QUALITY MANAGEMENT SYSTEM (QMS) IN CLEANROOM MANUFACTURING UNIT [A CASE STUDY OF THE FRED HOLLOWS INTRA-OCULAR LENS LABORATORY, TILGANGA EYE CENTRE]

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RECOMMENDATION

This is to certify that the thesis

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[A case study of The Fred Hollows Intra-ocular Lens Laboratory,
Tilganga Eye Centre]

has been prepared as approved by this department in the prescribed format of Faculty of Management. This thesis is forwarded for examination.

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VIVA-VOCE SHEET

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and found the thesis to be the original work of the student and written according to the prescribed format. We recommend the thesis to be accepted as partial fulfillment of the requirements for Master's Degree in Business Studies (M.B.S.)

Viva-Voce Committee

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DECLARATION

I hereby declare that the work reported in this thesis entitled **"Quality Management System (QMS) in cleanroom manufacturing unit [A case study of The Fred Hollows Intra-ocular Lens Laboratory, Tilganga Eye Centre]"** submitted to Office of the Dean, Faculty of Management, Tribhuvan University, is my original work done in the form of partial fulfillment of the requirement for the Master's Degree in Business Studies under supervision of Prof. Dr. Kamal Das Manandhar, Assistant Dean of Management, Tribhuvan University.

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There may be some errors in my study, I apologize for the errors. Please kindly accept my apology for any occurrence of errors in my research work.

Finally I am hopeful that this study will also serve as a stepping stone to the students of QMS, to the general people for conceptual knowledge on QMS, to the executives/managers for practical implementation of QMS in an organization, and to those who wish to make further research under this topic.

Shiva Raj Malakar

July, 2010

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LIST OF ABBREVIATIONS

APO	Asian Productivity Organization
AQL	Acceptance Quality Level
ATR	Analytical Test Record
C of A	Certificate of Analysis
CA	Corrective Action
CL	Central Line
DFTQC	Department of Food Technology and Quality Control
ETO	Ethylene oxide
FH IOL Lab	Fred Hollows Intra-ocular Laboratory
HEPA	High Efficiency Particulate Air
IOL	Intra-ocular Lens
ISO	International Organization for Standardization
LCL	Lower Control Limit
MR	Management Representative
MSS	Material Specification Sheet
N/A	Not Applicable
NBSM	Nepal Bureau of Standards and Metrology
NC	Nonconformance
NCS	Nepal Council for Standards
NQPCN	Network for Quality, Productivity and Competitiveness-Nepal
NS	Nepal Standard
PA	Preventive Action
PDCA	Plan, Do, Check, and Act
PMMA	Poly Methyl Meth Acrylate
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
QSP	Quality System Process
SGS	Societe Generale de Surveillance
SOP	Standard Operating Procedure
TQM	Total Quality Management
UCL	Upper Control Limit
WTO	World Trade Organization

CHAPTER 1 • INTRODUCTION

1.1 Background of the Study

Economic development in a country is possible only through the industrial development in the country. And the industrial development is possible only through the quality production in compliance with required standards. So quality is being regarded as the over arching parameter of national growth and development.

Quality has become one of the most important competitive strategic tools, and many organizations have realized that it is the key to developing products and services that support continuing success. Quality systems are designed to set a clear direction for organizations to follow enabling understanding and involvement of employees proceeding towards a common goal. The aim of business is long-term profitability. Over a considerable length of time, earnings are achieved by pleasing customers with good products/services while keeping production cost at a minimum. The use of quality tools and techniques provides long-term dividends through lower costs and productivity improvement.

As competition increases and changes occur in the business world, we need to have a better understanding of quality. Quality concerns affect the entire organization in every competitive environment. Therefore, top managers need to understand and apply quality philosophies to achieve high performance levels in products and processes and to face the challenges of new global competition. Consumers demand high quality levels of products/services at reasonable prices to achieve value and customers satisfaction. There is an increasing focus on quality throughout the world. With increased competition, companies have recognized the importance of quality system implementation in maintaining effectiveness in a volatile business environment. Specifically meeting the needs and desires of the customer is critical and must be done much better and efficiently than it has been done in the past. All types of industries, both public and private provides,

have reduced costs increased process efficiency and improved the quality of their products and services by working to meet the needs of the people they serve through the application of Quality Management System (QMS) principles.

Sustainable growth and development are only possible in an enabling environment that focuses on enhancing the quality of life driven by core human values. Such an enabling environment demands that individuals, systems and the country inculcate values and attitudes regarding quality, productivity and competitiveness, especially as we enter the globalizations and WTO regimes. Quality as the key driver of economic prosperity of the nation has gained more significance today than ever before. (www.nqpcn.org.np)

Though quality is reflected in the final product and services, the quality is essential in each and every parts and components of a system; even a small part cannot be ignored. For ensuring quality in the final output, there must be quality inputs and quality processing. An organization has many resources like human, material, plants & machinery, information etc and the growth and development of the organization depends upon the quality of these resources. For this purpose, Quality Management System (QMS) plays the vital role.

1.1.1 Historical Background of Quality

The quality movement can trace its roots back to medieval Europe, where craftsmen began organizing into unions called guilds in the late 13th century. Until the early 19th century, manufacturing in the industrialized world tended to follow this craftsmanship model. The factory system, with its emphasis on product inspection, started in Great Britain in the mid-1750s and grew into the Industrial Revolution in the early 1800s.

In the early 20th century, manufacturers began to include quality processes in quality practices. After the United States entered World War II, quality became a critical component of the war effort: Bullets manufactured in one state, for example, had to work consistently in rifles made in another. The armed forces initially inspected virtually every unit of product; then to simplify and speed up this process without compromising safety,

the military began to use sampling techniques for inspection, aided by the publication of military-specification standards and training courses in Walter Shewhart's statistical process control techniques.

The birth of total quality in the United States came as a direct response to the quality revolution in Japan following World War II. The Japanese welcomed the input of Americans Joseph M. Juran and W. Edwards Deming and rather than concentrating on inspection, focused on improving all organizational processes through the people who used them.

By the 1970s, U.S. industrial sectors such as automobiles and electronics had been broadsided by Japan's high-quality competition. The U.S. response, emphasizing not only statistics but approaches that embraced the entire organization, became known as total quality management (TQM).

By the last decade of the 20th century, TQM was considered a fad by many business leaders. But while the use of the term TQM has faded somewhat, particularly in the United States, its practices continue. In the few years since the turn of the century, the quality movement seems to have matured beyond Total Quality. New quality systems have evolved from the foundations of Deming, Juran and the early Japanese practitioners of quality, and quality has moved beyond manufacturing into service, healthcare, education and government sectors. (www.asq.org/learn-about-quality/history-of-quality)

1.1.2 Quality and Productivity Movement in Nepal

The productivity movement in the country is noticed to begin only from early 1960s after Nepal joined the regional productivity organization, Asian Productivity Organization (APO) in 1961 (Gongal and Pradhan, 2004). With the government's Industrial Policy in 1974, economic development in the country is aimed to achieve through industrial development, which in turn is the result of quality production of products and services in the country. Thus, it can be said that the quality movement in the country started with the government's Industrial Policy in 1974. To fulfill the need of a centralized organization at

national level that looks after the activities concerning standardization and quality control in the industrial production, National Standards Body like Nepal Bureau of Standards & Metrology (NBSM) came into existence. Yet the pace for quality & productivity movement remained slow and passive until the establishment of Network for Quality, Productivity and Competitiveness - Nepal (NQPCN) in 2004 by various professionals, experts and institutions to drive the nation economically and socially forward through sharing and learning of their knowledge and experiences in the field of quality and productivity. The people involved in the initial ground work in establishing the network are managers, entrepreneurs, practitioners, consultants, academicians with a common bottom line belief in quality as the over arching parameter of growth and development.

1.1.3 International Quality Certifications in Nepal

Now, the world has become a global village and the people are linked together economically and socially by trade, investments and governance. These links are spurred by market liberalization and information, communication and transportation technologies. With the entry in WTO in 2004, Nepal has opened its border for free international trade leading the entry of many multinational companies. Now, Nepali industry has to compete in domestic as well as global markets with quality products. So, Nepali organizations are getting certified by International Standards to meet the international quality demand.

Many organizations, from manufacturing to service sector in Nepal are already ISO (International Organization for Standardization) certified and many industries are on the process of certification. This ratio of quality certification is found increasing year by year.

1.2 Introduction of Organization

'Nepal Eye Program' popularly known as 'Tilganga Eye Centre' is regarded as highly successful NGO working for blindness prevention in Nepal and around 8 countries in Asia & Africa. Nepal Eye Program is supported many national and international organizations.

Tilganga Eye Center consists of

- Eye Hospital- full-fledged hospital with intensive eye care services
- Eye Bank- cornea collection, harvesting & transplantation unit
- FH IOL Lab- Intra-Ocular Lens (IOL) manufacturing facility maintaining compliance to ISO 9001:2008, ISO 13485:2003 (E), CE Mark 120, EN 46002, NZ standards.
- Community Eye Centres- district level eye care units working in partnership with local NGOs, Red Cross and youth groups.

1.2.1 Laboratory Profile

The Fred Hollows IOL Laboratory was established in 1992 with funding from The Fred Hollows Foundation, Australia with the express intention of providing developing nations with a source of high quality affordable IOLs for use in extra-capsular cataract extraction and lens replacement surgery. The Laboratory was constructed by the people of Nepal under the direction of engineers and technicians from New Zealand and Australia. It was designed specifically for the production of intra-ocular lenses. FH IOL Lab has exported its products world-wide to over 30 countries in Asia, Australia, South Pacific, Africa, and South America. It is committed to fully contribute to programs for prevention of blindness all over the world by being a reliable source for intraocular lenses. Adherence to the Highest Quality Standards is a consistent feature - FH IOL Lab was the first IOL manufacturer of Southeast Asia to have received the CE mark in. The Laboratory was certified by ISO in 1998 and CE Notified Body 0120 in 1998 by SGS, UK.

The Laboratory manufactures the following medical products:

- Posterior Chamber Intra-Ocular Lenses (PC IOL): FH model & TG models
- Anterior Chamber Intra-Ocular Lenses (AC IOL)
- Foldable Intra-Ocular Lenses : Flex, Tetra, Slick etc.
- Capsular Tension Ring (CTR)

1.2.2 General Information- Cataract and IOL

As people age, the lens in their eyes gradually becomes less transparent (hardens with age). The lens becomes cloudy and this interferes with the passage of light to the retina. At this stage it is called a cataract. As the cataract worsens, it becomes more and more difficult to see through it, and eventually the lens becomes opaque, blocking out all light to the retina. This is the most common form of cataract blindness.

The treatment for cataract is surgery. The natural lens is extracted and replaced by an Intraocular lens (IOL). IOLs are permanent optical implants for visual correction following cataract extraction. Insertion of an IOL is now the most commonly performed eye surgical procedure; cataracts are the most common eye disease. The procedure can be done under local anesthesia with the patient awake throughout the operation which usually takes less than 30 minutes in the hands of an experienced ophthalmologist.

1.3 Statement of the Problems

Economic development in a country is possible only through the industrial development in the country. And the industrial development is possible only through the quality production. So quality is being regarded as the major parameter of national growth and development. Improved quality lowers the cost of operations and increases the productivity. Optimal utilization of resources can be achieved through quality management at the enterprise level. The profitability of a firm can be ensured by the supply of quality products which increases customer satisfaction through meeting/exceeding customer requirements. Globalization, economic liberalization, and entry of multinational companies have intensely increased competition- locally as well as globally. The quality has been established as a key factor for business competitiveness and long term sustainability of the business.

Increasing consumer rights movement and formulation of different consumer protection laws have demanded the products to be compliance to regulatory quality standards. As the result of the rapid advancement in information technology, keen competition,

educational advancement, people of the world are getting more and more conscious in the quality of products or services they receive. The logo of quality standard in the product has become the criteria to select the product. Public health & Environment (PHE) issues are becoming increasingly important in the world. Due to increasing public pressure, government rules and international concerns, quality standard has to be maintained to prevent public health hazards and environmental degradation. Moreover pharmaceutical, biopharmaceutical, chemical, medical products have direct impact on public health. Increasing advocacy for public health and environmental issues enforces the products to meet certain quality standards.

1.4 Objectives of the Study

Objectives are the desired outcomes for activity. The main objective of this research is to conduct study on current quality management system of the FH IOL Lab.

The main objectives of this research are as follows:

- To explain Quality Management System (QMS) in the FH IOL Lab
- To explain quality control practices followed in the FH IOL Lab
- To examine the physical work environment in the FH IOL Lab
- To explore the documentation system for implementing quality management system in the FH IOL Lab

1.5 Significance of the Study

Nepal is a developing country. The quality practice in Nepal is not matured. Due to lack of quality awareness in people and lack of professional quality experts, the quality concepts and practices in Nepal are traditional and confined to only 'acceptance and rejection' criteria on products. Most of the Nepalese customers are not interested in the quality of products or services they purchase. Even foodstuffs, medicines and medical devices are not checked for their quality like proportion of components, expiry date and other specifications. This leads to low quality products/services to be manufactured, that is, the producers are not bound to produce quality products and services. Nepalese

entrepreneurs and managers are also unaware of Quality Philosophies developed in foreign countries. They search quality only in the product, not in the process, not in human resources, not in information. Their definition of quality is just acceptance or rejection of products/materials on the basis of certain criteria. This thesis on QMS will help to change the psychology of Nepalese people regarding quality and quality management that quality is a system approach which includes all parts and elements involved from input, processing to output.

Improved quality at the enterprise level lowers its cost of operations and increases its productivity. The firm's ability to produce better products at a reduced (or even the same) price boosts its market share. More productive firms would be able to produce goods or provide services at lower cost thereby attracting more customers and increasing their market share. As shown in Figure 1.1, increased productivity, larger market share and the customers' willingness to pay higher prices due to perceived quality all result in increased sales revenues, larger profits and competitiveness (Garvin, 1984). The benefits that accrue from improved quality at individual firm level also augment national competitiveness. Hence, many world class firms and nations use quality as a powerful competitive tool. The adoption of a management strategy that emphasizes quality and excellence would help improve performance at the enterprise level. The success of individual firms through quality and productivity would render products more attractive both to domestic and international customers. In turn, this would generate increased production both for domestic consumption as well as to meet higher demand from abroad. This would boost employment at home, increase foreign exchange earnings, improve the nation's trade balance, and set in motion a virtuous circle of economic activities that would stimulate growth and development. Hence, there exists positive relationship between quality improvement & increased competitiveness and development.

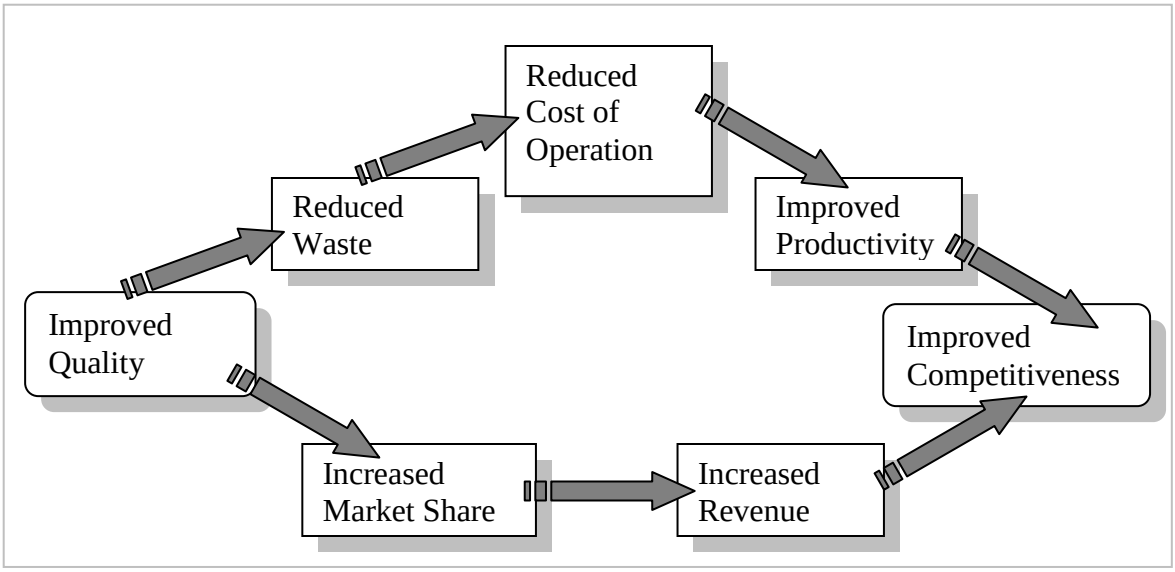


Figure 1.1: The relationship between quality and competitiveness

The world has become a global village. People are linked together economically and socially by trade, investments and governance. These links are spurred by market liberalization and information, communication and transportation technologies. Trade has been conducted across the borders. Now a local business firm has to compete with multinational corporations. Therefore quality matters most in today's world. Since 23 April 2004, Nepal has been a member of World Trade Organization (WTO) which is an international organization for liberalizing trade worldwide among nations. As per WTO's regime, the land of Nepal is open for foreign companies to enter and to launch their products and services freely. As a result, there are many multinational companies operating in Nepal like Coca Cola, Pepsi, etc and the number is increasing fast. Therefore local industries in Nepal have to compete those large companies and the tool for competition is quality. Thus the quality has been established as a key factor for business competitiveness and long term sustainability of the business.

With the advent of the 20th century, consumer rights gained importance in the world. The Western countries played the pioneer role in creating awareness and in enacting different kinds of consumer protection laws. The rights of consumers got international recognition when in 1985 the UN promulgated the basic guidelines regarding consumer rights protection. By the end of the 20^{th} century, consumer rights protection became a

movement. After the promulgation of 1990 Constitution, consumer issues started getting importance in Nepal. However, in a poor country like Nepal, where the level of poverty, unemployment and illiteracy is high, the people are facing numerous problems regarding consumer issues. Lack of awareness is the major obstacle. It is important to check the manufacturing and expiry dates, and the components used in the foodstuff, drugs, medical devices etc to see that they meet the standards. According to the annual report of Department of Food Technology and Quality Control (DFTQC), 52 cases were registered at the Kathmandu District Administration Office during a fiscal year alone in this regard. The illiterate consumers are caught in a vicious circle of low quality products. There are numerous acts in Nepal regarding consumer rights for example, Consumer Protection Act 1999, Food Act 1966, Essential Commodities Control Act 1960, Drugs Act 1978, Nepal Drinking Water Corporation Act 1989 and many more. (Subedi, 2007)

As the result of the rapid advancement in information technology, globalization, increasing number of multinational companies, keen competition, economic liberation, people of the world are getting more and more conscious in the quality of products or services they receive. As a result, various national and international quality standards have been established around the world. The quality standard marks like NS, ISO, CE etc have great psychological influence on people.

The pharmaceutical, biopharmaceutical, chemical, medical products have direct impact on public health. The quality of such products is the sensitive public issue in the society. So, there must be strict quality control & management system in the manufacturing process to ensure required quality standards and better quality. Public health & Environment (PHE) issues are becoming increasingly important in the world. Environmental friendly products are popular and being appreciated. Quality standards has to be maintained at specified level to prevent public health hazards and environmental degradation due to increasing public pressure, government rules and international concerns.

Moreover, the study of QMS in FH IOL Lab may be useful to all parties who are interested on QMS for gaining knowledge on QMS or establishing and implementing QMS in an organization. It may give guidelines to establish and follow Quality Control & QMS processes in an organization. It not only helps the manufacturing sectors but also help other large and small sectors including service sector, non-profit making organizations etc. As per the author's acknowledgement, the thesis on QMS has not been written before; so this research will play a crucial role in this field. This study will be also helpful to the TQM students who wanted to do a further intensive study on QMS.

1.6 Limitations of the Study

Many information and data are needed for a complete study of QMS. There are many limitations in the study due to various reasons like unavailability of data and resources, limiting product range to single model by exclusion of many models of products, cost & time constraints etc. The limitations of the study can be summarized as follows:

- Detail analysis could not be conducted due to organizational resistance to supply of data and information for confidentiality of the organization.
- Sufficient books, materials, articles and previous research papers related to the subject area are not available. So, only few books and materials, whatever available, were studied and some websites are visited for the relevant information.
- The primary data collected though interviews and data sheets, which depend upon the respondents in the interviews and data recording personnel in data sheets, are assumed to be accurate and reliable.
- Interview could not be conducted with top level managers. Middle level managers, supervisors & lower level staffs were interviewed for the study.
- The respondents in the interview did not represent all the departments. The respondents belonged to only four departments- Quality Assurance, Production, Procurement and Sales/Marketing, thereby excluding other departments like administration, finance, store, and engineering.
- The research was prepared by focusing only FH model of intra-ocular lenses out of several models due to constraints in time, cost, information & practicability; so

quality control practices and activities may vary to some degree or greater for other models of products.

- In process control, the samples represent for certain period of time of the process. Thus it can be argued whether the result of such sample can be generalized to other periods of time. Besides, many parameters of the lenses in the process were ignored while constructing control charts.

1.7 Organization of the Study

The report is organized into following 5 chapters:

Chapter 1: Introduction

The first chapter is the introduction chapter which provides the summery of overall study. This chapter includes background of the study, introduction of the organization, statement of the problem, objectives of study, significance of the study, limitation of study and organization of study.

Chapter 2: Review of Literature

Review of literature is an important part of the research. This chapter includes the theoretical background of the study. The review of literature includes review of theoretical concept of the subject, which has theoretical aspect to gain insight and knowledge on the theory, concepts, and principles on the subject matter of the research. This chapter also includes review of studies on the subject matter like published and unpublished articles, journals, periodicals, previous studies.

Chapter 3: Research Methodology

This chapter constitutes the methodology adopted to conduct the study, data analysis techniques and processes. This chapter contains Research design, Nature and Sources of data, Population and Sample, Data Collection Method, Data Analysis technique and tools.

Chapter 4: Data Presentation and Analysis

This is the main chapter in which all the data collected are sorted and arranged as per requirement for data presentation and analysis. In this chapter, data and information are critically analyzed to reveal the output of the study, to interpret the results, to find out the solution of the problem, to specify drawbacks/defects of the current system.

Chapter 5: Summary, Conclusion and Recommendation

This chapter contains summary, conclusions and recommendations of overall study.

CHAPTER 2 • REVIEW OF LITERATURE

2.1 Concept of Quality

Quality, being an abstract term and universally applicable in each and every aspect, is a very difficult concept to define with any precision. Quality has a board definition under different aspects. The most fundamental definition of the quality product is one that meets the predetermined specifications and meets the expectations of the customer. Quality means to guarantee that the products or services are supplied as conceived and planned.

The quality can be perceived from different angles as

- *User based definition*: customer perception
- *Manufacturing based definition*: degree of conformance to specification
- *Product based definition*: product characteristics

The concept of quality has evolved far much in the journey from classical to modern era

- *Classical concept*: degree of conformance to specification
- *Modern concept*: customer satisfaction with his expressed requirements
- *Emerging concept*: customer delight with unexpected latent requirements

According to ISO, Quality refers to "Degree to which a set of inherent characteristics fulfills requirements". The key words in this definition are:

- Degree: level or extent of fulfillment of requirements
- Inherent Characteristics: Characteristics are features. Inherent Characteristics are permanent or essentially existing features.
- Requirements: Requirements are needs or expectations. Requirements may be stated, implied or obligatory

Quality can be defined as "The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs". (American Society of Quality Control)

2.2 Evolution of Quality Concept

The definition of quality has evolved from very specific and confined approach of meeting predetermined standard to very broad and wide approach of satisfying the needs of all stakeholders like customers, employees, government, suppliers, general public and so on as shown in the figure 2.1 (Fukui et al., 2007).

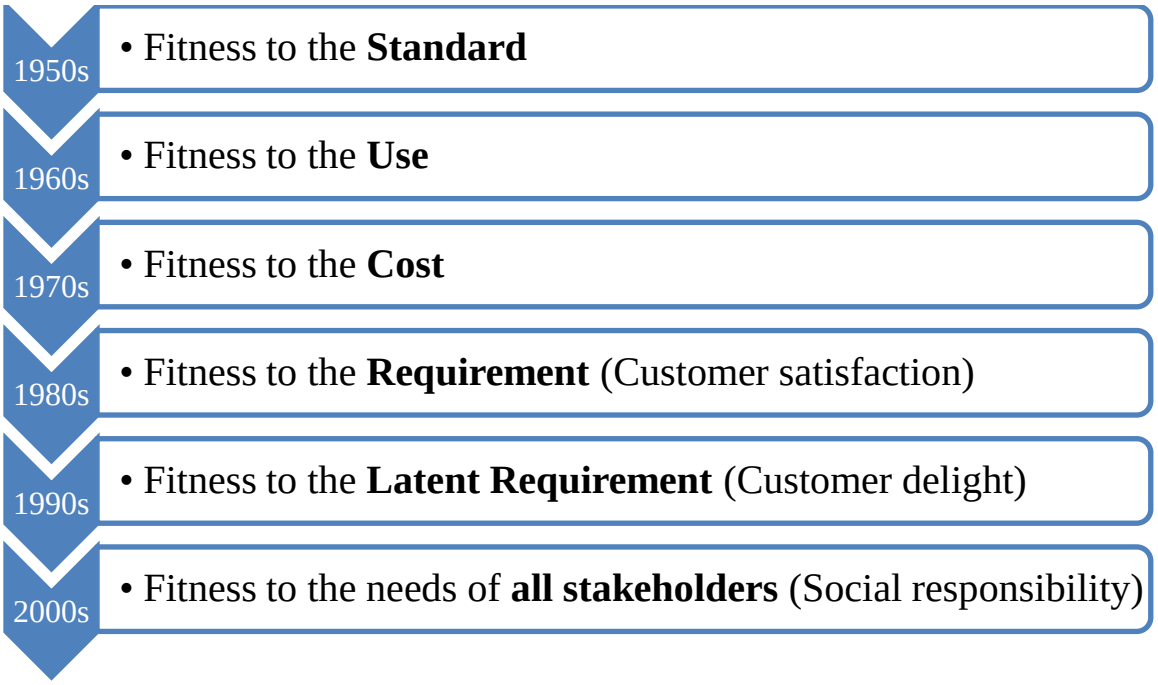


Figure 2.1: Evolution of Quality Definition

In 1950s the concept of quality was only in terms of meeting a standard. Now merely meeting a standard is not enough. The subsequent progression of decades brought new criteria to the fore. Now in the 21st century, the concept of quality has broader meanings including social responsibility, human rights, environmentally friendly, employee quality

of life. Creating quality is the process that involves all stakeholders and lends social responsibility to the society.

