Addis Ababa University
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Mechanical Engineering Department
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Course Title: Industrial Engineering Design Seminar

Title of the Project: Quality Management System Development based on ISO 9001:2000 case studies in Ethio-Plastic Share Company

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Chapter 1

1. INTRODUCTION

1.0 Background

1.1 Introduction to plastics

The term 'plastic' is as common as are the articles made from plastic material. It would be difficult in deeded to go through an average day with out coming into contact with at least one plastic article. The pens we write with, the steering wheels on our cars, the rugs we walk on, the clothes we wear, the stockings that cover shapely legs are made from one variety of plastic or another. The plastic industry plays a very vital role in other industries. In communication field for the production of radios, telephones, televisions and films; in the textile industry for the manufacturing of a wide range of so-called "miracle fabrics", in the automotive industry for the manufacturing of accessories and safety glass-plastics have become a very important material in our modern industrial society.

Any one of a large and varied group of materials consisting wholly or in part of combinations of carbon with oxygen, hydrogen, nitrogen and other organic and inorganic elements which, while in the finished state, at some stage in its manufacture is made liquid, and thus capable of being formed into various shapes, most usually through the application, either singly or together, of heat and pressure.

Plastic materials are divided in to two groups:

- Thermosetting ,and
- Thermoplastic.

The thermosetting material as the word implies, are set by the application of heat and pressure. The material cannot be restored to its original state after it has been changed to an infusible state. As mentioned before, a chemical reaction or change takes place when these materials are set or hardened into permanent shape by molding or other

processes. A chemical change takes place when the compound formed has new or different characteristic than the original elements or compound. Once the thermosetting plastic has undergone the chemical change, it is impossible to reuse the material for molding purposes; it is a great deal like the setting of cement.

Fillers of various kinds are used to give thermosetting materials desired properties. Some of the common fillers are wood floor (ground- up wood), chopped fabric (rags, canvas), asbestos, mica, and glass fibers. By varying the amount of filler, the type of filler and by adding various chemicals to the basic plastic compound, a broad range of characteristic can be obtained.

Since the Ethiopian plastic factory uses only thermoplastic materials we restrict our selves to the thermoplastic materials. Below are listed some of the basic thermoplastic materials.

Thermoplastic materials are capable of being molded when heated and they harden when cooled. No chemical change takes place during the molding process as in the thermosetting material. Only a physical change takes place and the chemical structure of the compound is not altered. Since no chemical change has taken place, the molded material can be reground into powdered form, reheated, and remolded. This characteristic of thermoplastic materials has been compared to the melting and re melting of wax.

Some of the thermoplastic materials are listed below:

i. celluloses
   A. cellulose Acetate
   B) Cellulose Acetate Butyrate
   C) Cellulose propionate
   D) Ethyl cellulose
ii. styrene polystyrene
iii. A.B.S(Acrylonitrile-butadrine-styrene)

iv. Vinyl group
v. Acrylic
vi. Nylon (polyamide)
vii. Polyethylene:
viii. Polypropylene
ix. Polycarbonate

1.2 Brief Descriptions of the Company Ethio-Plastics Sh.Co. (EPSC)

Ethio-Plastics Sh.Co. was established in 1957 by Italian shareholders. Firstly, the company is located around an area which traditionally called Mexico Square in Higher 21 Kebele 4, but now on this plant is transferred to Gerji area near A.M.C.E. The initial capital was 750,000(Seven hundred fifty thousand) Birr. In 1978 the plant was nationalized with the capitals of 2,200,000(two million two hundred thousand). At present, the company has around 377employees; Most of the employees are working in three shifts. The turnover rate of the company is 1.25 million birr in 1998 E.C. Currently, the company is operating under Public Enterprises Supervising Authority and attempts are being done to privatize it. The company hierarchy is established to ensure their policy and objectives are met. An organizational structure has been established with defined functional responsibilities and lines of communication for the appropriate direction and execution of activities.

1.2.2 The Vision of the Company

The vision of the organization or company is to be highly competent in plastic industries and related products in the global market by quality product with customer satisfaction.

1.2.3Corporate Strategy

The company has planned as its strategic plan for implementation of TQM, ISO 9001 certification up to 2008.

1.2.4The Objectives of the Company

Using different plastic raw materials and processing using the art-of-state for sufficiently providing them for selling in both local and the global market

Continuous improvement of the industry and expanding its infrastructure and it's over all operations.

Enhancing any business activities that could help the organization achieve its objectives

1.2.5 Organizational Structure of the Company

It has well-established organizational structure where by the production and technique department and quality control service are independently accountable to the General manager. EPSC has about 377 employees; that are permanent employees. The number of professionals including M.SC and B.SC do not exceed fifteen. Moreover, the company has significant number of diploma graduate and technicians.

Table 1 Educational back ground of the organizations

S.N	Educational level	Male	Female	Total	Percentage
1.	First Degree and above	15	3	18	4.8
2.	College Diploma	10	5	15	4.0
3.	Vocational and technique Diploma	46	21	67	17.8
4.	Grades 9-12	63	44	107	28.4
5.	Grades 1-8	72	62	134	35.5
6	Employee's who can't read &write	17	19	36	9.5
	Total	223	154	377	

Table 2 Distribution of labor in Organizational Sections

S.N	Section	Percentage (%)
1.	Administration	21.2
2.	Production and Technique	59.9
3.	Commercial Section	9.9
4.	Finance	8.2
5.	Quality Control	0.8

The organizational structure of the company is shown below.

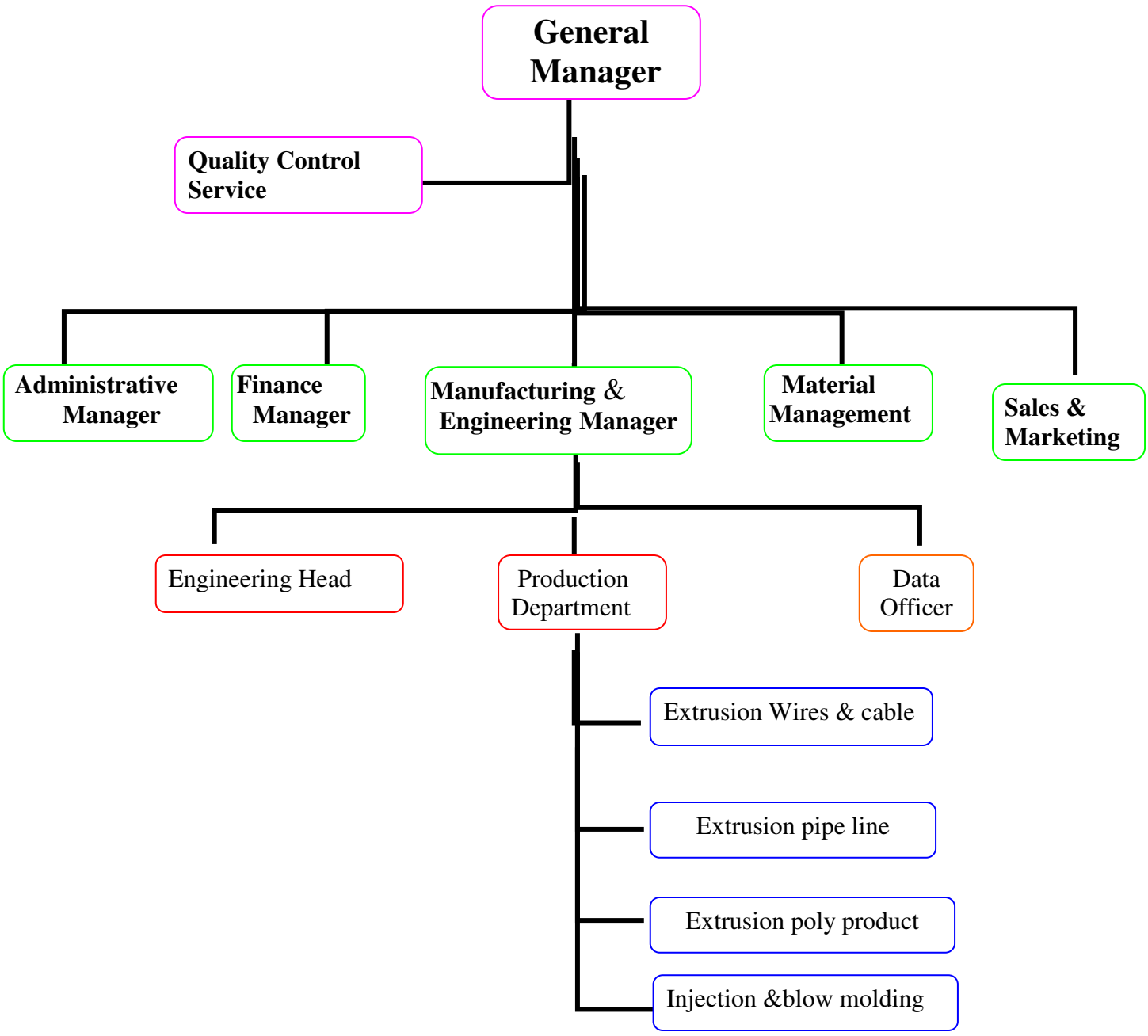

Figure 1 organizational structure of EPSC

1.2.6 Processes, Products and Capacity of the Company

Ethio-Plastics Sh.Co. (EPSC) Products, Processes & capacities

Ethiopia Plastics Sh.Co. products are divided into two main groups. Those products are general goods and construction materials under the general goods the following are produced.

I) **1) For Packaging Purpose**

- Polyethylene films of different sizes out of which different sizes of printed and unprinted bags are made.

2) Households plastics articles such as: -

- Jugs
- Cups -
- Lunch boxes
- Chair strap
- Big & small
- Big &small size bottles
- Plastic combs
- Tray
- Seal fresh box
- Honey jar & etc…

3) Plastics for agricultural activities

- Special plastics films
- Hoses for irrigation

4) Products of general purposes

- Ballpoint pen
- Ribbon band
- Stool cups
- Special bottles etc…

II) **b) Under construction materials: -** the following products are produced

- Electric wire
- Cables
- Conduits
- Low & High pressure pipe
- Flour tiles
- Shutter profiles

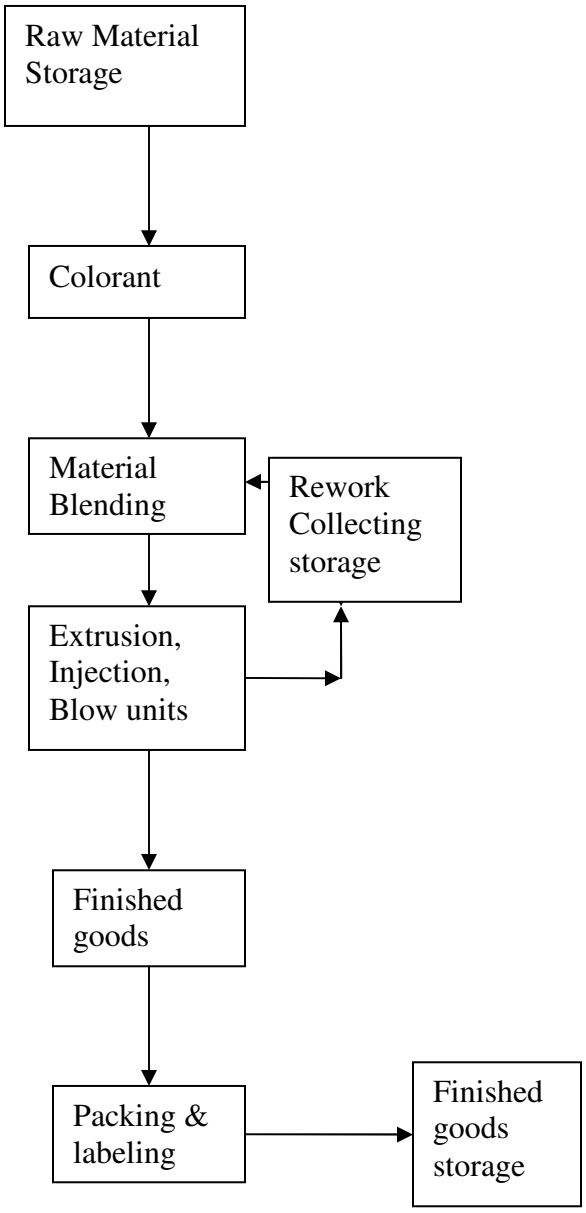

Figure 2 the main process flow diagram in EPSC

The main processing units in EPSC are the following

Film blowing unit

Extrusion unit

Injection unit

Blow molding unit

Film Blowing

Thermoplastics raw material of low-density polyethylene is fed on the hopper. The poured raw material enters in the film blowing extrusion machine with the help of screw rotation. The material is heated in the feeding zones of the extruder up to 115-170°c.

After complete homogenizations, the melt is changed into films by the help of external and internal air blowing system. The film is cooled by air and the tubular film produced taken to the store while others to the printing section. After printing it goes to the cutting and sealing section.

The finished product is weighed &taken into the store. The scraps of film products sent into recovery unit.

Extrusion

Pipes, conduits, shutter profiles and hoses use an extrusion machine the product passing through central mandrel for shaping the pipe wall and support it. The products are cooled and cut into the required sizes and taken to stock.

In the extrusion machine wire & cable coating used a crosshead die with the wire travailing at right angles to the flow of PVC insulation. After passing through the die the covered wire passes through a cooling water and metering section. The main temperature range of these sections is from 150-210°C.

Injection Unit

In injection molding thermoplastics pellets are heated until fluid, then resolidifies to reproduce the shape of the mold. Time, pressure and temperature are basic variables that must be controlled, given the poor thermal conductivity of the thermoplastic.

The fluid plastic is forced into the mold through the nozzle connecting the cylinder and the mold. The area of contact between mold and cylinder is small to minimize the flow of heat from the cylinder to the mold.

Blow molding

The blow molding process is used to make hollow articles especially bottles, barrels and other liquid containers. A tubular perform called a parison, is either injection molded or extruded and cut to length. The hot parison is placed in a split hollow mold and blown up to conform to the contour of the mold by air pressure in the interior of the parison.

The blow molding process has four basic operations

1. Production of parison.
2. Positioning of the mold halves to entrap the parison.
3. Forming the neck of the container.
4. Injection of air and cooling of the mold.

Raw material for EPSC

Man has learned to extract basic chemical from petroleum, natural gas, coal, air, water and agricultural by products and to recombine them into wholly new substance called plastics. EPSC uses the raw materials that are imported .The raw materials that are commonly used by EPSC are Low density poly-ethylene(LDPE) ,High density poly-ethylene(HDPE) ,Poly-vinyl-chloride(PVC) ,Poly-propylene(PP) ,Polystyrene(PS).Each raw materials used for different purposes.

LDPE:-Used for film production that are used for bags and packaging purpose.

HDPE:-Used for injection molding &blow molding that are used for household & container articles

PVC:-

- For production of boots & sandals
- For production of flexible garden hose
- For production of roller shutter
- For pressure pipes

PP:-used for production of caps of ballpoint pen

Capacity

Table 3 Estimated machineries production capacity

Machine Type	**Attainable capacity(kg/hr)**	**Yearly production(kg)**
Film blowing	194	937,250
PVC Extrusion	603.8	2,181,150
Injection & Blow molding	42.9	142,600
Boots	46.6	233,000
Machine Type	**Attainable capacity(mt/hr)**	**Yearly production(mts)**
Electric wire & cable	4,680	21,800,000

1.2.7Customers of the Company

The main customer of the company is from inland, some of them are; EEPCO,ETC,city administrator, constructors, laundries , garment & textile factories, Wonji sugars, ministry of defenses, whole sellers, retailers, house holds and others like governmental and non-governmental organizations.

Marketing is executed in different way, these are; distributing their product to their customer by their own vans, whole sale to the retailers, there are also shop of the company that sales the items directly to the individual customers and van sales on the road sides.

1.2.8Suppliers of the Company

Concerning suppliers, EPSC has no specific suppliers of raw materials, which it depend upon. Any legal trade organization which accepts the bid agreement can participate in providing sample plastic materials according to the specification described in bid announcement. The sample raw materials are tested for their important quality in the factory's laboratory or other professional external laboratories. Based on sample result, the martial management decides on the acceptance and rejection of supplier. Following the acceptance the formal bid evaluation is processed.

99% of the raw materials is imported from Middle East countries and only 1% (socks for boots is locally available).

So far diversified organizations are participated in the supply process from the local importers as well as different foreign countries. Suppliers from:

- United Arab Emirate
- Singapore
- Egypt
- Saudi Arabia and
- Ethiopia is common ones.

The main suppliers of the company are different agents like Dune Corporation, Endeco, Pharoe Plastic Corporation Egypt, Qatar Petrochemical, Kraimers Industry, AGECA, PetlinLd, and Industrial Resins Buatan Malaysia . The raw materials are received as per the contractual agreement between the company and suppliers. The raw materials are inspected up on receiving it.

1.2.9 Quality Control Section and Educational background of the Company

The current quality practice at the company is concerned mainly with reference to the quality control service department. The quality service of the factory is responsible for the quality of imported raw materials and the factory's products. The personnel of this service supervise the factory's processes by checking the raw materials and products according to desired specification. Generally quality in the organization is managed by inspection only. No preventive action is taken to avoid the occurrence of nonconformity.

Chapter 2

2.1 OBJECTIVE

General objective

The general objective of this report is to investigate implementation of Quality Management System (QMS) in Ethio-Plastic Share Company (EPSC) based on ISO 9001:2000

Specific objective

1. Develop a conceptual understanding of the basic principles and methods associated with QMS;
2. Develop an understanding of how these principles and methods have been put into effect in a variety of organizations;
3. Prepare the preliminary guidelines to commence the QMS promotion.
4. Develop the frame work of implementation of QMS tailored the EPSC needs, management style and the inherent working culture.
5. The complete project plans including the activities, estimates and implementation details.

2.2 METHODOLOGY:

The first step in this research is to review literatures in depth concerning QMS and major obstacles for its implementations, its principles and implementation strategies.

The second step will be to see the general background and existing conditions of the company under consideration.

The third step is data collection by interviewing, questionnaires, visiting and personal contact.

The forth step is analyzing and evaluating the collected data with respect to the implementation of QMS and devising best QMS strategy to the company.

The last step is recommending the best QMS implementation methodologies to the company.

2. 3 SIGNIFICANCE OF THE STUDY

An appropriate documented Quality Management System will help an organization not only achieve the objectives set out in its policy and strategy, but also, and equally importantly, sustain and build upon them. It is imperative that the leaders take responsibility for the adoption and documentation of an appropriate management system in their organization if they are serious about the quality journey. The Systems section discusses the benefits of having such a system, how to set one up and successfully implement it. The Quality Management System shall foster and provide guidance for the continual improvement efforts including customer satisfaction, and the quality and reliability of our products, processes and services.

The term ISO (Greek word isos, meaning "equal") is not, as many think, an acronym for International Standards Organization. Instead, it is short for the International Organization for Standardization, which established the ISO 9001` quality standards. The ISO 9001 series is used as a framework or set of guidelines for every organization's quality system. This series of standards is applicable to virtually any business.

The purpose of ISO 9001, is "to ensure that a manufacture's product is exactly the same today as it was yesterday, as it will be tomorrow" and that the "goods will be produced at the same level of quality even if all the employees were replaced by a new set of workers."

The standards are quality measurements (guidelines) that cover virtually all aspects of an enterprise. Unlike product standards, these standards are for quality management systems. They go beyond technical specifications. These standards can be used to establish a company –wide quality system for manufacturers and service entities alike. It is commonly used as a two-part contractual document between buyer (company) and seller (suppliers). Registration ensures that a company's quality systems meet international standards, thus eliminating many of the quality audits global customers normally require. The ISO 9001 forces companies to share information and understand who their internal and external customers are. An impartial third–party audit is a prerequisite to registration.

The ultimate objective of a quality management system (QMS) is to assist the organization in its quest for financial health. It achieves this aim through proceduralizing organizational activities to increase uniformity and conformity of repeated tasks. In recent times two strong approaches have grown up towards auditing whether or not organizations have in place adequate quality management systems. The first is concentrated around the ISO 9001 series of quality management system standards. This is a worldwide system which monitors the effectiveness of:

- the quality policy ;
- standardization of procedures;
- defect identification and elimination;
- system for corrective and preventive action ;
- Management review of the whole quality management system.

Chapter 3

3. PROBLEM STATEMENT

Developing countries face several problems concerning quality. The nature of these problems differs depending on the phase of development the country is in Consequently, the solutions to the problems also differ.

An increasing number of developing countries like Ethiopia are liberalizing

Their economies and adopting export- oriented policies. These changes lead to an increased awareness of the importance of quality. Moreover, the manufactured products can be sold on the International market, where they have to compete with products from other countries that have fully developed industrial economies. Foreign buyers are increasing requesting suppliers to the international market, where they have to compete with products from other countries that have to products from other countries that have fully developed industrial economies.

Foreign buyers are increasingly requesting suppliers to conform to the international standards on quality management systems (ISO 9001). The industries now have to develop, document, and introduce such systems. They must also, in many cases ensure that these systems are certified by an accredited institution.

To overcome the challenges and become competitive in the international market, companies should build QMS into their process that enables them to deliver quality at expected time and competitive price.

