes, and stocklist * Prototype model * Onsite qualification documnts * Plan development

APPENDIX B
(Continued)

2. Process Control

Input	Activities	Output
* Product and process design information * Product manufacturing information * Raw material testing * Customer documentation * Product requirements * Process requirements * Process documentation * Inspection and testing * Maintenance and repairs documentation * Test reports * Inspection and review data * Quality review and results * Production reports * Handling and storage requirements * Packaging and delivery requirements	* Design and production samples * Product samples, process parameters, and resource availability * Testing characteristics to requirements and specification * Verify user interface and documentation * Track quality of product and processes * Develop methods, tools and training * Write procedures to follow inspection and inprocess testing * Procedures for repairs and maintenance, and current engineering systems * Keep records of lots, batches to trackdown postproduction defects in products * Product test and process test	* Product qualification documents - reports and specifications * Raw material quality and supplier's ability to meet specified material as per contract * Verification of raw manterial for further use * Verify customer / user needs as per contract * Products - interface and - interchangeability * Manufacturing yields and interface * Training cources * Quality reports and records * Nonconforming product control * Process capabilities * Feed back for improvement of product and manufacturing process * Handling, packaging, storage documentation * Operating test facility and process facility * Corrective action report

APPENDIX B
(Continued)

Input	Activities	Output
	records to track product and process quality for control	* Interdepartmental team for internal auditing and system evaluation
	* Control nonconforming products * Any change required in the system to control process * etailing special handling and storage requirement * Departmental procedure documentation for ease	

APPENDIX B
(Continued)

3. Process Measurement

Input	Activities	Output
* Verification and test specification of manufacturing product * Internal auditing team * Documentation team * Corrective action reports * Maintenance of machines and equipments	* Inspection and measurement of product * Inprocess inspection to track status of product * SQC techniques * Quality system * Root cause analysis * Process parameters	* Quality reports * Product conformity and assessment * Servicing * Correctie action * Eliminates reoccurance of, defective of defective product and process parameters * Process control

APPENDIX B
(Continued)

4. Process Improvement

Input	Activities	Output
* Quality reports * Corrective action * Production reports * SQC and SPC charts and data * Audit frequency plan * Preventive maintenance * Training * Documentation	* Investigation of causes * Implementation of actions * Verification of effectiveness * Data and charts analysis * Quality system audit * Training to internal audit team	* Prevent reoccurance of nonconforming products * Identification of nonconforming product * Process control * Quality system efficiency and effectiveness * Audit reports * Evaluation of corrective action needs * In-house trained audit team for periodic checking

APPENDIX B
(Continued)

5. Administrative

Input	Activities	Output
* Commitment * Define objective * Provide resources * Development plans * Organization stretagy * Customer documentation * Planning * Define general quality assurance policies	* Management review * Decision and actions -quality of product & process * Motivation to develop quality system * Time devotion * Appoint quality representative * Identify training needs * Documentation * Improvement and review of problems	* Quality policy * Quality system documentation * Quality system implementation and process * Training of employees * Approval quality manual * Technical specification of product * Training records * Establish phase cost of quality elements

APPENDIX C

QUESTIONNAIRE

1. Type of Quality Assurance System currently used.

   Please specify :

2. Company's registration under : ISO 9001 ❑ ; ISO 9002 ❑ ; ISO 9003❑

3. Reason for seeking registration :

   Please specify :

4. Measurement of quality cost :

   i) Failure cost ❑ increased by _____ % ❑ decreased by _____ % over total turnover.

   ii) Total quality cost : % of turnover _____ % , in dollar value $ _____ .

   iii) Total savings over a period of one year $_____ .

5. Time rquired for certification _____ months.

6. Benefits achieved : i) Retention of existing customer ❑

   ii) Gained new customers ❑

   iii) Access to oversea business ❑

   iv) Increase in market share ❑

   v) Improved product quality ❑

   vi) Unit cost per product ❑ increased / ❑ decreased by _____ % .

7. Change in the manufacturing enviornment :

   Do you have to change: i) current process ❑ Yes ❑ No

   ii) product design ❑ Yes ❑ No

   iii) process design ❑ Yes ❑ No

   iv) layout ❑ Yes ❑ No

APPENDIX C
(continued)

v) safety procedures ❑ Yes ❑ No

vi) material handling ❑ Yes ❑ No

vii) internal set up ❑ Yes ❑ No

viii)deviate from normal manufacturing process ❑ Yes ❑ No

ix) equipments and machines ❑ Yes ❑ No

8. In order to obtain certification for ISO 9000 standards, which new system did your company has to implement.

Please specify :

9. Training :

Whether personnel were required to train ❑ Yes , ❑ No.

10. Any problem encountered during the certification process :

i) Management related problem : ❑

ii) Process or material related problem : ❑

iii) Employee related nproblem : ❑

iv) Registrar or auditor related problem : ❑

v) Problem due to lack in standard itself : ❑

Please specify :

11. What is the average cost of maintaining certification per year in

$ _____ .

(It may include retention of quality manager, internal cost of maintaining certification, external cost such as recalibration, consultancy, audit etc..)

12. Special comments or any additional comment on the ISO 9000 certification process.

(Please use separate sheet to fill up data if required, give point no.)

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