The evolution of the concept of quality can be condensed into the emergence of three main conceptual stages that have developed from control to assurance and finally to total quality management as shown in the figure 2.2.
(www.oitcinterfor.org/public/english/region/ampro/cinterfor/publ/papel)

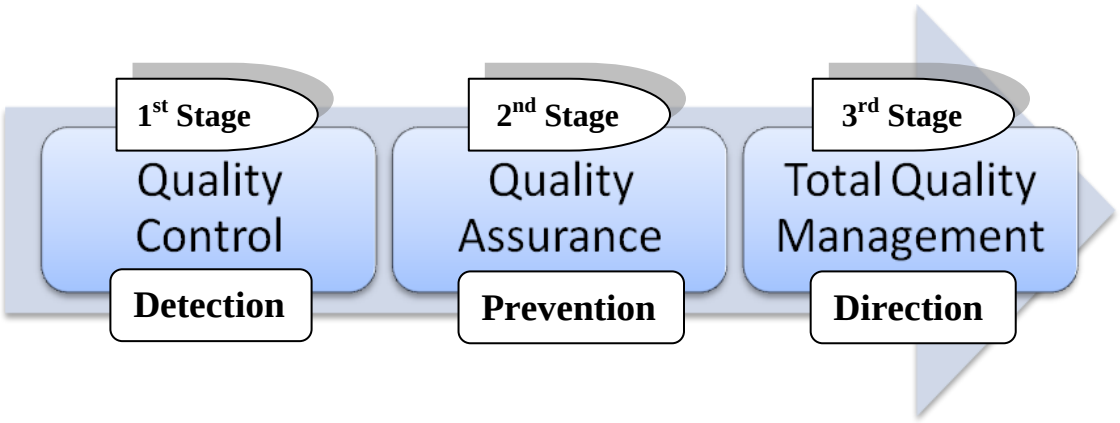


Figure 2.2: Evolution of Quality

First Stage- Quality Control: This stage lasts from the industrial revolution until the Second World War. In this, the concept of quality was linked to detecting and solving problems stemming from lack of uniformity in the product, that is to say to checking the characteristics of the final product and discarding defective items. Statistical checking procedures were introduced, which made for a consequent reduction in final inspection levels, and the concept of quality that predominated in the 1940s emerged, whereby quality was gauged by the degree to which the final product conformed to initial specifications.

In the first stage, **control** or inspection was carried out either in the product preparation phase or when the product had been completely finished. The aim here was to rectify mistakes or reject defective products.

Second Stage- Quality Assurance: This stage lasts from the 1940s until the 1970s. In this period the Japanese economic miracle took place and the Deming Model, whereby quality was linked to satisfying the demand of domestic and foreign customers, became widespread.

In the second stage, **assurance**, the emphasis was on verifying that production processes were efficiently managed. There was an effort to do things well from the outset so as to avoid having to reject finished products, and thus, as well as trying to save costs, there is a guarantee that the quality of the product is up to the required standard. External and/or internal audits were employed to standardize processes and verify that they were being carried out correctly. This is a reactive stance in that the producer merely reacts to the customer's demands.

Third Stage- Total Quality Management: This stage starts from the end of the 20th century and the start of the 21st. This has been the period of total quality management, whereby enterprises make organizational changes so that all their departments are involved in the design and execution of quality policies. In this case, quality means that all the members of the organization participate and share responsibility.

In the last stage, which is **management**, account is taken not just production processes but all of the processes that take place in the enterprise. Quality management involves all the processes in the organization, or at least those that have to do with the requirements of customers. What is added in this new notion of quality is the conception of objectives and of continual improvement (a pro-active attitude). Being pro-active means fully understanding and anticipating possible future customer demands so as to be able to satisfy them adequately and in the shortest possible time. What is more, in this stage it is not only quality department staff in enterprises that are responsible for quality management. This new conception means that everyone in the enterprise or organization is responsible for quality management and has a genuine role to play, with the managers taking the lead.

2.3 PDCA Cycle

The concept of the PDCA Cycle was originally developed by Walter Shewhart, the pioneering statistician who developed statistical process control in the Bell Laboratories in the US during the 1930's. It is often referred to as 'the Shewhart Cycle'. It was taken up and promoted very effectively from the 1950s on by the famous Quality Management authority, W. Edwards Deming, and is consequently known by many as `the Deming Wheel'. (www.hci.com.au/hcisite3/toolkit/pdcacycl.htm)

This cycle consists of four steps: *Plan*, *Do*, *Check*, and *Act*. These steps are commonly abbreviated as PDCA which is illustrated in the figure 2.3.

- **Plan:** Establish objectives and processes required to deliver the desired results.
- **Do:** Implement the process developed.
- **Check:** Monitor and evaluate the implemented process by testing the results against the predetermined objectives
- **Act:** Apply actions necessary for improvement if the results require changes.

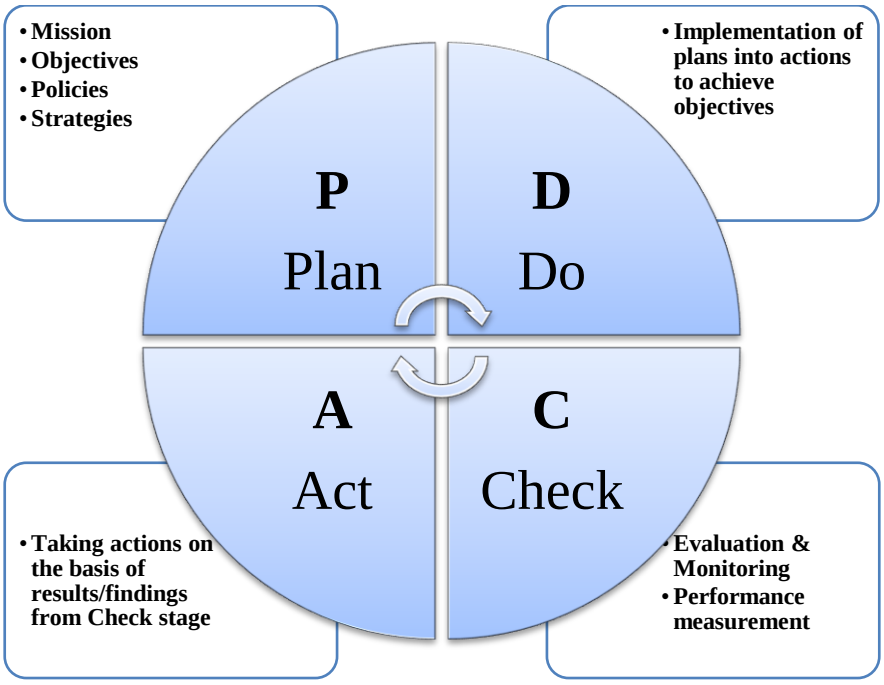


Figure 2.3: PCDA Cycle

It is a universal improvement methodology, the idea being to constantly improve, and thereby reduce the difference between the requirements of the customers and the performance of the process. The cycle is about learning and ongoing improvement in a systematic way; and the cycle repeats with no end; after one cycle is complete, another is started for continuous improvement.

2.4 Total Quality Management

Total Quality Management refers to a management process and set of disciplines that are coordinated to ensure that the organization consistently meets and exceeds customer requirements. TQM engages all divisions, departments and levels of the organization. Top management organizes all of its strategy and operations around customer needs and develops a culture with high levels employee participation. TQM companies are focused on the systematic management of data in all processes and practices to eliminate waste and pursue continuous improvement.

The separate words of TQM carry the meaning as:

- **Total**: Everyone associated with the organization should be involved in continuous improvement including suppliers and customers. Each and every person and every function should be involved from lowest to highest level in an organization ensuring organized integrated approach by all departments.
- **Quality**: The extent to which features and characteristics of a product or service bear on its ability to satisfy stated or implied needs.
- **Management**: Planning, organizing, directing, coordinating, motivating, controlling, evaluation for continuous improvement and sustainable growth.

TQM is an integrated organizational approach in delighting customers (both external and internal) by meeting their expectations on a continuous basis through everyone involved with organization working on continuous improvement in all products/processes along with proper problem solving methodology. It is managing the entire organization so that it excels on all dimensions of products and services that are important to the customers

rather than conformation to specification. TQM organizes managers and workers in a totally systematic and integrated effort toward improving performance at every level. For an organization to be really effective, quality must span all functions, all people, all departments and all activities. Hence, TQM is the way of managing for the future, and is far wider in its application than just assuring product or service quality – it is a way of managing people and business processes to ensure complete customer satisfaction at every stage, internally and externally.

2.4.1 TQM Model

The core of TQM is the ***customer-supplier*** interfaces, both externally and internally, and at each interface lie a number of ***processes***. This core must be surrounded by ***commitment*** to quality, ***communication*** of the quality message, and recognition of the need to change the ***culture*** of the organization to create total quality. These are the foundations of TQM, and they are supported by the key management functions of ***people, processes*** and ***systems*** in the organization as shown in the figure 2.4.

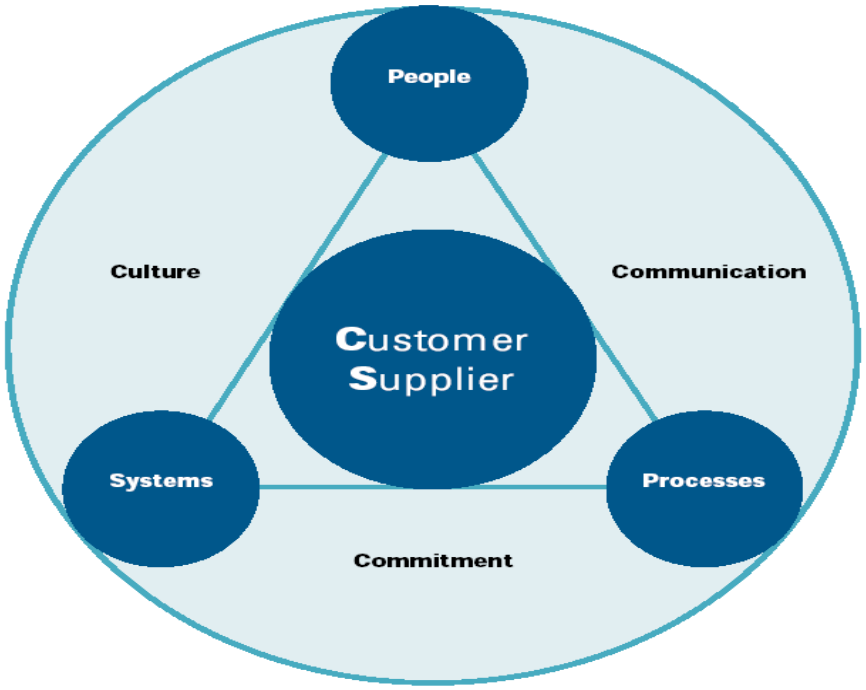


Figure 2.4: TQM Model

Customers and suppliers

There exists in each department, each office, each home, a series of customers, suppliers and customer-supplier interfaces. These are "the quality chains", and they can be broken at any point by one person or one piece of equipment not meeting the requirements of the customer, internal or external. The failure usually finds its way to the interface between the organisation and its external customer, or in the worst case, actually to the external customer. Failure to meet the requirements in any part of a quality chain has a way of multiplying, and failure in one part of the system creates problems elsewhere, leading to yet more failure and problems, and so the situation is exacerbated. The ability to meet customers' (external and internal) requirements is vital. To achieve quality throughout an organization, every person in the quality chain must be trained to ask the following questions about every customer-supplier interface:

Customers (internal and external)

• Who are my customers?
• What are their true needs and expectations?
• How do, or can, I find out what these are?
• How can I measure my ability to meet their needs and expectations?
• Do I have the capability to meet their needs and expectations?
(If not, what must I do to improve this capability?)
• Do I continually meet their needs and expectations?
(If not, what prevents this from happening when the capability exists?)
• How do I monitor changes in their needs and expectations?

Suppliers (internal and external)

• Who are my internal suppliers?
• What are my true needs and expectations?
• How do I communicate my needs and expectations to my suppliers?
• Do my suppliers have the capability to measure and meet these needs and expectations?
• How do I inform them of changes in my needs and expectations?

As well as being fully aware of customers' needs and expectations, each person must respect the needs and expectations of their suppliers. The ideal situation is an open partnership style relationship, where both parties share and benefit.

Commitment & leadership

TQM is an approach to improving the competitiveness, effectiveness and flexibility of an organization for the benefit of all stakeholders. It is a way of planning, organizing and understanding each activity, and of removing all the wasted effort and energy that is routinely spent in organizations. It ensures the leaders adopt a strategic overview of quality and focus on prevention not detection of problems. Whilst it must involve everyone, to be successful, it must start at the top with the leaders of the organization. All senior managers must demonstrate their seriousness and commitment to quality, and middle managers must, as well as demonstrating their commitment, ensure they communicate the principles, strategies and benefits to the people for whom they have responsibility. Only then will the right attitudes spread throughout the organization. A fundamental requirement is a sound quality policy, supported by plans and facilities to implement it. Leaders must take responsibility for preparing, reviewing and monitoring the policy, plus take part in regular improvements of it and ensure it is understood at all levels of the organization. Effective leadership starts with the development of a mission statement, followed by a strategy, which is translated into action plans down through the organization. These, combined with a TQM approach, should result in a quality organization, with satisfied customers and good business results.

Culture change

The failure to address the culture of an organization is frequently the reason for many management initiatives either having limited success or failing altogether. Understanding the culture of an organization and using that knowledge to successfully map the steps needed to accomplish a successful change, is an important part of the quality journey. The culture in any organization is formed by the beliefs, behaviors, norms, dominant values, rules and the "climate". A culture change, e.g., from one of acceptance of a

certain level of errors or defects to one of right first time, every time, needs two key elements:

- Commitment from the leaders
- Involvement of all of the organization's people

There is widespread recognition that major change initiatives will not be successful without a culture of good teamwork and cooperation at all levels in an organization.

Processes

Everything we do is a Process, which is the transformation of a set of inputs, which can include action, methods and operations, into the desired outputs, which satisfy the customers' needs and expectations. In each area or function within an organization there will be many processes taking place, and each can be analyzed by an examination of the inputs and outputs to determine the action necessary to improve quality. In every organization there are some very large processes, which are groups of smaller processes, called key or core business processes. These must be carried out well if an organization is to achieve its mission and objectives. An organization should identify processes and emphasize how to improve them, and the process implementation covers how to prioritize and select the right process for improvement.

People

The only point at which true responsibility for performance and quality can lie is with the people who actually do the job or carry out the process, each of which has one or several suppliers and customers. An efficient and effective way to tackle process or quality improvement is through teamwork. However, people will not engage in improvement activities without commitment and recognition from the organization's leaders, a climate for improvement and a strategy that is implemented thoughtfully and effectively. The organization should address on human issues, covering roles within teams, team selection and development and models for successful teamwork.

Management system

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.

Communication

In order to sway the employees of an organization to accept TQM approach, effective communication with those employees must be achieved. The quality strategy and goals must be clearly communicated from top management to all employees. Employees must be educated to understand their role in the TQM process, as well as the benefits that the TQM process offers. The combination of empowered and trained employees, well structured team and adequate communication of the organization's quality strategy will make the employees committed the TQM efforts of the organization.

2.4.2 TQM Tools

There are mainly TQM seven tools applied frequently:

Check Sheet: A check sheet is a paper format on which items to be checked have been printed so that data can be collected easily and concisely. Its main purposes are twofold:

- To make data collection easy; and
- To arrange data systematically for ready reference

Pareto Analysis: Pareto Analysis, named after the innovator, an Italian economist V. Pareto, is a graphical analytical tool to identify the vital few and the many trivial problems. The concept behind this widely used tool is that most of the loss will be due to a few specific defects, and these defects can be attributed to a very small number of the losses by concentrating on these particular causes, leaving aside many other trivial defects for the time being. The Pareto analysis efficiently shows the vital few problems through a Pareto diagram.

Cause and Effect Analysis: Cause and Effect Analysis is a problem structuring method which helps in identifying various causes and effects of a problem through brainstorming among small groups. It is difficult to solve complicated problems without considering the problem's structure, which consists of multiple chains of causes and effects. This analysis is presented as a Cause and Effect Diagram which is also called the Fish-bone Diagram, or Ishikawa Diagram. This tool was first introduced by Mr. K. Ishikawa. The Cause and Effect Diagram is a method of expressing the hierarchical structure of causes of the problem in a simple and easy way.

Histogram: Data are collected, facts are discovered and necessary actions are taken on these facts to solve problems. The value of the data is not the same all the time, there are some variations. Furthermore, sometimes it may not be possible to collect all data of the problem population and one has to depend on that of sample problems. Histogram is a graphical tool to represent the frequency distribution of the occurrence of the collected data from a sample, which can highlight the nature of variation of problem areas. By organizing the data collected into a histogram, one can understand the overall problem areas with statistical confidence. This tool is widely used for process capability analysis and to prepare control charts.

Control Chart: A very famous quality control tool, introduced by W. A. Shewhart , is a graphical tool used to identify the assignable and chance causes of defects. A control chart consists of a central line, a pair of control limits, one each, allocated above and below the central line, and characteristic values plotted on the chart which represent the state of the process. If all these values are plotted within the control limits without any particular tendency, the process is regarded as being in the controlled state. However, if they fall outside control limits or show a peculiar form, the process is said to be out of control. The control chart is used not only for problems in quality but also to monitor productivity problems.

Scatter Diagram: Scatter diagram is another graphical tool to understand the relationship between two variables affecting the problem. This analysis not only helps in

understanding the overall relationship of two variables but also provides certain efficiency in solving the problem by identifying and eliminating the redundant variable for detail analysis.

Regression Analysis: Regression analysis is a mathematical method to calculate the correlation of two variables which are plotted in the scatter diagram. If the scatter diagram shows some important relationship, especially linear ones, then the regression analysis is used to estimate the value of dependent variable for each independent variable. This is expressed in a mathematical equation in a form such as: Y=A+B.X in which X is independent variable, Y is dependent variable, and A and B are constants. The correlation coefficient, symbolized by (a), gives the confidence limit of the mathematical equation derived from the regression analysis.

2.5 Quality Management System

System is a set of function or activities that work together for an aim in an organization. A successful quality system enables an organization to achieve, sustain and improve quality economically. It is a planning, which is well evaluated and organized to produce a required quality performance. A quality system is a tool used to achieve all the desirable quality goals. Quality systems focus on the quality of what the organization produces, the factors which will cause the organization to achieve its goals, the factors influencing the customer satisfaction and identify any non-conforming product.

Quality Management System (QMS) can be defined as a set of co-ordinated activities to direct and control an organization in order to continually improve the effectiveness and efficiency of its performance. These activities interact and are affected by being in the system, so the isolation and study of each one in detail will not necessarily lead to an understanding of the system as a whole. The main thrust of a QMS is in defining the processes, which will result in the production of quality products and services, rather than in detecting defective products or services after they have been produced. A QMS enables an organization to achieve the goals and objectives set out in its policy and

strategy. It provides consistency and satisfaction in terms of methods, materials, equipment, etc, and interacts with all activities of the organization, beginning with the identification of customer requirements and ending with their satisfaction, at every transaction interface.

QMS can be envisaged as a wedge that both holds the gains achieved along the quality journey, and prevents good practices from slipping as shown in the figure 2.5.

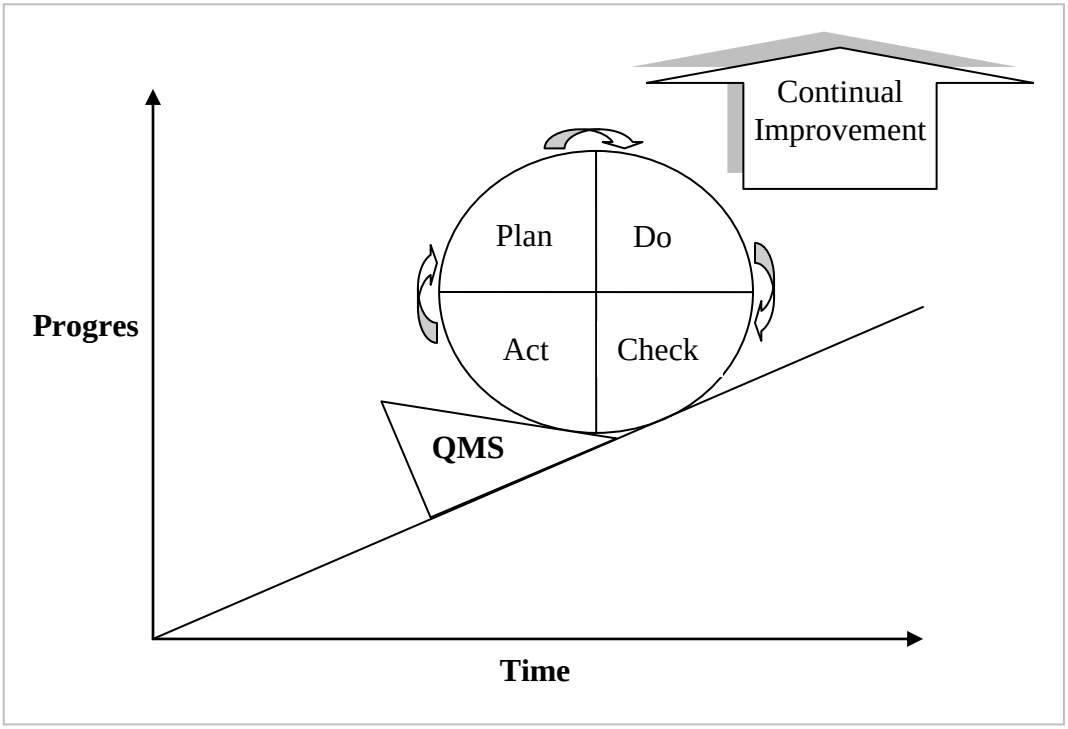


Figure 2.5: QMS and Continual Improvement

2.5.1 QMS Process Model

QMS promotes the adoption of a process approach when developing, implementing, and improving a quality management to enhance customer satisfaction by meeting customer requirements. An organization has to identify various activities, link them together and assign resources to them, thus building up a system of communicating processes. The QMS is structured around interlinked processes that provide the necessary implementation controls to ensure customer and regulatory requirements are met and continual process improvement. It provides the basis for policies and procedures that

implement a comprehensive quality management system. These processes are those that define activities that are directly necessary to create the item or service, and those that provide the supporting infrastructure to enable the direct processes to operate under the required controls, and continually improve.

The quality management system is designed as a system of interrelated processes. All main activities in the company are defined as Quality System Processes (QSPs) and are grouped into the following six categories:

- Customer Requirements,
- Product Realization,
- Measurement, Analysis and Improvement,
- Management Responsibility,
- Resource Management, and
- Continual Improvement,

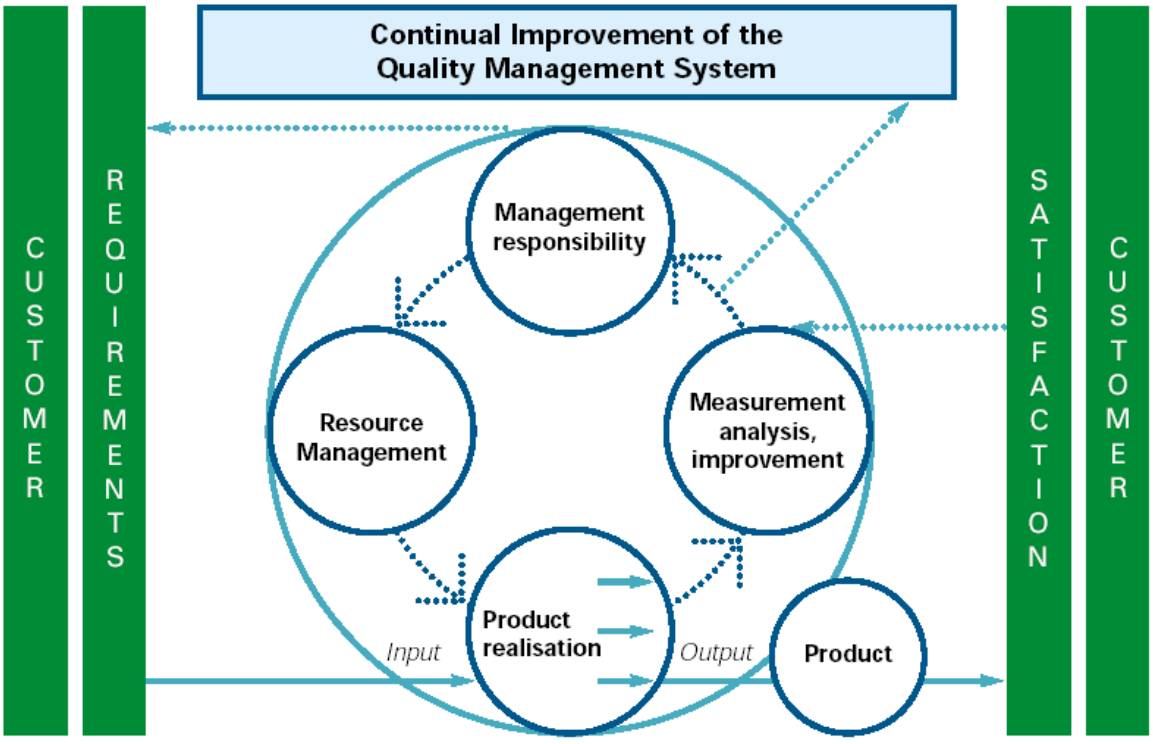


Figure 2.6: QMS Process Model

Figure 2.6 illustrates such a process-based QMS. Customers play an important role in this model since their requirements are used as input to the product realization process and their satisfaction is continually analyzed. The figure illustrates the way organizations should manage numerous linked activities in order to function effectively to produce the required output. It reveals that the process starts with identification of customer requirements which is continuously assessed by top management and ends with customer satisfaction that is continuously measured, analyzed and improved. An organization uses product realization processes to convert inputs into outputs; this conversion is managed through human as well as other resources. If this cycle is continually monitored it can sustain continual improvement of the quality management system through managing related activities embedded within the organizational system. This approach is emphasizing the model that can be applied to identify processes of value adding and this will emphasize the importance of: understanding and meeting requirements, the need to consider processes in terms of added value, obtaining results of process performance and effectiveness, and continual improvement of processes based on objectives measurement.