Chapter 4

4. Quality

4.1 Definitions and Contrasts

What is Quality?

The term quality means different things to different people. For example, a quality automobile may be one which has no defects and works exactly as we expect. Such a definition would fit with an oft-repeated definition by J.M Juran (1988): "Quality is fitness for use." However, there are other definitions widely discussed. Quality as "conformance to specifications" is a position that people in the manufacturing industry often promote. Others promote wider views which include the expectation that a product or service exceed the expectations of the customer. Such as Gitlow who believes quality is a judgment by customers or users of a product or service; it is the extent to which the customers or users believe the product or service surpasses their needs and expectations, and Ozeki and Asaka who believe. It means delivering products and services that 1) meet customer standards, 2) meet and fulfill customer needs, 3) meet customer expectations, and 4) will meet unanticipated future needs and aspirations. Still others simply ignore definitions and say "I'll know quality when I see it." It seems that we all 'know' or 'feel' somehow what quality is. A product or service that exceeds our preconceived idea about the quality of the product or service to be received is likely to be designated as a quality product or service. It is equally clear that the best of a group of bad products is not likely to be perceived as a quality product.

Table 4. Definitions of Quality from different angle

1. Customer-Based	Fitness for use, meeting customer expectations.
2. Manufacturing-Based	Conforming to design, specifications or requirements, having no defects.
3. Product-Based	The product has something that other similar products do not that adds value.
4. Value-Based	The product is the best combination of price and features.
5. Transcendent	It is not clear what it is, but it is something good...

4.1.1 The Terminology of Quality

The table below presents some of the terms that will be found throughout this document. Almost a litany of buzzwords, 'quality-speak' is becoming part of our culture. Already used widely in Japan, the terms in the table may well enter the mainstream of America's culture during the upcoming years. The terms displayed here were selected as some of the more widely used in the quality industry. Most terms are explained in upcoming chapters. For now, these quick definitions will provide a useful reference point.

Table 5. Terms Used in the Quality Field (In this table the term 'service' could be substituted for the 'term' product.)

TERM	DEFINTITIONS
Benchmarking	Comparing your product to the best competitors.
World-Class	The best in the world.
Six-Sigma Quality	Meaning 99.999997% perfect; only 3.4 defects in a million.
SPC	Statistical process control; used for measuring the conformance of a product to specifications.
Total Quality Control (TQM)	Controlling everything about a process.
A Process	What is actually done to create a product?
Design	The creation of a specification from concepts.
Manufacturing	Creating a product from specifications.
Test	Testing the product for defects.
Concurrent or Simultaneous Engineering	Integrating the design, manufacturing, and test processes.
Continuous Improvement	The process of iteration, which results in improving a product.
Customer Satisfaction	'Just what the term says...'
Quality Tools	Tools used to measure and observe every aspect of the creation of a product.
Metrics	Ways to measure: for example, time, cost, customer satisfaction, quality.
Flow Charting	Creating a 'map' of the operations of a process.
Adding Value	Adding something that was not there before that the customer wants.
'Bring to the Table'	Refers to what each individual in a meeting can contribute to a

	meeting, for example, a design or brainstorming meetings.

4.1.2 Quality in Different Areas in Society

What is quality? Several definitions have been given above. Also, the definition will vary depending on the domain under consideration. The table below lists several different areas in our society and indicates some things that might be considered to be related to quality in each.

Table 6. Quality in Different area

AREA	EXAMPLES
Airlines	On-time, comfortable, low-cost service.
Health Care	Correct diagnoses, minimum wait time, lower cost, security.
Food Services	Good product, fast delivery, good environment.
Postal Service	Fast delivery, correct delivery, cost containment.
Academia	Proper preparation for future, on-time knowledge delivery.
Consumer Products	Properly made, defect-free, cost effective
Insurance	Payoff on time, reasonable cost.
Military	Rapid deployment, decreased wages, no graft.
Automotive	Defect-free.
Communications	Clearer, faster, cheaper service.

What is the common denominator of these ten examples? Although the terms used to explain each area vary somewhat, almost all areas can be explained in terms of four basic parameters: cost, time, customer satisfaction, and defects. It is easy to see that some of these parameters are more important in some areas than others. For example, in health care it is vitally important that defects be minimized. In all cases, the bottom line is customer satisfaction. If you take an airline flight that is on-time, inexpensive, and there are no defects, you are satisfied!

4.1.2 Quality definition for managing quality (Jurans)

Of the many meaning of the word 'quality', two are of critical importance to managing for quality according to Juran.
'Quality' means those features of products which meet customer needs and these by provide customer satisfaction in this sense, the meaning of quality is oriented to income. The purpose of such higher quality is to provide greater customer satisfaction, and one hopes, to increase income. However, providing more and/ or better quality features usually requires on investment and hence usually involves increases in cost. Higher quality is this sense usually 'costs more'.

1. 'Quality' means freedom from deficiencies-freedom from errors that require doing work again (rework) or that result in field failures, customer failures, customer dissatisfactions, customer claims, and so on. In this sense, the meaning of quality is oriented to costs, and higher quality usually 'costs less'.

Product features that meet customer needs
Higher quality enables companies to:

Increase customer satisfaction make
Products salable
Meet competition
Increase market share
Provide sales income
Secure premium prices.
The major effect is on sales. Usually, higher quality costs more.

Freedom from deficiencies
Higher quality enables companies to:

Reduce error rates
Reduce rework, waste
Reduce warranty charges
Reduce customer dissatisfaction
Reduce inspection, test
Increase yields, capacity
Improve delivery performance
Major effect is on costs. Usually, higher quality costs less.

Table7 shows the attitude of quality which has little concern for quality (traditional attitude) and big concern for quality (Modern approach)

Topic	Content of little Q	Content of big Q
product	Manufactured goods	All products, goods, and services, whether for sales or not
processes	Processes directly related to manufacture of goods	All process manufacturing support, business, etc.
Industries	Manufacturing	All industries, manufacturing service, government, etc. whether for profit or not.
Quality is viewed as	A Technological problem	A business problem
Customer	Clients who buy the products	All who are affected, external and internal?
How to think about quality	Based on culture of functional departments	Based on universal trilogy
Quality goals are included	Among factory goals	In company business plan
Cost of poor quality	Costs associated with deficient manufactured goods	All costs that would disappear if every thing were perfect
Evaluation of quality is based on	Conformance to factory specifications, procedures, standards	Responsiveness to customer needs
Improvement is directed at	Departmental performance	Company wide
Training in managing quality is :	Concentrated in the quality department	Company wide
Coordination is by:	The quality manager	A quality council of upper managers.

4.2 Cost of Quality

Why is it important?

Quality processes cannot be justified simply because "everyone else is doing them" - but return on quality (ROQ) has dramatic impacts as companies mature. Research shows that the costs of poor quality can range from 15%-40% of business costs (e.g., rework, returns or complaints, reduced service levels, lost revenue). Most businesses do not know what their quality costs are because they do not keep reliable statistics. Finding and correcting mistakes consumes inordinately large portion resources. Typically, the cost to eliminate a failure in the customer phase is five times greater than it is at the development or manufacturing phase. Effective quality management decreases production costs because the sooner an error is found and corrected, the less costly it will be.

When to use it?

Cost of quality comprises of four parts:

- External Failure Cost
- Internal Failure Cost
- Inspection Cost
- Prevention Cost

How to useit?

1. Gather some basic information about the number of failures in the system,

2. Apply some basic assumptions to that data in order to quantify the data,

3. Chart the data based on the four elements listed above and studies it,

4. Allocate resources to combat the weak-spots,

5. Do this study on a regular basis and evaluate your performance

Cost of quality (COQ) is a phrase coined by Philip Crosby, noted quality expert and author and originator of the “zero defects” concept, to refer to the costs associated with providing

poor-quality products or services. Many quality practitioners thus prefer the term cost of poor quality (COPQ).

Four categories of costs contribute to an organization's overall COQ:

Internal failure costs - costs associated with defects found before the customer receives the product or service. These are costs that would disappear if no defects existed prior to shipment to the customer. These costs include rework, scrap, recheck or re inspection, corrective action, redesign, vendor defects, and other like defects.

External failure costs - costs associated with defects found after the customer receives the product or service. These are also costs that would disappear if no defects existed in the product after shipment to the customer. These costs include warranty and repair costs, product liability, and product recall.

Appraisal costs - costs incurred to determine the degree of conformance to quality requirements. These are costs incurred while performing inspections, checking, testing, or other planned activities to assure the hardware and software confirm to a certain requirement. These costs include first time inspection, Checking, supplier surveillance, receipt inspection, and other like costs.

Prevention costs - costs incurred to keep failure and appraisal costs to a minimum. These are the cost related to all activities to prevent defects from occurring and to keep appraisal and Failure to a minimum.

4.2.1 Hidden Quality costs/Tip of the Iceberg

The hidden taken as overhead cost

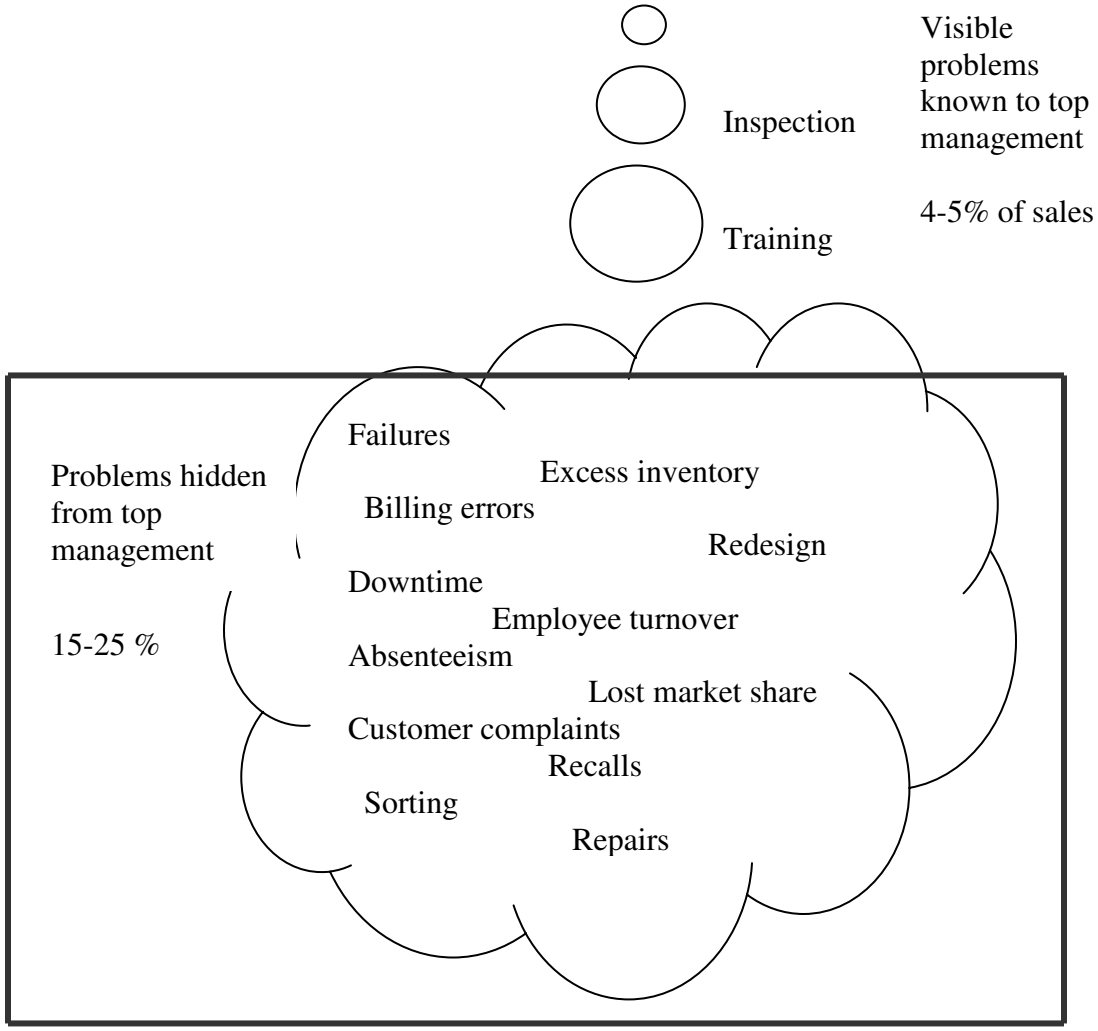

Figure 3: Costs of quality

Chapter 5

5. The Structure of ISO 9001: 2000
Quality Management System (4.)

5.1 Quality System – General Requirements(4.1)

The Organization model for the quality management system is derived from ISO 9004 and is supplemented by customer specific requirements. As specific quality system models, ISO 9001, Determine the sequence and interaction of the processes needed to maintain the quality management system;

- Determine criteria and methods needed to ensure that both the operation and control of the processes are effective;
- Measure, monitor and analyze these processes and implement actions necessary to meet goals and to drive continual improvement;
- Initiate action to prevent nonconformance;
- Initiate action to identify, record, and correct problems;
- Initiate, recommend or provide solutions;
- Verify implementation of solutions;
- Control further processing, delivery, or installation of nonconformance;
- Utilize the DMAIC (Define, Measure, Analyze, Improve and Control) process to implement breakthrough improvement;

Documentation Requirements(4.2)

Quality Policy and Quality Objectives(4.2.1)

Quality manual contains the statement of the Quality Policy and Quality Objectives.

Quality Manual(4.2.2)

The Quality function shall establish, implement, and maintain a documented quality system as a means of ensuring that products and services conform to specified requirements.

The documented quality system shall provide for timely consideration of the following activities in meeting specified requirements:

- Quality planning;
- The identification and facilitation of controls, processes, inspection, equipment, fixtures, production resources, and skills that may be needed to achieve the required quality;
- The updating, as necessary, of quality control, inspection, and testing techniques, including the development and acquisition of new instrumentation;
- The clarification and documentation of standards of acceptability for all features and requirements, including those which may contain a subjective element;
- For the entire product life cycle, ensuring the compatibility of the design, support services, production process, installation, inspection and test procedures, and the accuracy of the applicable documentation;
- The identification of suitable verification at appropriate stages of product or service development;
- The identification, preparation, and maintenance of quality records.

Document and Data Control (4.2.3)

The document control process shall provide for the timely review (e.g. business days, not weeks or months), distribution and maintenance of documentation for policies, processes, procedures, or techniques. The process shall provide for document approval, the use of a unique identifier for each controlled document, a distribution list or an equivalent method for identifying recipients, and change control. This control applies to documents regardless of format or media.

A master list or equivalent document control procedure shall identify the current revision of documents in order to preclude the use of non–applicable documents. Where practicable, this list shall be available on line to provide timely knowledge of, or access to, the appropriate revision of the controlling document. A history file of document revisions shall be retained.

Changes shall not be permitted in data records that verify product, process, or system acceptance without adequate control and approval.

Corporate forms should be used where possible; equivalent forms may be generated electronically as long as they contain the same information.

Customer supplied documents that can influence the design, verification, validation, inspection, testing or servicing of the product shall be controlled in accordance with the established procedures.

Documents shall be reviewed and changes implemented based on the customer-required schedule. A record of

the date on which each change is implemented in production shall be maintained. (TS)

Initial Issue (4.2.3.1)

The initial issue of internally controlled documents shall be coordinated with and approved by the appropriate authorized personnel prior to release of the documents. Initial release of documents shall be through the documented Engineering Change process. When non–Organization documents have been verified as applicable to Organization, the revision status shall be monitored and distribution shall be controlled within the company by the chartered function.

Changes (4.2.3.2)

Subsequent changes to controlled documents shall be made in accordance documented procedures and shall be reviewed and approved by the same functions that performed the original review and approval unless specifically designated otherwise. The procedure shall require date of approval and the effective date that product / document compliance to the change is required. When changes are made to products or processes or when new processes are initiated that affect

the customer drawing or product specification, identified internal and external customers shall be notified in accordance with documented procedures.

Product Part Approval Process (PPAP) documents shall be updated when affected by changes to controlled documents. (QS)

Drawings, Standards, and Specifications(4.2.3.3)

All drawings shall be prepared in accordance with Organization Drafting Standards. The Development / Product Engineering function shall be responsible for the preparation, maintenance, standardization, and obsolescence of all product drawings. All applicable Organizational Standards and Specifications – such as Design, Material, Mold, Finish, Quality, and Packaging – shall be used. The applicable Engineering function shall be responsible for the preparation, maintenance, standardization, and obsolescence of all standards and specifications.

Control of Quality Records(4.2.4)

It is the responsibility of all Business Units to identify, collect, maintain, store, and dispose of quality records to demonstrate conformance to established requirements and the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable.
Quality records include:

- Records of customer contracts that require less stringent quality systems procedures;
- Management quality system reviews;
- Employee qualifications and training records;
- Design, development, and testing activities;
- Customer contract and / or purchase order reviews;
- Design inputs;
- Design reviews and resulting actions;
- Results of verification and validation testing, including any necessary actions;
- Changes during the development process;
- Supplier records;
- Qualified processes, equipment, and personnel as appropriate;

- Unique identification of the individual product or lot – when traceability is a specified requirement;
- Notification to the customer when customer property is lost, damaged, or is otherwise unsuitable for use;
- Calibration records and test software verifications;
- Quality system audits;
- Inspection plans / control plans and results, including, as applicable, receiving, in–process, and final;
- Records of nonconforming material transactions, including: inspection rejections, internal rejections, deviations, customer complaints, and return material;
- Corrective and preventive actions;
- ***Other records as specified by the customer. (TS)***

Safeguards shall be maintained for records on any media that protects against disaster, system obsolescence, and loss.

Record Retention(4.2.4.1) ***(QS)***

Production part approvals, tooling records, purchase orders and amendments shall be maintained for the length of time that the part (or family of parts) is active for production and service requirements plus one calendar year unless otherwise specified by the customer. (QS)

MANAGEMENT RESPONSIBILITY (5.)

Management Commitment (5.1)

Senior management has total quality leadership responsibility for Total Quality Management and Six Sigma Operational Excellence. This includes ensuring the availability of resources, establishment and review of the quality policy and quality objectives, implementation, and continual improvement of the quality management system and deployment of breakthrough process improvement initiatives. Senior management also has the responsibility to communicate the importance of meeting customer, safety and

regulatory requirements. The Business Unit Leaders, including Quality Assurance, Engineering, Operations, Sales and Marketing support and assist senior management in these initiatives.

Senior management shall monitor the product realization processes and the support processes to assure their

effectiveness and efficiency. (TS)

Customer Focus (5.2)

Organization should welcomes the opportunity to meet with representatives of customers. Frequently these meetings involve the review of our performance as a supplier to these customers. The Sales and Marketing organization is the primary representative during these customer meetings. They will request participation from other applicable functions depending on the agenda for the meeting. Additionally, the opportunity to host customer representatives in manufacturing and engineering facilities frequently results in a better mutual understanding of customer requirements and supplier capabilities. The various organizational structures and entities, such as teams, account management, industry management and customer service are deployed by management to align our internal capabilities with the needs of our customers.

Quality Policy (5.3)

"It has to be the policy of organization to deliver error–free products and services on time. Processes and controls shall be implemented such that tasks are performed properly the first time and to ensure that all products and services provided to customers and to internal operations meet established requirements. Quality, continual improvement and customer satisfaction are the personal responsibility of each employee."

Planning (5.4)

Quality Objectives(5.4.1)

The quality management system and sustaining processes must support the Quality Policy and the company's goal of achieving EBIT (Earnings Before Interest and Taxes) performance. An effective quality management system will assist the company in meeting the needs of customers through the on time delivery of error free products and services. The quality management system will provide for timely and effective corrective action and provide a factual basis for continual improvement and defect prevention. Six Sigma Operational Excellence utilizes the DMAIC process to achieve breakthrough results. Performance against the targets that are established for the applicable measurements will be monitored at the senior management level:

- Total problem reports
- Problem report fix time
- Overdue problem fix responsiveness
- On time delivery.

Each Business Unit is responsible for establishing quality and performance objectives and for conducting regular management reviews to ensure that processes are meeting customer requirements and internal improvement goals.