2.5.2 Principles of QMS

A Quality Management Principle is comprehensive and fundamental rule or belief, for leading and operating an organization, aimed at continually improving performance over the long term by focusing on customers while addressing the needs of all other stakeholders.

Principle 1: Customer focus

Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

Principle 2: Leadership

Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

Principle 3: Involvement of people

People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit. This is done by motivating and encouraging people to be committed and involved in the organization. The innovation and creativity of every level management will help furthering the organization's objective.

Principle 4: Process approach

A desired result is achieved more efficiently when activities and related resources are managed as a process. Proper process approach allows lower costs and shorter cycle times through effective use of resources. It also focused and prioritized improvement opportunities.

Principle 5: System approach to management

Identifying, understanding and managing interrelated processes as a system contribute to the organization's effectiveness and efficiency in achieving its objectives. This principle identifies, understands and manages a system of interrelated processes for a given objective to improve the organization's effectiveness and efficiency in achieving its objectives.

Principle 6: Continual improvement

Continual improvement of the organization's overall performance should be a permanent objective of the organization. The performance can be continually improved through alignment of improvement activities at all levels to an organization's strategic intent.

Principle 7: Factual approach to decision making

Effective decisions are based on the analysis of data and information. It helps an increased ability to demonstrate the effectiveness of decisions through reference to factual record.

Principle 8: Mutually beneficial supplier relationships

An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value. Application of this principle improves flexibility and speed of joint responses to changing market or customer needs and expectations.

2.6 ISO 9001: 2008 Quality Management Systems Requirements

Standards are documented agreements containing technical specifications or other precise criteria to be used consistently as rules, guidelines, or definitions of characteristics, to ensure that materials, products, processes and services are fit for their purpose. The standard is a basis for achieving certain level of quality. Quality Standards are set by standards organization, an entity whose primary activities are developing, coordinating, promulgating, revising, amending, reissuing, interpreting, or otherwise maintaining standards that address the interests of a wide base of users outside the standards development organization. By geographic designation, there are international, regional, and national standards bodies.

As a result of increasing focus on quality around the world and with the need for uniformity in quality standards around the world, International Organization for Standardization (ISO), an international standard setting body came into existence for harmonization of various quality standards used worldwide. Its purpose is to promote worldwide quality standards for uniformity of quality systems among various businesses and nations.

For harmonization of various quality standards used worldwide, ISO issued the ISO series of standards. The ISO series of international standards were developed by quality experts from around the world to be used by companies that either want to implement in-house quality systems or ensure that suppliers have appropriate quality systems in place. The standards were developed under the auspices of the International Organization for Standardization (ISO). International standards promote international trade by providing one consistent set of requirements recognized around the world. The requirements are generic and independent of any specific industry or economic sector.

Many countries have endorsed the ISO standards and accepted them as the national quality model.

Any organization willing to have ISO certification will have to be able to demonstrate all the activities on the organization and fulfill the requirements of these clauses and sub-clauses as per ISO 9001: 2008 Quality Management Systems Requirements as listed in the table 2.1.

Table 2.1: ISO 9001:2008 QMS Requirements

Section	Clause		
4	**Quality Management System**		
	4.1	General Requirements	
	4.2	Documentation Requirements	
		4.2.1	General
		4.2.2	Quality Manual
		4.2.3	Control of Documents
		4.2.4	Control of Records
5	**Management Responsibility**		
	5.1	Management Commitment	
	5.2	Customer Focus	
	5.3	Quality Policy	
	5.4	Planning	
		5.4.1	Quality Objectives
		5.4.2	Quality Management System Planning
	5.5	Responsibility, authority and communication	
		5.5.1	Responsibility and authority
		5.5.2	Management Representative
		5.5.3	Internal Communication
	5.6	Management Review	
		5.6.1	General
		5.6.2	Review Input
		5.6.3	Review Output
6	**Resource Management**		
	6.1	Provision of resources	
	6.2	Human Resources	
		6.2.1	General
		6.2.2	Competence, awareness and training
	6.3	Infrastructure	
	6.4	Work environment	
7	**Product Realization**		
	7.1	Planning of product realization	

	7.2	Customer-related processes	
		7.2.1	Determination of requirements related to the product
		7.2.2	Review of requirements related to the product
		7.2.3	Customer communication
	7.3	Design and development	
		7.3.1	Design and development planning
		7.3.2	Design and development inputs
		7.3.3	Design and development outputs
		7.3.4	Design and development Review
		7.3.5	Design and development verification
		7.3.6	Design and development validation
		7.3.7	Control of Design and development changes
	7.4	Purchasing	
		7.4.1	Purchasing process
		7.4.2	Purchasing information
		7.4.3	Verification of purchased product
	7.5	Production and service provision	
		7.5.1	Control of Production and service provision
		7.5.2	Validation of processes for Production and service
		7.5.3	Identification and tracebility
		7.5.4	Customer property
		7.5.5	Preservation of product
	7.6	Control of monitoring and measuring devices	
8	**Measurement, analysis and improvement**		
	8.1	General	
	8.2	Monitoring and measurement	
		8.2.1	Customer satisfaction
		8.2.2	Internal Audit
		8.2.3	Monitoring and measurement of processes
		8.2.4	Monitoring and measurement of product
	8.3	Control of nonconforming product	
	8.4	Analysis of data	
	8.5	Improvement	
		8.5.1	Continual improvement
		8.5.2	Corrective Action
		8.5.3	Preventive Action

ISO standard adopts the eight principles of QMS as shown in the following table 2.2, which reveals the interrelationship between the QMS principles and clauses of ISO 9001:2008 (Poudel, 2004). Thus ISO clauses work as vehicles for implementation of QMS principles.

Table 2.2: QMS Principles & ISO 9001:2008 clauses

QMS Principles	Applicable Clauses ISO 9001:2008	
1. Leadership	5.1	Management Commitment
	5.3	Quality Policy
	5.4.1	Quality Objectives
	5.6	Management Review
2.Continual Improvement	4.1	QMS General Requirements
	5.1	Management Commitment
	5.3	Quality Policy
	5.4.1	Quality Objectives
	5.5.2	Management Representative
	5.6	Management Review
	6.1	Provision of Resources
	8	Measurement, analysis and improvement
3. Customer Focus	5.1	Management Commitment
	5.2	Customer Focus
	5.5.2	Management Representative
	6.1	Provision of Resources
	8.2.1	Customer Satisfaction
	8.4	Analysis of Data
	8.5.2	Corrective Action
4. Factual Approach to Decision Making	7.1	Planning of product realization
	7.5.1	Control of Production and service provision
	7.6	Control of monitoring and measuring devices
	8.1	General-Measurement,analysisand improvement
	8.2.2	Internal Audit
	8.2.3	Monitoring and measurement of processes
	8.2.4	Monitoring and measurement of product
	8.3	Control of nonconforming product
	8.4	Analysis of data
5. Involvement of People	5.3	Quality Policy
	5.5.1	Responsibility and authority
	5.5.3	Internal Communication
	6.2	Human Resources
	6.4	Work environment
6. Process Approach	4.1	QMS General Requirements
	5.4.2	QMS Planning
	5.5.2	Management Representative
	7.1	Planning of product realization
	7.2	Customer-related processes
	7.3	Design and development
	7.5	Production and service provision
7. System Approach	4.2	Documentation Requirements
	6.1	Provision of resources
	6.3	Infrastructure
8.Mutually Beneficial Supplier Relationship	7.4	Purchasing

2.7 Quality Management Gurus

Over the past few decades, quality gurus such as Deming (1986), Juran (Juran and Gryna, 1993), Crosby (1979), Feigenbaum (1991), and Ishikawa (1985), the primary authorities of quality management, have developed certain propositions in the field of quality management, which have gained significant acceptance throughout the world. Their propositions are the foundation for understanding the concept of quality management. Their insights provide a good understanding of the philosophy, principles, and practices regarding quality and quality management. Therefore, an extensive review of literature was carried out to identify the concept of quality management from quality gurus Deming, Juran, Crosby, Feigenbaum, and Ishikawa. The following sections present the main principles and practices of quality management proposed by these quality gurus.

2.7.1 Deming's Philosophy

The theoretical essence of the Deming approach to quality management concerns the creation of an organizational system that fosters cooperation and learning for facilitating the implementation of process management practices, which, in turn, leads to continuous improvement of processes, products, and services as well as to employee fulfillment, both of which are critical to customer satisfaction, and ultimately, to firm survival. Deming (1986) stressed the responsibilities of top management to take the lead in changing processes and systems. Leadership plays in ensuring the success of quality management, because it is the top management's responsibility to create and communicate a vision to move the firm toward continuous improvement. Top management is responsible for most quality problems; it should give employees clear standards for what is considered acceptable work, and provide the methods to achieve it. These methods include an appropriate working environment and climate for work-free of faultfinding, blame or fear.

Deming (1986) also emphasized the importance of identification and measurement of customer requirements, creation of supplier partnership, use of functional teams to identify and solve quality problems, enhancement of employee skills, participation of employees, and pursuit of continuous improvement. The means to improve quality lie in

the ability to control and manage systems and processes properly, and in the role of management responsibilities in achieving this. Deming (1986) advocated methodological practices, including the use of specific tools and statistical methods in the design, management, and improvement of process, which aim to reduce the inevitable variation that occurs from "common causes" and "special causes" in production. "Common causes" of variations are systemic and are shared by many operators, machines, or products. They include poor product design, non-conforming incoming materials, and poor working conditions. These are the responsibilities of management. "Special causes" relate to the lack of knowledge or skill, or poor performance. These are the responsibilities of employees. Deming proposed 14 points as the principles of quality management (Deming, 1986), which are listed below:

(1) Create constancy of purpose toward improvement of product and service, with the aim to become competitive and to stay in business, and to provide jobs.
(2) Adopt the new philosophy. We are in a new economic age. Western management must awaken to the challenge, must learn their responsibilities, and take on leadership for change.
(3) Cease dependence on mass inspection to quality. Eliminate the need for inspection on a mass basis by building quality into the product in the first place.
(4) End the practice of awarding business on the basis of price tag. Instead, minimize total cost. Move toward a single supplier for any one item, on a long-term relationship of loyalty and trust.
(5) Improve constantly and forever the system of production and service, to improve quality and productivity, and thus constantly decrease costs.
(6) Institute training on the job.
(7) Institute leadership. The aim of supervision should be to help people and machines and gadgets to do a better job. Supervision of management is in need of overhaul, as well as supervision of production workers.
(8) Drive out fear, so that people may work effectively for the company.

(9) Break down barriers between departments. People in research, design, sales, and production must work as a team, to foresee problems of production and in use that may be encountered with the product or service.

(10) Eliminate slogans, exhortations, and targets for the workforce asking for zero defects and new levels of productivity. Such exhortations only create adversarial relationships, as the bulk of the causes of low quality and low productivity belong to the system and thus lie beyond the power of the workforce.

(11) (a) Eliminate work standards (quotas) on the factory floor. Substitute leadership. (b) Eliminate management by objective. Eliminate management by numbers, numerical goals. Substitute leadership.

(12) (a) Remove barriers that rob the hourly worker of his right to pride of workmanship. The responsibility of supervisors must be changed from sheer numbers to quality. (b) Remove barriers that rob people in management and in engineering of their right to pride of workmanship. This means, inter alia, abolishment of the annual or merit rating and of management by objective.

(13) Institute a vigorous program of education and self-improvement.

(14) Put everybody in the company to work to accomplish the transformation. The transformation is everybody's job.

2.7.2 Juran's Philosophy

Quality management is the system of activities directed at achieving delighted customers, empowered employees, higher revenues, and lower costs (Juran and Gryna, 1993). Juran believed that main quality problems are due to management rather than workers. The attainment of quality requires activities in all functions of a firm. Firm-wide assessment of quality, supplier quality management, using statistical methods, quality information system, and competitive benchmarking are essential to quality improvement. Juran's approach is emphasis on team and project work, which can promote quality improvement, improve communication between management and employees coordination, and improve coordination between employees. He also emphasized the importance of top management commitment and empowerment, participation, recognition and rewards. According to Juran, it is very important to understand customer

needs. This requirement applies to all involved in marketing, design, manufacture, and services. Identifying customer needs requires more vigorous analysis and understanding to ensure the product meets customers' needs and is fit for its intended use, not just meeting product specifications.

Thus, market research is essential for identifying customers' needs. In order to ensure design quality, he proposed the use of techniques including quality function deployment, experimental design, reliability engineering and concurrent engineering. Juran considered quality management as three basic processes (Juran Trilogy): Quality control, quality improvement, and quality planning. In his view, the approach to managing for quality consists of: (1) The sporadic problem is detected and acted upon by the process of quality control; (2) The chronic problem requires a different process, namely, quality improvement; such chronic problems are traceable to an inadequate quality planning process. Juran defined a universal sequence of activities for the three quality processes, which is listed in Figure 2.7.

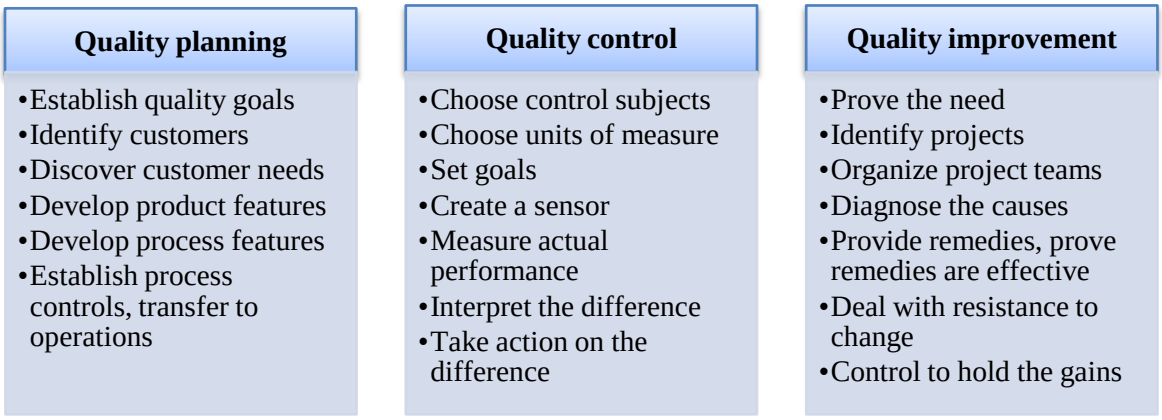


Figure 2.7: Universal Processes for Managing Quality

Juran defined four broad categories of quality costs, which can be used to evaluate the firm's costs related to quality. Such information is valuable to quality improvement. The four quality costs are listed as follows:

- *Internal failure costs* (scrap, rework, failure analysis, etc.), associated with defects found prior to transfer of the product to the customer;

- *External failure costs* (warranty charges, complaint adjustment, returned material, allowances, etc.), associated with defects found after product is shipped to the customer;
- *Appraisal costs* (incoming, in-process, and final inspection and testing, product quality audits, maintaining accuracy of testing equipment, etc.), incurred in determining the degree of conformance to quality requirements;
- *Prevention costs* (quality planning, new product review, quality audits, supplier quality evaluation, training, etc.), incurred in keeping failure and appraisal costs to a minimum.

2.7.3 Crosby's Philosophy

Crosby (1979) identified a number of important principles and practices for a successful quality improvement program, which include, for example, management participation, management responsibility for quality, employee recognition, education, reduction of the cost of quality (prevention costs, appraisal costs, and failure costs), emphasis on prevention rather than after-the-event inspection, doing things right the first time, and zero defects. Crosby claimed that mistakes are caused by two reasons: Lack of knowledge and lack of attention. Education and training can eliminate the first cause and a personal commitment to excellence (zero defects) and attention to detail will cure the second. Crosby also stressed the importance of management style to successful quality improvement. The key to quality improvement is to change the thinking of top managers-to get them not to accept mistakes and defects, as this would in turn reduce work expectations and standards in their jobs. Understanding, commitment, and communication are all essential. Crosby presented the quality management maturity grid, which can be used by firms to evaluate their quality management maturity. The five stages are: Uncertainty, awakening, enlightenment, wisdom and certainty. These stages can be used to assess progress in a number of measurement categories such as management understanding and attitude, quality organization status, problem handling, cost of quality as percentage of sales, and summation of firm quality posture. The quality management maturity grid and cost of quality measures are the main tools for managers to evaluate their quality status. Crosby offered a 14-step program that can guide firms in pursuing quality improvement. These steps are listed as follows:

(1) Management commitment: To make it clear where management stands on quality.

(2) Quality improvement team: To run the quality improvement program.

(3) Quality measurement: To provide a display of current and potential nonconformance problems in a manner that permits objective evaluation and corrective action.

(4) Cost of quality: To define the ingredients of the cost of quality, and explain its use as a management tool.

(5) Quality awareness: To provide a method of raising the personal concern felt by all personnel in the company toward the conformance of the product or service and the quality reputation of the company.

(6) Corrective action: To provide a systematic method of resolving forever the problems that is identical through previous action steps.

(7) Zero defects planning: To investigate the various activities that must be conducted in preparation for formally launching the Zero Defects program.

(8) Supervisor training: To define the type of training that supervisors need in order to actively carry out their part of the quality improvement program.

(9) Zero defects day: To create an event that will make all employees realize, through a personal experience, that there has been a change.

(10) Goal setting: To turn pledges and commitment into actions by encouraging individuals to establish improvement goals for themselves and their groups.

(11) Error causal removal: To give the individual employee a method of communicating to management the situation that makes it difficult for the employee to meet the pledge to improve.

(12) Recognition: To appreciate those who participate.

(13) Quality councils: To bring together the professional quality people for planned communication on a regular basis.

(14) Do it over again: To emphasize that the quality improvement program never ends.

2.7.4 Feigenbaum's Philosophy

Feigenbaum (1991) defined TQC (total quality control) as: An effective system for integrating the quality development, quality-maintenance, and quality-improvement efforts of the various groups in a firm so as to enable marketing, engineering, production, and service at the most economical levels which allow for full customer satisfaction. He claimed that effective quality management consists of four main stages, described as follows:

- Setting quality standards;
- Appraising conformance to these standards;
- Acting when standards are not met;
- Planning for improvement in these standards.

The quality chain, he argued, starts with the identification of all customers' requirements and ends only when the product or service is delivered to the customer, who remains satisfied. Thus, all functional activities, such as marketing, design, purchasing, manufacturing, inspection, shipping, installation and service, etc., are involved in and influence the attainment of quality. Identifying customers' requirements is a fundamental initial point for achieving quality. He claimed that effective TQM requires a high degree of effective functional integration among people, machines, and information, stressing a system approach to quality. A clearly defined total quality system is a powerful foundation for quality management. Total quality system is defined as follows:

The agreed firm-wide operating work structure, documented in effective, integrated technical and managerial procedures, for guiding the coordinated actions of the people, the machines, and the information of the firm in the best and most practical ways to assure customer quality satisfaction and economical costs of quality.

Feigenbaum emphasized that efforts should be made toward the prevention of poor quality rather than detecting it after the event. He argued that quality is an integral part of the day-today work of the line, staff, and operatives of a firm. There are two factors affecting product quality: The technological-that is, machines, materials, and processes; and the human-that is, operators, foremen, and other firm personnel. Of these two factors,

the human is of greater importance by far. Feigenbaum considered top management commitment, employee participation, supplier quality management, information system, evaluation, communication, use of quality costs, and use of statistical technology to be an essential component of quality management. He argued that employees should be rewarded for their quality improvement suggestions, quality is everybody's job. He stated that effective employee training and education should focus on the following three main aspects: Quality attitudes, quality knowledge, and quality skills.

2.7.5 Ishikawa's Philosophy

Ishikawa (1985) argued that quality management extends beyond the product and encompasses after-sales service, the quality of management, the quality of individuals and the firm itself. He claimed that the success of a firm is highly dependent on treating quality improvement as a never-ending quest. A commitment to continuous improvement can ensure that people will never stop learning. He advocated employee participation as the key to the successful implementation of TQM. Quality circles, he believed, are an important vehicle to achieve this. Like all other gurus he emphasized the importance of education, stating that quality begins and ends with it. He has been associated with the development and advocacy of universal education in the seven QC tools (Ishikawa, 1985). These tools are listed below:

- Pareto chart-
- Cause and effect diagram (Ishikawa diagram);
- Stratification chart;
- Scatter diagram;
- Check sheet;
- Histogram;
- Control chart.

Ishikawa (1985) suggested that the assessment of customer requirements serves as a tool to foster cross-functional cooperation; selecting suppliers should be on the basis of quality rather than solely on price; cross-functional teams are effective ways for

identifying and solving quality problems. Ishikawa's concept of TQM contains the following six fundamental principles:

- Quality first- not short term profits first;
- Customer orientation-not producer orientation;
- The next step is your customer-breaking down the barrier of sectionalism;
- Using facts and data to make presentations-utilization of statistical methods;
- Respect for humanity as a management philosophy, full participatory management;
- Cross-functional management.

Dr. Ishikawa recognized the significance of shifting the responsibility for problem identification and problem solving to these on the factory floor. People on the factory floor are closest to the problems that interfere with delivering a quality product and meeting production schedules. It is recognized that having personnel outside the immediate work center identity and solve problem entailed another serious detractor and that is resistance to change. Ishikawa rezoned that by including the personnel closest to the problem, identification and solving process would be more effective and quick. So, Dr. Ishikawa introduced the concept of Quality Circle in 1962 and it soon became very popular and formed an important link in the company's quality management system. Quality circle offered an excellent vehicle for pushing problem identification, solution development and corrective action implementation to the shop floor problem solving technologies. The intended purpose of a Quality Circle is to;

- Support the improvement and development of the company
- Respect human relations in the workplace and increase job satisfaction
- Draw out employee potential

CHAPTER 3 • RESEARCH METHODOLOGY

3.1 Research Model

The research begins with problem identification. The identified problems are defined as objectives of the study. Then detail review of literature is conducted to build theoretical framework for the study. Many websites are visited and books/materials are studied during the period. Assessment of existing quality management system and quality control practices is done by collection of data through unstructured interviews, observations and distributed data sheets. The collected data are sorted as per requirements. The data collected are analyzed using different tools. The data are presented in different ways and formats to have easy and simple understanding. The conclusion is drawn from the data analysis and recommendations are presented for improvement. The overall research design adopted in this study is presented in the following figure 3.1.

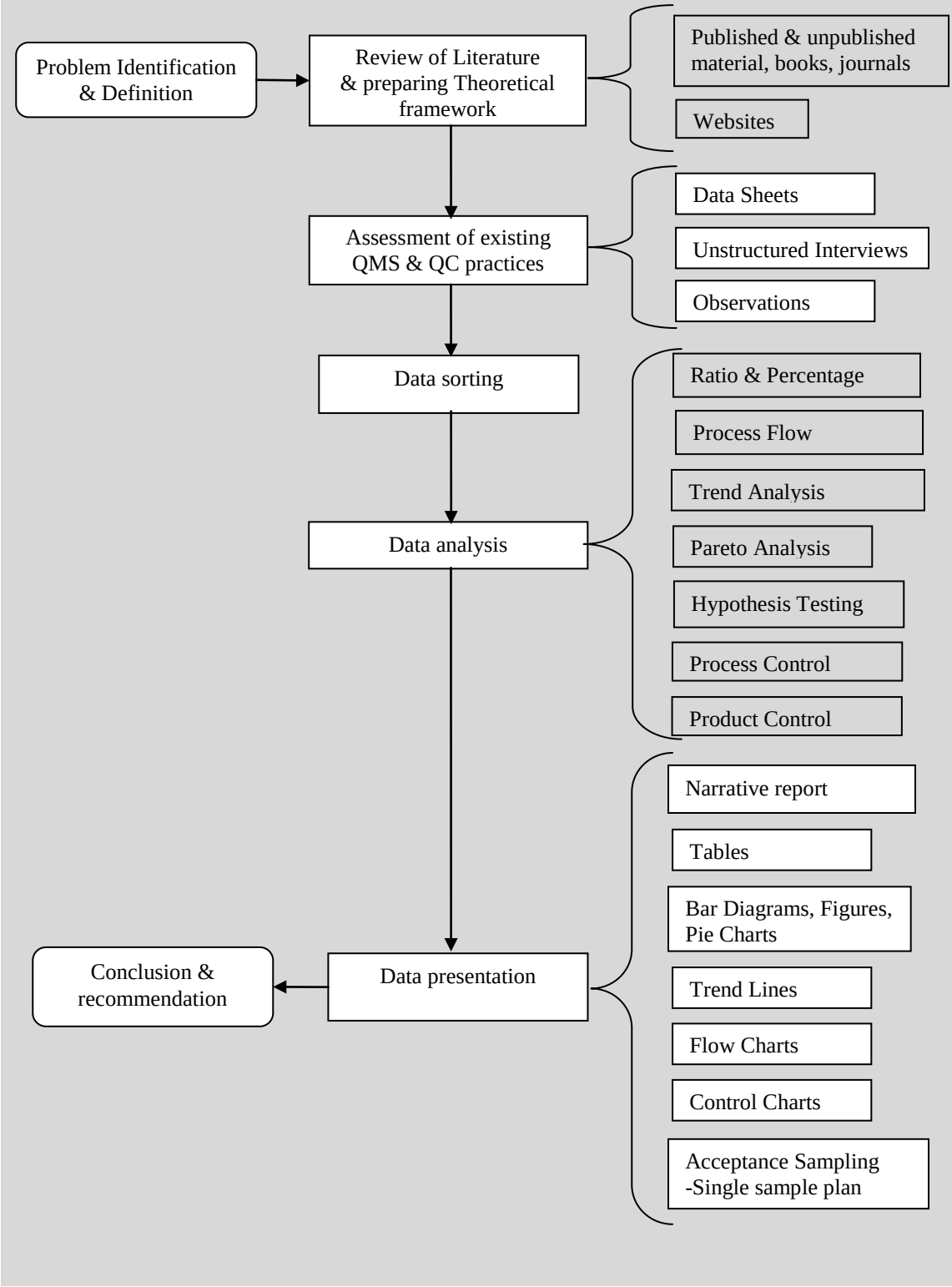


Figure 3.1: Research model

3.2 Research Design

This research combines both qualitative and quantitative methods. The main difference between the two methods concerns the use of numbers and statistics. A quantitative method is formalized and structured by surround information that can be measured and valued numerically. A quantitative approach is usually applied when the purpose is to verify existing theories or test hypotheses developed based on previous research. Qualitative methods are on the other hand deeper to create understanding in a specific subject, occurrence or situation. The central is to get a deeper understanding of the studied problem, collecting, analyzing and interpreting data that cannot be expressed in numbers.

3.3 Rationale on Selection of the Organization

The organization and the type of samples are determined on the basis of meeting the information requirements for the research. In this research, FH IOL Lab, a manufacturing unit of Tilganga Eye Centre is selected for the study though there are many large or medium-sized manufacturing firms implementing ISO Quality Management System.

FH IOL Lab- Intra-Ocular Lens (IOL) manufacturing facility has maintained compliance to ISO 9001:2008, ISO 13485:2003 (E), CE Mark 120, EN 46002, NZ standards. The Laboratory was certified by ISO in 1998 and CE Notified Body 0120 in 1998 by SGS, UK. FH IOL Lab was the first IOL manufacturer of Southeast Asia to have received the CE mark in (www.fh-iol.com). For manufacturing of IOLs which are medical devices used in cataract surgery to replace the eye's natural crystalline lens, the laboratory has maintained high standard clean room environment inside the laboratory.

Therefore, it can be assumed that the laboratory could have more experiences of implementing QMS, have more qualified respondents to fill in questionnaires, response interview questions, and take the questionnaires seriously. Thus the study on the FH IOL Lab might be enough for the study of QMS in clean room manufacturing unit and the research results might be generalized to some degree or greater to all clean room manufacturing units like medicine & medical device manufacturing firms in Nepal.

3.4 Nature and Sources of Data

Throughout the study, the author used both primary and secondary data sources. Keeping in the view of nature of the study, primary source is the main source of information and data; yet secondary sources of data play important role for theoretical framework of the study. Primary sources are directly related to the study purpose. Primary data consists of all the data collected throughout the study that directly can be related to the study purpose, both personally gathered as well as data from a third party that has been collected with equivalent purpose. Secondary data on the other hand, contains relevant data that has been collected with a different purpose, but from which conclusions is valuable for the purpose.

Primary Data

The primary data were collected through an empirical study. The empirical study was made through distributing data sheets to record raw data, conducting unstructured interviews and direct observations.

Secondary Data

Secondary data were widely used while preparing this report. The secondary data were collected through a theoretical study to form theoretical framework of this study. The theoretical study comprised of books and articles, research papers, websites etc.

3.5 Population and Sampling

As the term ‘Populations' reveals universal set, it includes all the number of any well defined class of people event or objects. Every staff, who is directly or indirectly involved in FH IOL Lab, is an element or member for interview purpose in this research study. Therefore, all the staffs of FH IOL Lab, from lowest position to highest position in hierarchy & from all sections, constitute the population for interview purpose in this research study. In this study, purposive sampling method was applied to select the respondents from different departments for the interviews as per the purpose and scope of the inquiry. Hence, following personnel listed in the table 3.1 were approached and

interactive unstructured interviews were performed with them. Attempt had been made to include both managerial as well as lower level staff from different departments.

Table 3.1: Respondents and Scope of Interviews

SN	Department	Respondents	General scope to cover in Interview
1	Quality Assurance	QA Manager	*QMS for overall organization, quality objectives/policies, quality audits, staff training, non-conformance, management review, corrective action, preventive action, deviation, validation, customer complaint*
2	Quality Assurance	QA Supervisor	*quality control practices and techniques, authority & responsibility, organizational chart, clean room environment, identification & traceability*
3	Production	Production Supervisor	*manufacturing process and stages, product line and product model, job description and job specification, hazards and safety*
4	Sales & Marketing	Sales & Marketing Officer	*customer communication, finished goods storage, customer satisfaction survey, Shippment & delivery process*
5	Procurement	Procurement Officer	*purchase process, purchase documents, supplier communication, approval of suppliers, supplier relationship*
6	Quality Assurance	QC Technician	*incoming material inspection method, in process quality control checks, calibration/maintenance of machines/equipments*
7	Quality Assurance	Microbiology lab Technician	*microbiological test and processes, chemical test and processes*
8	Production	Production Technician	*production and rejects, day to day production activities, measurement of product parameters*
9	Quality Assurance	Document controller	*documentation system, control of documents, distribution of documents, SOPs, Log books, Records*

From the product aspect, every medical product manufactured by the Laboratory represents the member or element for the study and the total constitutes the population of this research. Since the Lab has many product lines and each line has separate manufacturing & quality control processes, it is very difficult to include all the product lines in the study. Therefore, only lenses of FH model, which were also the first product line launched by the Lab at the time of its establishment, were selected for the study purpose. The sampling method & sample size for different observations in this study were listed in the following table 3.2.

Table 3.2: Sampling and sample size

Observation	**Stage of Production**	**Parameter under measurement**	**Sample size**	**Method of Sampling**
Hypothesis Test -mean test	Button cutting	diameter of PMMA buttons	100	Random sampling
Process Control -mean chart -range chart	1st cut Lathe	vault diameter of 1st cut lens	50	successively cut lenses
Process Control -mean chart -range chart	2nd cut Lathe	optic power (focal length) & haptic area thickness	50	successively cut lenses
Process Control -mean chart -range chart	Milling of lens	optic diameter, haptic diameter & overall diameter	50	successively cut lenses
Process Control -p chart	Polishing of lens	surface quality	1000	randomly 100 lenses from each 10 polishing lots

To conduct Hypothesis Testing for the diameter of PMMA buttons, 100 samples were randomly taken from QC released lot of buttons. To construct control charts- mean chart & range chart in 1st cut lathe, 50 successively cut lenses were taken as samples to measure the vault diameter. Similarly, to construct control charts- mean chart & range chart in 2nd cut lathe, 50 successively cut lenses were taken as samples to measure optic

power and haptic area thickness. Similarly, to construct control charts- mean chart & range chart in milling of lenses, 50 successively cut lenses were taken as samples to measure optic diameter, haptic diameter and overall diameter. For process control chart in polishing of lenses, 10 polishing lots were taken & 100 polished lenses were randomly taken as samples from each polishing lot.

3.6 Data Collection Procedure

The following methods were applied to collect data and information related to quality management in FH IOL Lab.

I. Unstructured Interview

Unstructured interviews were conducted with the concerned authority to generate detail knowledge on quality management system, documentation system, working procedures & quality control practices in the Lab. An informal list of main questions to be asked during the interviews was prepared. Lab personnel were approached with the informal list of questions and interactive unstructured interviews were performed with them on the basis of the list. The nature of the research being a new and complicated, the question answer session was made interactive so that the respondents could explain freely after understanding the meaning and the objective of the questions. Attempt had been made to include both managerial as well as lower level staff from different departments.

II. Direct Observation

In the course of preparation of this study, researcher frequently visited to organization to collect the information through direct observation. Observations played an important role in understanding the work environment inside the Lab & generating knowledge on conversion process of raw material into finished product, packaging methods, actual working procedures, quality control techniques, data recording system etc. During the observation visits in the Lab, short informal communications were performed on the spot with the staffs responsible for day to day operational activities, which helped to gain

insight on quality issues. The outcome of observations had great impact in the preparation of this thesis.

III. Data Sheets

As per requirement of this study, data sheets were designed and distributed to the concerned staffs to record the raw data during the manufacturing process. The author himself approached the related personnel of the Lab with the data sheets and conducted short briefing session with the related staffs on structure of the data sheet and guidelines for recording the raw data in those sheets. The structure of data sheets was made as easy and simple as possible to avoid confusion during data input.

3.7 Methods of Data Analysis and Presentation

For presentation and analysis of data, following methods were applied:

- Ratio and Percentage
- Process Flow
- Pareto Analysis
- Process Control (Control charts-X chart, R chart, P chart)
- Product Control (Acceptance Sampling)
- Hypothesis Testing

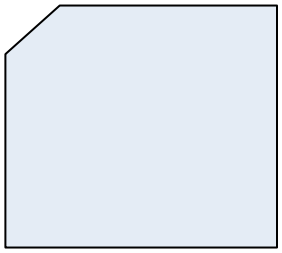
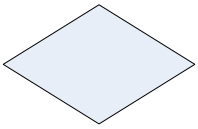
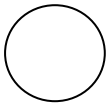
3.7.1 Process Flow

Process flow involves identification of processes in completing an activity and determination of the sequence & interaction of these processes from starting point to ending point. Graphically the process flow is represented by a flow chart.

A flowchart is a diagrammatic representation of a step-by-step solution to a given problem. It is a common type of diagram that represents an algorithm or process, showing the steps as boxes of various kinds, and their order by connecting these with arrows. Data is represented in these boxes, and arrows connecting them represent flow / direction of flow of data. Flowcharts are used in analyzing, designing, documenting or managing a

process or program in various fields. (en.wikipedia.org/wiki). Following table 3.3 shows the symbols used in modeling flowchart in this study.

Table 3.3: Symbols used in modeling Flowchart

Objects	Symbols	Description
Start/ End		Represents the start and end of process
Process		Represents detailed procedures in system
Record document		Represent documents to record the data
Decision		Represents decision making process in system
Flow Lines or flow of control		Represents direction or control of flow from one object to another
Connector		Represents connector of system

3.7.2 Pareto Analysis

It is a technique for focusing attention on the most important problem areas. The Pareto concept, named after the 19th century Italian economist Vilfredo Pareto, is that a relatively few factors generally account for a large percentage of the total cases of problems or defects. This principle supports that normally 80% problems are created by 20% of the total cases. This principle can be applied to quality improvement to the extent

that a great majority of problems (80%) are produced by a few key causes (20%). If we correct these few key causes, we will have a greater probability of success.
This technique classifies the cases according to degree of importance and then focus on resolving the most important, leaving the less important, thus grouping the problem areas into 2 categories: i) vital few & ii) trivial many. The vital few cases are focused and resolved.

3.7.3 Process Control

Process control is the method of controlling the quality of the goods in the process of production. With the help of process control, it is known whether the production process is stable or not over time period. A stable process is one that is consistent over time with respect to the center and the spread of the data. Process control is achieved through control charts.

A control chart is a graphic presentation of time-ordered data which are outcomes of a process. It presents a graphic display of process stability or instability over time. It is a tool or device for acquiring statistical process control. Control chart is used to separate assignable variation form natural variation, thus enabling to take immediate remedial actions whenever assignable variations are present to maintain process stability.

Variations in the magnitude of a given characteristic of the product are inherent and inevitable in a process. Natural variations are due to some ‘stable pattern of variation’ or ‘a constant cause system’ inherent in any system of production and inspection. Natural variation is random in nature, which is due to such causes beyond the control and cannot be prevented or eliminated. The range of such variation is the natural tolerance of the process. The assignable causes are non random factors which can be identified and eliminated. Assignable variation in a process can be traced to a specific reason. Factors such as machine wear, misadjusted equipment, fatigued or untrained workers, or new raw materials are all potential sources of assignable variation.

Types of Control charts

There are 2 types of control charts- i) for variables & ii) for attributes

Control charts for Variables

If the quality characteristics under consideration can be measured in quantitative terms of measurements such as weight, length, diameter etc, then the control chart is called Control charts for Variables.

Control charts for Variables are:

- Mean Chart (X chart)
- Range Chart (R Chart)

Control charts for Attributes

If the quality characteristics under consideration is attribute i.e. cannot be measured in quantitative terms but can be classified as being either defective or non-defective, then the control chart is called Control charts for Attributes. The Control charts for Attributes are p-chart.

Figure 3.2 shows a typical control chart which consists of the following lines

1. A central line (CL), indicating the desired standard quality or level of controlled process. It is average line.
2. Upper Control Limit (UCL), indicating the upper limit of variation
3. Lower Control Limit (LCL), indicating the lower limit of variation

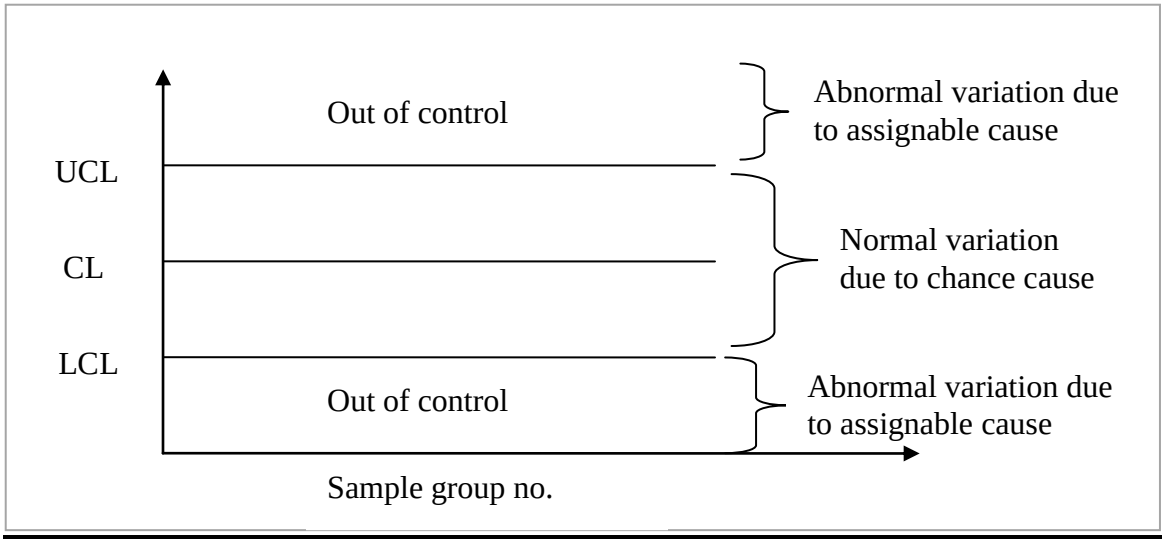


Figure 3.2: A typical Control Chart

Issues and Interpretation in Control charts

- *Out of Control*

Any one or more plots lying outside the limit i.e. lying above the UCL or lying below LCL is/are said to be out of control. It is the indication of presence of assignable variation. Investigation should be made for the causes.

- *2 consecutive sample points near UCL or LCL within the limits*

If any two or more consecutive plots lie near the UCL or LCL, even though they lie within the limits, the case is subject to investigation for poor performance.

- *Run of 5 consecutive sample points above or below CL within the limits*

If any 5 or more consecutive sample plots lie above the CL or below the CL, investigation should be made for the causes.

- *Upward or downward Trend of 5 consecutive plots*

If any 5 consecutive plots make an increasing or decreasing trend, it is the indication that the process is running towards the direction of out of control i.e. towards the UCL or LCL and may cross the limits. So, causes should be identified and eliminated.

- *Extreme variation/fluctuation*

If there is great fluctuation, sudden changes i.e. successive plots vary greatly, the case is subject to study for the causes of sudden and extreme variation.

3.7.4 Product Control

Product control is concerned with classification of raw materials or finished products into acceptable and non-acceptable through inspection of samples. Product control can be achieved through 'acceptance sampling.'

Acceptance sampling is a form of sampling that is applied to lots or batches of items. It involves taking random samples of lots or batches of products, conducting inspection on samples and deciding whether to accept or reject the entire lot based on the results. Hence, acceptance sampling determines whether a batch of goods should be accepted or rejected. It is mostly used in the cases

i) when the final products are awaiting shipment to warehouses or customers (Outgoing)
ii) when purchased raw materials or supplies are arriving (Incoming)

Lots or batches that satisfy the standards are passed or accepted and those that do not are rejected. Rejected lots are subject to either i) 100 % inspection i.e. every item in the lot is inspected and cut out all the defects, or ii) return to supplier in case of purchase

The procedure for acceptance sampling plans – single sampling plan is illustrated in the following figure 3.3.

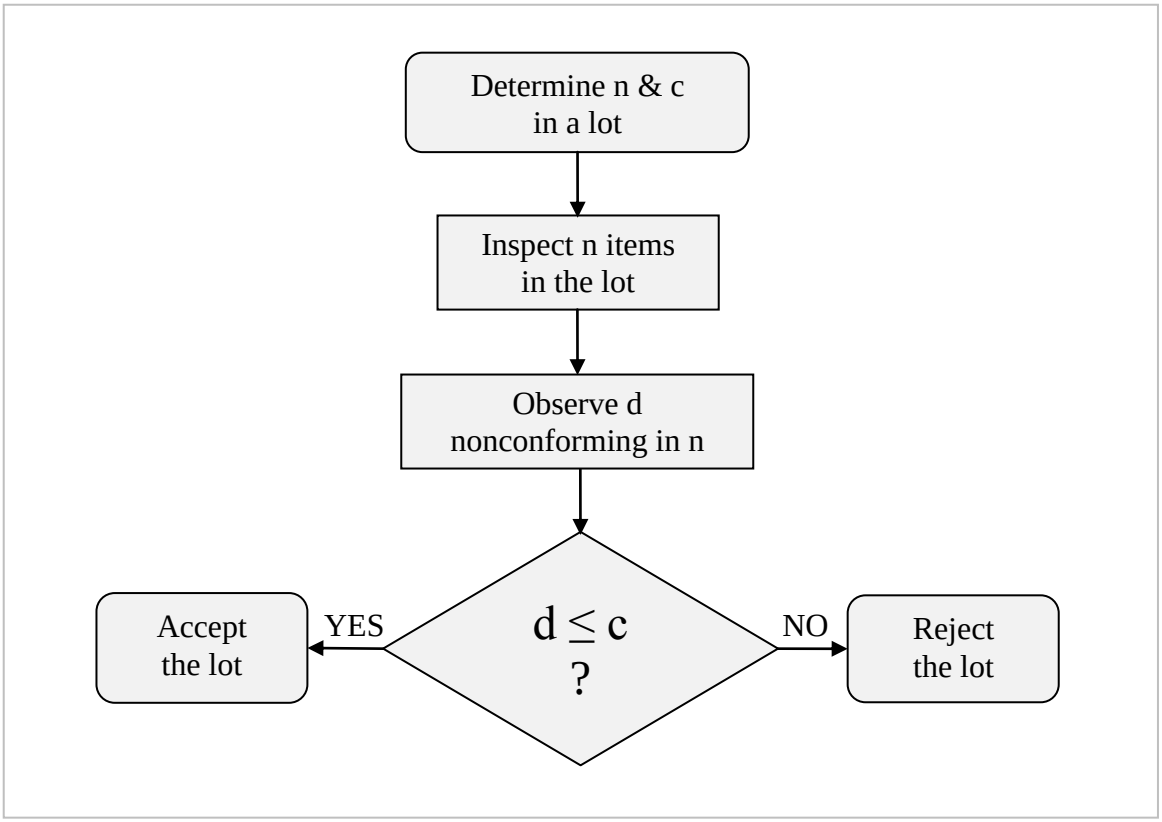


Figure 3.3: Single Sampling Plan method

In the figure 3.3

N=lot size

n=sample size

c=acceptance number i.e. maximum number of allowable defectives in the sample

d=no of defectives in the sample

1. Select a random sample of size n from the lot of size N
2. Inspect all items of the sample and find the defectives, let's say d
3. If d<c, accept the lot. Replace all the defectives with good ones.
4. If d>c, reject the lot. Inspect 100% of the lot. Replace all the defectives with good ones.

3.7.5 Hypothesis Testing

A hypothesis is an assumption or a supposition to be tested for its validity i.e. to be proved or disproved.

Hypothesis testing process

The process of hypothesis test includes 5 steps as shown in the figure 3.4.

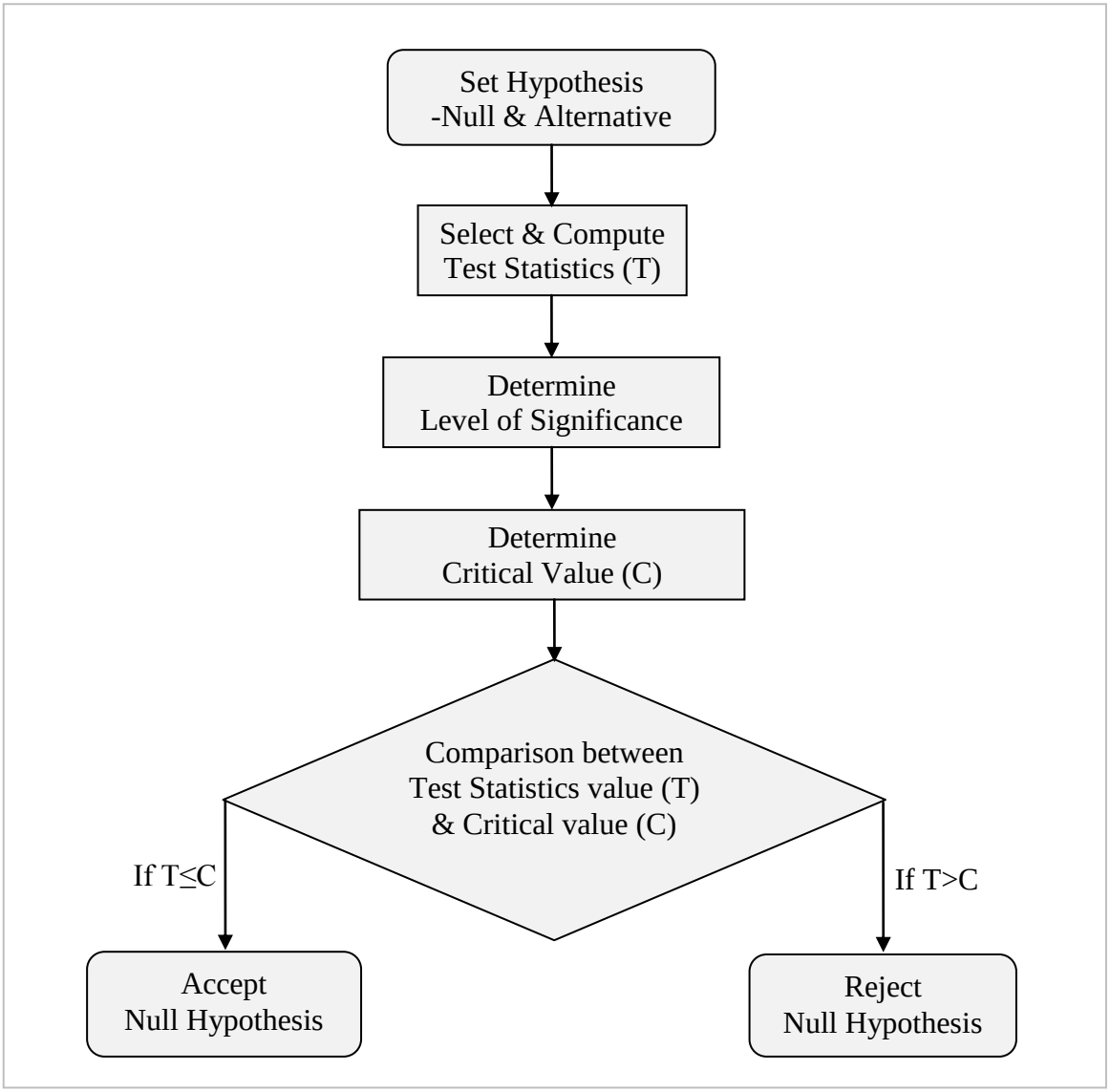


Figure 3.4: Hypothesis testing process

Step 1: Setting of Hypothesis

a. Null Hypothesis: It is the hypothesis of no difference.
b. Alternative hypothesis: It is a hypothesis complementary to null hypothesis and set in such a manner that the rejection of null hypothesis implies the acceptance of the alternative hypothesis and vice versa.

Step 2: Selection & Computation of proper Test Statistics

After setting the hypothesis, appropriate test statistics is selected depending upon sampling distribution. On the basis of observations, test statistics (T) is calculated.

Step 3: Determination of Level of Significance

Next step is to fix the level of significance. It is the maximum probability of committing type I error i.e. rejecting null hypothesis though it is true.

Step 4: Determination of Critical value

The fourth step is the determination of critical value. It presents the decision criteria in the next step. The entire sample space is divided into two subsets- one corresponding to acceptance region and another corresponding to rejection region. The value which separates these two regions is the critical value (C).

Step 5: Decision making

The last step in the test of hypothesis is to make the decision about the null hypothesis. Calculated test statistics (T) is compared with the critical value (C) and decision is made whether to accept or reject null hypothesis as shown below:

- If $T \leq C$, accept Null Hypothesis i.e. reject Alternative Hypothesis
- If $T > C$, reject Null Hypothesis i.e. accept Alternative Hypothesis

CHAPTER 4 • DATA ANALYSIS AND PRESENTATION

4.1 Analysis of Interview Respondents

Total 9 interviews were successfully conducted with the FH IOL Lab staffs who were involved in tendering matters of the organizational operational activities as shown in the following table 4.1.

Table 4.1: Respondents in Interviews

SN	Department	Respondents	Interview conducted
1	Quality Assurance	QA Manager	1
2	Quality Assurance	QA Supervisor	1
3	Production	Production Supervisor	1
4	Sales & Marketing	Sales & Marketing Officer	1
5	Procurement	Procurement Officer	1
6	Quality Assurance	QC Technician	1
7	Quality Assurance	Microbiology lab Technician	1
8	Production	Production Technician	1
9	Quality Assurance	Document controller	1
Total			**9**

The interviews included both managerial level as well as lower level staffs of the FH IOL Lab as shown in the following table 4.2.