Quality Management System Planning(5.4.2)

Quality planning at the company level shall consist of implementation, updating, and maintenance of this Quality Manual, Specification and the supporting quality specifications. Customer and supplier feedback, as supplied through formal reports, through performance reviews, during audits or through surveys shall be considered during the update reviews of Quality manual. The approach and deployment of quality planning within the Business Unit shall include, as appropriate:

- Design / Development Assurance Plans;

- Short and long term plans, including Six Sigma Black Belt projects, with goals for improving quality and customer satisfaction. Performance to these goals shall be monitored and reported. These plans shall address:
  - Product quality
  - Cycle time
  - Customer service
  - Training
  - Cost
  - Delivery commitments
  - Process capability
  - Product reliability
  - Maintaining methods for disaster recovery;
  - Cross–functional teams;
  - Subcontractor / supplier input;
  - Feasibility reviews;
  - Potential Failure Mode and Effects Analysis (FMEA);
  - Control plans, inspection and testing techniques;
  - Identification of customer special characteristics;
  - ***Consideration and awareness of product safety issues relative to design and process control; (QS)***
  - ***Utilization of mistake proofing methodologies when planning processes, facilities, equipment and tooling; (QS)***
  - ***Quality Planning, QS–9000 Supplemental Manuals (APQP and Control Plan, FMEA, SPC, MSA, and PPAP). (QS)***

Quality Planning Requirements For Suppliers(5.4.2.1) *(QS)*

Suppliers shall utilize quality planning to support the requirements of APQP and PPAP. (QS)

Business Plan (5.4.2.2) ***(TS)***

Each Business Unit shall have the authority and responsibility for ensuring compliance to the company's Business Plan requirements. As appropriate, the Business Plan shall be communicated throughout the organization. Comprehensive continual improvement activities shall be included in the plan. These activities shall address opportunities in quality and productivity. Business Plan results shall be tracked, reviewed, and revised by management at appropriate intervals. Records of such reviews shall be maintained. (QS) Senior management of the Business Unit shall define quality objectives that address customer expectations and measurements that shall be included in the Business Plan and used to deploy the Quality Policy. (TS)

Responsibility, Authority and Communication (5.5)

Responsibility and Authority (5.5.1)

The responsibility, authority, and interrelationship of all personnel and functions who influence product design, quality, processes, preventive and corrective action, or the quality system are defined through, but not limited to, organizational charts, job or position descriptions, skill requirements, individual performance reviews
(e.g. PBRs – Performance for Business Results, PEP – Performance Excellence Program), documented quality specifications, and the functional responsibilities defined in this document. All levels of personnel have the authority to halt nonconforming processes and initiate, recommend, or provide corrective / preventive solutions through designated channels.

Business Unit Representative Responsibilities(5.5.1.1)

- Ensuring that the requirements of the Total Quality Management Process are implemented, maintained and communicated and ensuring compliance with the

requirements of the ISO 9001, TL 9000 and / or QS–9000 / TS 16949 standards;

- Ensuring adequate resources and trained personnel for management and support of work;
- Approving Six Sigma Operational Excellence projects, including the goals, objectives and expected results;
- Establishing and maintaining appropriate communication processes within the unit.

Quality Assurance Representative or Manager Responsibilities (5.5.1.2):

The organizational Quality Assurance Representative and Managers shall have the authority and responsibility for ensuring that the requirements of the Total Quality Management Process are implemented and maintained.

- Regularly reporting to management the current performance of the Quality System and the level of customer satisfaction as a mechanism for continual improvement;
- Ensuring that the Business Unit complies with the applicable requirements of ISO 9001
- Providing liaison with external bodies on matters relating to the Quality System;
- Ensuring annually that the Business Unit has deployed the latest revision of ISO 9001 and / or QS–9000 / that supports this Quality Manual;

Six Sigma Champion Responsibilities (5.5.1.3):

- Developing and implementing the specific Six Sigma Operational Excellence strategy within the Business or designated portion of the Business;
- Mentoring and supporting the Master Black Belts, Black Belts and Green Belts within the Business or designated portion of the Business.

Management / Supervision Responsibilities (5.5.1.4):

- Ensuring that every employee under their direction is properly trained and aware of their role and responsibilities in carrying out the assigned quality activities that are defined in the quality policy and applicable quality specifications;
- Serving as the Six Sigma Operational Excellence Deployment Champion for Black Belt projects within their facility or team;

- Participating in the periodic review of the Total Quality Management Process and the implementation of any identified required improvements;
- Ensuring that adequate resources are assigned and made available for the completion of the appropriate quality activities within their assigned scope of responsibility;
- Determining the sequence and interaction of the processes needed to maintain the quality management system;
- Measuring, monitoring and analyzing these processes and implementing actions necessary to meet goals and to drive continual improvement;
- Ensuring the availability of information necessary to support the operation and monitoring of these processes;
- Ensuring compliance with applicable safety and regulatory requirements.

Team / Product Engineering Responsibilities (5.5.1.5):

- Assurance and validation that all newly released products for sale comply with all agreed upon customer requirements;
- Ensuring that all customer requirements are identified and planned for as part of the product design documentation, including but not limited to, material requirements, requirements for packaging and shipping, and required / agreed upon documentation that may be required with shipments;
- Identifying, analyzing, reviewing, and documenting any special customer quality, test, packaging requirements, including any exceptions prior to submitting a quotation or proposal;
- Internal coordination of customer / product line approvals and periodic product requalification;
- Measuring, monitoring and analyzing these processes and implementing actions necessary to meet goals and to drive continual improvement.
- Utilizing the DMAIC process when participating on Six Sigma Operational Excellence project teams or other applicable improvement activities.

4.6.2.5.1.6. Team / Manufacturing Engineering Responsibilities (5.5.1.6):

- Definition, validation, and installation of manufacturing processes that will consistently produce product in accordance with all identified safety, regulatory and customer requirements, including any applicable process control methodologies to assure conformance to requirements;
- Ensuring that appropriate process documentation is initiated and maintained;
- Implementing appropriate methods for the initiation / collection of any customer required process documentation (e.g. process control records, SPC, test / inspection records, traceability etc.);
- Measuring, monitoring and analyzing these processes and implementing actions necessary to meet goals and to drive continual improvement.
- Utilizing the DMAIC process when participating on Six Sigma Operational Excellence project teams or other applicable improvement activities.

Master Black Belt Responsibilities(5.5.1.7):

- Works with senior management to identify, classify and prioritize Six Sigma Operational Excellence projects;
- Organizes and provides Six Sigma training within the Business or designated portion of the Business;
- Coaches and assists the Black Belts and Green Belts with the technical aspects of the DMAIC process.

Black Belt Responsibilities(5.5.1.8):

- Serving as the key Six Sigma Operational Excellence project leader within the Business or designated portion of the Business;
- Implementing the principles, practices and techniques of Six Sigma and LEAN to achieve the goals and objectives of the assigned project;
- Providing on–site project management and support;

- Coaches and provides technical support to the Green Belts assigned to Six Sigma projects within the Business or designated portion of the Business;
- Utilizing the DMAIC process on assigned projects.

Green Belt Responsibilities(5.5.1.9:

- Participate on or lead Six Sigma Operational Excellence teams as directed by management;
- Utilizing the DMAIC process on assigned projects.

Human Resources Organization Responsibilities(5.5.1.10):

- Cultivate a culture that provides employees with the opportunity to realize their fullest potential to pursue the quality and performance objectives;
- Recruitment and placement qualified new employees;
- Promotion and recognition of employee contributions;
- Encouragement of increased employee empowerment, involvement, responsibility and innovation;
- Ensuring a work environment conducive to the well being, growth, and development of all employees in the organization.

4.6.2.5.2. Management Representative(5.5.2)

Company and Business Unit senior management shall appoint representatives who, irrespective of other responsibilities, shall have the responsibility and authority for:

- Ensuring that the requirements of the Total Quality Management Process are defined, implemented, and maintained, and ensuring compliance with the requirements of ISO 9001 and / or QS–9000 / standards and other quality system requirements agreed to by contract with the customer;
- Reporting to senior management on the current performance of the quality system as a basis for continual improvement;

- Assisting senior management in promoting customer requirements and continual improvement throughout the organization.

Total Quality Management Committee(5.5.2.1):

This is an ad hoc committee composed of the Quality Management, which has the following responsibilities:

- Assisting senior management with the deployment of the Total Quality Management Process;
- Maintaining, and improving the Total Quality Management Process;
- Developing and implementing company policy, systems, and procedures covering requirements for corrective action, preventive action, quality, reliability and other product assurance factors;
- Providing input to training programs with regard to policies and procedures relating to customer quality and reliability activities.

Customer Representative(5.5.2.2): ***(TS)***

Senior management shall designate individual(s) to represent the needs of the customer in internal functions in addressing QS–9000 and TS 16949 requirements (e.g. selection of special characteristics, setting quality objectives, training, corrective and preventive actions, product design and development). (TS)

Internal Communication (5.5.3.)

Senior management shall promote awareness of the quality policy; disseminate progress on quality performance and customer satisfaction and changes in the quality management system. This promotion may include activities such as meetings of key personnel, Intranet sites, videotapes, voice message announcements, newsletters, training programs, status reports, daily interactions, group meetings, and customer contact.

Management Review (5.6)

General (5.6.1)

The senior management team representing the scope of the certification shall review the Quality System semi–annually. This review identifies trends and adjusts policy and business plans, as necessary to meet the established goals for customers, suppliers, Organizations International and internal activity. The reviews shall also address, as appropriate, suitability of the Quality Policy, quality objectives and Quality Management System; changing business needs, customer satisfaction, operational and performance results, quality trends, continual improvement, assessment of resources, the results of quality audits, and corrective and preventive action activities. The management team of a Business Unit is responsible for local deployment of the Total Quality Management Process and for reviewing the quality management system. The purpose of the review is to assess the adequacy of resources, effectiveness and continuing suitability of the quality system. This review shall include all elements of the entire quality system and must be conducted at least annually. Records of quality system reviews shall be maintained. ***Management review shall include all elements of the quality management system, performance trends, monitoring the quality objectives and reporting and evaluation of the cost of poor quality. Results of the review shall address achievement of the objectives specified in the Quality Policy and Business Plan and customer satisfaction. (TS)***

Review Input (5.6.2)

The input to management review shall include information on:

- Audit results;
- Feedback from customers;
- Process performance and product conformity;
- Status of preventive and corrective actions;
- Follow up actions from previous management reviews;
- Changes that could affect the quality management system;

- Improvement recommendations;
- ***Analysis of actual and potential field failures and their impact on quality, safety or the environment; (TS)***
- ***Design and development project summary measurements. (TS)***

Review Output(5.6.3)

The output from the management review shall include any decisions and actions related to:

- Improvement of the effectiveness of the quality management system and it's supporting processes;
- Improvement of product related to customer requirements;
- Resource needs.

RESOURCE MANAGEMENT (6.)

Provision of Resources (6.1)

It is the responsibility of Business Unit management to ensure that the resources that are essential to the achievement of the organization's objectives, including implementing, maintaining and improving the quality management system and enhancing customer satisfaction, are identified during the planning processes. Resource requirements are usually planned during the budgeting process and adjusted during the year in response to sales growth, profit plans, capacity constraints, changing customer requirements and other internal needs. Management shall review the adequacy of resources and adjustments shall be made based on identified business needs.

Human Resources (6.2)

General (6.2.1)

Adequately trained personnel shall be provided to perform the required activities. Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

Competence, Awareness and Training (6.2.2)

The need for training can be identified through a comparison of job skills with the job description, changes in procedures, and nonconforming activity. When a need has been identified, training shall be scheduled and completed. Personnel who are qualified to perform their assigned tasks in accordance with established standards shall perform tasks affecting product, process, or system quality. Qualification shall be based on education, experience, and / or training.

Human Resources Organization(6.2.2.1)

The Human Resources organization has the responsibility for establishing, maintaining and implementing company wide training programs. Internal training courses shall be planned, developed and implemented in accordance with established procedures. Company–wide programs may be augmented with programs deployed at the local level.

Qualification Training (6.2.2.2)

Job training shall be provided for personnel, including contract or agency personnel, in any new or modified job affecting product quality. Local Business Unit management shall establish operator qualification and requalification requirements as appropriate. Requirements for qualification shall, at a minimum, address employee education, experience, training and demonstrated competency. Employee qualification records shall be maintained at the local facility and be available to the employee and supervision.
Records of formal training, including supervisor–conducted programs, shall be maintained on file as part of the employee's personal history in Human Resources.

Personnel with product design responsibilities shall be qualified to achieve the design requirements and shall be skilled in applicable tools and techniques. (TS)

Quality Training (6.2.2.3)

To ensure that there is an awareness of the importance of quality, employees who have a direct impact on the quality of the products, including the senior management, shall be trained in the fundamental concepts of quality improvement, problem solving and customer satisfaction. ***Personnel whose work can affect quality shall be informed about the consequences to the customer when there is a nonconformance to specified quality requirements. (TS)***

Training Requirements and Awareness (6.2.2.4)

Training requirements shall be defined for all employees. Employees shall be made aware of training opportunities.

A documented procedure shall be established and maintained for identification of training needs and achievement of competency of all personnel performing activities affecting product quality. Attention shall be given to satisfy any customer specific requirements. (TS)

Training Effectiveness (6.2.2.5)

The effectiveness of a training program is expected to manifest itself through improvement in job performance and / or product quality. Program evaluations shall be conducted to verify this relationship. Methods such as pre– and post–testing, audits, employee interviews and performance appraisals may be used.

Employee Motivation and Empowerment *(TS)* (6.2.2.6)

A process for motivating employees to achieve quality objectives, to make continual improvements and to create an environment to promote innovation shall be established. The process shall include the promotion of quality and technological awareness throughout the organization. (TS)

The Business Unit shall have a process to measure the extent to which employees are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives. (TS)

Infrastructure (6.3)

Business Unit management shall define, provide and maintain the infrastructure necessary to ensure that product conforms to established requirements.

Facility Planning (6.3.1)*(TS)*

A system shall be utilized which uses a multi–disciplinary approach for developing facilities, processes and equipment plans. Plant layouts shall optimize travel, handling and value–added use of floor space and shall facilitate synchronous material flow. Methods shall be developed and implemented to evaluate and monitor the effectiveness of existing operations. (TS)

Work Environment (6.4)

Facilities, including workstations and associated equipment, shall be maintained in a state of order, cleanliness, and repair appropriate to the product(s) manufactured or to the service being provided. All work areas must comply with established safety, regulatory and environmental standards and codes.

The established requirements, as described in the Quality Policy, include addressing of product safety and means to minimize potential risks to employees. These requirements

shall especially be addressed in design, development, and manufacturing process activities. (TS)

PRODUCT REALIZATION (7.)

Planning of Product Realization (7.1)

It is the responsibility of the Business Unit to identify and plan for the production processes necessary for product realization. These processes should be carried out in accordance with documented procedures.

Life Cycle Model (7.1.1)

The organization should developed a set of guidelines to model the activities required to take customer requirements and convert them into internal requirements and specifications that support manufacturing and maintaining the integrity of the products, delivering the products and discontinuing the products as customer demands change.

New Product Introduction(7.1.2)

The design review process is utilized to assure appropriate introduction of new products. Procedures and processes for the introduction of new products are detailed in Section 7.3 (Design and Development Planning) and in the related quality specifications. Safe Launch procedures may be applied to a new product introduction or to significant product or process changes.

Disaster Recovery Planning(7.1.3)

Business recovery plans are developed and maintained at the facility level to ensure the ability to maintain product and service continuity in the event of a disaster. Contingency plans shall be prepared in the event of emergency (e.g. utility interruptions, labor shortages,

key equipment failure, field returns) to reasonably protect the customer's supply of product. (TS)

End of Life Planning (7.1.4)

Organizations should develope a process to ensure the efficient discontinuance of products. This process attempts to minimize the inconvenience for the customer, while at the same time, allowing the organization to achieve the required business objectives.

Configuration Management (7.1.4)

Configuration management is maintained through the utilization of engineering change control and through control of the process documentation.

Customer Related Processes (7.2)

Determination of Product Requirements (7.2.1)

The Marketing / Sales function shall launch the establishment of product requirements by:

- Determining the need for a product or service;
- Evaluating the potential for delivering a profitable product or service;
- Accurately defining the market demand and sector, since doing so is important in determining the grade, quantity, price, and timing estimates for the product or service;
- Accurately determining customer requirements, including the requirements for availability, delivery and support, by a review of contract or market needs; including an assessment of any unstated expectations or biases held by customers;
- Communicating all customer requirements clearly and accurately.

The Marketing / Sales function shall provide a formal statement or outline of product requirements which translates customer requirements and expectations into a preliminary set of specifications as the basis for subsequent design work.

Development / Product Engineering is responsible for documenting any other product requirements, including regulatory requirements into the design objectives /product specification or equivalent.

Customer Contract / Purchase Order Review (7.2.2)

Records of the results of the review of customer contracts and / or purchase orders shall be maintained.

Customer Service (7.2.2.1)

The Customer Service function shall be responsible for:

- Ensuring adequate definition of customer requirements;
- Forwarding to the appropriate functions customer specifications, requests for quotes, contracts, or purchase orders in which the customer is ordering product with nonstandard requirements;
- Requests for alterations to products and services as specified in the customer documentation.

Customer Specification Review(7.2.2.2)

The appropriate functions responsible for verifying that the customer request can be satisfied shall review the purchase order, request for quote, drawing or specification. Appropriate action shall be initiated to resolve differences to ensure satisfaction of contractual requirements before acceptance of the order. This verification shall include a consideration of verbal and electronic ordering methods as well as a means to convey changes to existing order requirements. Amendments to contracts shall be reviewed and appropriate actions shall be initiated to resolve any differences. The review of customer specifications shall include as appropriate:

- The Development / Product Engineering function shall be responsible for determining product compliance with the customer's requirements and the initiation of the cross–reference process;
- The Quality function shall be responsible for determining compliance to those quality requirements that include measurement data, performance criteria, verification requirements, customer special requirements, audit parameters and processing customer complaints;
- The Packaging Engineering function shall be responsible for determining compliance to special labeling and packaging requirements;
- The Materials function shall be responsible for determining compliance to the delivery requirements;
- The Contracts Administration function in conjunction with the Legal Department, shall be responsible for review of any contract documents containing other than the organization standard terms and conditions;
- ***The Manufacturing Engineering function shall investigate, confirm and document the manufacturing feasibility of the proposed products, including risk analysis. (TS)***

Customer Communication(7.2.3)

The Sales and Marketing organization is the primary interface for ensuring that all customer requests for information are satisfied. In addition, there are multiple electronic systems to assist customers in obtaining product information. Customer Service is the primary function for providing responses to customer inquiries about purchase orders and delivery dates. Quality Assurance is the primary function for establishing the process for resolving customer complaints, including problem escalation, customer feedback and product recall. Quality Assurance, in conjunction with Field Sales, is also responsible for communicating with customers during the resolution of complaints or product nonconformity issues.

Customer communications shall include the ability to exchange information and data in a customer–specified language and format. (TS)

Design and Development(7.3)

Design and Development Planning (7.3.1)

The design of a product must be the result of thorough and careful consideration of the customer's requirements, the potential use of the product, the potential product life cycle and the manufacturability of the product. The following activities shall be the responsibility of Business Unit Engineering and Quality functions. Records shall be kept of design, development, and testing activities.

Project Planning(7.3.1.1)

Timely project plans shall be prepared by engineering management that identify the responsibility, budgets, staffing and schedules for each design and development activity. The plans shall be updated and communicated to the appropriate individuals as each design evolves. The plans, based on the life cycle model, shall describe or reference the following activities, as applicable:

- Organizational and technical interfaces between different groups (internal and external) shall be identified and the necessary information documented, transmitted, and reviewed;
- Project roles and responsibilities;
- Project reporting requirements, including tracking and resolving open issues;
- Risk management and contingency plans;
- Performance, safety, security and other critical requirements;
- Any project specific training requirements;
- Usage or licensing rights;
- Post project analysis.

Product Test Planning(7.3.1.2)

Product available for sale shall be described with product specifications. If the product is intended
to meet an equivalent specification – such as government, agency, specific customer specification, or a recognized industry standard – that document shall be considered the controlling or minimum specification of the requirements. A preliminary document clearly marked "Design Objectives" shall be prepared for use during engineering development and related testing activity by the Development / Product Engineering function, with the assistance of the Quality and/or Reliability Engineering functions. This specification shall define the intended performance characteristics.

Design and Development Input((7.3.2)

Design input requirements relating to the product requirements shall be identified, documented and reviewed by the Business Unit. Records of design input shall be maintained. Design inputs shall consider, but not be limited to:

- Requirements established by the customer input;
- Functional and performance requirements;
- Design constraints;
- Requirements for certification / agency approvals;
- Overall fitness for and impact on the customer's application, including, as applicable, installability, usability and maintainability;
- Supplier capability and input;
- Performance characteristics such as environmental and usage conditions, including any reliability requirements;
- Ergonomic characteristics such as ease of handling and ease of use;
- Installation, configuration, or fit;
- Industry standards and safety and regulatory requirements;

- Packaging and marking;
- Quality / product assurance inspection activities;
- Verification and validation testing requirements;
- Application requirements;
- Manufacturing and procurement requirements;
- Analysis of similar product (including competitive product) and process designs, work operations, deviations, quality records, service reports, and customer complaints to detect and eliminate potential causes of nonconforming product;
- Manufacturability of design, ***including any design constraints, nominal values and tolerances; (QS)***
- ***Appropriate resources and facilities to utilize computer–aided product design, engineering and analysis and technical leadership for these functions if subcontracted; (QS)***
- ***CAD / CAE systems two way interface with customer systems; (QS)***
- ***Establishment of targets for product quality, life, reliability, durability, maintainability, timing and cost. (TS)***

Customer and Supplier Input(7.3.2.1)

During the development of a new product, or during the extension of an existing product, customer input can be received in a variety of formal and informal methods, including:

- Customer supplied documents and prints;
- Industry standards and documents;
- Field Sales Proposal Requests or Sales Logs;
- Customer Visit Summaries.