Table 4.2: Position Levels of Respondents in Interview

Level	Interview conducted	% in Total
Management Level (Supervisor, Officer & Manager)	5	55.56%
Lower Level	4	44.44%
Total	**9**	**100.00%**

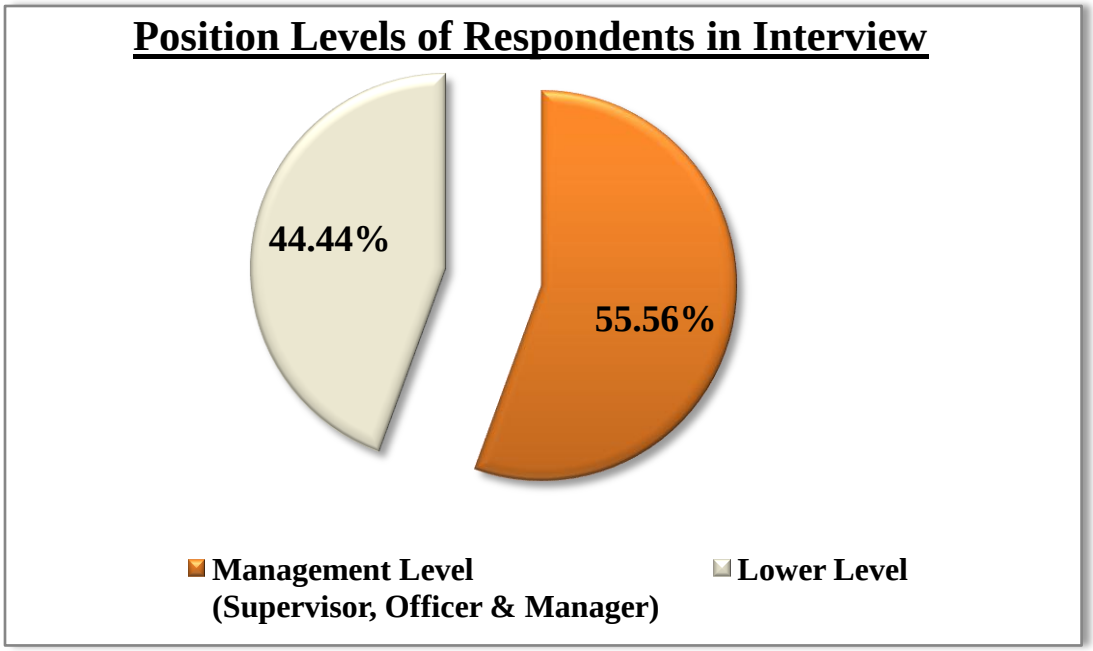


Figure 4.1: Position Levels of Respondents in Interviews

From the figure 4.1, it is clear that 55.56% of the respondents of interview belonged to managerial level whereas 44.44% respondents belonged to lower level of the organization.

The respondents in the interviews were selected from different functional departments as shown in the following table 4.3.

Table 4.3: Departments of Respondents in Interview

Department	**Interview conducted**	**% in Total**
Production	2	22.22%
Quality Assurance	5	55.56%
Sales & Marketing	1	11.11%
Procurement	1	11.11%
Total	**9**	**100.00%**

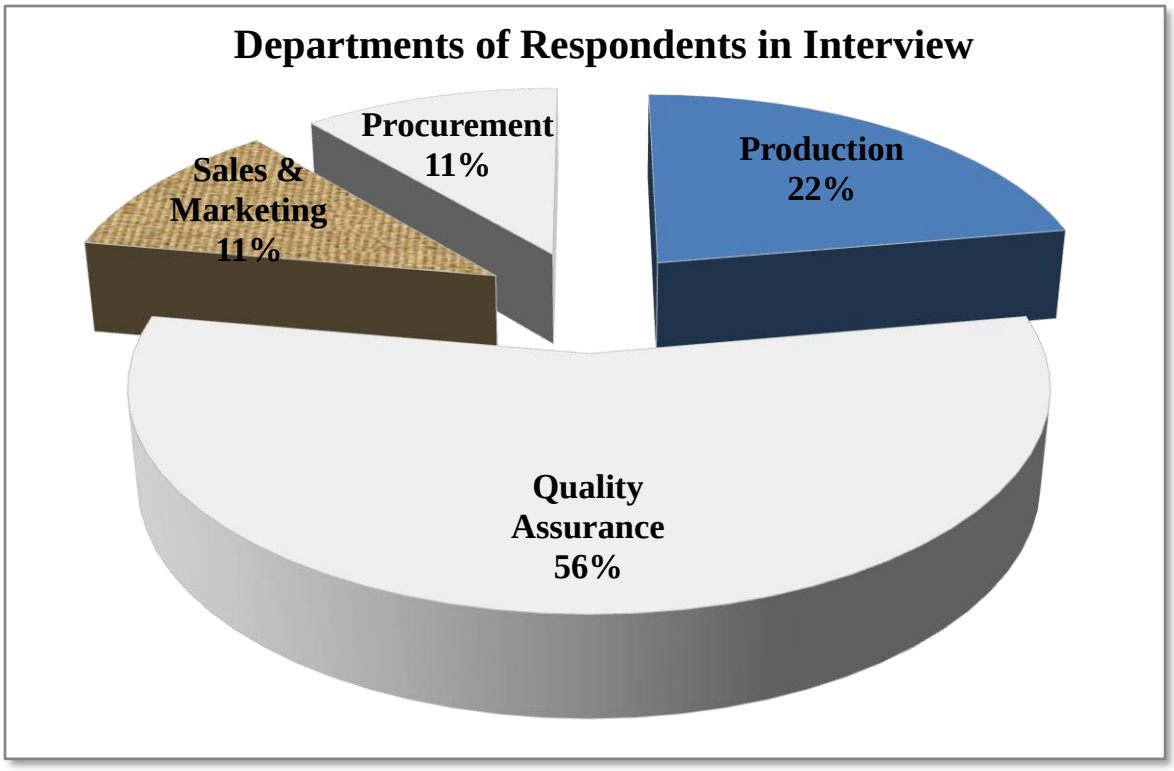


Figure 4.2: Departments of Respondents in Interviews

From figure 4.2, it is clear that most of the respondents were from Quality Assurance Department from where 56% of total respondents were interviewed. 22% of the respondents belonged to Production Department. The Procurement and Sales/Marketing Department each represented 11% of the respondents.

4.2 Production vs Quality Assurance Personnel

In the conversion process of raw material into finished products, the Production Department and Quality Assurance Department are directly involved in different stages of manufacturing process from inspection of incoming materials to secondary packing of lenses which are ready for sale. The Production Department is responsible for manufacturing of lenses and the QA Department is responsible for quality checks, quality control and quality system in the FH IOL Lab. The total no of personnel in both Production and QA Department is 57. The Production Department has 41 personnel

which constitute 72% of the total and the no of personnel in QA Department is 16 which constitute 28% of the total as shown in the following table 4.4 and figure 4.3.

Table 4.4: Production vs Quality Assurance personnel

Department	No of Personnel	Percentage
Production	41	72%
Quality Assurance	16	28%
Total	**57**	**100%**

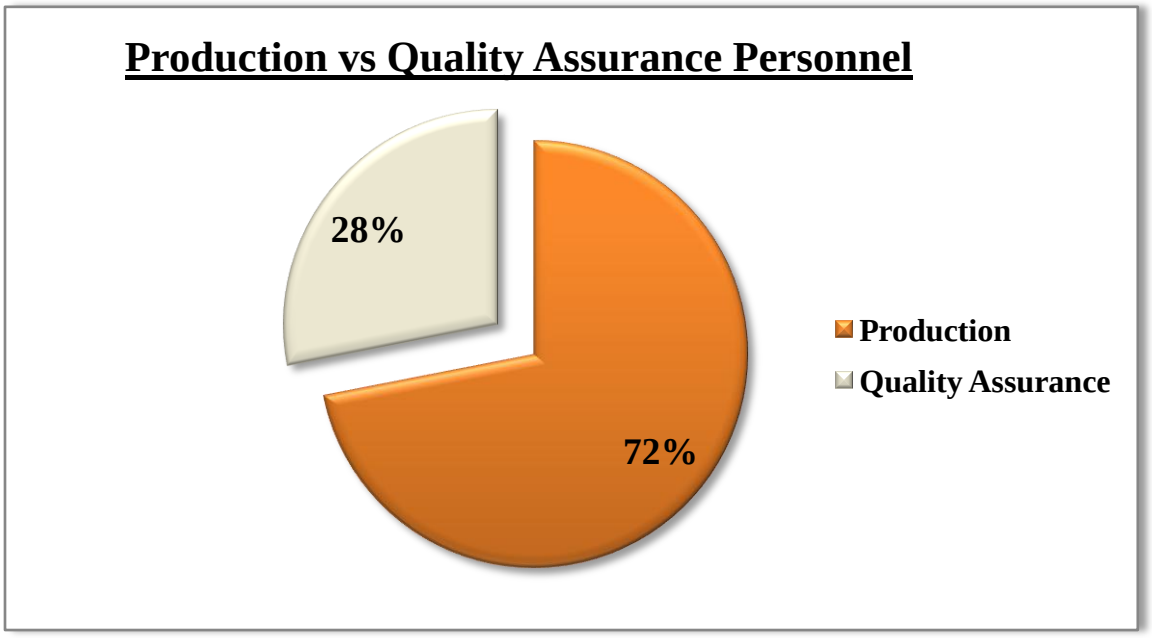


Figure 4.3: Production vs Quality Assurance personnel

The ratio of production personnel to quality assurance personnel is 2.5. Hence, there is 1 quality assurance personnel for 2.5 production personnel in average i.e. the manufacturing activities of 2.5 production personnel are monitored and verified by 1 quality assurance staff.

4.3 Mission statement, Quality Policy and Objectives

The top management of the FH IOL Lab has established its mission, quality policy and quality objectives for quality commitment to meeting requirements and to continual improvement on QMS. The quality manual of the FH IOL Lab includes the mission statement, quality policy and quality objectives as follows:

Mission Statement

"The mission of FH IOL Laboratory, Kathmandu, Nepal is to integrate international and Nepali work culture to maintain a high technology ophthalmic medical device manufacturing laboratory capable of producing world class quality products at low cost which will facilitate eradication of blindness in developing countries."

Quality Policy

"The FH IOL Laboratory, Kathmandu strives to continuously improve Production and Quality Assurance Processes of Intra-ocular Lens in an effort to better satisfy our customer needs. Our goal is to deliver defect free products to our customers on time, each and every time.

In order to maintain the above Quality Policy the Laboratory has the following objectives:

- Maintain compliance to ISO 9001:2008, ISO 13485:2003(E) and Medical Device Directives 93/42/EEC for the relevant product(s).
- Expansion of market base
- Resources optimization
- Acknowledge the importance of staff and provide adequate training and employment conditions and encourage staff loyalty, high productivity besides the maintenance of the Quality Management System and product quality."

Following major implications are embedded in the mission statement, quality policy and quality objectives of the FH IOL Lab:

- The purpose of the FH IOL Lab is to manufacture a world class quality intra-ocular lens and it is reflected in the phrase of the quality policy "Production and ……..of Intra-ocular Lens".
- In the quality policy of the FH IOL Lab, the phrase "strives to continuously improve ……Processes" indicates the commitment of top management for continual improvement of the effectiveness of the QMS.
- In the quality policy, the phrases "an effort to better satisfy our customer needs" and "Our goal is to ……..... every time" direct towards customer satisfaction by meeting customer requirements.
- The phrase "In order to maintain ……. the following objectives" indicates that the quality objectives are consistent with the quality policy.
- In the quality objectives, the statement "Maintain compliance to …… the relevant product(s)" includes the commitment to comply with the requirements of QMS.
- The statements in the quality objectives "Resources optimization" and "Acknowledge the importance …… product quality" have implications for internal communication, capability for high technology, cost reduction etc.

4.4 Product Profile

The Laboratory manufactures the following medical products:

- Posterior Chamber Intra-Ocular Lenses (PC IOL): FH model & TG models
- Anterior Chamber Intra-Ocular Lenses (AC IOL)
- Foldable Intra-Ocular Lenses : Flex, Tetra, Slick etc.
- Capsular Tension Ring (CTR)

Among many product lines offered by the FH IOL Lab, only FH model of IOLs was selected for the study. The FH model of IOLs is made up of a special type of optical material called Poly Methyl Meth Acrylate (PMMA). Figure 4.4 illustrates the different product dimensions on Front view & Side view.

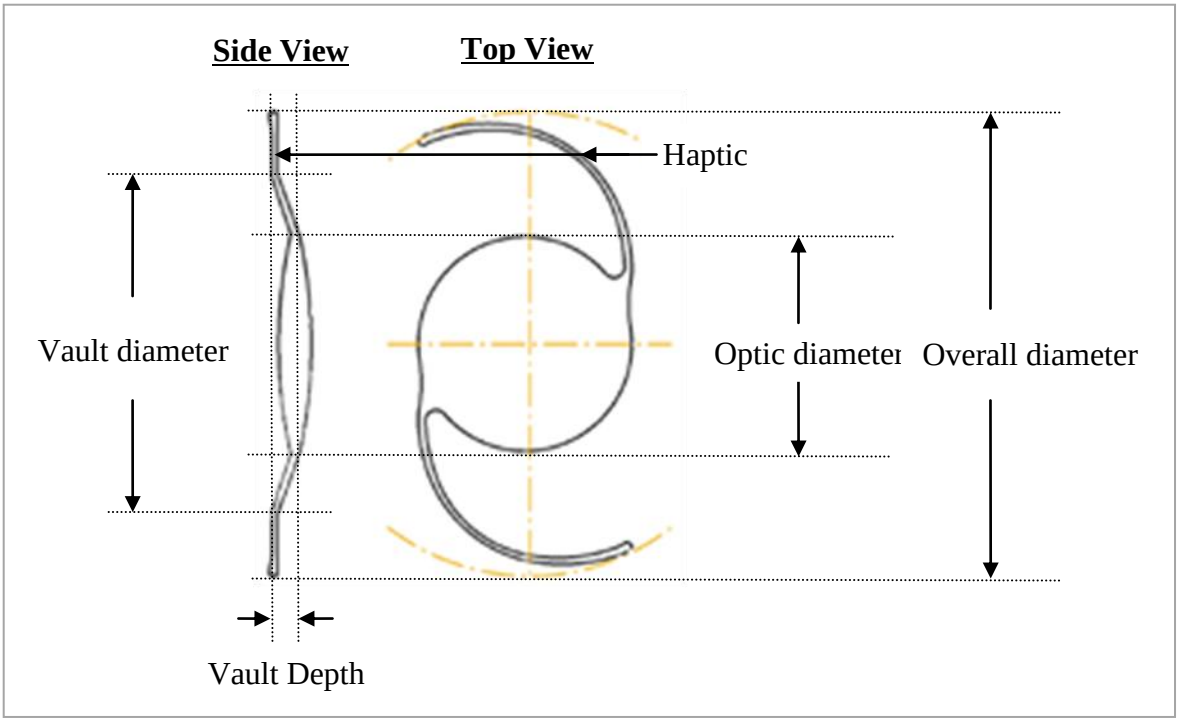


Figure 4.4: FH Model of IOL

The single piece FH model of IOL has an optic body in the centre and two "arm" like structures known as 'haptics' at the two side of the optic body.

4.5 Quality Management System (QMS) Process

The FH IOL Lab has established, documented, implemented and maintained Quality Management System in accordance with the requirements of ISO.

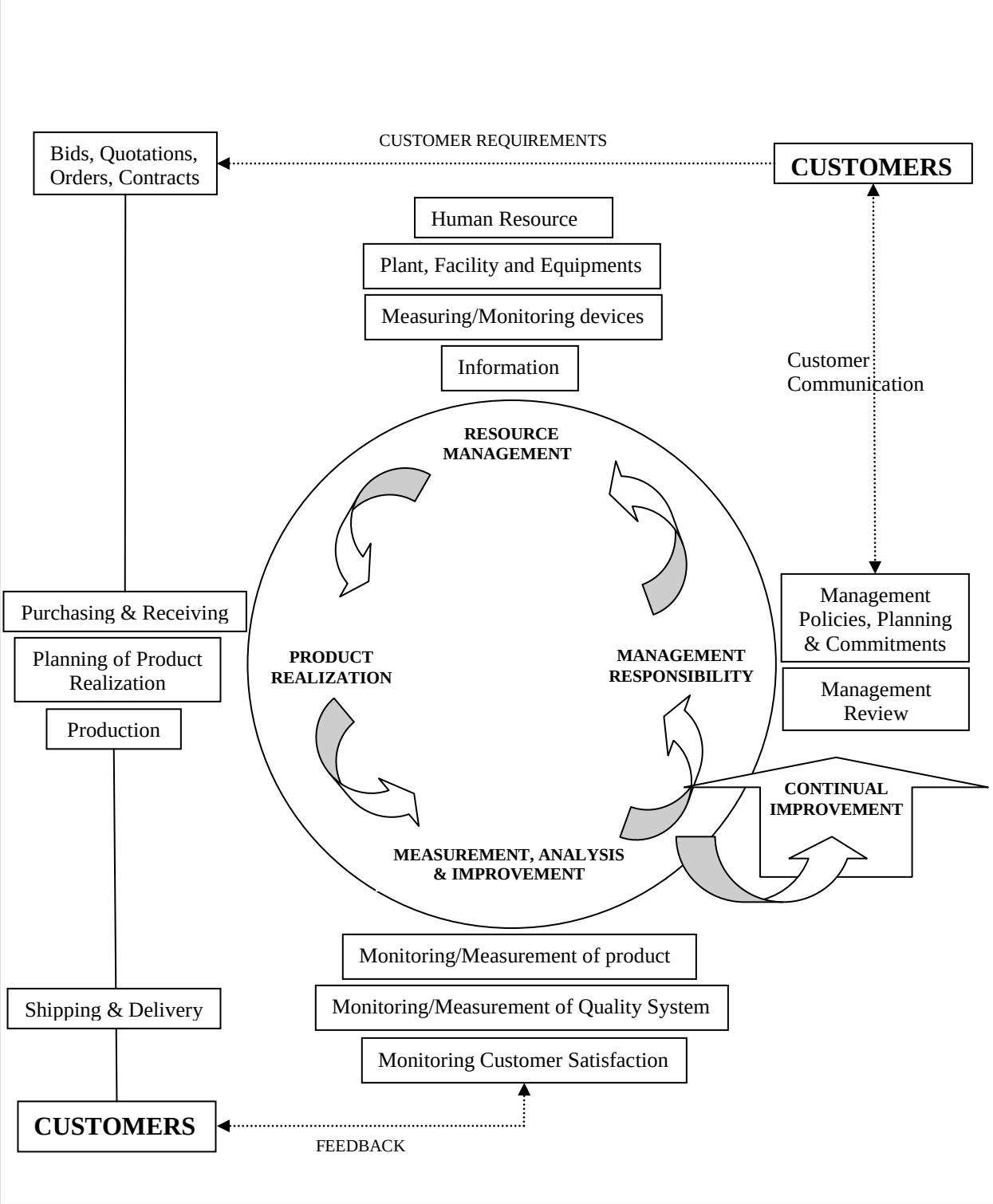


Figure 4.5: QMS Process

Figure 4.5 illustrates a process-based QMS of the FH IOL Lab. Customer requirements are used as input to the product realization process and their satisfaction is continually

measured and analyzed through annual customer satisfaction survey. Top management establishes mission, objectives & goals, policies & procedures for the overall organization.

The product realization process of the FH IOL Lab is the conversion process that involves converting inputs into outputs. The basic input i.e the raw material in the conversion process is the PMMA sheet and output is the intra-ocular lens. The procurement process for required materials precedes the conversion process whereas after product realization sales and distribution activities are held. This conversion is managed through human resources, plants and machinery, information resources, and other resources. QMS is structured around all the interlinked processes that provide continual improvement.

4.6 Documentation

The documentation structure in the FH IOL Lab is 4 tier system as illustrated in the documentation pyramid figure 4.6. Mission statement, Quality policy and Quality objectives lie at the top level. As per the requirement of ISO standards, FH IOL Lab has maintained a quality manual. A quality manual a master piece or the top level document that governs the quality system of FH IOL Lab. The quality manual of FH IOL Lab includes mission statement, quality policy, quality objectives, scope of the quality manual. The scope of the quality manual is described as 'The Quality Manual describes Quality Management System (QMS) for FH IOL Lab and applies to all products manufactured by Lab'. The quality manual of the FH IOL Lab has excluded the ISO clause '7.3 Design and development' under the section '7 Product Realization'. Under the quality manual lie quality sub manuals covering major functions of the Lab- production, quality assurance, engineering, microbiology and administration. Each of these quality sub manual consists of many Standard Operating Procedures (SOPs) which are sets of operational instructions for the activity to be carried out. At the bottom of the pyramid lie records, forms, templates, drawings, log books that are appendices of different SOPs. The

information level is general and external at the top of the pyramid whereas the information level is highly specific and internal at the bottom of the pyramid.

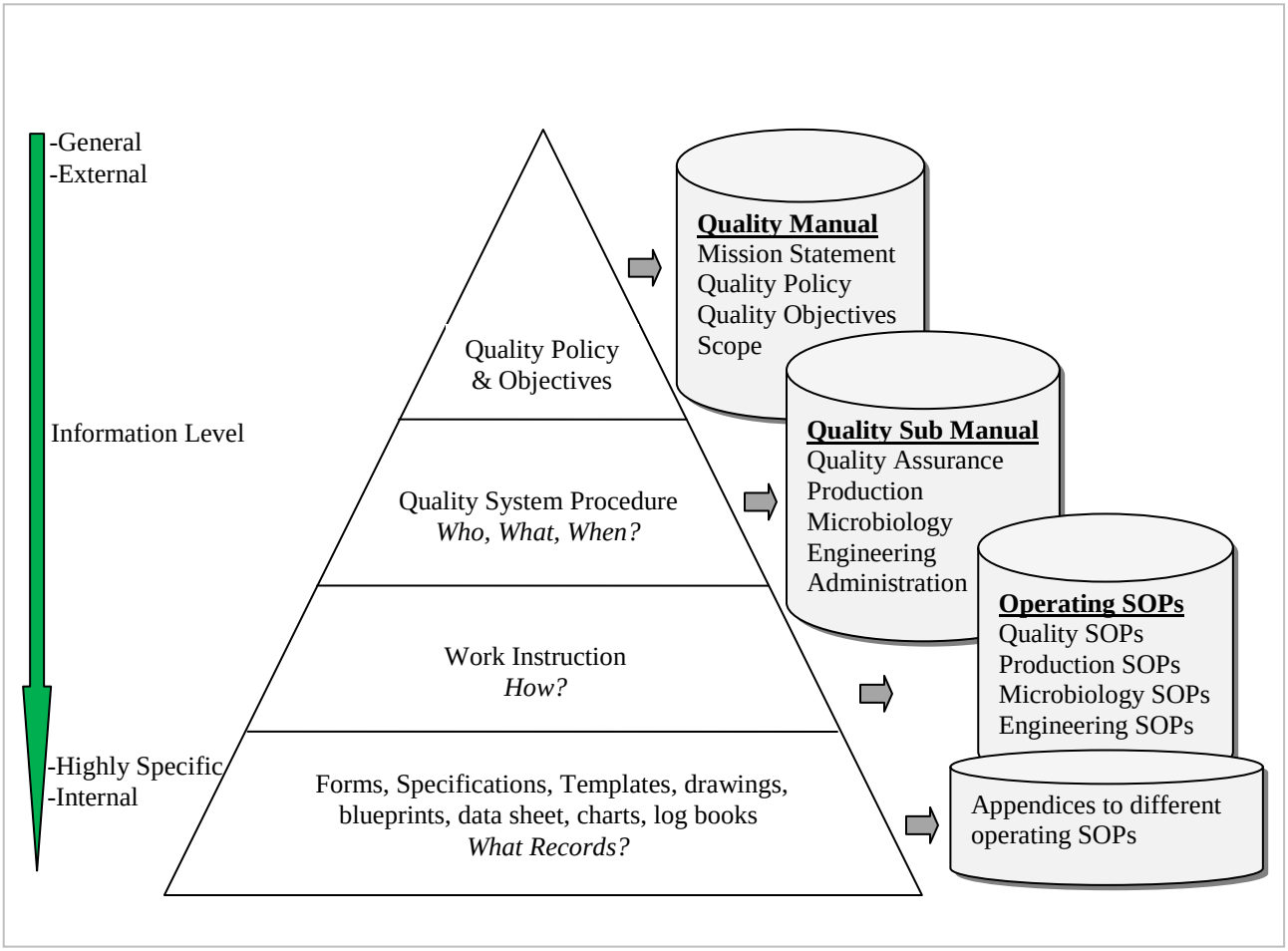


Figure 4.6: Documentation pyramid of the FH IOL Lab

4.6.1 Standard Operating Procedure (SOP)

The International Conference on Harmonization (ICH) defines SOPs as "detailed, written instructions to achieve uniformity of the performance of a specific function". A SOP is a written document or instruction detailing all steps and activities of a process or procedure. These should be carried out without any deviation or modification to guarantee the expected outcome. Any modification or deviation from a given SOP should be thoroughly investigated and outcomes of the investigation documented according the internal deviation procedure. A SOP specifies why, who, when, how, where a job is performed.

SOPs form the basis for the routine training program of each staff. The training of staff using SOPs becomes very important, so that staff actually become aware of why and how SOPs can play an important role in fulfilling the required quality standards and other regulatory requirements. SOPs are regularly updated to assure compliance to the regulatory requirements and the working practice. A minimum review schedule of 5 years is mandatory in FH IOL Lab. Changes of SOPs are in general triggered by process or procedural changes / adjustments. The internal change-control procedure manages these changes. Such changes are updated in the related SOP by obsolescing previous SOP. SOPs are in place for all quality systems plus the specific operational activities on site. ISO essentially requires the documentation of all procedures used in any manufacturing process that could affect the quality of the product.

In the FH IOL Lab, there are 5 types of SOPs to scope the areas- production, quality assurance, microbiology, engineering & administration as listed below. These areas cover all the major functions of the FH IOL Lab that have direct or indirect impact on the quality of the product.

- Quality SOPs: quality assurance activities, management review, internal quality audit, non-conformance, corrective action, inspection, customer complaints etc
- Production SOPs: manufacturing activities, measurement of parameters etc
- Microbiology SOPs: microbiological tests and processes
- Engineering SOPs: calibration/maintenance of machines/equipments, validation, drawings, specifications, standards etc
- Administration SOPs: general administration, sales/marketing, procurement, housekeeping, security, job description, organization chart etc

The structure of a SOP used in FH IOL Lab is shown in the figure 4.7.

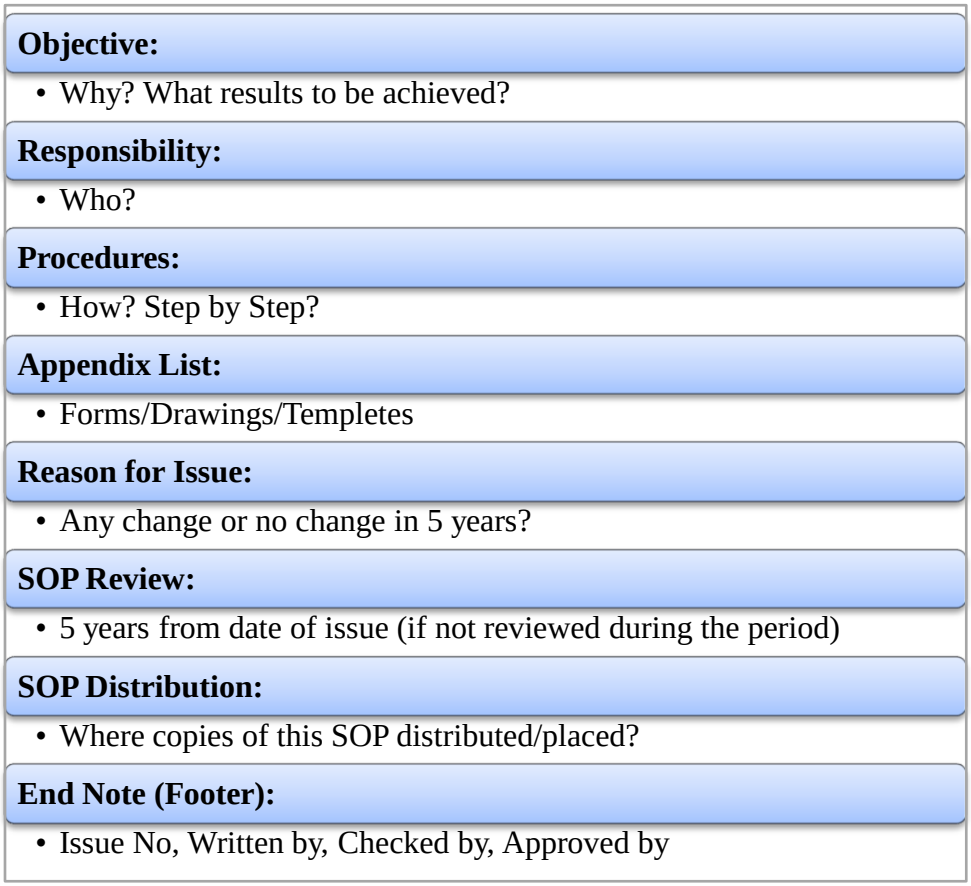


Figure 4.7: Elements of SOP in the FH IOL Lab

A SOP of the FH IOL Lab includes

Objective defines why an activity is done, the purpose of the activity, goal/result to be achieved by doing the activity

Responsibility defines the responsible personnel for the activity to be carried out successfully

Procedures defines step by step method to carry out the activity to lay the guidelines for doing the activity and to ensure the standard way of doing the activity

Appendix list defines no of appendices in the SOP and title of contents in the appendices.

Reason of Issue defines the reason of current issue of the SOP which reveals the details of the change made in the previous SOP. It is mandatory to review the SOP if there is no change in the SOP during 5 years.

SOP distribution defines the places/locations where the copies of the SOP are distributed to control the documents.

End Note (Footer) includes issue no of the SOP, initial in 'written by', initial in 'checked by', and initial in 'approved by' to identify the authorized SOP.

4.6.2 Process Flow with Documentation

The basic processes for FH IOL Lab activities include purchase, receiving, production & sales/shipping. These basic processes are supported by the support processes like quality control checks, maintenance/calibration of machines/equipments and microbiological tests. All the processes- both basic as well as support processes have work instruction as defined by SOP and recording/reference instruments as laid by the appendices of the relevant SOP as shown in the figure 4.8.

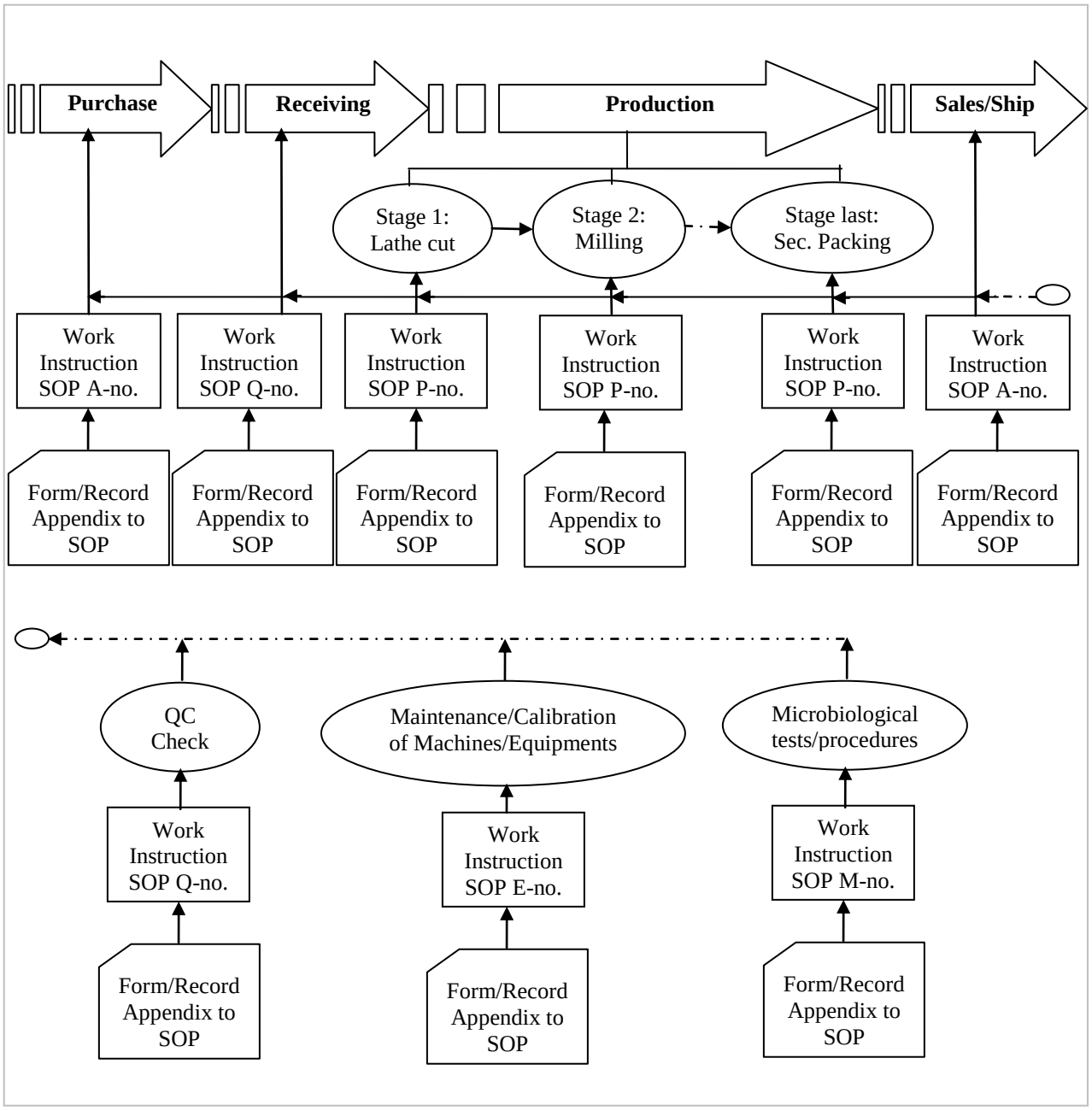


Figure 4.8: Process flow with documentation

4.6.3 Control of Documents

The documents/records in the FH IOL Lab are controlled by controlling the following control elements:

- *Date of preparation/revision*: Each QMS document indicates its preparation date. When a document is revised, the date of revision is indicated in the document.
- *Periodic review of unchanged documents:* It is mandatory to review the SOP if there is no change in the SOP during 5 years.
- *Issue No. for document*: The version/issue no of document is indicated in the document.
- *Approval of document*: New documents and document changes may be initiated by anyone in the organization, but only be issued by authorized personnel. All documents are reviewed and approved prior to issue.
- *Document master files*: The master files are marked by red stamp indicating 'MASTER FILE' to avoid unauthorized duplication of master documents and they are kept in document controller room under the direct supervision of QA manager.
- *Copy documents*: The copy files are marked by blue stamp indicating 'COPY' to avoid duplication of copy documents.
- *Obsolete documents*: The Obsolete master documents are retained and obsolete copy documents are removed from points of use. Retained masters or copies of obsolete documents are marked by red stamp indicating 'OBSOLETE' and they are kept separate from active documents.
- *Document distribution*: Documents are distributed to personnel and locations where they are used. The document displays in itself a distribution list of its copies. Only the most current documents (latest issue) are available to all staff at the locations where they are needed for staff to perform their assigned job tasks.
- *Storage of document*: The documents are stored in steel filing cabinet in document controller room under the direct supervision of QA Manager.
- *Backup of document*: - The master documents and records are backed up with their electronic files.

- *Document generation*: Only document controller generates the copy documents under the direct supervision of QA Manager.
- *Destruction/disposal of documents*: The documents are destroyed by incineration under the direct supervision of QA manger.
- *Records*: Records are legible, recorded in indelible ink, identifiable, and retrievable, and protected against damage, deterioration, or loss.
- *Validity of documents*: Documents are considered valid when they are validated by stamp, initialed, or signed and dated, by authorized personnel.

4.7 Responsibility and Authority

As per requirement of ISO, the FH IOL Lab has established its organizational chart to ensure the authority and responsibility in each position in the organization as shown in the following figure 4.9. The relevant SOPs form the basis for job description in each position in the Lab and the job description of each personnel is clearly communicated through the training on relevant SOPs in the organization.

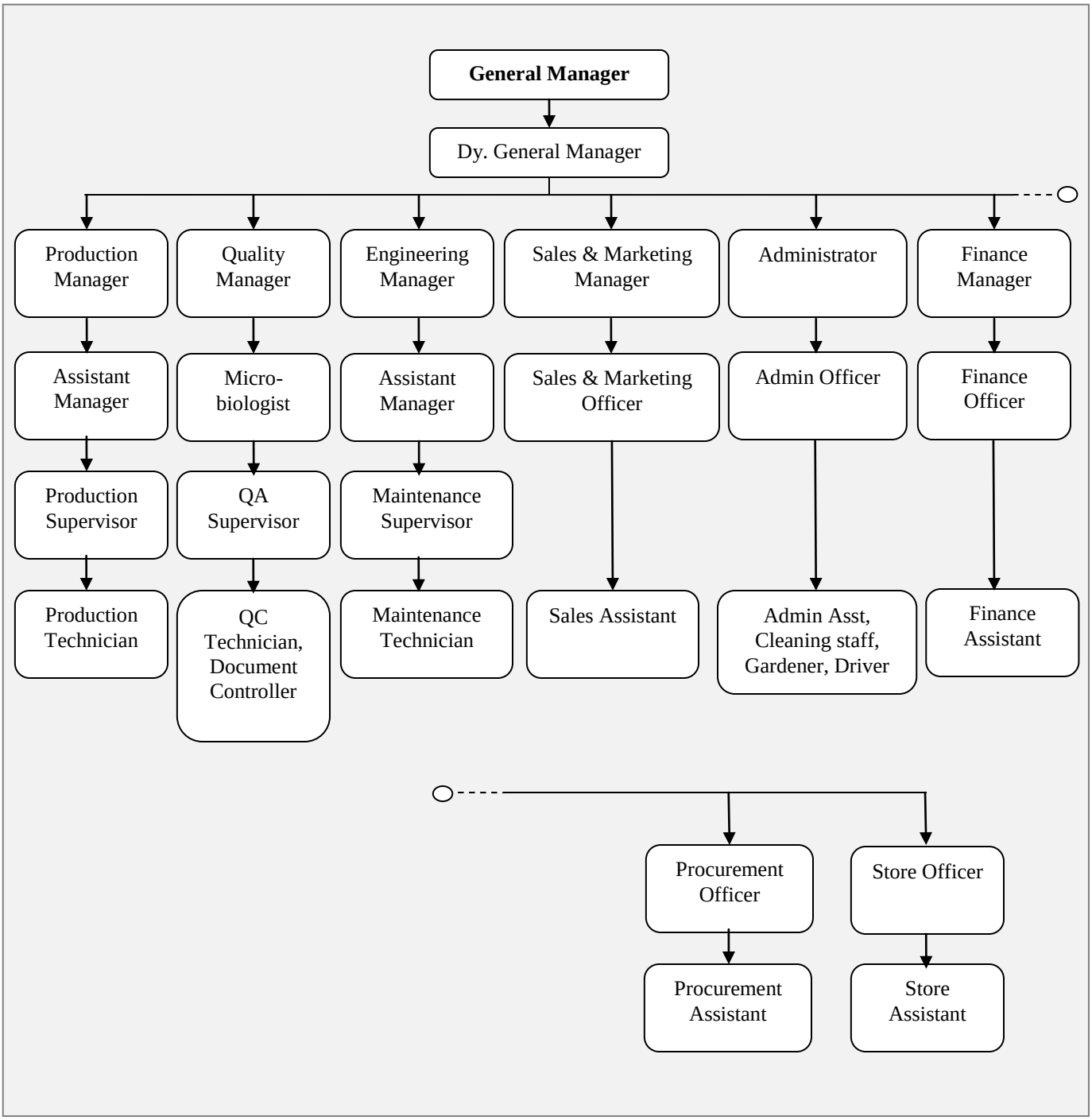


Figure 4.9: Organizational Chart of the FH IOL Lab

The highest position in the organizational hierarchy is General Manager who bears the overall responsibility for the FH IOL Lab and assumes the highest authority within the organization. The General Manager & Deputy General Manager are the members of top level management in the organization. Under them lie middle level managers who are

functional managers as per functions of the organization - Production Manager, Quality Assurance Manager, Engineering Manager, Sales & Marketing Manager, Finance Manager, and Administrator. These functional managers assume the responsibility of their respective functions. Functional managers are supported by assistant managers as per requirements of the organization. Officers & supervisors are the members of lower level management who directly interfere the technicians and other employees responsible for day to day operational works.

The Organizational Structure in FH IOL Lab includes a separate department called Quality Assurance (QA) Department which is responsible for overall quality management system (QMS) and implementation throughout the whole organization. The QA Manager is in charge of the department.

Functional organizations, such as Quality Assurance, is responsible for performing and controlling activities to ensure that items and services supplied meet specified quality requirements. Engineering is responsible for performing the various technical functions associated with the specification, design, servicing and replacement of items. Production is responsible for the manufacture, testing, and primary/secondary packaging of lenses. Purchasing is responsible for all procurement services and serves as the primary interface with suppliers. Marketing is responsible for the preparation of offers and for managing customer communications. Each functional organization is responsible for ensuring, to the degree necessary, that its personnel are aware of organizational quality objectives that their activities may support.

Communication channels are established within the organization for internal communication between the various levels and functions regarding the QMS and its effectiveness. The FH IOL Lab conducts two way communications within the organization through:

- Formal/informal meetings
- LAN connected computer system
- Intercom facility

- Internal employee review and evaluation meetings
- Email
- Internal Memo

4.7.1 Management Representative

As per the requirement of the ISO standard, the top management appointed QA Manager as the management representative (MR) of FH IOL Lab. Management Representative is the apparent face of the management, who is responsible for the entire quality management system development and implementation. MR draws support from other functional authorities for system development at functional level and implementation in the functional area. The management representative directly reports to the top management through management review meeting. The role of QA manager as management representative is shown in the following figure 4.10.

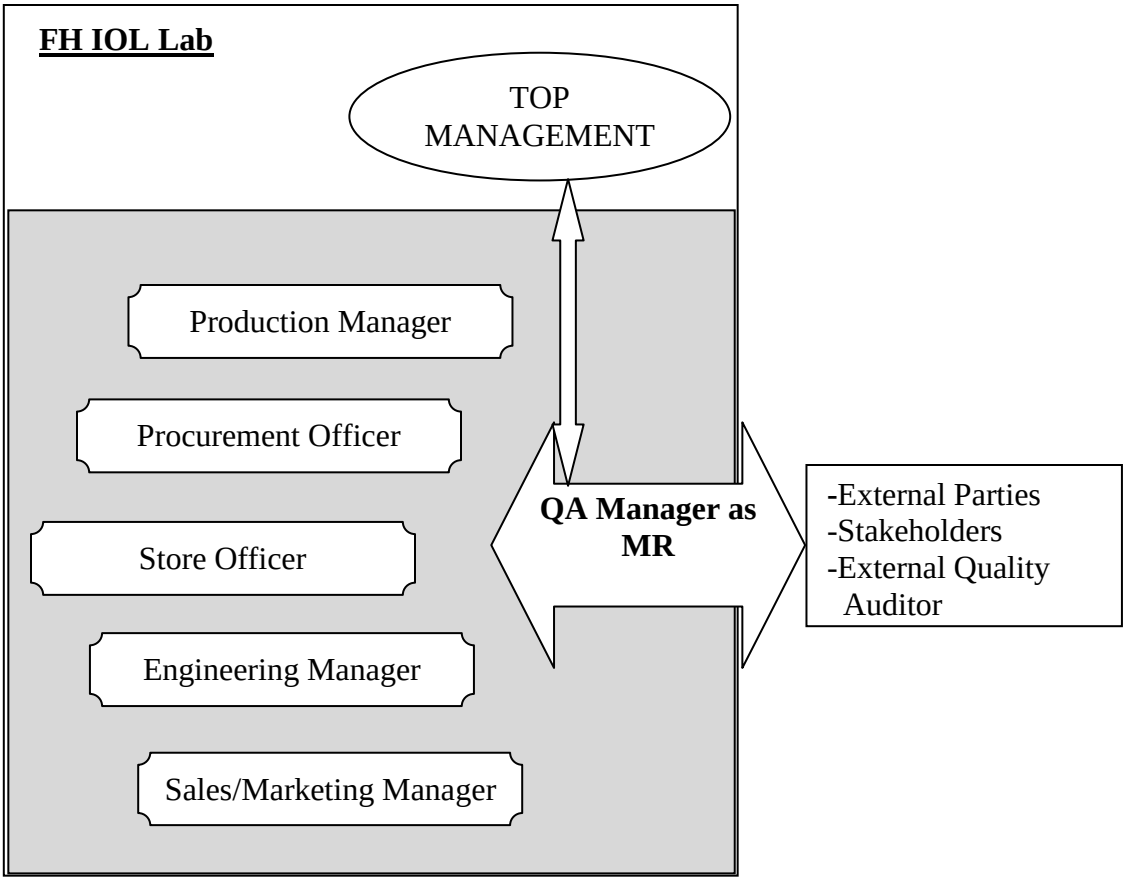


Figure 4.10: Role of QA Manager as Management Representative

The QA manager as management representative assumes the responsibility and authority for:

- ensuring the processes of QMS are established, implemented and maintained;
- reporting to Top Management on the performance of the QMS, including needs for improvement;
- promoting awareness of customer requirements throughout the organization.
- liaison with external parties with external parties on matters relating to the QMS.

4.7.2 Management Review

Management review is the formal evaluation of QMS by the top management in relation to quality policy and objectives. Management Review of FH IOL Lab is held at least twice a year. Management Representative (MR) convenes management review meeting. The members of Management Review meeting are Medical Director, General Manager, Quality Assurance manager, Production Manager, Engineering Manager, Sales/Marketing Manager. Thus the Management Review body ensures the involvement of top management by including Medical Director and General Manager of the FH IOL Lab. These members of top management have overall responsibility for the design and implementation of the laboratory's quality system, for technical operations of the laboratory and for taking decisions resulting from the findings of internal audits and external assessments. The presence of QA Manager is compulsory in management review meeting; else the management review meeting cannot be carried out. QA manager is responsible for ensuring that management reviews are conducted in a systematic manner according to the established procedure defined by the SOP, and that the results of the management review are recorded. The QA manager and respective operational managers are responsible for ensuring that actions identified during the management review are implemented in the planned way within the specified time. For this purpose follow up actions are carried out in every 3 months.

The input to management review includes

- Audit results
- Customer feedback
- Product conformity

- Corrective and preventive actions
- Follow up from previous management reviews
- Training needs identification
- Recommendation for improvement
- Resources requirements

The output of the management review includes actions related to improvement of effectiveness of the quality system.

4.8 Human Resource

4.8.1 Competence, Awareness and Training

In FH IOL Lab, the training needs are recognized in the entry of new employee, introduction of new method/process, change & update of existing method/process, evaluation of Nonconformance.

The purpose of training is to make sure that each employee is qualified for their position on the basis of their education, training, skills, and experience as specified, as appropriate in the job descriptions. The trainings are given to employees by department managers. To determine the effectiveness of training, each employee is reviewed annually by his or her manager to ensure the highest work quality. The results of these reviews are archived in the individual employee's file located in administration. Staff training records are maintained in the individual employee files, which are kept in document controller room.

In the FH IOL Lab, 3 types of staff trainings are recognized- General, Job Specific and Supplementary. *General training* is given to all the employees to make aware of general procedures, general structure and general issue of the Lab. *Job Specific training* is given to an employee to perform his/her day to day work. So, different employees receive different job specific training as per the nature and requirements of his/her particular job. *Supplementary trainings* include retraining, annual general training, skill development training inside and/or outside the Lab, knowledge enhancement training inside and/or outside the Lab.

Annual staff training as supplementary training is given by the QA Manager on the general topics as indicated in the following table 4.5.

Table 4.5: Annual Staff Training on General topics

Category	Topic
General	Staff Training
	Procedures for Visitors
	Deviation Procedure
Authority & Responsibility	Personnel Structure
	Personnel Job Description
Security	Facility Security
Quality System	Quality Manual
General Engineering procedure	Equipment Purchasing, Qualification, Calibration and Maintenance Procedures
Customer complaint	Complaint Procedure
Documentation	Authorized Signatories
	Log Books
Housekeeping	Housekeeping and Hygiene of Non-Production Areas
	Pest Control of Non Production Area
	Laboratory Building and Internal Surface
Health & Safety	Evacuation Procedure
	Evacuation Procedure for ETO Spills
Clean Room	Clothing Standards and Gowning Procedures
	Final Clean Room Operation Procedures
General Production procedures	Manufacturing and QC Flow Chart
Non conformance	Control of Non Conforming Products, Materials and Processes
Improvement Procedures	Corrective Action
	Preventive Action

SOPs form the basis for the routine training program of the staff in the FH IOL Lab. The training of staff using SOPs lays the uniformity by instructions to perform a specific work so that staff actually becomes aware of fulfilling the required quality standards and other regulatory requirements. Every employee of FH IOL Lab must have training on related SOPs to perform the works. No one is authorized to work without training in related SOPs.

4.8.2 Hazards and Staff Safety

All employees receive annual safety training to meet safety requirements. Training includes instruction on emergency response, evacuation procedure, first aid care and hazard communication. Under general training, all the staffs receive 2 safety trainings- i) *Evacuation procedure* in emergency and ii) *Evacuation procedure for ETO spills.* ETO gas is used to sterilize the lenses in ETO sterilization room. It is highly poisonous gas having no odor and no color. The inhalation of ETO gas results reproductive hazards, cancer and even to death. To minimize the spread of ETO gas, sterilization rooms have negative pressure inside. If there is ETO spill in ETO room, as air flows from higher to lower pressure, air flows from other rooms to ETO Room where pressure is negative. So, there is low possibility of spreading ETO gas over other rooms of the lab from ETO room and thus minimizing the risk. ETO room has outlet of air to outside the manufacturing premises. Annual medical checkup of all staff is conducted to ensure good health and their fitness in the job.

In the manufacturing premises inside the FH IOL Lab, physical hazards are particles, chips, temperature, pressure etc. Chemical hazards are environment pesticides, various types of cleaning agents, chemical substances for product maintenance, sterilization, etc. Biological hazards include bacteria, virus, parasite, protozoan and fungi. The hazards in the FH IOL Lab are listed in the following table 4.6.

Table 4.6: Physical, Chemical and Biological Hazards

	Cause for Hazard	**Main activities for possible Hazard**	**Harms due to Hazard**	**Prevention method**
Physical Hazards	PMMA chips, PMMA pieces	Button cutting, Lathe cutting, Milling	Eye, Inhalation, physical wound	Gloves, Masks, Safety Goggles, Vacuum suction at cutting area
	Air Pressure/ Temperature-high/low	Clean rooms	Breathing	Daily monitoring & recording of temperature/pressure, Staff evacuation if out of limit
	Occupational Injury	Processing tools, equipments & machines	physical injury	First aid box
	Fire			Fire Extinguishers
	Earthquake			
Chemical Hazards	Alcohol	Cleaning of clean room facility, Tool sharpening in Milling machine	Allergy	Gloves, Safety Goggles, Masks
	Bactericidal solution	Spraying for sanitization of clean room facility	Allergy, eye	Gloves, Safety Goggles, Masks
	ETO gas	Sterilizing process of lenses in Sterilizer, ETO canister storage in ETO room	Reproductive hazard, Cancer, Death	Negative pressure in ETO room, Gloves, Safety Goggles, Masks, Staff training on Evacuation on ETO spill
Biological Hazard	Bacteria	Incubation of Biological Indicators, Microbiological processes/tests	Bacterial infection	Gloves, Sterilization in Autoclave
	Virus	Personal contact	Viral infection	Viral infected persons are not allowed in the Laboratory

4.9 Infrastructure and Work Environment

The conversion process is carried out in two storeys of the building. The Laboratory is equipped with the latest high-precision Computerized Numerical Control (CNC) machines- CNC Lathe machines & CNC milling machines to develop optical power and shaping the lenses. The lenses are polished in tumble polishing machine to produce superior polished surfaces. Sealing machine is used for primary packing of final cleaned lenses. Sterilizer, Aerator and Autoclave machines are used to free the micro-organisms and to free the residual chemical contents on the lenses. Water plant has been installed for supply of highly purified water inside the lab. HEPA system filters the air and supplies it in the laboratory with required adjustment of temperature and pressure. In-House Microbiology Laboratory is equipped with its own hi-tech microbiological, chemical and physical testing facility to ensure safety & efficacy of its products. The work environment is maintained to ensure that the processes are stable and employees are adequately comfortable.