Manufacturing Process Design *(TS)* (7.3.2.2)

The manufacturing process design shall be identified, documented and reviewed. Design inputs shall include: (TS)

- ***Data from the output of the product design; (TS)***
- ***Targets for productivity, process capability and cost; (TS)***
- ***Applicable customer requirements; (TS)***
- ***Experience from similar products and previous process development. (TS)***

Design and Development Outputs(7.3.3)

The design output shall be documented and expressed in terms of requirements, calculations and analyses, and shall:

- Meet the design input requirements;
- Provide the information required for manufacturing the product – including any purchasing information;
- Define the acceptance criteria;
- Conform to documented industry, safety and regulatory requirements where appropriate;
- Identify those characteristics of the design that are crucial to the safe and proper functioning of the product;
- Result from a process that makes appropriate use of the Basic and Advanced Quality Tools, such as Design of Experiments (DOE), Failure Mode and Effects Analysis (FMEA); Statistical Tolerance Analysis, etc.;
- ***Identify special characteristics in the control plan; (TS)***
- ***Comply with customer specified definitions and symbols by providing these symbols or equivalent on control plans, drawings, FMEA's and operator instructions; (TS)_ Consider product error–proofing as appropriate. (TS)***

Manufacturing Process Design Output (7.3.3.1) *(TS)*

The manufacturing process design output shall include: (TS)

- ***Specifications and drawings; (TS)***
- ***Manufacturing process flow chart or layout; (TS)***
- ***Process FMEA's; (TS)***
- ***Control plan; (TS)***
- ***Work instructions; (TS)***
- ***Process approval acceptance criteria; (TS)***
- ***Data for quality, reliability, maintainability and measurability; (TS)***
- ***Results of error–proofing activities as appropriate; (TS)***
- ***Identification of methods for rapid detection and feedback of product and process nonconformances. (TS)***

Design and Development Review(7.3.4)

All product, process, and application tooling designs shall be analyzed via a formal design review
process. Design review activities shall be held at key times during the development cycle. Design
review activities shall be documented and administered in accordance with the specification for
design review. Records of design review activities and resulting actions shall be maintained.
The design review activities shall include verification that the design output meets the design input requirements as identified by the customer or Marketing, the identification of any problems and their proposed resolution. Design verification shall include, as appropriate, alternative
calculations, comparison to a comparable proven design, and / or testing.

Confidentiality(7.3.4.1)

Confidentiality of customer–contracted products under development and related product

information shall be ensured.

Monitoring (7.3.4.2) *(TS)*

Measurements at specified stages of design and development shall be defined, analyzed and reported with summary results as an input to management review. (TS)

Design and Development Verification(7.3.5)

During development, every product shall be subjected to a testing program designed to evaluate the ability of the product to meet the design objectives for its intended end use. These programs shall be planned, established and conducted jointly by the Product / Development, Quality, and/or Reliability Engineering functions to:

- Investigate potential failure modes and verify their effects on both the design and the manufacturing processes;
- Demonstrate the product design capability for each performance characteristic specified in the design objectives.

The design of these tests should consider mechanical and environmental stresses at least as severe as the design objectives, the necessity to generate data for statistical analysis, and, when required, the establishment of a reliability statement. Records of the results of verification testing and any necessary actions shall be maintained.

Design and Development Validation(7.3.6)

Following successful completion of design verification, product for sale shall be validated to ensure compliance with the product specification.

Qualification Tests (7.3.6.1)

At the appropriate point in the development cycle of the product, ***or as required by timing of the customers program, (TS)*** the Design / Quality function shall coordinate a product

performance evaluation. This shall be done by submitting product(s) certified as acceptable by the responsible function in the Business Unit to the qualification test sequence described in the preliminary product, customer, or agency specification. A report of the results shall be prepared, and any differences between specification requirements and test data must be reconciled and documented, to permit product qualification. Successful qualification shall permit removal of the "Design Objectives" qualifier from the product specification. Records of the results of validation testing and any necessary actions shall be maintained.

Production Prototypes(7.3.6.2)

Customers shall be supplied with production prototypes as required. Whenever possible, these prototypes shall utilize the same suppliers, tooling and processes that will be used during production.

Control of Design and Development Changes(7.3.7)

All design changes – for example: product, process, system, software, packaging style, packaging type, and material or component substitution – shall be identified, documented, reviewed, and approved by authorized personnel before implementation. Records of changes during the development process shall be maintained. Development / Product Engineering is responsible for monitoring and ensuring that the changes do not adversely affect product quality, performance or reliability. Customers shall be notified of design changes affecting the form, fit, function, packaging style or packaging type of a product. In addition and where contracted or mandated by quality system certification requirements, customer approval of design changes shall be obtained. An internally defined or customer directed process for obtaining such approvals shall be utilized.

For proprietary designs, impact on form, fit, function, performance and reliability shall be reviewed with the customer. (TS)

Purchasing (7.4)

Purchasing Process (7.4.1)

Purchasing, in consultation with the Business Unit, Advanced Materials Technology, Product Engineering, Manufacturing, Supplier Quality Assurance and Legal, is responsible for supplier selection. Purchasing is also responsible for on–going support, risk analysis, supply base management, technical leadership, contract definition and ensuring that proprietary, usage and licensing agreements are completed. Order releases may be done by the Purchasing function, the Materials organization, or Contract Administration. To ensure that the supplier has the necessary documentation to provide what is requested, Purchasing is responsible for coordinating with the appropriate function such items as drawings, referenced specifications, packaging and labeling requirements, and quality assurance requirements for all initial purchase orders. This
documentation shall be updated by the appropriate function to include any changes on an as–needed basis and shall be transmitted to the supplier by Purchasing. Records of acceptable suppliers shall be maintained. Purchased product shall comply with all governmental, safety, and environmental requirements for the country of manufacture and sale.

New Suppliers (7.4.1.1)

New suppliers of production materials, components and assemblies, as well as service suppliers that could impact product quality or delivery, shall be evaluated prior to classification as an approved supplier. Acceptable methods include: surveys (including statistical enhancement of survey results), on–site audits, first article submittal, certification by a known source, and experience of customers. It is the responsibility of the Purchasing and Quality functions to complete this evaluation. Records of the results of evaluations and any necessary actions resulting from supplier evaluations shall be maintained by Purchasing. In the event an external customer has an approved subcontractor list, the responsible Business Unit must coordinate with Purchasing to make sure that those suppliers are included in the organization supply base. The organization is responsible for products and services purchased from customer designated suppliers. Optionally, the

Business Unit may work with the customer to have the organization supplier added to their list of approved suppliers.

The supplier shall comply with the applicable legal and environmental requirements.

Supplier Performance(7.4.1.2)

Quality and delivery performance ratings shall be transmitted to the suppliers based on supplier activity. ***Additional supplier monitoring indicators include customer disruptions, field failures and special status customer notifications related to quality or delivery issues. (TS)*** Purchasing and Supplier Quality Assurance shall administer the evaluation of suppliers' performance. The supplier's quality system shall be subject to development by the organization as required. Options for development may include training, supplier days, and one–on–one sessions with suppliers for corrective action review. ***Suppliers shall be third party registered to ISO 9001:2000 with the goal of compliance to TS 16949. (TS)*** Additional development activity can be identified utilizing the monthly supplier reports that are sent to the supply base. Purchasing / Supplier Quality Assurance, in response to poor performance as identified by the reports and based on status and importance, will solicit corrective actions to eliminate this poor performance. ***Additional assistance may be offered to the supplier if the development activity or corrective action is determined by the Business Unit to be significant. (QS)Business Units shall utilize the Logistics reporting for the tracking of premium freight charges. Tracking shall facilitate whether the premium freight was for inbound or outbound freight. (QS)***

Purchasing Information(7.4.2)

Purchase orders placed with suppliers shall define the product, the revision level and any additional quality assurance requirements beyond those established in the organization Quality Assurance Requirements for Suppliers.

Verification of Purchased Products(7.4.3)

Process control is an essential part of our product assurance requirements. Production suppliers are encouraged to ensure that their processes are continuously capable of producing within specified limits via statistical process control or other appropriate method that will provide confidence in the quality and delivery of the product at a competitive price. Under requirements of the purchase order, appropriate data may be requested from a supplier's process control system, ***or The organization may verify the product at the supplier's site. (TS)***

First Article Approval(7.4.3.1)

When purchasing any production tooling that requires first–article approval, the Quality, Manufacturing, and Materials organizations shall ensure that the required documentation is sent to the supplier. The purchase order shall note requirements for first–article approval. ***For products supplied to automotive customers, the PPAP methodology, or other customer recognized procedures, shall be utilized for production tool approval. (QS)***

Receiving Inspection(7.4.3.2)

It shall be the responsibility of the Business Unit to determine the means of verifying that suppliers meet their contractual obligations related to the quality of the procured items. This can be accomplished by one of five methods:

- Stock as Received (SAR) – following receipt of the material, it can be placed directly into stores without any receiving inspection activity. Material may be designated Stock as Received based on supplier or part number certification as administered through Purchasing / Supplier Quality Assurance or as approved by the Business Unit. Purchasing /Supplier Quality Assurance is responsible for periodic assessments of certified suppliers.
- Supplier warrants or Certificate of Analysis (C of A), with test results, submitted with the material.

- Incoming inspection – each lot of received material shall be inspected to confirm conformance to specifications.
- Skip lot inspection – lots of received material are inspected as defined by a skip lot plan.
- Product is evaluated and reported as acceptable by an accredited supplier or test laboratory.

In the event that materials are needed for manufacturing commitments before receiving inspection is complete, a plan shall be developed to provide for positive identification and control of the product produced until the material is deemed to be acceptable. Unless the manufacturing site or the Business Unit implements specific directives, material received from other locations or subsidiaries of The organization shall be processed directly into stock without receiving inspection of product characteristics. Product acceptance shall be completed as defined in documented procedures. In all cases it is the responsibility of the supplying operation to ensure the product meets established requirements. It shall be the responsibility of receiving inspection to identify and segregate nonconforming procured items so they are not inadvertently used. Disposition of nonconforming items shall be made by the responsible engineering disciplines, or designee. The supplier shall be formally advised of both the rejection and if there is a requirement to provide corrective action.

Production and Service Processes (7.4.3.3)

Control of Production and Service Processes (7.4.3.3.1)

Identification and planning of production and service processes that directly affect quality shall ensure that these processes are carried out with documented procedures. The organization shall comply with reference standards and codes, engineering / production drawings and specifications, quality plans and other documented procedures to monitor and control suitable process parameters and product characteristics. These product characteristics include special characteristics, which need specific attention because excessive variation might affect a product's safety, compliance with customer specified characteristics, government regulations, fit, function, appearance or the quality of

subsequent manufacturing operations. Qualified operators shall carry out the processes. The organization shall identify key process equipment, monitoring / measuring devices and provide appropriate resources for machine / equipment maintenance and develop an effective, planned total preventive maintenance system. Maintenance activities are deployed to sustain process capability requirements and product quality requirements. ***As a minimum, the preventive maintenance system shall include planned maintenance activities, packaging and preservation of equipment, tooling and gauging, availability of replacement parts for key manufacturing equipment and documenting, evaluating and improving maintenance activities. (TS)***

Records shall be maintained for qualified processes, equipment and personnel, as appropriate. ***Predictive maintenance methods shall be used to continually improve the effectiveness and efficiency of production equipment. (TS)***

Control Plans (7.4.3.3.1.1) ***(TS)***

Control plans shall be developed and maintained for pre–launch and production operations for raw materials, components and finished product. Control plans shall consider the output from the design and process FMEA's. Control plans shall include: (TS)

- ***Controls for the manufacturing process; (TS)***
- ***Controls for special characteristics; (TS)***
- ***Applicable customer requirements; (TS)***
- ***The specified reaction plan when the process becomes unstable or not statistically capable. (TS)***

Control plans shall be reviewed and updated whenever any change occurs affecting the product, manufacturing process, measurement technique, logistics, supplier or FMEA. (TS)

Tooling Management (7.4.3.3.1.2) ***(QS) (TS)***

A tooling management system shall be implemented which includes: (QS)

- ***Maintenance and repair facilities and personnel; (QS)***
- ***Storage and recovery; (QS)***
- ***Setup; (QS)***
- ***Tool change programs for perishable tools; (QS)***
- ***Tool modification, including tool design documentation and engineering change level; (QS)***
- ***Tool identification and defining the status of the tool. (QS)***

The Business Unit shall provide resources for tool and gauge design, fabrication and verification activities. (TS) The Business Unit is responsible for monitoring these activities when any of this work is completed by external suppliers. (TS)

Delivery (7.4.3.3.1.3)

The organization shall arrange for storage that will protect the quality of product after final inspection and test. Product shall be shipped to customers in accordance with the requirements recorded on the distribution shipping papers. The organization shall adhere to up–to–date customer–specified transportation mode, routings, and containers. In addition, records of premium freight shall be maintained.

Electronic Communication(7.4.3.3.1.3.1)

A computerized system for receipt of customer planning information and ship schedules shall be utilized, unless waived by the customer.

Production Scheduling(7.4.3.3.1.3.2)

The production scheduling activity shall be order–driven to maintain conformance to customer requirements.

Delivery Performance Monitoring (7.4.3.3.1.3.2)

The organization shall have a systematic approach to develop, evaluate and monitor adherence to established lead–time requirements. A system shall be implemented to monitor performance to customer delivery requirements where corrective actions shall be taken as appropriate.

Early Warning(7.4.3.3.1.3.3)

An early warning system shall report instances of anticipated late delivery.

Shipment Notification System (7.4.3.3.1.3.5) ***(QS)***

Unless waived by the customer, a computerized system for on–line transmittal of advanced shipment notifications (ASNs), transmitted timely to shipments shall be maintained. A back–up method shall be in place in the event that the on–line system fails. In such an event it shall be verified that all ASNs match shipping documents and labels. (QS)

Servicing(7.4.3.3.1.4)

When applicable, procedures shall be established and maintained to ensure that contractual service agreements and product warranties are fulfilled. The procedures shall address verification that service meets customer requirements and / or expectations and that appropriate manufacturing, engineering, and design activities are aware of service concerns. When these procedures exist, problem severity, classification, resolution, ***training of servicing personnel (TS)*** and emergency service processes shall be addressed.

Validation of Production and Service Processes (7.5.2)

Process Monitoring and Operator Instructions (7.5.2.1)

Documented process monitoring and work instructions shall be prepared for all employees having responsibilities for operation of production and service processes. These instructions shall be accessible at the workstation. ***The work instructions shall be derived from sources such as the quality plan, the control plan, production drawings and the design review process. (TS)***

Maintaining Process Control(7.5.2.2)

Process capability or performance, as dictated by the customer requirements, shall be maintained or exceeded. Significant process events (e.g. tool change, machine repair) should be noted on the control charts. When process and / or product data indicate a high degree of capability (e.g. Six Sigma capability), the work instructions may be modified.
Process studies shall be completed on all new manufacturing processes to verify process capability and provide input for control of the process. Manufacturing process documentation shall include operating procedures, measurement, test and maintenance procedures. Objectives for manufacturing process capability, reliability, maintainability, capacity and acceptance criteria shall be documented. (TS) Process capability or performance shall be maintained as specified by the requirements of the customer part approval process. And shall ensure implementation of the control plan and process flow diagram, including adherence to the specified measurements techniques, sampling plans, acceptance criteria and reaction plans. (TS) Reaction plans for either unstable or non–capable processes should include containment of process output and 100% inspection. A corrective action plan shall then be completed indicating specific timing and assigned responsibilities to assure that the process becomes stable and capable. The plans are to be reviewed with and approved by the customer when so required. (QS)

Modified Process Control Requirements(7.5.2.3)

In some cases, the customer may specify capability or performance requirements. In these cases, the work instructions shall be annotated accordingly.

Verification of Process Setups and Operational Changes(7.5.2.4)

Process setups shall be verified whenever a setup is performed (e.g. initial run of a job, material changeover, job change, significant time periods lapsed between runs, etc.). Verification shall include a critical inspection of the initial product produced after the setup is completed. Job instructions shall be available for setup personnel. ***Where applicable, statistical methods of verification shall be utilized. (TS)***

Process Changes(7.5.2.5) ***(QS)***

Records of process change effective dates shall be maintained. Changes to promote continuous improvement are encouraged. The customer may be consulted for guidance on approval requirements for such changes. (QS)

First Article Examination (7.5.2.6)

First–article examination requirements shall indicate the amount of inspection and documentation required. This objective evidence shall verify that new or modified molds, dies, assembly machines, and other manufacturing tools and processes are capable of producing parts that conform to the engineering drawings and specifications.

Product Identification and Traceability (7.5.3)

All production materials in process and in inventory shall be identifiable as to part number, and shall be traceable to revision level, and inspection status. A comparable identification

methodology shall apply to sample / prototype / preproduction parts which must meet customer requirements. Configuration control shall be maintained in accordance with documented procedures for product and process change control. Specific traceability from raw material to final item is not required, with the following exceptions:

- Where alternate polymeric compounds are authorized, the specific raw material identity shall be maintained through final inventory;
- Where lot traceability is required by customer contract and has been properly negotiated as to additional costs and requirements, then records shall be maintained for the unique identification of the individual product or lot;
- The identification of the material part number of the plastic in the housing that touches the metal contact(s) shall be maintained through finished goods inventory.

All product in final inventory shall be date–coded on the part or the package. To the maximum extent possible, the date–code shall identify the week of the manufacturing operation / inspection of the item.

Inspection and Test Status(7.5.3.1)

All production materials in–process or in inventory shall be identifiable as acceptable for further processing or shipment. This marking shall appear on each unit container used for handling and storage. This marking may be on cartons, reel tags, routing cards, product travelers, or any other suitable location, provided there is a clear indication that prior verification operations have been performed. The verification status indication shall permit identification of the operator(s) / inspector(s) who performed the prior inspection(s) or review. Records shall be maintained of authorized identifiers.

When required by the customer, additional verification / identification requirements shall be met. (TS)

When the status is identifiable through machine–readable code, there shall be sufficient information provided to identify verification status when the reader is not available.

It shall be the responsibility of the supervisor of any stores area to receive into stock only items that are clearly identified as acceptable. For the service and support areas of the

company, an appropriate indication of approval shall be used; when verification is electronic, this identifier shall take into account computer security measures.

Traceability of Design Changes(7.5.3.2)

Manufacturing date codes and factory order numbers are utilized to maintain production lot / batch traceability.

Control of Customer Supplied Product(7.5.4)

Documented procedures for the control of verification, storage, and maintenance of customer–supplied product, including customer–owned packaging, for incorporation into the supplies or for related activities shall be established and maintained. Any such product that is lost, damaged or is otherwise unsuitable for use shall be reported to the customer and records shall be maintained.

Control of Customer Owned Tooling(7.5.4.1)

Customer–owned tools and equipment used in the manufacture and / or inspection of product shall be permanently marked so that the ownership of each item is visually apparent. Maintenance shall be in accordance with customer contracts.

Preservation and Packaging of Product(7.5.5)

Documented procedures shall be established and maintained for handling, storage, packaging, preservation and delivery of product. Methods for handling product that prevents damage or deterioration shall be provided. Designated distribution warehouse storage areas, general warehouse storage areas or stock rooms are utilized to prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such areas shall be stipulated. Each stocking

location shall apply appropriate methods for preservation and segregation of product to ensure that material or product will remain undamaged pending use or delivery. In order to detect deterioration, each stocking area shall, at appropriate intervals, assess the condition of the product. Inventory systems to optimize inventory turns over time, assure stock rotation, and minimize inventory levels shall be utilized. Packaging and labeling / marking processes shall be controlled to the extent necessary to ensure conformance to established requirements. This shall include systems to conform to specific customer packaging and labeling requirements.

Anti–Static Protection(7.5.5.1`)

Where applicable, anti–static protection shall be employed to provide protection against electrostatic discharge (ESD) damage. Packaging Engineering is responsible for establishing the requirements for product packaging. Manufacturing Engineering is responsible for establishment of ESD controls within the manufacturing operations.

Packaging and Labeling Audit(7.5.5.2)

The quality plan shall include assessments for adherence to the requirements for packaging and labeling, including, but not limited to, correct part number, count accuracy, and label formats.

Shelf–Life(7.5.5.3)

Materials that have a shelf life shall be clearly marked with an expiration date, or a date of manufacture that can be used to calculate an expiration date. Materials shall not be used past the expiration date.

Control of Inspection, Measuring and Testing Devices(7.6)

Gages, measuring devices, and testing equipment used to determine the acceptability of components, assemblies, materials, and tooling affecting product quality shall be specified and / or provided by the Engineering, Manufacturing, or Quality functions as appropriate.