4.9.1 Clean Room

The Fred Hollows Intraocular Lens Laboratory has been specially designed & constructed with environmental controls to minimize biological and particulate contamination.

A clean room is an environment, typically used in manufacturing or scientific research, that has a low level of environmental pollutants such as dust, airborne microbes, aerosol particles and chemical vapors. More accurately, a clean room has a controlled level of contamination that is specified by the number of particles per cubic meter at a specified particle size. (http://en.wikipedia.org). Clean rooms are frequently found in electronics, pharmaceutical, biopharmaceutical, medical device industries and other critical environments. Sub-micron airborne contamination is generated by people, process, facilities and equipment. The level to which these particles need to be removed depends upon the standards required. The only way to control contamination is to control the total environment. Air flow rates and direction, pressurization, temperature, humidity and specialized filtration all need to be tightly controlled. And the sources of these particles

need to controlled or eliminated whenever possible. Strict rules and procedures are followed to prevent contamination of the product. The air entering a clean room from outside is filtered to exclude dust, and the air inside is constantly re-circulated through high efficiency particulate air (HEPA) and/or ultra low particulate air (ULPA) filters to remove internally generated contaminants.

As per Requirements of AS1386.3, Non laminar flow clean room-Class 350, the following conditions have been maintained inside the FH IOL Lab:-

- HEPA Filter Integrity
- Particles counting
- Air pressure differentials
- Room air changes per hour
- Illuminance
- Sound level

The Laboratory clean rooms comply with Class M5.5 (Class 10,000 US Fed Std 209) clean room standard (AS 1386); while final cleaning and primary packaging of lenses are conducted in class 3.5 (Class 100 US Fed Std 209) Laminar Flow workstations, which provide an essentially particle less manufacturing environment. The assessment of clean rooms in the FH IOL Lab is annually done by Total Air Care, New Zealand. The particle size and maximum no of particles in the Lab are shown in the table 4.7.

Table 4.7: Air Cleanness Class inside the FH IOL Lab

Area	Air Cleanness Class	Maximum no of particles (US System): particle size 0.2 micron (0.0002 mm)	Remarks
Non Production Area/Machine Room	N/A	N/A	Outside environment
General Production Area	10,000 class	10,000 particles per cu.ft.	Clean room environment
Final Cleaning Room	1000 class	1000 particles per cu.ft.	Clean room environment
Laminar Flow Hood	100 class	100 particles per cu.ft.	Clean room environment

Non production area includes Material receiving room (Quarantine room) and change room. General production area includes all the rooms including corridor where manufacturing process is carried out. In final cleaning room, lenses are re-cleaned and re-inspected on the microscope inside the Laminar Flow Hood to check the surface quality and those complying are labeled and primary packed in pouch.

The acceptable no of colonies of bacteria and fungi in the respective areas are listed in the following table 4.8:

Table 4.8: Acceptance Level of micro-organisms inside the FH IOL Lab

Area	Bacteria	Fungi	Remarks
Non Production Area/Machine Room	140 colonies	140 colonies	Outside environment
General Production Area	20 colonies	3 colonies	Clean room environment
Final Cleaning Room	3 colonies	1 colony	Clean room environment

For the maintenance of clean room environment in the manufacturing areas, following monitoring activities are performed:

- Every 2 months air bio-burden, surface bio-burden and product bio-burden tests are performed and results of the tests are recorded. Air bio-burden tests are conducted to count the micro-organisms like bacteria and fungi in the clean room

environment and surrounding rooms. Surface bio-burden tests are performed on the floors of clean rooms and surface of working tables. Product bio-burden tests are performed on final cleaned lenses, rinse water in final cleaning, lens case etc.

- The materials/components, which are used during the manufacturing process and that have direct interface with the product, are purchased from clean room manufacturers to avoid the contamination from incoming materials/components.
- The temperature inside the clean rooms is maintained within the range 15ºC to 25ºC. Air pressure is maintained to +15 Pa to +25 Pa except sterilization rooms. ETO room and steam sterilization room have air pressure within the range -30 Pa to -45 Pa. Temperature & air pressure are daily recorded by QC Technician with the help of calibrated thermometer and calibrated pressure gauge.
- Food, drinks, medicines, cell phones, pencils are not allowed inside the clean room areas to avoid possible contamination.
- Persons suffering from cold or flu and persons having skin wounds that will contaminate the environment adversely are not allowed to enter.
- Persons with personal clothes are not allowed to enter the clean rooms. There is a change room inside the clean environment before entering other clean rooms. Anyone entering into the clean room has to put on cleaned special dresses to cover from head to foot. One has to put on the full head cover to cover the head, the coverall dress to cover the body, the overshoes to cover the legs and gloves to cover the hands. Only 4 persons at a time are allowable in the change room to prevent the excessive flow of humans.
- Every Friday, all production areas including clean rooms as well as other surrounding general rooms are thoroughly cleaned. All areas wall, ceiling, floor, equipments/instruments, furniture are cleaned by cleaning materials and solutions & then the rooms are sanitized through spraying bactericidal solution. The main objective of weekly cleaning and sanitizing is to reduce chemical, biological and physical contamination in the manufacturing environment. Moreover, personnel clothing are also cleaned every Friday by laundry staffs.
- Periodic inspections are conducted on physical facilities inside the FH Lab and immediately repaired if defects observed.

- The water system continually circulates highly purified water in the Lab. Every day chemical tests like PH scale and conductivity tests are performed on supplied water. Moreover, every 2 months the supplied water is tested for its chemical properties and biological contamination. The chemical tests include testing for PH scale, conductivity, chlorine and nitrate. The biological tests include test for bacteria and fungi on supplied water.
- Entry in the clean room is strictly prohibited. Only the authorized personnel are allowed to enter the clean room. To avoid unauthorized entry digital lock system has been installed in the door and access code is given to only authorized personnel of the lab. General public and even employees other than production, quality assurance and engineering department have no access to clean room.
- An emergency exit door has been established with direct link from the corridor of the clean room so that staffs have direct access to outside in case of emergency.
- High efficiency particulate air (HEPA) filters supply the air inside the clean room with clean and conditioned air. This air is not reused. It is exhausted after one pass. During the exhaust process, the clean air from all clean room flows to sterilization room where air pressure is maintained negative and the air is exhausted outside through sterilization room. This minimizes exposure to exhaust air thus minimizing the contamination in the clean rooms.
- Closed laboratory rooms have glass in the doors and often have extra windows for workers' safety and allow visitors to tour the laboratory without having to enter work areas.

4.10 Calibration, Maintenance and Validation

Routine calibration is conducted on inspection, measuring, and test equipments. The results of calibration must be within the specifications required of the application for which the equipment is used. Failure to meet these specifications requires that the equipment be removed from service and clearly labeled as “Out of Service” until repaired. When returned to service, such equipment must be calibrated, verified, and the calibration documented. Calibrated equipment is visibly tagged or labeled by ‘Calibration

Label', indicating the last calibration date and expiration date. This label also has the authorized signature of the person that performed the calibration. Calibration labels are used on all required machines/equipments to alert operators that calibration is adequate or due. If calibration is overdue, operators are to immediately alert quality assurance and suspend use of the equipment until calibration is completed. However, it is the responsibility of each operator to check equipment calibration status prior to each measurement. Safeguarding Calibration labels and/or seals are placed in an appropriate location to prevent adjustments. If the label/seal is broken, the calibration becomes invalid, and the equipment may not be used until recalibrated. Operators are not allowed to make any adjustments to equipment. All adjustments are under the control of quality assurance. The measurement standards used in calibration in the FH IOL Lab are also externally calibrated through international or national standards. The calibration records with result data are maintained.

Routine maintenance is conducted on machines and equipments to keep the facility in a functional, reliable, and safe condition. 'Maintenance Label' is tagged on the machines and equipments with date of maintenance, due date of maintenance, authorized signature. If maintenance is overdue, operators are to immediately alert quality assurance and suspend use of the equipment until maintenance is completed.

Introduction of new machines/equipments and new processes in the FH IOL Lab requires validation prior to use in normal process to prove that the new machines/equipments and the introduced processes have ability to achieve the planned results. In validation, test products are processed in controlled conditions and the results are inspected. 3 types of validation are conducted in machines: i) *Installation Qualification* for physical properties like wiring, ii) *Performance Qualification* for the specifications claimed by the supplier/manufacturer; and iii) *Operational Qualification* for the requirements of the FH IOL Lab. Revalidation of the machines is performed in defined interval as per requirements and importance. Records of validation and revalidation are maintained.

4.11 Product Realization, Inspections and In-Process Quality Checks

Management group of FH IOL Lab is responsible for the planning of product realization. The raw material in the manufacturing process is the PMMA sheet which is converted into intra-ocular lens as finished product. The conversion process has many stages of manufacturing verified by various quality control checks as shown in the figure 4.11.

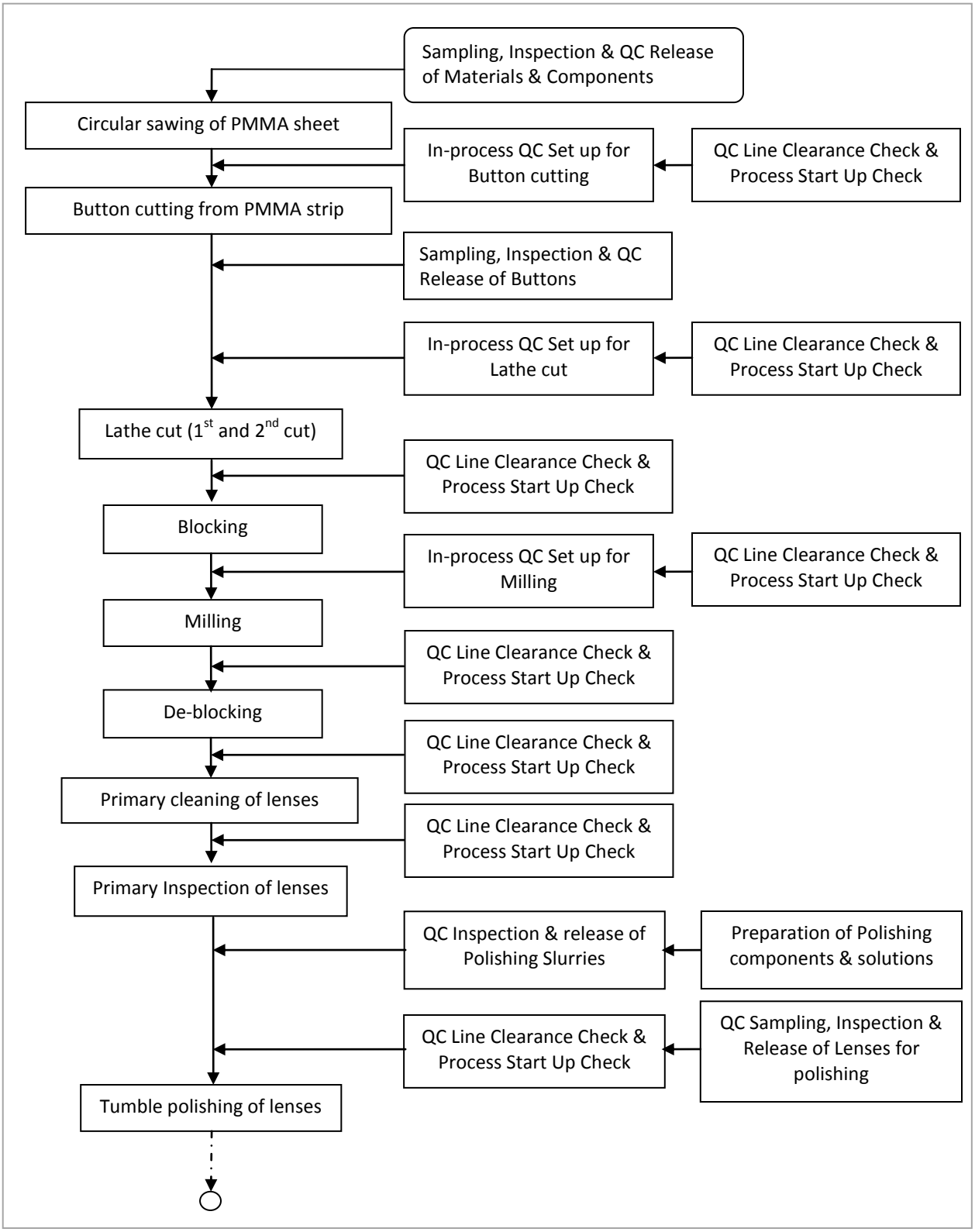


Figure 4.11: Manufacturing & Quality Control Flow Chart (1 of 2)

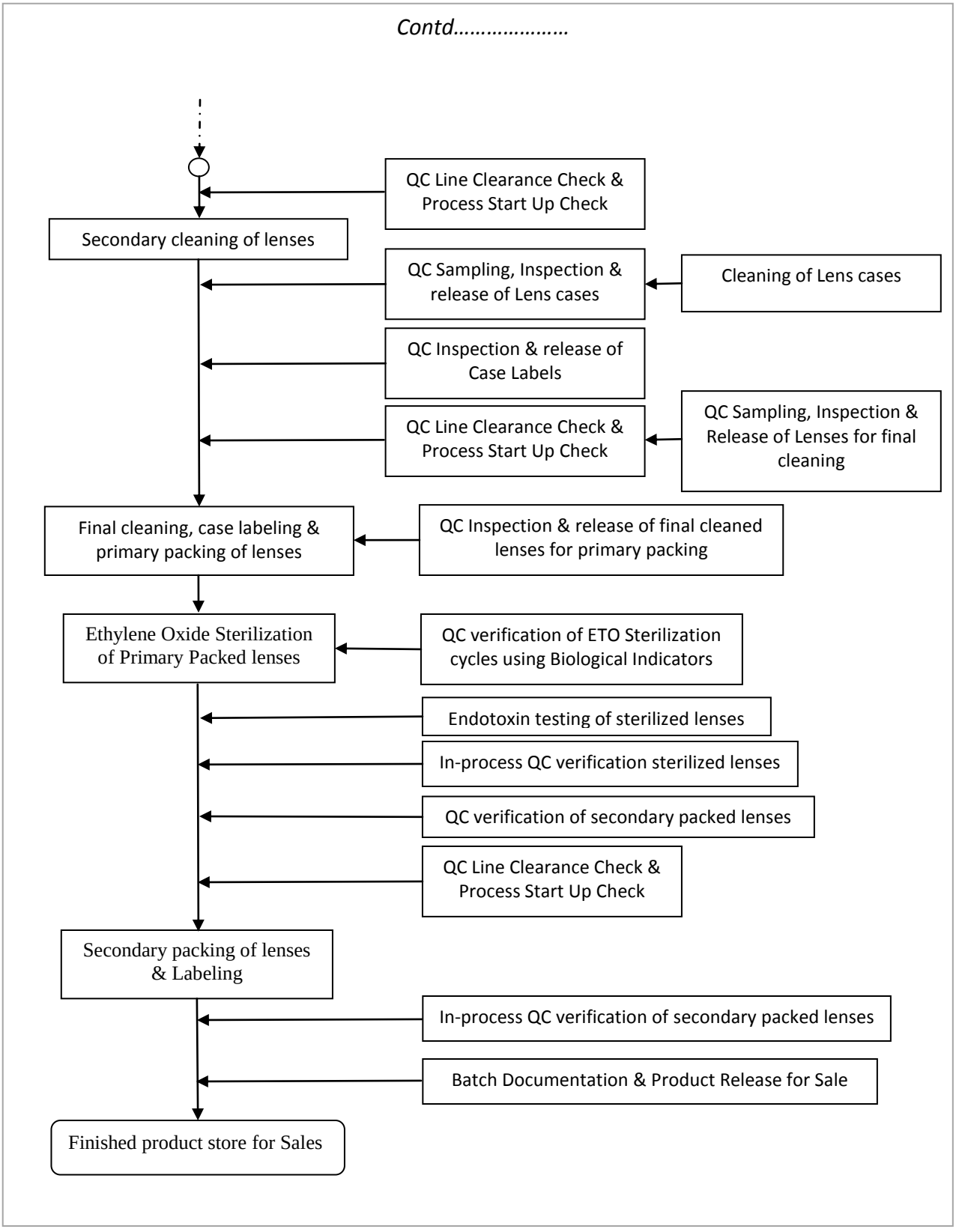


Figure 4.11: Manufacturing & Quality Control Flow Chart (2 of 2)

The major manufacturing stages are briefly described below:

Button cutting: Buttons are cut from PMMA sheets.

Lathe cutting: Both sides of the buttons are cut by a computer controlled diamond tool. The centre of the buttons reveals a convex optic on both sides. It is the stage of generation of optical power measured in focal length.

Blocking: The lathe cut lens is blocked with optical wax on metal block.

Milling: It is the shaping/profiling of the lens. The perplex surrounding the optic is with a high speed steel tip, leaving only the "arms"- known as haptics- used to hold the lens in place in the eye.

De-blocking: Deblocking process is carried out to detach the lenses from the block by dissolving the wax with hot water.

Primary cleaning: Lenses are primary cleaned and checked for a number of characteristics, including scratches, centre uncut, lathe mark, edge quality. Its main purpose is to remove particles, chips, dust, stain, wax residue for smooth polishing.

Primary Inspection: Haptic thickness is inspected with the help of calibrated Drop Indicator and back focal length long with resolution is inspected for whole batch with the help of calibrated Lens bench. With focal length, the optical power of the lenses is verified whereas resolution of the lens gives visual clarity.

Polishing: Lenses are polished with polishing slurry by tumbling on tumbling machine to smooth the surface of the lens.

Secondary cleaning: The lenses are secondary cleaned and checked individually for surface quality.

Final Cleaning and Primary Packing: Final clean is the last station to check the surface quality of the lenses and it is primary packed in labeled pouch. Polished lenses are re-cleaned & re-inspected on the microscope inside the Laminar Flow Hood and those complying are placed in lens case, labeled & packed in the pouch.

ETO Sterilization: It is the process to free micro-organisms present on the lenses by exposing Ethylene oxide gas. Sterilization is followed by Aeration process, which is washing away the residue of ETO contents on the lenses by air circulation under compressed air pressure. It is carried out for 7 hours in Sterilizer and aerated for 48 hours in aerator.

Secondary Packing: Lenses are packed in a box and released for sale.

4.11.1 QC Line Clearance, Process Startup and Setup Checks

As shown in the figure 4.12, in-process QC checks are performed by QC technician in every stage of production prior to normal production work. In-process QC checks are required while beginning the work, issuance of new batch, change of employee to work. The production technician cleans the workstation and removes all the unnecessary batches and materials. The quality control technician performs line clearance check by inspecting the workstation and if found satisfactory, the workstation is approved for use by QC signature. After getting approval from QC Technician, lenses/semi-products, necessary materials for processing, Batch Record, necessary labels are brought to the workstation. Then the QC Technician performs process start up checkup which includes verifying of dioptre, model, quantity of lenses/semi-products; material no, expiry date, QC Release status of materials; recording of the detail in Batch Record. If everything is alright, the QC Technician approves for starting work. For machinery processing of lenses/semi-products, some samples are cut by setting up required parameters. The setup parameters are measured and recorded in Batch Record.

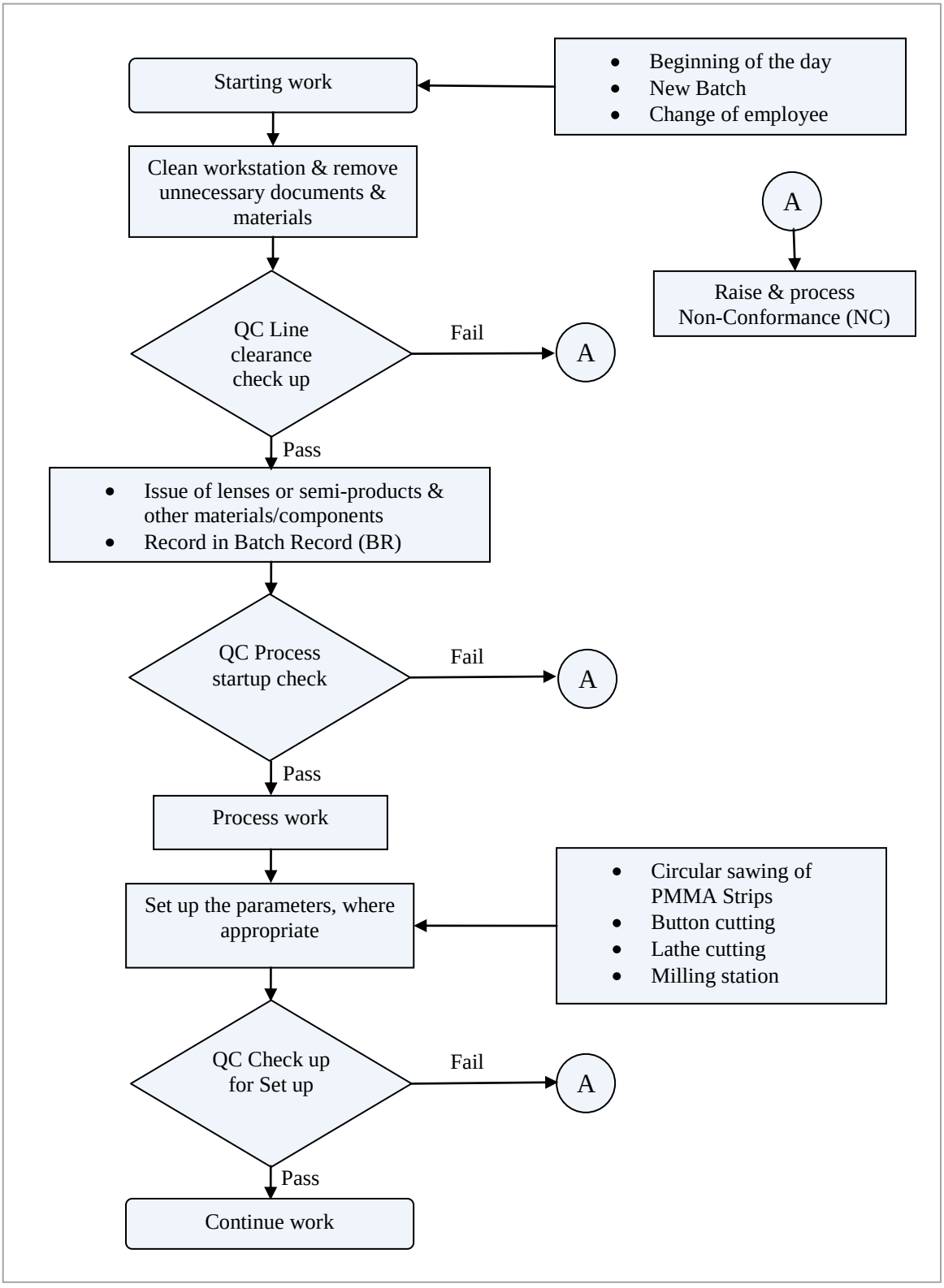


Figure 4.12: QC Line Clearance, Process startup and Setup checks

4.12 Customer

The FH IOL lab defines a customer as a distributor, a non government organization, a private or public hospital, medical institution, an individual doctor or surgeon.

4.12.1 Customer Communication and Sales Procedure

Customers are communicated and feedbacks are taken through questionnaires, telephone, visiting etc. During the process of information search about the product, customers come into contact with the Lab through websites, national & international conference/seminar, and personal contacts. Then the customers make inquiry about the products through email, telephone, fax, and letter. The sales/marketing department replies to the customer about the details of the products. If the customer is satisfied with the product, purchase order is placed by the customer. The order form is filled up and performa invoice is issued to the customer. The ordered lenses are packed in shipping cartons and packing list is made accordingly. The packed lenses are verified by QA Manager for the dioptre, model, expiry date, batch no, carton/bundle no etc by comparing with the packing list. If found satisfactory, lenses are released for sale and ‘QC release’ labels are affixed on the cartons. Then final invoice is prepared. The lenses are insured and shipped to the customer with packing list and the invoice. If found any error during the process, non-conformance is raised to handle the same. The sales procedure is illustrated in the following figure 4.13.