These shall be controlled and calibrated in accordance with a system that conforms to the requirements and intent of ISO 10012–1, –2 / 17025, or equivalent national or industry standard. Where system test and verification relies on software–controlled devices, the functionality shall be verified through the Quality function. The control of inspection, measuring, and test equipment shall include:

- Process and product measurement devices that provide the required accuracy and recision shall be selected and verified before production. Measuring and monitoring devices shall be controlled to ensure that measurement capability is consistent with measurement requirements.
- All measuring devices used to verify product quality shall be uniquely identified and calibrated at prescribed intervals against certified equipment having a known relationship to a nationally or internationally recognized standard. If no standard exists, the method of calibration shall be identified and recorded.
- Procedures shall be developed for the calibration process and resulting records with adequate controls that protect product quality. All measuring devices shall have an indication of calibration status. If the calibration status indication is invalid, the measuring device shall not be used.
- All inspection, measuring and test equipment that does not require calibration shall be appropriately identified.
- A process shall be established that assesses the validity of previous inspection and test results when measuring devices are found to be out of calibration. Records of this assessment shall be maintained.
- Conditions shall be established that provide a suitable environment for calibration and use of measuring devices and that these devices are stored and handled in a way that maintains accuracy and fitness for use.
- Methods shall be developed to safeguard measuring devices, including test hardware and software, from adjustments which would invalidate the calibration settings.
- Appropriate statistical studies of the variation present in measurement and test systems shall be completed as part of process capability analysis and as specified in

customer approved control plans. Such studies shall conform to generally recognized measurement system analysis methodologies.

- All product produced with suspect measuring equipment shall be segregated and audited. Customer notification / product recall shall be considered if suspect product was shipped.
- Non–standard measuring equipment, such as pin detectors, vision systems, etc., shall be verified by the local manufacturing location by using product having known defects or other suitable means. This internal verification schedule shall be established by the Product / Manufacturing Team. The verification results shall be recorded.
- Should non–standard measuring equipment be determined non–functional, it shall be removed from service until it is repaired and declared operational, and another inspection method substituted as developed by the Quality function.
- Devices that are either inactive or unsuitable for use shall be visibly identified and shall not be used.

The variation of measuring and test equipment referenced in the control plan must be analyzed through the completion of appropriate statistical studies. (TS)

Internal Laboratory Requirements (7.6.1) *(TS)*

The organization laboratories shall have a defined scope and documented laboratory procedures that are analogous or traceable to the applicable industry standard. Laboratory personnel shall be qualified to conduct testing. Records of test results shall be maintained. (TS)

External Laboratory Requirements(7.6.2) *(TS)*

External laboratories that are utilized for inspection, test or calibration services shall have a defined scope and shall be accredited to ISO / IEC 17025 or national equivalent. There shall be evidence that the external laboratory is acceptable to the customer. (TS)

MEASUREMENT, ANALYSIS AND IMPROVEMENT (8.)

Inspection and Testing (8.1)

Processes shall have sufficient controls at all stages to ensure that only acceptable products and services are delivered to internal operations or to the external customer. Defect prevention techniques

- particularly statistical process control, error proofing, and / or automated techniques
- shall be used wherever possible. Inspection and test results shall be recorded.

Statistical Techniques (8.1.1)

The Quality organization shall identify the need for and use of statistical techniques required for establishing, controlling, and verifying process or product inputs that impact product characteristics and process capability. Statistical tools, if applicable, for each process or product should be determined during the design assurance process or as a result of a Six Sigma project or the QOS reviews. The SPC requirements shall be included in the appropriate control plan. Process measurements shall be implemented and monitored at the appropriate points to ensure continual product conformance and to promote increased effectiveness of the process. The appropriate personnel should understand basic statistical concepts such as variation, control (stability), process capability and over–adjustment. Understanding and deployment of statistical concepts shall be accomplished through training and documented procedures

Appropriate statistical tools for each process shall be determined during the advanced quality planning process and included in the control plan. Basic statistical concepts shall be understood and utilized throughout the organization. (TS)

Monitoring and Measurement(8.2)

Customer Satisfaction(8.2.1)

There shall be a documented process for determining customer satisfaction, including frequency of determination, and how objectivity and validity are assured. Trends in customer satisfaction and key indicators of customer dissatisfaction shall be documented and supported by objective information. As appropriate, these trends should be compared to those of competitors, or benchmarks, and reviewed by senior management.

Customer satisfaction data are received in a variety of methods, including:

- Feedback received in response to answers to customer complaints;
- Dialogue between the customer and Field Sales or Product Management which is then documented in a Field Report or trip visit summary;
- Industry positioning surveys;
- Lost business reports;
- Supplier "report cards";
- Meetings with customers;
- Ship to customer request performance.

Customer satisfaction / dissatisfaction will be included as a topic within the senior level management review. If applicable, actions taken will be monitored within the management review process. Customer recognition and awards are posted on the Organizations Intracomm and the Quality Systems and In addition, numerous other reporting methods exist, including Global Delivery Scorecard, backlog status, Customer Service metrics and local QOS reviews.

Performance indicators for customer satisfaction shall be based on objective data and include, but not be limited to: (TS)

- ***Delivered product quality performance; (TS)***
- ***Customer disruptions, including return material; (TS)***
- ***Delivery performance, including premium freight; (TS)***
- ***Customer notifications related to quality or delivery issues. (TS)***

Manufacturing process performance shall be monitored to demonstrate compliance with customer requirements for product quality and process efficiency. (TS)

Internal Audit (8.2.2)

Quality system audits shall be conducted annually to verify compliance with planned arrangements, effectiveness, and suitability to meet objectives of the organization Total Quality Management Process, and ISO 9001, TL 9000, QS 9000 and / or TS 16949. Results of these audits shall be reviewed by management as feedback for continual improvement and verification of conformance to the quality system. Records of such audits and reviews shall be maintained. Each organization shall conduct audits of the quality system in accordance with established specifications at regular intervals based on status and importance of the activity. Audits of the quality system shall be carried out by qualified personnel independent of those having direct responsibility for the area being audited and should cover all shifts. Follow–up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

Internal audits shall cover all the quality system, activities and shifts and shall be completed in accordance with an annual plan. When nonconformities (internal and external) or customer complaints occur, the audit frequency shall be appropriately increased. (TS)

The effectiveness of each manufacturing process shall be evaluated through audits that are completed at defined intervals. Product audits shall be completed at appropriate stages of the production process. (TS)

Customer Surveys and Inspection of Facilities (8.2.2.1)

The organization should recognize that it will be necessary for some customers to perform supplier audits. During such customer surveys, source inspections, or quality audits, employees shall neither demonstrate nor discuss manufacturing equipment, processes, methods, etc. which are considered to be proprietary. In those circumstances where the customer may require additional information about aspects of manufacturing considered proprietary, additional consideration may be possible through the use of confidential disclosure agreements. Customer requests to review nonproprietary manufacturing inspection data, including review of SPC data, capability data, and other statistical data

shall be supported. However, the organization should reserves the right to deny requests for process data below the level of the customer drawing / specification on the premise that such information is regarded as proprietary.

Quality Management System Processes Monitoring and Measurement(8.2.3)

The results of the audits of the quality system, coupled with the assessment of customer satisfaction and dissatisfaction shall be the primary indicators of the effectiveness of the defined Total Quality Management system. When audits determine an inadequacy in the implementation of the Quality Management system, appropriate corrective action shall be taken. This corrective action could include, but is not limited to:

- Development and deployment of training to bring actual practice into alignment with documented requirements;
- Change the documented requirements to ensure alignment with current business needs and practices;
- Change the documented requirements to cause deployment of new practices.

  The manufacturing process documentation and / or the quality inspection plan shall include measurements and control points to ensure the continued suitability and effectiveness of the process to produce conforming product.

Monitoring and Measurement of Product(8.2.4)

Product characteristics shall be measured and monitored throughout the manufacturing process to ensure that the product meets the established requirements. Usually these inspection and testing activities are documented in a quality inspection plan for the part number, product or process. Evidence of conformity with the acceptance criteria shall be maintained and the records shall identify the individual(s) completing the inspection activities. Where applicable, inspection plans shall classify characteristics for impact on the customer. This impact shall be guided by the following:

- Critical characteristic
  - a characteristic where judgment and experience indicate that nonconformance is likely to result in hazardous or unsafe conditions for individuals using or depending on the product or service;

- Major characteristic
    - a characteristic other than critical, where nonconformance renders the product incapable of performing its intended function or materially reduces the usability of the product or service;
- Minor characteristic
    - a characteristic including workmanship, appearance, etc., where nonconformance does not materially reduce the usability of the product or service.

In–Process Inspection (8.2.4.1)

In–process inspection, test, or review operations shall be clearly identified in all process documentation. The Quality function shall be responsible for ensuring that appropriate inspection, test, or review operations are included. They shall also ensure that adequate instructions are provided for such operations and that adequate records are maintained and properly retained. All non-conformances at these operations shall be identified, segregated from acceptable material
(when practical), and shall become the responsibility of the Quality function, which shall coordinate disposition and corrective action. Where operator inspection or automatic inspection devices are utilized to determine product acceptance, appropriate product auditing shall be maintained to insure the integrity of the Quality System. Where in–process inspection, test, or review operations are performed by other than the Quality
function (such as an engineer, technician, operator, setup person, or team member), records of verification performed and results of that verification must still be provided and retained. ***One of the goals of the quality system is to direct process activities toward defect prevention methods rather than defect detection. (QS)***

Final Inspection (8.2.4.2)

When specified in a documented procedure, final inspection and / or testing are performed to complete the evidence of conformance of the finished product to established requirements. Records of final inspection / testing shall be maintained. All finished goods

shall have visible indication of acceptability. This acceptability indication normally shall be applied during or following the final manufacturing inspection operation. However, if the Quality function has identified the need for a final inspection or audit operation, the evidence of acceptability will be applied after product compliance is verified.

Quality Assurance shall coordinate the activity of layout inspection and functional verification at a frequency as negotiated with the customer. Final package material audits (e.g. product integrity, packaging, labeling, documentation, quantity, marking) should be scheduled at appropriate intervals.

Sampling Inspection Strategies (8.2.4.3)

When sampling inspection is used, the following shall apply:

Attribute sampling:

- Critical characteristics shall be controlled to ensure 100% conformance;
- Major and minor characteristics shall be subjected to zero–acceptance–number sampling plans. Variables sampling plan shall be in accordance with the quality inspection plan or control plan as applicable. “Skip Lot” strategies may be used when supported by inspection history.

Re–Testing (8.2.4.3)

If design changes or changes to the manufacturing process that have the potential of affecting the form, fit, or function of the product are specified by customer requirements, agency requirements or when determined by a requirement established within the design review process, the Quality function shall coordinate requalification testing. Product / Development Engineering, in concert with the test laboratory, will define the content of the re–testing. Requalification tests may be limited to those tests that are affected by the design or manufacturing process change. Quality Assurance may also request requalification testing in response to analysis of field failure data, product extensions, manufacturing process location changes or material changes. The utilization and frequency of requalification testing shall be in accordance with the customer contracts or as established by the Business Unit Quality and Engineering functions to periodically reassess the ability of the product to continue to meet the requirements of the product specification.

Control of Nonconforming Product (8.3)

All product – whether production materials, components, assemblies, final product, or other types of work – detected or suspected as not conforming to requirements shall become the responsibility of the Quality function for:

- Controlling further movement of the material to prevent material from unintended use or delivery;
- Documenting and reviewing material;
- Coordinating the disposition action;
- Notifying appropriate personnel;
- Initiating and verifying corrective action and effectiveness;
- Establishing and tracking a prioritized defect reduction plan;
- Trend analysis and providing input for corrective and preventive action.

Nonconforming or suspect nonconforming material, including unidentified material, shall immediately be positively and visually identified as nonconforming, and shall be prevented from inadvertent further processing, where practicable, by storage in an area that is visually identified and segregated for this purpose.

Review and disposition of nonconforming or suspect nonconforming material shall be coordinated by Quality with the appropriate operations / manufacturing and engineering functions. The material may be sorted, reworked, returned to the supplier, scrapped, or deviated.

Nonconforming product may be released for use when a deviation has been processed and approved. All deviations shall clearly specify the temporary limits of acceptability, state the definitive corrective action and be approved by the appropriate engineering functions. If the affected dimension, feature, or characteristic is a specified customer requirement, no deviation shall be issued unless the customer has granted documented concession. This applies equally to product or services purchased from suppliers. The Business Unit shall concur with any requests by a supplier before submission to the customer. The Business Unit shall maintain records of the expiration date or quantity authorized. The Business Unit

shall also ensure compliance with the original or superseding specification and requirements when the deviation expires. Internally,

components shipped under deviation shall reference the deviation number on each unit container. Material shipped with authorization for concession shall be identified on each shipping container as required by the customer. If the nonconforming material is accepted for rework / repair, rework instructions shall be provided and the material shall be reinspected to an approved quality plan before it returns to the process. Authority to dispose of defective material shall be defined by the manufacturing organization.

Records of nonconforming material transactions, including deviations, shall be maintained.

Measurement and Analysis of Organizational Performance (8.4)

The Quality Assurance Director / Manager and each Business Unit Director shall have the responsibility to maintain performance data including the required TL 9000 metrics, ***TS 16949 measurements, (TS)*** and trends in quality, customer satisfaction and / or dissatisfaction, operational performance (e.g. productivity, efficiency, effectiveness) for key products and services. Customer satisfaction / dissatisfaction is evaluated through several tools that may include: customer complaints, customer feedback responses, the Quality Operating System (QOS) process, reports and information from Field Sales and Product Management and from Industry Reports. Trends in quality and operational performance shall be compared with progress toward objectives. Data

shall be translated into actionable information to support the Quality Policy, business plans, and customer satisfaction. Business Unit Management on a periodic basis shall evaluate the measurements and goals. All functions shall utilize facts, data, and quality records for improvement planning, for minimizing repetitive nonconformance situations, and for determining corrective / preventive action strategies. As appropriate, summaries of quality costs, in–process and final inspection results, quality audits, disposition of nonconformances, supplier performance and requalification test activity shall be prepared by the Quality function and submitted to management.

Improvement (8.5)

One of the major objectives of organizations Total Quality Management Process and the Six Sigma Operational Excellence initiative is to foster improvement in all aspects of organizations business. The company strives to improve the satisfaction of customers with organizations products and services. This can be best accomplished by the on–going initiatives to improve the quality and reliability of organizations products and to improve the operating effectiveness of the manufacturing equipment and processes. Employees are encouraged to review the information posted on the organizations Intracomm website to learn more about the various improvement tools and for feedback on customer satisfaction.

Continual Improvement (8.5.1)

The Business Units shall promote and manage continual improvement in quality, productivity, service, and value. Improvement projects shall include as appropriate: external customer, corporate, supplier, safety and regulatory requirements. Continual improvement shall be measured against goals and objectives. One or more of the following techniques may assist with achieving the goals and objectives:

- **Quality Operating System (QOS):**

  A regular review by management to demonstrate that processes are meeting customer requirements and internal continual improvement goals; utilizing trend chart(s), goal(s), Pareto analysis, problem summary chart(s), and verification chart(s).

- **LEAN:**

  A series of tools and techniques that focus on process optimization through cycle time reduction and the elimination of waste.

- **Successfully Demonstrated Practices (SDP):**

  A total employee involvement technique focused upon implementing best practices that are successfully deployed in the organization facilities.

- **Manufacturing Resource Planning (MRP):**

A formal process for integrating and controlling all business planning processes for the purpose of balancing supply and demand in the most effective and efficient way.

- **Application of Statistical Sciences:**

  Utilization of the "Engineering for Quality" tools, including: Statistical Process Control (SPC), Design of Experiments (DOE), Regression Analysis, Analysis of Variance (ANOVA).

- **Management Methods:**

  Self Assessment and Gap Analysis (SAGA), ISO 9001 / AS 9100 / ISO 9004 / TL 9000 / QS–9000 / TS 16949 assessments, benchmarking, suggestion systems, taskforce teams, cross functional teams, Performance for Business Results, performance reviews, training, apprentice programs, bonus programs and business planning.

Continual improvement shall focus upon control and reduction of variation in product characteristics and manufacturing process parameters. (TS)

Quality Improvement Program(8.5.1.1)

The spirit of organizations quality improvement program is to cost effectively achieve the basic tenets of the organizations Quality Policy: delivery of error free products and services, on time. Improvement initiatives should be directed at reaching this state of "zero defects". This quality improvement program consists of many activities including:

- The on–going review of Quality Manual and the supporting documents;
- Actions resulting from audits, management review, corrective action, preventive action and the Quality Operating System (QOS) process;
- Analysis of customer provided information, such as satisfaction data, supplier performance reports, and data relative to the quality and reliability of products;
- Analysis of measurements and actions directed at improving customer satisfaction, process performance, and product quality, such as improving delivery, improving response time to customer communications, decreasing scrap, improving

manufacturing utilization, decreasing inventory, and reducing design and manufacturing lead times.

Continual improvement is the personal responsibility of each employee. Formal methods for encouraging employee involvement may include: employee recognition systems, employee suggestion systems, department / shift / team meetings, bonus programs, and participation on problem solving or improvement teams.

Corrective Action (8.5.2)

Corrective action eliminates the root cause of a known problem; it is reactive. Preventive action eliminates the root cause of an anticipated problem; it is proactive. A problem is an undesirable effect that involves any situation that results in customer dissatisfaction or waste. In all cases where a nonconformance is identified or where analysis indicates a nonconformance, the responsible function shall be notified in writing and shall receive a corrective action statement. The corrective action plan shall be reviewed with the function(s) responsible for implementation of the corrective action. The function responsible for corrective action shall use disciplined problem solving methods and mistake proofing methodologies. A system shall be implemented and maintained to transfer any customer complaints to the owning Business Unit such that the issues may be resolved in a timely fashion as defined by the customer. Where a nonconformance is identified, the responsible Business Unit shall implement corrective action according to a documented procedures. Unless there is a specific format required by the customer, the Eight Discipline (8–D) process for problem solving and corrective action shall be
utilized for all complaints received from external customers. Consideration should be given to utilizing the Eight Discipline process when responding to internal failures. Corrective action shall be to the degree appropriate to the magnitude of the problem and commensurate to the risks encountered. Understanding the benefits, risks, and costs are crucial in maintaining a balance in implementing the Total Quality Management Process. The corrective action process shall include but not be limited to:

- The effective and timely handling of customer complaints, return of defective material, reports of product nonconformance (from internal operations and external suppliers), and internal and external audit corrective action requests;

- Identifying and investigating the root cause of nonconforming product, nonconforming processes, and systemic quality system deficiencies, and recording the results of the investigation;
- Determining the corrective action needed and applying controls to ensure corrective action is taken and root cause has been addressed;
- Implementing and recording changes in procedures resulting from corrective action;
- Analyzing customer impact and notifying customers who are under contract for notification;
- ***Prompt notification of the persons responsible for corrective action when a product or process fails to meet the required specifications. (QS)***

Records of the results of action taken shall be maintained and shall be included as an input for management review.

Preventive Action (8.5.3)

Preventive action can take two forms. The first is the elimination of potential failure modes. This technique should be deployed in the advanced quality planning stage of new product or process development. The designer and the design assurance engineers are responsible for deploying these quality tools. The following tools shall be considered when designing a new product or process:

- Design FMEA's;
- Process FMEA's;
- Quality Function Deployment;
- Similar product / process baselining / benchmarking;
- Design of Experiments.

The second form of preventive action is the elimination of potential failure modes when information from processes, systems, work operations, process capability studies, yield analyses, deviations, concessions, quality records, audit reports, service reports, or customer complaints suggests a nonconformance may occur. Steps shall be taken according to documented procedures to eliminate potential nonconformances. The minimum, preventive action process should include, but not be limited to:

- Determining the steps needed to verify or deny the potential nonconformances;

- Gathering and analyzing the required data;
- Determining the effectiveness of the implemented containment actions;
- Applying controls to ensure the solution is effective in resolving the problem at an acceptable level corresponding to the risks encountered;
- Reviewing preventive action activities by management for trends and impact on procedures, products, processes, and systems.

The following tools should be considered:

- Product and process audits;
- Equipment preventive and productive maintenance;
- Value–added audits;
- Review of Product and Process FMEA's.

Records of preventive action shall be maintained and shall be included as an input for management review.

Alternative Action (8.5.3.1)

If corrective / preventive action is not implemented, one of two alternatives shall be exercised:

- The responsible function shall change the requirements for the item in question so that the nonconforming condition is acceptable by specification or drawing; or
- A fixed–quantity or fixed–duration deviation may be issued. No nonconforming condition

shall be deviated for a period exceeding 12 months. The Quality function incorporates the deviation into the inspection acceptance instructions as necessary.

Six Sigma Operational Excellence(8.5.4)

Six Sigma Operational Excellence is a comprehensive approach to business process

improvement. Six Sigma Operational Excellence is lead by senior management and deployed through Champions, Master Black Belts, Black Belts and Green Belts. Breakthrough improvement is achieved through the disciplined methodology known as the DMAIC process. Within the organization , the tools utilized for Six Sigma projects are a blend of the traditional statistical tools and the tools associated with LEAN technology. The basic elements of the DMAIC process:

- **Define:**
  - Identify the gap in meeting the business strategy or objective
  - Establish the scope and boundary for the project
  - Identify the Black Belt and the project team
  - Establish the project goals and savings
  - Obtain the endorsement of the Business Executive
- **Measure:**
  - Understand the current process
  - Characterize the baseline performance
  - Determine measurement capability
- **Analyze:**
  - Understand the key product performance characteristics and how they are impacted by the process variables
  - Understanding of the relationship between the input and output variables
- **Improve:**
  - Identification of the root cause of the variation
  - Identification of what needs to be done to close the performance gap
  - Deploy appropriate tools
- **Control:**
  - the process Document revised process parameters to maintain the gains
  - Return to the process owner and sustaining operations

Chapter 6

6.ISO9001 Requirement in Plain form

ISO 9001: 4 Systemic Requirements

4.1 Establish your quality management system (QMS)	**Develop your quality management system** Identify the processes that make up your quality system. Describe your quality management processes.
	Implement your quality management system Use quality system processes. Manage process performance.
	Improve your quality management system Monitor process performance. Improve process performance.
4.2 Document your quality management system (QMS)	**4.2.1 Develop quality system documents** Develop documents to implement your quality system. Develop documents that reflect what your organization does.
	4.2.2 Prepare quality system manual Document your procedures. Describe how your processes interact. Define the scope of your quality system.
	4.2.3 Control quality system documents Approve documents before you distribute them. Provide the correct version of documents at points of use. Review and re-approve documents whenever you update them. Specify the current revision status of your documents.

- Prevent the accidental use of obsolete documents.
- Preserve the usability of your quality documents.

4.2.4 Maintain quality system records

- Use your records to prove that requirements have been met.
- Develop a procedure to control your records.
- Ensure that your records are useable.

ISO 9001: 5 Management Requirements

5.1 Support quality

Promote the importance of quality

- Promote the need to meet customer requirements.
- Promote the need to meet regulatory requirements.
- Promote the need to meet statutory requirements.

Develop a quality management system

- Support the development of a quality system.
- Formulate your organization's quality policy.
- Set your organization's quality objectives.
- Provide quality resources.

Implement your quality management system

- Provide resources to implement your quality system.
- Encourage personnel to meet quality system requirements.

Improve your quality management system

	Perform quality management reviews. Provide resources to improve the quality system.
5.2 Satisfy your customers	**Identify customer requirements** Expect your organization to identify customer requirements.
	Meet your customers' requirements Expect your organization to meet customer requirements.
	Enhance customer satisfaction Expect your organization to enhance customer satisfaction.
5.3 Establish a quality policy	**Define your organization's quality policy** Ensure that it serves your organization's purpose. Ensure that it emphasizes the need to meet requirements. Ensure that it facilitates the development of quality objectives. Ensure that it makes a commitment to continual improvement.
	Manage your organization's quality policy Communicate your policy to your organization. Review your policy to ensure that it is still suitable.
5.4 Carry out quality planning	**5.4.1 Formulate your quality objectives** Ensure that objectives are set for functional areas. Ensure that objectives are set at organizational levels. Ensure that objectives facilitate product realization. Ensure that objectives support the quality policy. Ensure that objectives are measurable.
	5.4.2 Plan your quality management system Plan the development of your quality management system. Plan the implementation of your quality management system. Plan the improvement of your quality management system. Plan the modification of your quality management system.
5.5 Control your quality system	**5.5.1 Define responsibilities and authorities** Clarify responsibilities and authorities.

	Communicate responsibilities and authorities.
	5.5.2 Appoint management representative
	Oversee your quality management system.
	Report on the status of your quality management system.
	Support the improvement of your quality management system.
	5.5.3 Support internal communications
	Ensure that internal communication processes are established.
	Ensure that communication occurs throughout the organization.
5.6 Perform management reviews	**5.6.1 Review quality management system**
	Evaluate the performance of your quality system.
	Evaluate whether your quality system should be improved.
	5.6.2 Examine management review inputs
	Examine audit results.
	Examine product conformity data.
	Examine opportunities to improve.
	Examine feedback from customers.
	Examine process performance information.
	Examine corrective and preventive actions.
	Examine changes that might affect your system.
	Examine previous quality management reviews.
	5.6.3 Generate management review outputs
	Generate actions to improve your quality system.
	Generate actions to improve your products.
	Generate actions to address resource needs.

ISO 9001: 6 Resource Requirements

6.1 Provide quality resources	**Identify quality resource requirements** - Identify resources needed to support the quality system. - Identify resources needed to improve customer satisfaction.
	Provide quality system resources - Provide resources needed to support the quality system. - Provide resources needed to improve customer satisfaction.
6.2 Provide quality personnel	**6.2.1 Use competent personnel** - Ensure that your personnel have the right experience. - Ensure that your personnel have the right education. - Ensure that your personnel have the right training. - Ensure that your personnel have the right skills.
	6.2.2 Support competence - Define acceptable levels of competence. - Identify training and awareness needs. - Deliver training and awareness programs. - Evaluate effectiveness of training and awareness. - Maintain a record of competence.
6.3 Provide quality infrastructure	**Identify infrastructure needs** - Identify building needs. - Identify workspace needs. - Identify hardware needs. - Identify software needs. - Identify utility needs. - Identify equipment needs. - Identify support service needs.

Provide needed infrastructure

- Provide needed buildings.
- Provide needed workspaces.
- Provide needed hardware.
- Provide needed software.
- Provide needed utilities.
- Provide needed equipment.
- Provide needed support services.

Maintain your infrastructure

- Maintain your buildings.
- Maintain your workspaces.
- Maintain your hardware.
- Maintain your software.
- Maintain your utilities.
- Maintain your equipment.
- Maintain your support services.

6.4 Provide quality environment

Identify needed work environment

- Identify factors needed to ensure products meet requirements.

Manage needed work environment

- Manage factors needed to ensure products meet requirements.

ISO 9001: 7 Product Realization Requirements

7.1 Control realization planning

Plan product realization processes

- Define product quality objectives and requirements.
- Identify product realization needs and requirements.

Develop product realization processes

- Develop product realization documents.

	Develop product realization record keeping systems.
	Develop methods to control quality during product realization.
7.2 Control customer processes	7.2.1 Identify customers' product requirements
	Identify the requirements that customers want you to meet.
	Identify the requirements that are dictated by the product's use.
	Identify the requirements that are imposed by external agencies.
	Identify the requirements that your organization wishes to meet.
	7.2.2 Review customers' product requirements
	Review requirements before you accept orders from customers.
	Maintain a record of your product requirement reviews.
	Control changes in product requirements.
	7.2.3 Communicate with your customers
	Develop a process to control communications with customers.
	Implement your customer communications process.
7.3 Control product development	7.3.1 Plan design and development
	Define your product design and development stages.
	Clarify design and development responsibilities and authorities.
	Manage interactions between design and development groups.
	Update your design and development plans as changes occur.
	7.3.2 Define design and development inputs
	Specify product design and development inputs.
	Record product design and development input definitions.
	Review product design and development input definitions.
	7.3.3 Generate design and development outputs
	Create product design and development outputs.
	Approve design and development outputs prior to release.
	Use design and development outputs to control product quality.
	7.3.4 Carry out design and development reviews
	Perform product design and development reviews.
	Record product design and development reviews.

	7.3.5 Perform design and development verifications Carry out product design and development verifications. Record product design and development verifications.
	7.3.6 Conduct design and development validations Perform product design and development validations. Record product design and development validations.
	7.3.7 Manage design and development changes Identify changes in product design and development. Record changes in product design and development. Review changes in product design and development. Verify changes in product design and development. Validate changes in product design and development. Approve changes before they are implemented.
7.4 Control purchasing function	**7.4.1 Control purchasing process** Ensure that purchased products meet requirements. Ensure that suppliers meet requirements.
	7.4.2 Document product purchases Describe the products being purchased. Specify the requirements that must be met.
	7.4.3 Verify purchased products Verify purchased products at your own premises. Verify purchased products at suppliers' premises (when required).
7.5 Control operational activities	**7.5.1 Control production and service provision** Control production and service processes. Control production and service information. Control production and service instructions. Control production and service equipment. Control production and service measurements. Control production and service activities.

	7.5.2 Validate production and service provision Prove that special processes can produce planned outputs. Prove that process personnel can produce planned results. Prove that process equipment can produce planned results.
	7.5.3 Identify and track your products Establish the identity of your products (when appropriate). Maintain the identity of your products (when appropriate). Identify the status of your products (when appropriate). Record the identity of your products (when required).
	7.5.4 Protect property supplied by customers Identify property supplied to you by your customers. Verify property supplied to you by your customers. Safeguard property supplied to you by your customers.
	7.5.5 Preserve your products and components Preserve products and components during internal processing. Preserve products and components during final delivery.
7.6 Control monitoring devices	**Identify monitoring and measuring needs** Identify the monitoring and measuring that should be done.
	Select monitoring and measuring devices Select devices that meet your monitoring and measuring needs.
	Calibrate monitoring and measuring devices Perform calibrations. Record calibrations.
	Protect monitoring and measuring devices Protect your devices from unauthorized adjustment. Protect your devices from damage or deterioration.
	Validate monitoring and measuring software Validate monitoring and measuring software before you use it. Revalidate monitoring and measuring software when necessary.

Use monitoring and measuring devices

Use devices to ensure that your products meet requirements.

ISO 9001: 8 Remedial Requirements

(Measurement, analysis and Improvement)

8.1 Perform remedial processes

Plan remedial processes

- Plan how remedial processes will be used to assure conformity.
- Plan how remedial processes will be used to improve the system.

Implement remedial processes

- Use remedial processes to demonstrate conformance.
- Use remedial processes to improve quality management system.

8.2 Monitor and measure quality

8.2.1 Monitor and measure customer satisfaction

- Identify ways to monitor and measure customer satisfaction.
- Monitor and measure customer satisfaction.
- Use customer satisfaction information.

8.2.2 Plan and perform regular internal audits

- Set up an internal audit program.
- Develop an internal audit procedure.
- Plan your internal audit projects.
- Perform regular internal audits.
- Solve problems discovered during audits.
- Verify that problems have been solved.

8.2.3 Monitor and measure quality processes

- Use suitable methods to monitor and measure your processes.
- Take action when your processes fail to achieve planned results.

8.2.4 Monitor and measure product characteristics

- Verify that product characteristics are being met.
- Keep a record of product monitoring and measuring activities.

8.3 Control nonconforming products	**Develop a procedure to control nonconforming products** - Define how nonconforming products should be identified. - Define how nonconforming products should be handled.
	Identify and control your nonconforming products - Eliminate or correct product nonconformities. - Prevent the delivery or use of nonconforming products. - Avoid the inappropriate use of nonconforming products.
	Re-verify nonconforming products that were corrected - Prove that corrected products now meet requirements.
	Control nonconforming products after delivery or use - Control events when you deliver or use nonconforming products.
	Maintain records of nonconforming products - Describe your product nonconformities. - Describe the actions taken to deal with nonconformities.
8.4 Analyze quality information	**Define quality management information needs** - Define the information you need to evaluate your quality system. - Define the information you need to improve your quality system.
	Collect quality management system data - Monitor and measure the suitability of your quality system. - Monitor and measure the effectiveness of your quality system.
	- Provide information about your customers. **Provide quality management information**
8.5 Make quality improvements	**8.5.1 Improve quality management system** - Use your audits to generate improvements. - Use your quality data to generate improvements. - Use your quality policy to generate improvements.

- **Use your quality objectives to generate improvements.**
- **Use your management reviews to generate improvements.**
- **Use your corrective actions to generate improvements.**
- **Use your preventive actions to generate improvements.**

8.5.2 Correct actual nonconformities

- **Review your nonconformities.**
- **Figure out what causes your nonconformities.**
- **Evaluate whether you need to take corrective action.**
- **Develop corrective actions to prevent recurrence.**
- **Take corrective actions when they are necessary.**
- **Record the results that your corrective actions achieve.**
- **Examine the effectiveness of your corrective actions.**

8.5.3 Prevent potential nonconformities

- **Detect potential nonconformities.**
- **Identify the causes of potential nonconformities.**
- **Study the effects of potential nonconformities.**
- **Evaluate whether you need to take preventive action.**
- **Develop preventive actions to eliminate causes.**
- **Take preventive actions when they are necessary.**
- **Record the results that your preventive actions achieve.**
- **Examine the effectiveness of your preventive actions.**

Chapter 7

ISO 9001 and TQM

It this case we will discover:

- What is TQM
- Why ISO 9000 helps to make TQM work
- How to avoid common mistakes with ISO 9000

What is TQM?

TQM is one of the vaguest business tools even invented. There is no TQM bible, and each of the many quality gurus said something different. That makes it very confusing.

Everyone has his or her own view of how TQM should be applied.

But as the case histories in this book show, there is more than one route towards TQM. You adapt it to meet the needs of your business. Many elements are common, and those are the ones highlighted in this book.

TQM means satisfying customers first time, every time. It means enabling your employees to solve problems and eliminate waste. TQM is not so much a management technique as a whole style of working. TQM is really just another word for good management.

It is difficult, perhaps impossible, to achieve total quality. But companies that aim for it are going in the right direction.

Where it came from

Ignored for years in his own country, W Edwards Deming was US statistician who held strong views on how to achieve excellence in manufacturing. Just after the Second World War, he was invited to Japan, where he talked about quality to packed audiences.

The Japanese quickly adopted his ideas, which contributed to Japan's miraculous post-war success. Later, the USA and other Western countries adopted Deming's ideas.

Understanding the principles

In Figure are the principles on which TQM is founded. During the course of the study, we explore these concepts and show how you can apply them.

The five principles of TQM

1. Concentrate on the customer

- Be customer focused.

2. Do it right?

- Do it right first time.

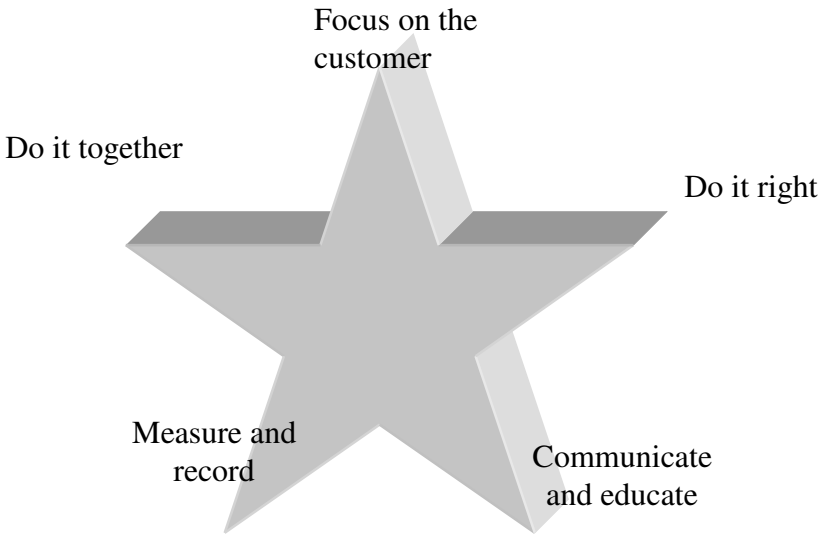

Figure 4 The five principles of TQM

- Constantly improve.
- Quality is an attitude, not an inspection process.

3. Communicate and education

- Tell staff what is going on.
- Educate and train.

4. Measure and record

- Measure the work.

5. Do it together

- Top management must be involved.
- Empower the staff.
- Make the business a good place to work.
- Introduce team working.
- Organize by process, not by function.

TQM concepts

In discussions about quality, the above principles are bandied freely around. It is worth pausing for a moment to see what each of them really means.

- **Be customer focused** means placing the customer at the centre of everything you do. This can be quite a shock for the production-oriented organization. It requires the company to check customers' attitudes regularly. It includes the idea of internal customers as well as external ones.
- **Do it right first time** means avoiding re-work. It means cutting the amount of defective work, whether on the shop floor or in the management offices.
- **Constantly improve**. 'Continuous improvement beats post-pond perfection.' Said a manager at Cummins, the engine maker. As the comment implies, continuous improvement allows the company gradually to get better. 'A 5 percent improvement in 100 per cent of the areas is easier than a 100 per cent improvement in 5 per cent of the areas' is another axiom sometimes used by TQM people.
- **Quality is an attitude**. There are no shortcuts to quality. The old methods of inspecting for defects are not good enough any more. Everyone has to be committed to quality. That means changing the attitude of the entire work force, and altering the way the company operates.
- **Telling staff what is going on** involves improved communication. Typically, this includes team briefings, one of the main elements of TQM.
- You have to **educate and train** your people, for an unskilled workforce makes mistakes. Giving more sills to workers means they can do a wider range of jobs, and do them better. It also means education staff in the principles of TQM, which is a completely new style of working.
- **Measure the work.** Measurements allow the company to make decisions based on facts, not opinion. They help to maintain standards and keep processes within the agreed tolerances.
- **Top management must be involved**. If senior management is not involved, the programme will fail. It is as simple as that. If you are the big boss, there is no problem. If you aren't, your programme cannot start until you have the boss's commitment.

- **Empowering the staff** means getting employees to think for themselves. We pay people to improve the business, not just perform to the status quo', said one organization.
- **Make it a good place to work**. Many companies are full of fear. Staffs are afraid of the sack, afraid of their boss, and afraid of making mistakes. In Spain, the UK and France, more than 60 per cent of full-time employees are very worried about losing their jobs, according to the Henley Centre. There is no pointing running a TQM programme unless the company drives out fear.
- **Introduce team working**. Teamwork boosts employee morale. It reduces conflict and in-fighting. It solves problems by hitting them with a wider range of skill. It pushes authority and responsibility downwards and it provides better, more balanced solutions. Yet the culture in most companies actively discourages teamwork. So the TQM programme has to foster it actively.
- **Organize by process, not by function.** This element of TQM seeks to reduce the barriers that exist between different departments, and concentrates on getting the product to the customer.

Why ISO 9000 helps TQM

Most activities follow a pre-set format. Raw materials arrive, are processed, and then packaged. The same thing happens in a public library or a software company. People or forms arrive, information is processed, and decisions are made. Replies are issued, computer buttons are pushed, and documents are dispatched.

But look at any of these processes, and you will see mistakes happening, even by dedicated staff. Production staff may use too much red dye or not enough yellow. An estate agent may send house hunters the wrong information. Records get misfiled, and time is lost searching for them.

ISO 9000 (also known as BS 5750 and EN 29000) solves these problems. In doing so, it givens TQM a solid base, with agreed systems that everyone can work to. ISO 9000 operates on the following principles.

Put in writing how tasks should be done

ISO 9000 gets you to write down how your main processes work. This means a new recruit will information about how the job should be done. It also ensures that the job is done in the best possible way. Michaels Page, the recruitment consultancy, found that ISO 9000 encouraged it to improve the structure of its job interviews.

Keep records

You should specify what records should be kept. It there is a faulty batch, the company can see what went wrong, and where. It can prevent the same mistakes from happening.

Do audits

You should regularly audit your system. This means checking that the written procedures are actually being followed. Internal auditors (usually from another department) will compare 'good practice' (as defined in the procedures) with what is actually happening.

Manage quality control

You should state where and when quality checks are to be made. This reduces the distance that a faulty batch will travel before being spotted.

Allocate responsibility

You should specify who is responsible for each major area. That way, every potential problem has an 'owner'.

Control the paperwork

If a bus company issues a new timetable, it is important that drivers receive copies without delay. It is also important to withdraw all the old ones, so that customers don't miss their bus. Similarly, you should manage your important documents, which include the written procedures. This reduces confusion, and makes sure that the company does it 'right first time'.

A new way looking at ISO 9000

Looked at like this, ISO 9000 is just a common-sense kind of activity. It formalizes systems that are already in use. You decide what the best way to do things is, and then you get everyone to adopt that method. This makes sure that everyone knows what their job is. It reduces staff uncertainty and process variation.

But despite all this, ISO 9000 is still a difficult system to work with.

Five reasons why companies dislike ISO 9000

Many companies dislike ISO 9000. There are five main criticisms, which we examine in more depth:

- It is bureaucratic
- It is internally focused
- It is imposed by a customer
- The company dislikes being assessed by an outsider
- The company doesn't want to pay for it.

Bureaucratic; Some quality managers construct Paper Mountains. They write procedures for the most obvious or irrelevant activities. They hand out huge quality manuals, which people never read. This can be avoided by designing a slim line system. ISO 9000 should be like a mountaineer's jacket: solid enough to protect you, not so heavy that it wears you down.

Internally focused; Many firms lose sight of why they are implementing ISO 9000. They focus on their internal processes, not the customers' needs. A TOM company will set ISO 9000 within the context of satisfying customers' requirements.

It is imposed by a customer; At least one in every two systems has been installed because a major customer insisted. As a result, staff feels that the standard has been imposed on them. The company sets up a system just to get the badge. The ISO 9000 culture does not take root.

One manager said, ISO 9000 is just a piece of paper saying you have quality systems in place. TQM is about the way you work, about striving to improve, and thinking about what you're doing. ISO 9000 seems to be all procedures and audits. The only times you hear of ISO 9000 is when Lloyds come to do a QA audit.

Some companies object to an outside certification body evaluating their quality. But an outsider will often spot weaknesses that are invisible to people who work in the business. So the certification body keeps the company on its toes. The assessors will point out the little slippages that the management may otherwise tolerate. Independent certification is a valuable way of maintaining quality.

Small companies don't like paying fees in consultants to set up the system, or paying a certification body to assess it. For smaller companies, ISO 9000 adds cost. But those costs

are usually recovered in greater efficiency. Some companies also get additional contracts once they can show they have ISO 9000.

Used correctly, ISO 9000 can help companies to perform much better. It is lower form of life than TQM, but ISO 9000 provides a firm foundation for it, as we shall see later. Without ISO 9000 a TQM company often lacks a systematic approach to quality.

How to fit ISO 9000 inside TQM

In order to make ISO 9000 work inside a TQM business, you need to adopt the following principles.

Get staff to take ownership of procedures

Staff must map their own processes and write their own procedures. These must not be imposed on them. Avoid handing them a set of procedures that have been written.

Make sure that all staff, including new recruits, understands the system Every one must be shown his work is documented in the quality system. You should explain how the system helps him, and how it makes the company more effective. (If you can't do that, you have a faulty system.)

Give refresher courses to all employees. These courses should encourage staff to question the elements of the system. This will ensure that if remains a live and useful support.

Set standards to meet customer requirements

ISO 9000 can be inward looking. It is often implemented by production people, who want to make sure that it prevents mistakes. But sometimes they can overlook the importance of the customer. All procedures should be designed to maximize customer satisfaction. For example, customers may need to be able to talk directly to production managers, rather than pass information via customer liaison staff.

Have a bias to action

There should be a bias to action, not a bias to bureaucracy. If a tool breaks, the operator should go and get a new one, not write a request form to the maintenance department.

What the right system looks like

- In the perfect quality system, each employee knows how the system works because he was involved in writing or updating it.
- Everyone knows how their job works because they are familiar with the written procedures.
- The workforce user the system to prevent and correct errors.
- Staffs use the quality manual as a source of information, and to remind them how a product should be made.

So ISO 9000 need not be the enemy of TQM. It can be the reverse of the same coin. TQM looks at the corporate culture, and ISO 9000 looks at the corporate systems. Together they help the company become world class.

Making quality programmes work together

As Figure 5 shows, several different initiatives can build a solid wall of quality for the company. Eventually, it will be difficult to see where one quality programme finishes and the next one starts.

Some companies start by introducing ISO 9000. That lays a firm foundation. They then use TQM to tackle people's attitudes. Then they solve particular problems by adopting specific tools, such as benchmarking.

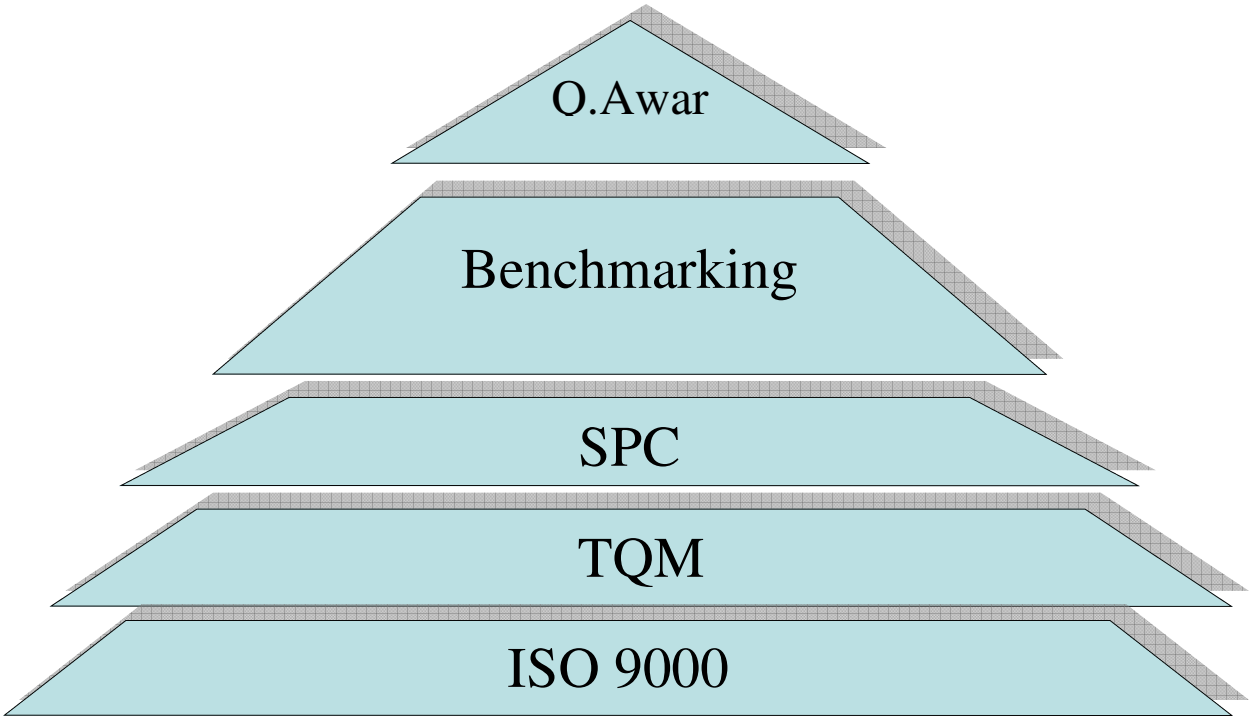

Figure 5 The Wall of Quality

Chapter 8

Case Study: Implementation of QMS based on ISO9001 at Ethiopia plastic Share Company (EPSC)

8.1Analysis of the current quality practices at plastic industries & EPSC

8.1.1 Quality control for plastic industries

In these days of rules and regulations, the only way any manufacturer can survive and be profitable is to have a firm grasp and a clear understanding of the science of quality control. For a plastics manufacturer or processor, the challenge is unique.

- The majorities of the materials are newly developed and are not precise in their composition.
- Manufacturing processes and procedures are different from conventional techniques
- Products made from such new materials have no previous history.
- Finally, the rapid growth of the plastic industry has created several problem in training new people.

A well-established quality control system serves many useful purposes.

- First, it leads customer satisfaction, which in turn attracts new business.
- Second, it allows one to meet all regulatory and contractual obligations.
- More important, the system acts as a signaling device for unseen problems and thereby reduces costly rejects.

In the case of plastics, controlling the quality of the product is not a simple matter of inspecting and testing the product as it comes off the machine or the assembly line. Many variables and unknowns, such as post-mold shrinkage, play an important role in controlling the ultimate quality of the product. Thus, it is highly recommended to implement the following **quality control system**.

Quality control system

Raw material quality control

Any well-established quality control system begins with control of purchased material. Such a system assures ones that the purchased material, in fact, meets the specified requirements. In most cases, processors rely on material suppliers to provide the same quality material time after time. If the end product or the particular process employed to make this end product is sensitive to changes in material quality and uniformity, such reliance on material suppliers may prove costly in the long run. The steps involved in setting up a good raw material quality control system are:

1. **Supplier selection**: the first step in setting up such a system is to select a reputable supplier of material. Items to check are past history, industry reputation, and future commitment. The supplier's ability to verify the quality of the material he is supplying should be investigated. One must also look at the quality and the type of supplier's manufacturing and test facility, the frequency of testing, quality control procedures and quantity, and more important , the equality of personnel . These considerations are of the utmost importance when a purchase of the material from a custom compounding house or from a totally unknown supplier is considered. If the product liability risk is high, it may behoove you to consider requiring material suppliers to certify the material, that is, it meets the minimum requirements specified in the material specifications.

2. **Receiving inspection.** Many types of tests have been devised for testing raw materials. Depending up on the severity of the need for inspection, the types of tests selected may vary from being very basic and simple to very sophisticated and complex.

Some of the most common basic tests are

- the melt index test
- specific gravity
- bulk density
- spiral flow test, and
- viscosity tests

Gel permeation chromatography, infrared analysis, thermal analysis, and rheometry are some of the more elaborate raw material quality control tests

Process quality control

In- process quality control serves the basic purpose of providing assurance that the product continues to meet the specified requirements. By employing process control chart techniques of statistical quality control, we are able to continuously monitor the process and determine whether the process is in or out of control. Patrol or floor inspection gives the inspector an opportunity to verify the visual and dimensional conformity of the processed parts.

Product quality control

There are two major areas of interest in product quality control. One of them is receiving inspection, where a product manufactured by an outside vendor is inspected when it is received. The other one is the out going lot inspection in which the product manufactured in-house is inspected prior to shipping. Here again, the principles of statistical quality control are applied. A sampling plan is selected based on the requirements and the AQL, LPTD, or AOQL value is specified. The product quality control involves visual inspection, measurement inspection, and in some cases, actual product testing. Preferably, the test will stimulate actual use , a part which aesthetically appealing and well within the specified tolerance only gives a partial indication of overall part quality.

Visual standards

One of the reasons for the tremendous success of plastic products in the consumer market is that the products made from plastic materials are aesthetically more appealing in terms of color and feel than products made from other materials. The majority quality control system fails to recognize the importance of visual standards or guide lines. Quite often, too much emphasis is placed on measurement and testing of the product and not enough on the visual standards.

Visual defects, such as orange peel, sinks, and cold flow, are quite common among fabricated plastic parts. These defects are not usually encountered in parts made from other materials. Further more, the terminology that prevails in the plastic industry to describe visual defects is totally different than the terminology used for conventional materials. Identifying visual defects is not only necessary in assessing the overall quality and strength of the part. For example, a visual defect such as splay marks on the part indicate the presence of moisture in the material, brown streaks indicate the beginning of material degradation, both of which can lower the overall properties of the material.

A visual standards manual must indicate the basic definitions and explanations of recurring visual defects along the proper illustrations. Since it is difficult to qualify the visual defects in terms of actual measurements, such as gauging a diameter or wall thickness, some guidelines, and accept reject criteria must be established.

Mold (tool) control

The quality of the mold part is only as good as the mold that produces that part. New equipment, skilled operators, or good molding practices can not make up for defective or worn out mold. In spite of this proven fact, the majority of the manufacturers often fail to recognize the importance of effective mold control systems.

A good mold control system starts with proper inventory control and adequate mold storage facilities. Documentation is the key word. From the inception of the mold, every little detail regarding the particulars of the mold must be logged.

Workmanship standards

Workmanship standards are nothing more than a simplified guide, explaining through the use of drawings, sketches, and photographs, the proper method of carrying out the specified task. The task may consist of simply deburring or hot stamping the parts or assembling those using solvent cementing techniques. The majority of the workmanship standards provide preferred, acceptable, and reject criteria.

Some of the most obvious advantages of such workmanship standards are a lower reject rate, elimination of unnecessary rework, early detection of defects, and reduced risk of rejecting good parts. Proper implementation of workmanship standards can improve quality and reliability by eliminating the time lost in rework because of varied interpretation and personal opinions.

Documentation

Documentation is the heart of the quality control system. The data compiled through documentation of test results, dimensional measurements, process capability studies, and sampling inspection can be used for statistical analysis. Many private and government agencies require the proper documents and records be retained for certain minimum time periods.

A good documentation system is one that is

- easy to implement
- easy to understand
- easy to maintain

The records documenting inspection must indicate

- the characteristic observed
- number of observations made
- number and types of discrepancies
- final disposition
- inspector identification

- and most important , date of documentation

Lastly, with out proper records it would be practically impossible to trace the reason for product failure. By carefully studying the dimensional measurement records of the part, one can also identify the equipment as well as the tool wear.

Quality assurance manual

A quality control system with out a quality assurance manual describing in detail a quality assurance program can not function adequately. The sole purpose of a quality assurance manual is to provide clear and precise written instructions and procedures so that there can be no misunderstanding and confusion between different organizations within and out side the company. Whenever possible, **oral instruction** should be avoided, since it can only result in misinterpretation and gross distortion of the message.

The following is a broad outline of a typical quality assurance manual

1. an organization chart describing the responsibilities of each individual in the organization
2. function and responsibility of the quality control organization
3. Material review board function and corrective action procedures.
4. receiving inspection procedures
5. in process inspection procedures
6. shipping inspection procedures
7. disposition guidelines
8. procedure for handling customers returns
9. gauge and test equipment calibration and maintenance procedure
10. mold control (tool and die)program
11. miscellaneous test procedures
12. method of recording inspection data and exhibit of sample forms
13. retention of records and documents
14. defective material rework and re inspection procedures
15. visual standards
16. Workmanship standards.

8.1.2 Quality control policies in Ethio-Plastic Share Company(EPSC)

The Ethio- Plastic Share Company (EPSC) has developed quality control policies that can be a guide for activities and procedures regarding quality. This policy has two parts: the first part discusses the raw material control policy and the second deals with process control and issues under process control.

The purpose of the policy is stated in the introduction part of the policy manual. It declares:

- To keep and maintain the quality standards of the plastic products produced by the factory
- To compare the raw material quality specifications with International plastic raw material quality specifications whether they fulfill the quality criteria or not before production since the property of raw materials is a determinant factor to produce standard products
- To produce quality products by avoiding the problems that may encounter during production process and by keeping the proper functioning of production machineries and auxiliaries

Control systems

The control systems are detailed in the manual. As previously indicated it can be classified into two.

Responsibility

Implementing the product quality policy is the responsibility of every department of the factory.

Raw material control policy

The Objective this section:

- To inspect in detail the basic physical properties of raw materials and then select materials that satisfy the need of the customer when processed by the existing facility

Guide lines to achieve this objective

This objective can be achieved by:

- ✓ Controlling raw material purchase

To control raw material purchase

- ➢ It communicates with Material Management Department about:

  - Preparation of raw material purchase
  - Raw material sample testing process
  - Preparation of certificate of raw material sample test result
  - Control and follow up raw material purchase result

Process quality control policy

The Objective of this part of the policy:

- ◆ To minimize production process problems and manufacture products that meets the factory's quality standard.
- ◆ To plan, produce and deliver products to consumers with the existing capacity.
- ◆ to meet market demand in variety, type and quality
- ◆ facilitate training for product quality awareness and improvement
- ◆ to encourage research, design and factory operation so as to improve product quality
- ◆ To organize important technological information to create sound process quality control system
- ◆ encourage team work habit so that the employees contribute up to their potential with out limitation

Guide lines to achieve this objective

Communicating and working with various bodies of the factory, such as:

- ◆ manufacturing and engineering department
- ◆ Sales and marketing department

And dealing about the issues of

- The process of quality improvement
- product quality control report preparation and execution
- product sample taking

- ◆ product quality assurance
- ◆ returned products issues

8.1.3 Identification of Problem

1.1. Investigation Procedure

In this case study, on implementing quality control tools and techniques in EPSC, certain investigation procedure has been followed.

- ➢ production process survey
- ➢ quality related problem assessment (problem statement)
- ➢ important data collection
- ➢ Analyzing the information
- ➢ Applying quality control tools and techniques.

1.2. Production process survey

The production process of the factory is a batch type. Thermoplastic materials of different resin, with addition of master batches, plasticizer, additives, and other ingredients and, some time, reconditioned scraps are processed using automatic and semi-automatic plastic processing machineries. With the exception of the main processing phase carried out by the machines, raw material handling, extraction, inspection, finishing, and handling of finished products all are manual activities.

EPSC is a large manufacturing plant that utilizes a wide range of processing technology. However, many of machineries have surpassed its useful life. The routine maintenance

and modification are the only reason they are still in operation. Since the introduction of these old machines, plastic industry has experienced many new technologies to adapt to complex product design, raw materials and processing parameter requirements.

8.1.4 Problem Assessment

After the production process survey and the overall picture of the plastic products manufacturing was envisioned, the focus was on assessing existing main problems with regard to quality characteristics. The method of exploring about the problems was based on:

- Opinions forwarded from the quality control service
- Information from the on hand documents.
- observation of production process surveys

According to these preliminary sources of information, there exists a quality problem in the factory which can be generalized in to four:

- The main problem is that machine performance is poor, which will influence quality.
- High Costs are incurred for scrap and nonconformance outputs
- Customers complain about defective food packaging products
- The laboratory is not well equipped to test essential quality characteristics

When the priority of each sited problem is considered, the first two problems are of major areas of quality problem. So, the scrap cost and machine performance problems are chosen for investigation through quality control techniques and tools.

8.1..4 Defects in Ethio-plastic Share Company

Major causes for the defect product in Ethio plastic share company factory

- A large amount of defect is produced when the machine is to set up, & power off.

- When there is transfer of one skilled worker from one department to the other.
- The machines are worn out and have been served for long years.
- When there is a test of raw materials
- When temperature is adjusted
- Poor motivation of workers
- Lack of training

8.1.5 Recording of nonconformance

- History of rejected products (nonconformance product) is not properly recorded. Since reasons of most rejected products(nonconformance product) are not explicitly stated. The reasons of good performance also are not recorded due to lack of this technique that may be used for future investigation.
- Data records of rejects (nonconformance product) are not consistent. It is obvious that the sum of rejected quantity and accepted quantity should be equal to total input quantity. However, we have encountered many reports with accepted quantity and rejected quantity different from total input quantity.

- Defect reports are prepared for the purpose of remanufacturing order but not for preventive action to be implemented.

- Defect data handling system is not well organized and centralized.
- Statistical process control techniques, especially control charts are not used in the company.
- In the factory the reasons for defective item are not mentioned, it is only the weight of defective item is registered.

8.1.6 Product variables

The product variables of a factory exist through the entire stages of the production process, and transporting them to the doors of the customer. However, important product variables (parameters) are can be generally classified as:

I. Input variables
II. Output variables and
III. Product variables

The variables (parameters) are the basis for analyzing and evaluating the capability of the process and in consequence to detect the focus points of the quality problem. In ***essence it is the data for reference in every analysis.***

8.1.7 Input variables

Input variables ***a***re those parameters related to characteristics such as amount, qualities and properties of the raw materials. Input materials of EPSC have different parameters listed on raw materials quality certification form. Among these properties the inherent in the resin are:

i. processibility
ii. melt flow index (rate),
iii. heat stability,
iv. working temperature,
v. toxicity,
vi. color,
vii. light fastness,
viii. light fastness and
ix. Packaging situation.

Although the experiment form suggest these property and 'quality control service' strongly accept as true on the importance of testing these important properties of these input materials, the laboratory testing apparatus are not well organized to carryout those tests. This is because some of the machines are not functional, some others are not available. In addition, the available functional testing machines are not suitable enough to be adapted for newly emerging resins from current plastic technologies that are highly improved in

properties and simplicity of processing. And consequently, the check is subjected to errors of rejecting acceptable raw materials. The other problem is the production machines. The machines are mostly old requiring raw materials their age. They do not fit to the current good quality resins.

However, EPSC do tests for two essential parameters specifically *melt-flow index/ rate* and *process ability* and obviously *package condition*. Depending on these parameters decision is made either to accept or reject the raw materials sample.

What ever the case may be EPSC has a quality control system to check input variables in its existing lab and always purchases raw materials based on this test result. The test results of many years are kept documented in the quality control service office.

8.2 Quality Costs in EPSC

Prevention, appraisal and failure costs in EPSC are tabulated below.

Table8: Prevention, appraisal and failure costs in EPSC

	Prevention costs	Appraisal costs	Failure costs
Quality assurance	-Quality planning -Training personnel	-Receiving and processing appraisal -Final product or service appraisal	-Internal failure -External failure
Cost incurred			
Research, design, and development	-Setting specifications (including services, materials, processes and products) -Pre-production /operation and prototype trials	-Inspection equipment • Maintenance of • Design and specifications for	-Rework and rectification -Downgrading of products and services product or service complaints
Cost incurred			
Production/operations	-Training-including supervisor training -Pre-production /operation and prototype trials -Material handling and storage during production or operations -Supervision of quality at all stages	-Line or process inspection (by production /operations personnel) -Finished product inspection or service checking (by production /operations personnel)	-Full cost of scrap or wasted effort -Rework or rectification -Replacement of rejected product or repeating service -Downgrading of products, materials and lab service
Cost incurred			
Marketing and sales	-Setting of product or service specifications Customer need analysis	-Analysis of degree of acceptance of goods and lab service	-Downgrading of products and lab service -Customer complaints,
Cost incurred			
Purchasing	-Supplier approval	-Vendor rating	Incorrect choice of supplier
Cost incurred			
Laboratory service section	-Product or service specification evaluation - Pre-production /operation and prototype trials -Planning of in-process control procedures	- Finished product or service performance evaluation	-Customer complaints -Product or customer service -Returned material investigations and repairs
Cost incurred			
Personnel	-Recruitment of	-Operation of staff	-Dealing with results of

	appropriate personnel -Competencies analysis	appraisal systems	poor recruitment process -Disciplinary procedures
Cost incurred			
Stores, transport and distribution	-Material handling and storage	-Receiving and checking materials, bought-out items or services -Checking and dispatching finished products and/or services	Sorting of reject finished goods in stock -Receiving and checking returned reject goods -Checking and dispatching replacement goods
Cost incurred			
Material control	-Ordering correct materials -Inventory system	Checking stock levels	-Scrap material control -Ordering of material or services for rework and rectification - Ordering of material or services and finished goods for replacement
Cost incurred			
Maintenance	-Prototype processes and equipment -Planning and maintenance of plant equipment and inspection equipment	-Equipment reliability monitoring	-Investigations and repairs following complaints, and return of goods
Cost incurred			
Finance	-Establishment of good financial systems	-Auditing accounts -Determination of quality-related costs	-Investigations and rework, following failure in the system
Cost incurred			

8.3 QMS Assessment

8.3.1 Questionnaire Design

The questionnaire designed for easy responses and simple analysis. At the end of each section, free space was open-ended to allow respondents to use their own words. The questionnaire consisted of nine sections and organized in two parts. The first Part designed to obtain background information about the surveyed company, including:

- The mission of the company;
- Existing workforce;

- Management perception of existing system;
- Methods used for improving quality;

And the second Part consisted of questions related to the principles and concepts of Quality Management System, including

- Quality Awareness;
- Quality policy;
- Quality manuals, documents and Procedures;
- How EPSC deal with their suppliers, employees and customers;
- Stock control, handling, storage, packaging, preservation and delivery;
- Control of Non-Conforming goods, corrective and preventive action and more - - -

8.3.2 Results and Discussions from the questionair

Out of 15 questionnaires distributed to the company 10 of them respond to the questionnaires and considered an adequate for the study. Thus, the effective overall response rate was 60% and the response rate for some questions is low since not all respondents answered all questions. From the questionnaires returned, the following results obtained.

In the first part of the questionnaire, 66.67% of them responded that, as they are a large-sized plastic company and having 350 numbers of employees. Nearly half of them (55.67%) have been in the company for more than 5 years and only about one-third of them (33.33%) decide their mission to be based on quality, while 44.44% of the company make their mission on providing goods with low price. The investigation also shows that there are employees in the company who do not know who are their customers and their potential customers and only half of them respond that they could identify and define their customers.

From the company research the result obtained is that the management and middle management of the EPSC are on planning for implementing a formal quality management program that require a more due attentions for the improvement of the services to be competitive in the market and for better customer satisfaction. On the other hand, from the collected data there are some inconsistencies in the responses that show half of them believe that their employees have quality awareness. The researcher believes that this result reports how much there is misconception about the concepts of quality in the company of EPSC because with out formal quality management program quality awareness may not be achieved. The EPSC not only fail to implement the formal quality program but also they don't introduce the whole work force to prepare themselves for the QMS implementation plan, which have great contribution for the action plan to be effective.

History of rejected products (nonconformance product) is not properly recorded. Since reasons of most rejected products (nonconformance product) are not explicitly stated. The reasons of good performance also are not recorded due to lack of this technique that may be used for future investigation. Data records of rejects (nonconformance product) are not consistent. It is obvious that the sum of rejected quantity and accepted quantity should be equal to total input quantity. However, we have encountered many reports with accepted quantity and rejected quantity different from total input quantity. Defect reports are prepared for the purpose of remanufacturing order but not for preventive action to implement. Defect data handling system is not well organized and centralized. Statistical process control techniques especially control charts not used in the company. In the factory the reasons for defective item not mentioned, it is only the weight of defective item is registered.

The survey reveals that only the top management group holds weekly regular meetings among themselves from the top management the researcher can understand this meeting is arranged to investigate the weekly report among the department. Manager and the whole employees meet on each quarter of the year to review the effectiveness of the existing system toward satisfying their customer and few of them responds that the meeting conducted whenever critical problems are occur.

The survey also includes how the EPSC Company deals with their supplier to know the degree of quality awareness in the company and to recommend for better customer – supplier partner ship. The survey indicated that if the company received con-conformance products from their supplier frequently, 77.77% of them believe that they will abandon the supplier totally without dealing the way to improve the service. Even though 66.66% of them believe that creating customer-supplier partnership is necessary to provide quality goods to the customer, they are practicing that ceasing the contract with the supplier that does not fulfill the requirement.

The researcher could observe that most of the supermarkets arrange various products on the shelf attractively and use special handling system to preserve perishable goods by identifying products, which require special care. The collected data and the interview provides the interval that supermarkets asses the condition of the stock. Three forth of them keep track daily the level of critical products in the stock and on the shelf and they check weekly the level of some products in the stock. They informed that non-conformance goods segregated and disposed in the appropriate way and 55.55% of the supermarkets keep track the amount of the disposed products through recording and maintaining the record to carry out corrective and preventive action to minimize the number of defective items. They believe that recording will help them to do profit-loss statement.

Almost the company's entire employee, as the survey shows, does not carryout conditional audits as well as planned/scheduled audit to ensure that each activity is performed according to expected. They also do not record and maintain the results of the audit to enable the company follow-up the results of the audits effectively. This result indicates that the company as a whole does not understand audit system to reduce loss of items.

The last section of the survey includes the most important aspects of customer satisfaction that can pave the way for the success of the business. That is how the company deal with their customer. 88.89% of them said that they accept the complaints of their customer and substitute the return product

Concerning their internal customer, most of them do not know that their employee is also their customer, but they believe that handling their employee is important for the success of the business. 44.44% of them accept the employee involvement and try to foster an environment where teamwork flourishes. What impressed more the author is that 88.89% of the owners of the company believe that providing efficient training for employee development at all level is not their concern. Because of the poor quality awareness in more of the employees, they do not have their own quality culture to support total employees involvement in quality improvement. Thus the quality vision, mission objective statement and relative measures are not clear or do not exist. When quality conflicts with quantity, quantity is above quality and short-term interest will override long-term interest.

8.4 Proposed Methodology for the Implementation of QMS in EPSC

Steps toward QMS Implementation

There are many ways to go about implementing a QMS. This section is intended to provide one such example of implementation that best suit EPSC. It provides solely as an example and should not be regarded as the only method of implementation.

These are three stages to the process

- **Development –** considering what happens in your business (i.e. your business processes).
- **Implementation-** putting the QMS into operation.
- **Maintenance-** Supporting and improving the QMS.

STAGE 1: Development

Step1: Top management commitment

Before starting implementation of the QMS ,it is extremely important that a top management agrees:

- The need for implementing QMS;
- To lead the project;
- Practices will have to change in EPSC;
- To give the project top priority; and
- It will do what it says.

If top management aren't committed to do these, it is a waste of time. What will be produced is a burden that doesn't fulfill its promise and looses credibility.

Top management commitment is evidenced by :

- Doing what you will say you will do;
- Not accepting sub-standard work;
- Not working by problems;
- Honoring plans and documents;
- Listening to workforce;

- Establishing effective ways of communication;
- Stating quality policy;
- Ensuring requirements are determined and met;
- Ensuring that quality objective are met;
- Ensuring availability of resources;
- Appoint management representative; and
- Conduct periodic management review.

Step 2: Assigning management representative

The management representative shall have the following main responsibilities:

- Coordinate and work with other management functions to ensure that the quality system is established ,implemented and maintained effectively and efficiently;
- Conduct quality audit and report on the performance of the quality system to the management in accordance with the internal quality audit program and procedure to ensure continuing improving and adherence to the quality system;
- Co-ordinate quality improvement programs by using suitable economic basis such as the principles of quality costs;
- Plan and initiate the top management to undertake periodic reviews on the effectiveness of the quality system;
- Initiate corrective and preventive actions on the identified actual and potential non-conformities;

Step 3 Creating task force/implementation team

The task force should include people from key functional areas and of manageable size. Also remember that involvement of employees at all levels has significant contribution for effective implementation and sustaining the quality system.

The responsibility of task force include :

- Prepare QMS implementation plan in their areas of responsibility ;
- Co-ordinate the creation of QMS documents and their implementation;
- Co-ordinate the revision of the existing QMS documents;
- Distribute the QMS documents to the locations where they are needed for implementation;
- Give information, training guidance to the employees on the documented QMS; and
- Initiate appropriate corrective actions.

Step 4: Training the task force

Train the task force on:

- Basic concepts of QMS ,
- QMS requirements,
- QMS documentation,
- Process mapping ,
- Implementation, and
- Internal quality audit

Step 5: Defining map of processes

Identify the processes that make up the QMS, including, product realization, resource provision, management, and monitoring and measurement processes and determine their sequence and interaction (see section 4.5)

Step 6: Conducting gap-analysis

Compare the current management practices to the requirements of ISO 9001:2000 QMS to identify the gaps . The activity includes preparing checklist, conducting the gap analysis and generating and reporting the gap analysis findings.

Steps 5 & 6 could help you to identify which requirements of clause 7 of the standard may not be applicable to your processes to be considered for exclusion.

Step 7: Develop QMS implementation plan

Based on your business processes and finding of the gap analysis, develop detail implementation plan , including ,

- Who does what ,
- The time frame , and
- The needed material resources.

Your documentation plan and general implementation plan may take the following formats, respectively.

Document Title	Responsibility	First Draft Date	Approval Date	Issue/Implementation Date
Document Control procedure				
Internal quality audit procedure				
Control of nonconforming product				
Etc.				

STAGE 2: Implementation

Step 8 : Quality Management System documentation

The QMS documentation should address all the documentation requirements of the standard (see chapter) and developed as per the plan established in step 7 above.

Now is the time to get everyone concerned involved in writing down how they carry out the parts of the business activities they are responsible for , stating who is responsible for performing and checking activities ,where the

- Activity takes place,
- When it will happen , and
- What happens, i.e. how the activity is performed?

Step 9: Put the **Quality Management System into operation**

To put the quality management into operation:

a. Everybody needs to have access to the documentation that relates to their activities. They need to be given some insight into how the quality management system works and why, for example, document control ensures that they have the latest copies of information relevant to their jobs and can rely on up-to-date information when making decisions.
b. Everybody needs to be trained to understand how to keep the QMS up-to-date. They also need to know how to make changes to the quality management system as well as noting problems and putting forward ideas for improvement. Remember that you need to approve any changes before they are put in place.

STAGE 3: Maintenance

Step 10: Conduct internal quality audit

An effective QMS uses feed back loops to improve how things are done in your business, which in turn should lead to an improvement in product or service quality.

Conduct the audit to assess the status and effectiveness of the implemented quality management system. The audit activities include,

- Defining objectives ,
- Planning the audit,
- Preparing audit checklist,
- Conducting the audit, and
- Reporting the audit findings.

Step 11: Conduct management Review

Conduct management review to ensure the suitability and continuity of the QMS using the feed back of information from the QMS, including audit findings and customer complaints.

Step 12 : Implement corrective actions

Consider the feedback of information from the QMS to lead to improvement in ideas and activities.

Take the corrective action to eliminate the identified nonconformities and introduce improvements. The activity includes ,

- Identifying the root causes of non-conformities,
- Plan date of realization,
- Take the corrective action, and
- Monitor the effectiveness of the corrective action taken

Chapter 9
Recommendations and Conclusions

9.1 Recommendations

Most activities follow a pre-set format in EPSC like other companies. Raw materials arrive, are processed, and then packaged. . People or forms arrive, information is processed, and decisions are made. Replies are issued, computer buttons are pushed, and documents are dispatched.

But look at any of these processes, and you will see mistakes happening, even by dedicated staff. Production staff may use too much red dye or not enough yellow. An estate agent may send house hunters the wrong information. Records get misfiled, and time is lost searching for them in EPSC.

ISO 9000 solves these problems. In doing so, it givens the quality culture of EPSC a solid base, with agreed systems that everyone can work to. ISO 9000 operates on the following principles.

Put in writing how tasks should be done

ISO 9000 gets you to write down how EPSC main processes work. This means a new recruit will information about how the job should be done. It also ensures that the job is done in the best possible way.

Keep records

EPSC should specify what records should be kept. It there is a faulty batch, the company can see what went wrong, and where. It can prevent the same mistakes from happening.

Do audits

EPSC should regularly audit its system. This means checking that the written procedures are actually being followed. Internal auditors (usually from another department) will compare ‘good practice’ (as defined in the procedures) with what is actually happening.

Manage quality control

EPSC should state where and when quality checks are to be made. This reduces the distance that a faulty batch will travel before being spotted.

Allocate responsibility

EPSC should specify who is responsible for each major area. That way, every potential problem has an 'owner'.

Control the paperwork

If a bus company issues a new timetable, it is important that drivers receive copies without delay. It is also important to withdraw all the old ones, so that customers don't miss their bus. Similarly, EPSC should manage its important documents, which include the written procedures. This reduces confusion, and makes sure that the company does it 'right first time'.

A new way looking at ISO 9000 that EPSC should look

Looked at like this, ISO 9000 is just a common-sense kind of activity. It formalizes systems that are already in use. You decide what the best way to do things is, and then you get everyone to adopt that method. This makes sure that everyone knows what their job is. It reduces staff uncertainty and process variation.

9.2 Conclusions

To conclude we have to answer the following two questions

1. **Will ISO 9001 improve EPSC financial performance?**
2. **Why should EPSC get ISO 9001 certified?**

QUESTION 1	**Will ISO 9001 improve EPSC financial performance?**
ANSWER	**ISO 9001 can improve EPSC company's financial performance if it is properly implemented. An ISO 9001 Quality Management System can help EPSC to improve its bottom line because it can reduce the costs associated with poor quality (the cost of repairs, rework, scraps, complaints, returns, warranty work, law suits, etc.). And, of course, if ISO 9001 helps EPSC keep its old customers and attract new ones, it will certainly improve EPSC's financial performance.**
QUESTION 2	**Why should we get ISO 9001 certified?**
ANSWER	**The purpose of ISO 9001 is to assure customers that suppliers can provide quality products and services. It is intended to serve the needs of customers. ISO 9001 is for customers. Supplier needs are secondary. So, why would you want to become ISO 9001 certified in EPSC? I recommend that you become ISO 9001 certified if EPSC meet at least one of the following conditions:** • **EPSC need to control the quality of its products and services.** • **EPSC need to reduce the costs associated with poor quality.** • **EPSC customers want you to become certified.** • **EPSC markets expect it to be certified.** • **EPSC competitors are already certified.**

REFERENCE

1. ISO 9001:2000 for small business, RayTricker,Second edition,2001

2. Joseph M.Juran,"Juran's Quality Hand book",R.R Donnely & Sons Company,5th ed.,1999.

3. Training Material for QMS and Implementation based on ISO
9001:2000, Compiled by QSAE, August 2004, Addis Ababa

4. John S. Oakland, Statistical ProcessControl, BH, 2nd ed.

5. Productivity Improvement, by EPSC (Ethio-Plastic Share Company), 2004

6.J.R. Taylor, Quality Control Systems, Procedures for Planning Quality Programs, McGraw–Hill Book Company, Singapore, 1989.

7. TQM and ISO 9001 http://www.gslis.utexas.edu/~rpollock/tqm.html

8. Total Quality Management tutorial
http://home.att.net/~iso9k1/tqm/tqm.html

Annex

Addis Ababa University
Post Graduate Program in
Industrial Engineering

The objective of this Questionnaire/ Survey is to assess and look into the quality of services in Ethiopia Plastic Share Company (EPSC) and produce possible recommendation for better achievement. To this effect, this questioner is developed to identify the core problems of the Company in relation to their product and service quality. The collected data will be analyzed using various general GAP Analysis tools and Quality Management concept that could help to recommend for better service improvement.

A. General

1. What is the classification of the company?

   Small ☐ *Medium* ☐ *Large* ☐

2. How long have you been in this *Company*?

   Less than 2 years ☐ *2-5years* ☐ *More than 5 years* ☐

3. What is the mission of your company based on?

   Low Price ☐ *Profit* ☐ *Quality* ☐ *No mission* ☐

   If your company has a mission, state the mission of the company:

   _____

   _____

5. Does Your Company clearly define and identify its customers?

   Yes ☐ *No* ☐

B. Quality Awareness

1. Does the company have a Quality policy?
   Yes ☐ *No* ☐ *On the way* ☐ *Not planned* ☐
2. Does the company have a Quality Objective?
   Yes ☐ *No* ☐ *On the way* ☐ *Not planned* ☐
3. Has your company installed a formal quality management program?
   Already Implemented ☐ *In Preparation* ☐ *Not Planned* ☐
4. How much the employees of the company have quality awareness?
   Much ☐ *enough* ☐ *low* ☐
5. Did you implement a process for improvement suggestions in your organization?
   Already Implemented ☐ In Preparation ☐ Not Planned ☐
6. Are you using a systematic approach for implementing a continuous improvement scheme in your organization?
   Already Implemented ☐ In Preparation ☐ Not Planned ☐

Comment: _____

_____

_____

C. Manual and Procedures

1. Is there quality manual and set of procedures available and utilized?
   Yes ☐ *No* ☐ *On the way* ☐ *Not planned* ☐
2. Are the functional roles, responsibilities and activities of each employee structured clearly and documented? *Yes* ☐ *No* ☐
3. Explain what type of documents the company records and maintain.

_____

_____

_____

D. Meeting

1. Do the board of directors, the manager and employees of the company hold regular meetings to review the effectiveness and efficiency of the existing system toward satisfying their customer? ☐*Yes* ☐*No*

   If the answer is *No*:

   The meeting conducted:

   When critical problems only occur: ☐

   Whenever it is necessary: ☐

   No at all: ☐

2. Does the meeting include results of internal and external audits as well as customer feedback and complaints? *Yes* ☐ *No* ☐

3. Does the decisions made during the meeting maintained and controlled?

   Yes ☐ *No* ☐

Comment: _____

_____

_____

E. Purchasing

1. Does the company have fixed suppliers? *Yes* ☐ *No* ☐ *N/A* ☐
2. Does the company clearly define the customer requirements so that the supplier will confirm? *Yes* ☐ *No* ☐ *N/A* ☐
3. Is there a flow-down of customer requirements to the supplier?

   Yes ☐ *No* ☐ *Not applicable* ☐
4. Is there a procedure for evaluation and selection of suppliers based on their ability to meet previously defined requirements? *Yes* ☐ *No* ☐ *N/A* ☐
5. Is there a procedure for purchasing? *Yes* ☐ *No* ☐ *N/A* ☐
6. Are Goods inspected when received from the suppliers? *Yes* ☐ *No* ☐

7. Do the purchased products from suppliers handled and protected during receiving process? *Yes* ☐ *No* ☐
8. Does your company create customer-supplier partnership? *Yes* ☐ *No* ☐
9 How do you ensure the quality of goods/services from your suppliers?
   ☐ Inspection ☐ Audit ☐ ISO 9000 ☐ Performance
10. Are goods received controlled to prevent mixing and ensure traceability from receiving goods through delivery process to the customer?
   Yes ☐ *No* ☐

Comment: _____
_____
_____

F. Stock Control, Handling, Storage, Packaging, Preservation and Delivery

1. Are goods stored in proper way to protect them from damage? *Yes* ☐ *No* ☐
2. Does the company use any special material handling system to handle able goods in suitable manner? *Yes* *No* ☐ *N/A* ☐ ☐
3. Are there procedures for, inspection, identification, verification, storage and maintenance of the customer supplied goods? *Yes* ☐ *No* ☐ *N/A* ☐
4. Are there appropriate procedures to ensure that those products which require special care are appropriately identified? *Yes* ☐ *No* ☐
5. Are critical activities which may affect quality, identified? *Yes* ☐ *No* ☐
6. Does the company assess the condition of stock at appropriate intervals?
   Yes ☐ *No* ☐ *N/A* ☐

7. Does the company give due consideration to special handling, storage, packaging, preservation and delivery requirements for goods?
   Yes ☐ *No* ☐ *N/A* ☐

8. Does the company ensure that the package is adequate to prevent damage and deterioration of the products? *Yes* ☐ *No* ☐

Comment: _____

_____

_____

G. Control of Non-Conforming Goods, Corrective and Preventive Action

1. Are there procedures for the review of non conforming materials and their disposition? *Yes* ☐ *No* ☐ *N/A* ☐
2. Are defective goods properly identified, segregated from acceptable material and held in a controlled area pending disposition? *Yes* *N*☐ ☐
3. Does the company ensure that appropriate records of reviews and dispositions are maintained? *Yes* ☐ *No* ☐ *N/A* ☐
4. Does the company carry out corrective and preventive action to minimize the number of defective items? *Yes* ☐ *No* ☐
5. Does the company implement a system to address the root cause of non-conformance? *Yes* ☐ *No* ☐

Comment: _____

_____

_____

H. Internal Audits

1. Does the company carry out conditional quality audits? *Yes* ☐ *No* ☐
2. Does the audits conducted by personnel not directly responsible for the area being audited? *Yes* ☐ *No* ☐
3. Does the company have audit plan/ schedule which ensure that all activities are audited according to their criticality? *Yes* ☐ *No* ☐
4. Does the company effectively follow-up the results of the audits?

Yes ☐ No ☐

5. Does the company record and maintain the results of the audit?

Yes ☐ *No* ☐

Comment: _____

_____

_____

I. Dealing With Customer

1. Does the company deal with customer complaints? *Yes* ☐ *No* ☐
2. Does the company survey the customers? Yes ☐ *No* ☐
3. How often do you survey your customers?

   every month ☐ 2-3 times a year ☐ once a year ☐ every 2 years ☐
4. Does the company implement a system for customers to express their feeling about the service? *Yes* ☐ *No* ☐
5. Does the company quickly answer the complaint and solve the customer's problems. *Yes* ☐ *No* ☐
6. If the customer receive unreliable product, how does your Company rectify the problem?

   It will accept any sold products: ☐

   It will sell the product with low price: ☐

   It will substitute the product: ☐

   It will substitute the product and give special bonus: ☐
7. Does your supermarket believe that the employees of the company are also its internal customer? Yes ☐ No ☐
8. Does the company foster an environment where employee involvement and teamwork flourish? *Yes* ☐ *No* ☐

9. Does the company provide an effective and efficient training for employee development at all level? *Yes* ☐ *No* ☐

10. How many Self-Assessments did you do every year?
more than 3 ☐ 2-3 ☐ Just 1 ☐ not at all ☐

11. How often do you survey your employees in a year?
every month ☐ 2-3 times ☐ once a year ☐ No at all ☐

Thank you for Your Kindly Co-operation