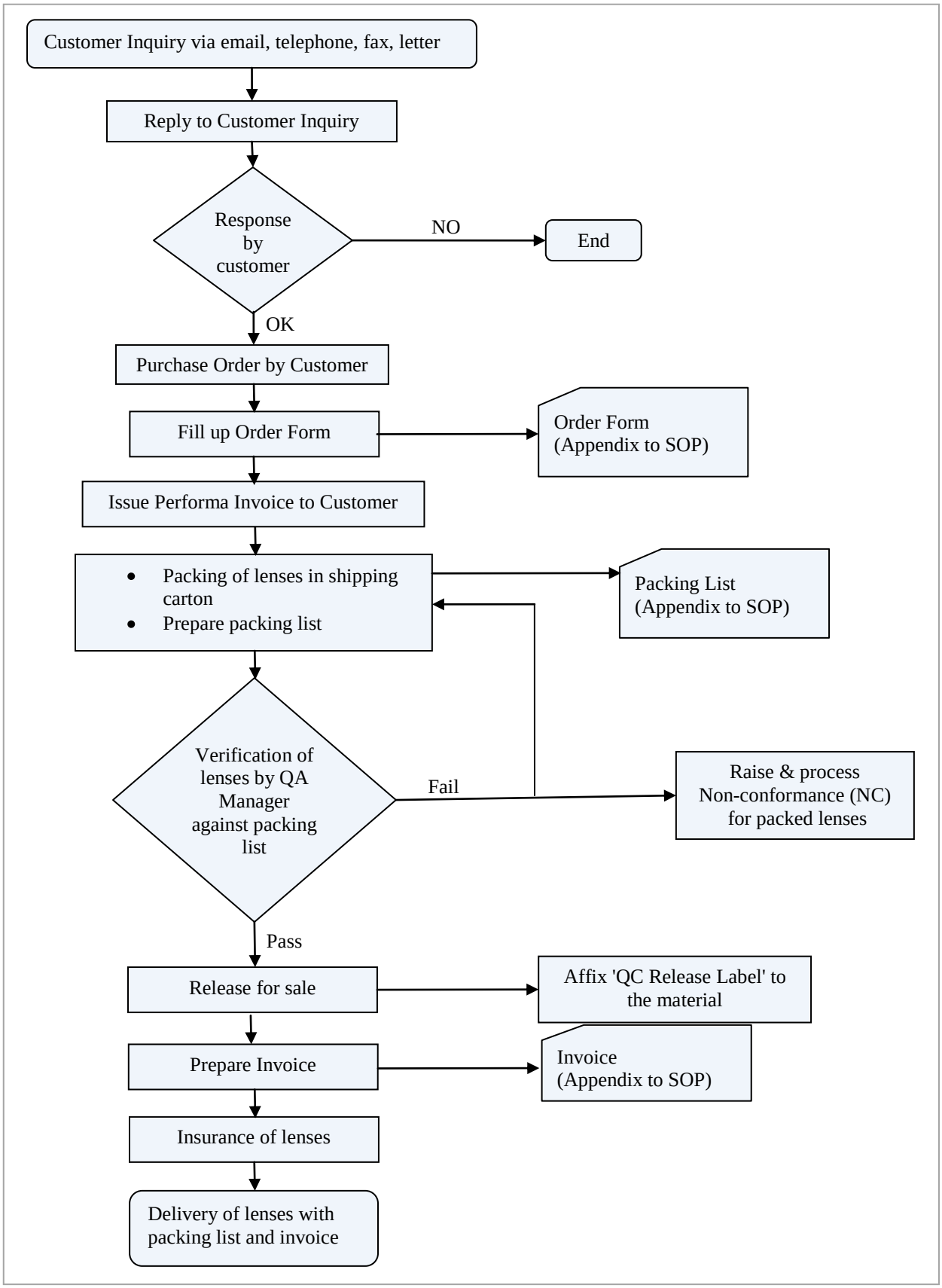


Figure 4.13: Sales procedure in the FH IOL Lab

4.12.2 Customer Complaints

The QA Manager is responsible for handling the customer complaints. For handling complaints of customers, a separate SOP defines the instructions in the FH IOL Lab. After receiving customer complaint, a unique identification number – Customer Complaint no is registered in the Customer Complaint Log Book and a customer complaint form is sent to the customer to fill up revealing the following details:

- Identify model, batch no, serial no. etc
- Source of complaint (customer name, address, phone/fax)
- Packaging components etc.

If sample is available for the complaint, sample analysis is performed and results are recorded in sample analysis form. Sample analysis includes microscopic and macroscopic analysis to find out the root cause of the problem. *Microscopic analysis* refers to measurement of various parameters of the lens whereas *macroscopic analysis* refers to physical observation of the lens and packaging conditions. A report is prepared on the basis of the sample analysis and one copy of the report is sent to the customer.

Table 4.9 shows the no of customer complaints received for 5 years from 2005 to 2009 with the sales figures.

Table 4.9: Customer complaints and sales volume (2005-2009)

Year	Sales volume	No. of Customer complaints
2005	193455	1
2006	176432	0
2007	208141	0
2008	241993	0
2009	294864	0
Total	**1114885**	**1**

In 2005, one customer complaint was registered while the sales volume of lenses was 193,455 units. In the following years from 2006 to 2009, there was no customer complaint in relation to the sales units 176,432, 208,141, 241,993 & 294,864 respectively.

4.12.3 Customer Satisfaction

Customer satisfaction survey, both national as well as international is conducted once a year by sales & marketing team through questionnaires which are sent via email, mail post, hand delivery. The no of questionnaires sent, the no of questionnaires returned and response rate during 5 years from 2005 to 2009 are shown in the following table 4.10.

Table 4.10: Customer Satisfaction Survey and Response Rate (2005-2009)

Year	Questionnaires sent	Questionnaires returned	Response Rate	Remarks
2005	-	10	-	Top 10 customers
2006	-	10	-	Top 10 customers
2007	20	8	40%	
2008	19	9	47%	
2009	21	10	48%	

In 2005 total 10 questionnaires from top ten customers were analyzed. Similarly in 2006 also total 10 questionnaires from top ten customers were analyzed. In 2007 total 20 questionnaires were sent by the sales/marketing department for customer satisfaction survey and out of 20 questionnaires, only 10 questionnaires were returned from the customers. In 2008 only 9 questionnaires were returned out of total 19 questionnaires sent. In 2009 total 21 questionnaires sent for the customer survey purpose and 10 questionnaires were returned. In the year 2005 and 2006 the numbers of questionnaires sent are unknown, but questionnaires from top ten customers were analyzed and reported. The customer response rate in 2007, 2008 & 2009 are 40%, 47% & 48% respectively.

In the customer satisfaction survey, the questionnaire contained 7 attributes, and 5 point rating scale was used to measure against these attributes as shown in the table 4.13. The reports from the customer satisfaction survey from the years 2005 to 2009 have been summarized in the following table 4.11.

Table 4.11: Customer Satisfaction Survey Report (2005-2009)

		Performance (Mean point)				
SN	**Attributes**	**2005**	**2006**	**2007**	**2008**	**2009**
1	Product Quality	4.70	4.30	4.37	4.11	4.10
2	Product Delivery	4.50	3.80	3.75	4.00	3.80
3	Attentiveness to Complaints	4.40	4.10	4.12	3.50	3.71
4	Relationship	4.50	4.33	4.00	4.22	4.70
5	Shipping packaging	4.50	4.44	4.70	4.11	4.40
6	Product packaging	4.60	3.88	3.25	3.77	4.00
7	Price vs Quality	3.70	4.11	4.00	4.00	3.60
	Total	**30.90**	**28.96**	**28.19**	**27.71**	**28.31**
	Overall Mean Rating (Satisfaction Index)	**4.41**	**4.14**	**4.03**	**3.96**	**4.04**
	Percentage on Total point (5)	**88%**	**83%**	**81%**	**79%**	**81%**

Rating Scale:

1	2	3	4	5
Poor	Fair	Average	Good	Excellent

Customer Satisfaction Survey Report 2005

The findings of the customer satisfaction survey report 2005 are illustrated in the figure 4.14.

Figure 4.14: Customer Satisfaction Survey Report 2005

In 2005, the mean value of customer rating for 'Price vs Quality' is the minimum with 3.70 mean whereas the mean value for 'Product Quality' is 4.70 which is the maximum value for the year. The customer rating values for 'Shipping packaging'; 'Relationship' & 'Product Delivery' are the same with 4.50 values. The customer rating mean points for 'Product packaging' & 'Attentiveness to Complaints' are 4.60 & 4.40 respectively. In 2005, the overall mean rating is 4.41 which is 88% of total point 5.

Customer Satisfaction Survey Report 2006

The findings of the customer satisfaction survey report 2006 are illustrated in the figure 4.15.

Figure 4.15: Customer Satisfaction Survey Report 2006

In 2006, the mean value of customer rating for 'Product delivery' is the minimum with 3.80 mean whereas the mean value for 'Shipping packaging' is 4.44 which is the maximum value for the year. The customer rating mean values for 'Price vs Quality', 'Product packaging', 'Relationship', 'Attentiveness to Complaints' & 'Product quality' are 4.11, 3.88, 4.33, 4.10 & 4.30 respectively. In 2006 the overall mean rating is 4.14 which is 83% of the total point 5.

Customer Satisfaction Survey Report 2007

The findings of the customer satisfaction survey report 2007 are illustrated in the figure 4.16.

Figure 4.16: Customer Satisfaction Survey Report 2007

In 2007, the mean value of customer rating for ‘’Product packaging’ is minimum with 3.25 mean whereas the mean value for ‘Shipping packaging’ is 4.70 which is the maximum value for the year. The customer rating values for ‘Price vs Quality’ and ‘Relationship’ are the same with 4.00 values The customer rating mean values for ‘Attentiveness to Complaints’, ’Product Delivery’ & ‘Product quality’ are 4.12, 3.75 and 4.37 respectively. In 2007 the overall mean rating is 4.03 which is 81% of the total point 5.

Customer Satisfaction Survey Report 2008

The findings of the customer satisfaction survey report 2008 are illustrated in the figure 4.17.

Figure 4.17: Customer Satisfaction Survey Report 2008

In 2008, the mean value of customer rating for 'Attentiveness to Complaints' is minimum with point 3.50, whereas the mean value for ''Relationship' is 4.22 which is the maximum value for the year. The customer rating values for 'Price vs Quality' and 'Product Delivery' are the same with 4.00 values. Similarly, the attributes 'Shipping packaging' and ''Product Quality' have same point as being 4.11. The customer rating mean point for 'Product packaging' is 3.77. In 2008 the overall mean rating is 3.96 which is 79% of the total point 5.

Customer Satisfaction Survey Report 2009

The findings of the customer satisfaction survey report 2009 are illustrated in the figure 4.18.

Figure 4.18: Customer Satisfaction Survey Report 2009

In 2009, the mean value of customer rating for 'Price vs Quality' is minimum with 3.60 mean point whereas the mean value for 'Relationship' is 4.70 which is the maximum value for the year. The customer rating mean values for 'Product packaging', 'Shipping packaging', 'Attentiveness to Complaints', 'Product delivery' and 'Product quality' are 4.00, 4.40, 3.71, 3.80 & 4.10 respectively. In 2009 the overall mean rating is 4.04 which is 81% of the total point 5.

Customer rating for the Attribute 'Product Quality'

Customer ratings for the attribute 'Product Quality' in the customer satisfaction surveys from 2005 to 2009 are illustrated in the figure 4.19.

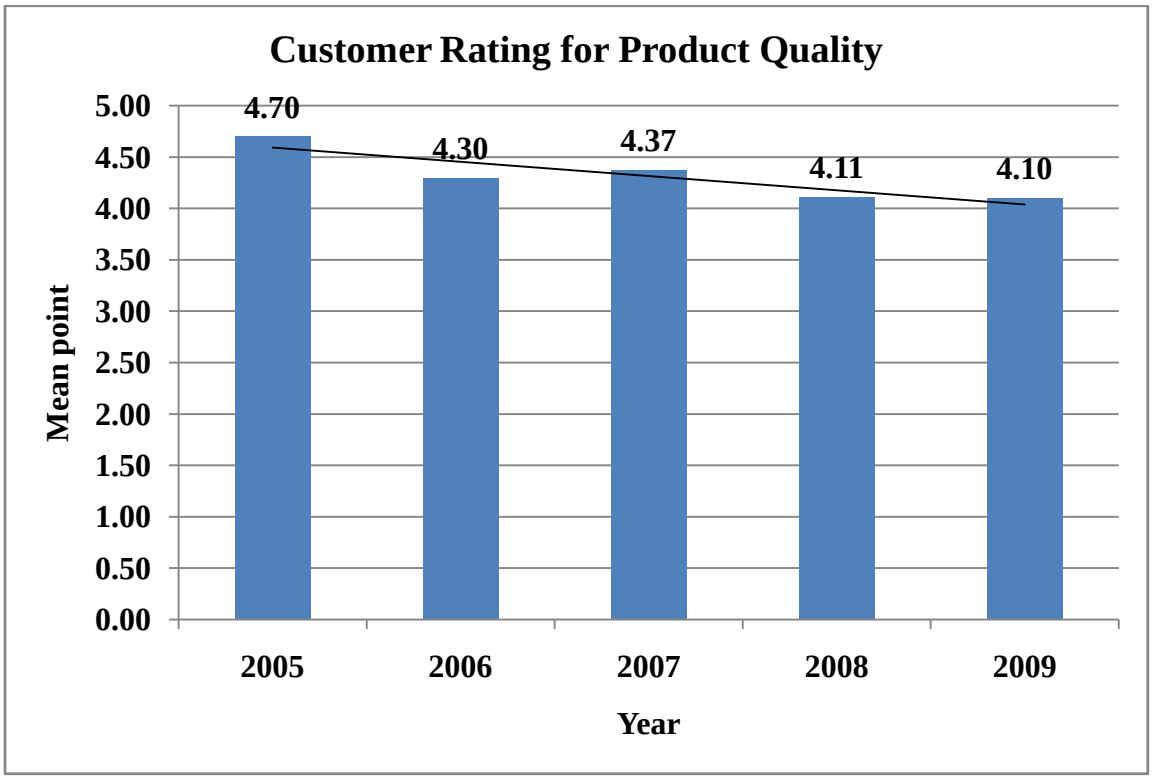


Figure 4.19: Customer rating for the attribute 'Product Quality'

Figure 4.19 shows the customer ratings for the attribute 'Product Quality' in the customer satisfaction surveys conducted in 2005 to 2009. The mean point of customer rating in 2005 is 4.70 which is the maximum value among the five years, whereas the customer rating is minimum in 2009 with mean value 4.10. The trend of customer rating for 'Product Quality' is decreasing as indicated by the trend line in the figure 4.19.

Customer rating for the Attribute 'Product Delivery'

Customer ratings for the attribute 'Product Delivery' in the customer satisfaction surveys from 2005 to 2009 are illustrated in the figure 4.20.

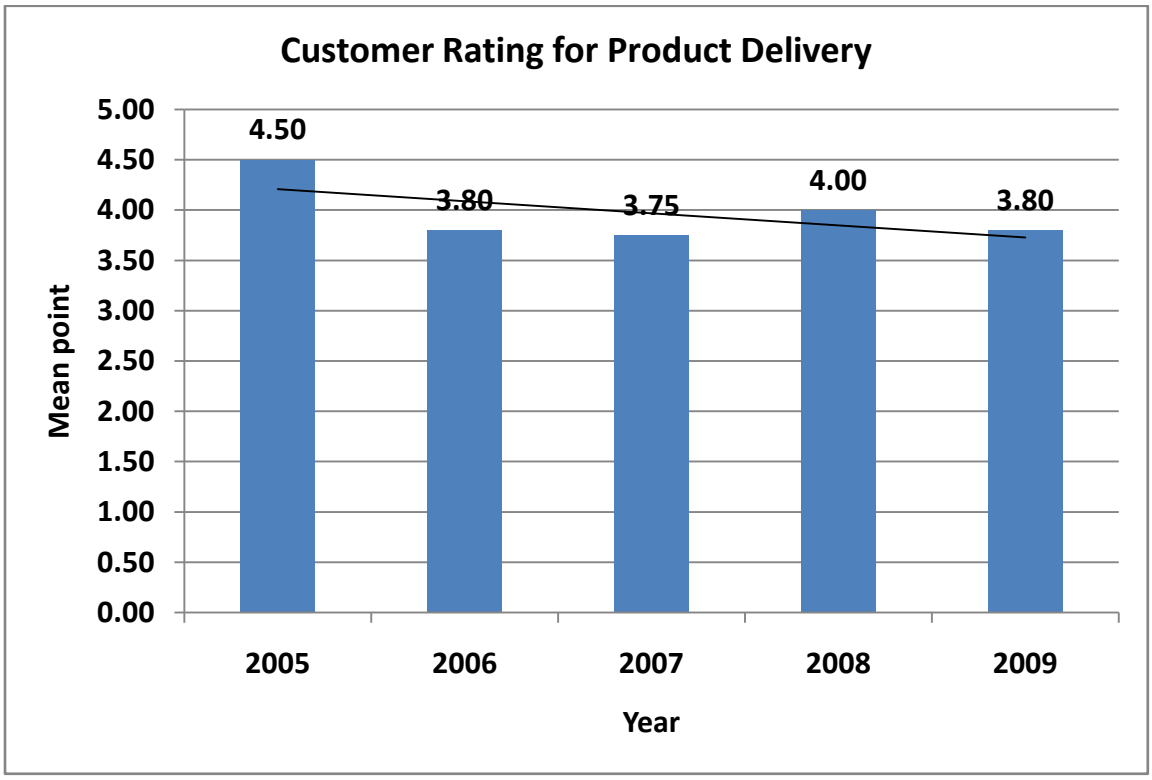


Figure 4.20: Customer rating for the attribute 'Product Delivery'

Figure 4.20 shows the customer ratings for the attribute 'Product Delivery' in the customer satisfaction surveys conducted in 2005 to 2009. The mean point of customer rating in 2005 is 4.50 which is the maximum value among the five years, whereas the customer rating is the minimum in 2007 with mean value 3.75. The customer ratings in the year 2006 and 2009 are the same with 3.80 values. The trend of customer rating for 'Product Delivery' is decreasing as indicated by the trend line in the figure 4.20.

Customer rating for the Attribute 'Attentiveness to complaints'

Customer ratings for the attribute 'Attentiveness to complaints' in the customer satisfaction surveys from 2005 to 2009 are illustrated in the figure 4.21.

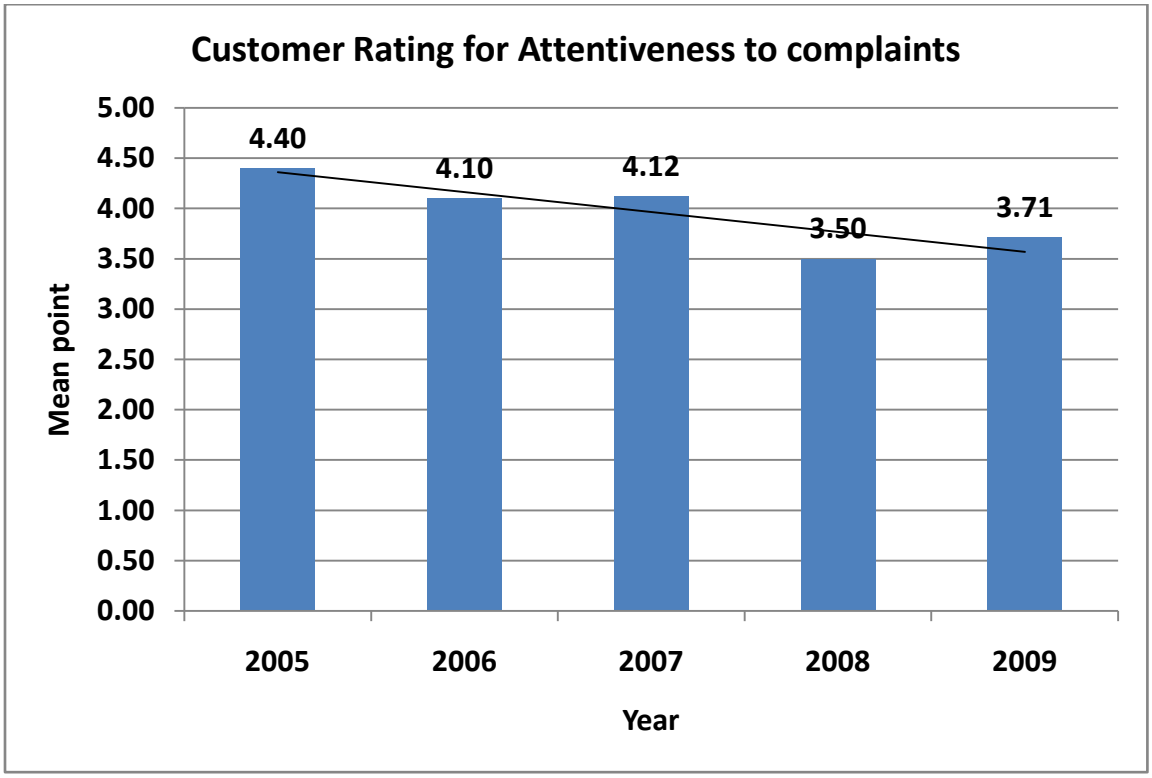


Figure 4.21: Customer rating for the attribute 'Attentiveness to complaints'

Figure 4.21 shows the customer ratings for the attribute 'Attentiveness to Complaints' in the customer satisfaction surveys conducted in 2005 to 2009. The mean point of customer rating in 2005 is 4.40 which is the maximum value among the five years, whereas the customer rating is minimum in 2008 with mean value 3.50. The trend of customer rating for 'Attentiveness to Complaints' is decreasing as indicated by the trend line in the figure 4.21.

Customer rating for the Attribute 'Relationship'

Customer ratings for the attribute 'Relationship' in the customer satisfaction surveys from 2005 to 2009 are illustrated in the figure 4.22.

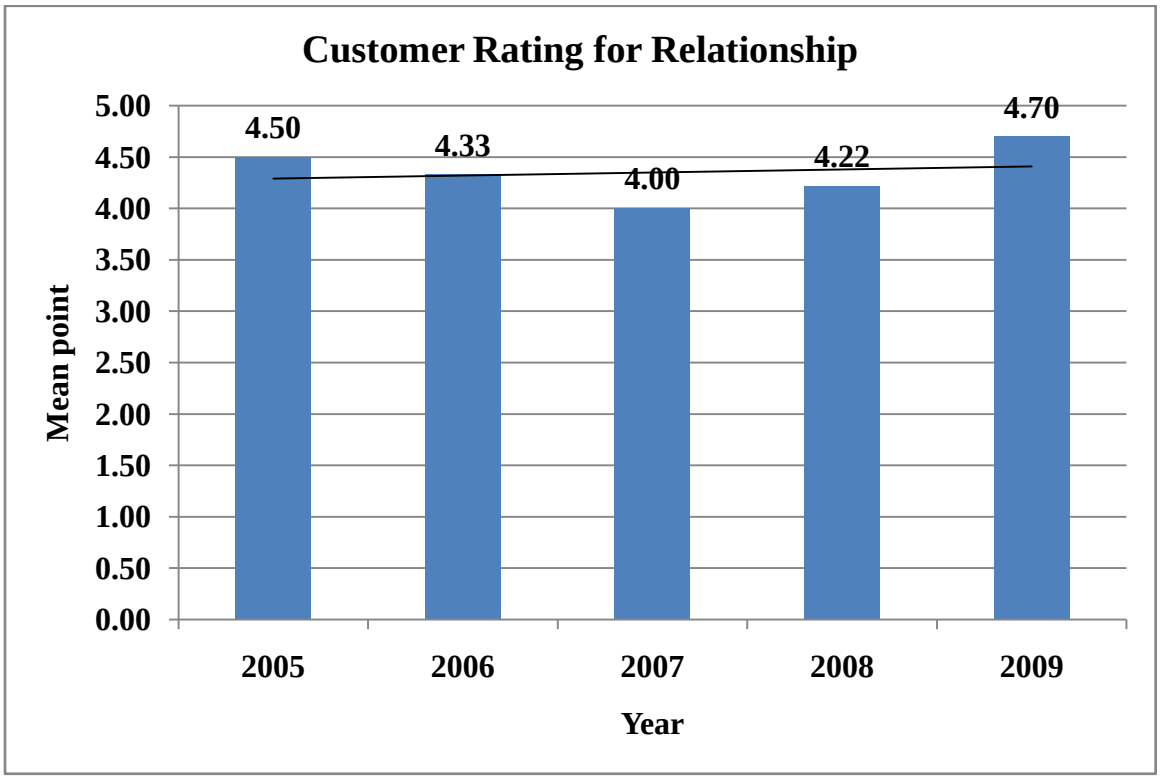


Figure 4.22: Customer rating for the attribute 'Relationship'

Figure 4.22 shows the customer ratings for the attribute 'Relationship' in the customer satisfaction surveys conducted in 2005 to 2009. The mean point of customer rating in 2009 is 4.70 which is the maximum value among the five years, whereas the customer rating for 'Relationship' is the minimum in 2007 with mean value 4.00. The trend of customer rating for 'Relationship' is slightly increasing as indicated by the trend line in the figure 4.22.

Customer rating for the Attribute 'Shipping Packaging'

Customer ratings for the attribute 'Shipping Packaging' in the customer satisfaction surveys from 2005 to 2009 are illustrated in the figure 4.23.

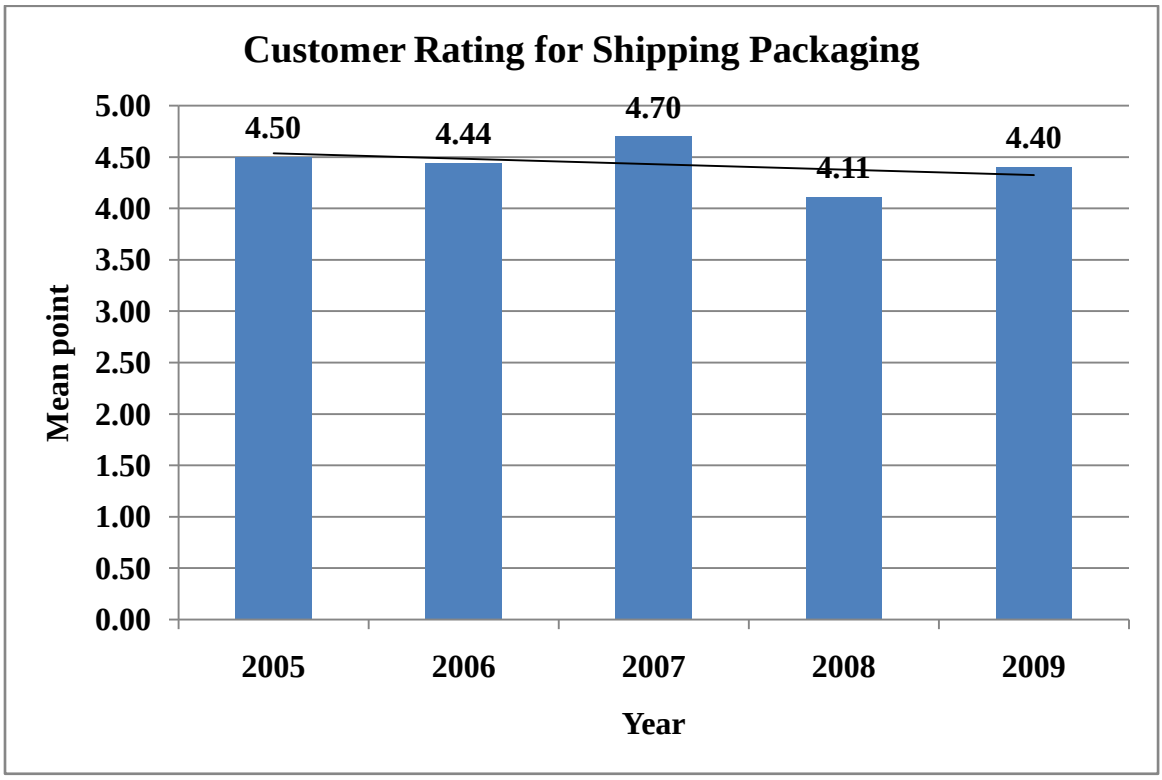


Figure 4.23: Customer rating for the attribute 'Shipping Packaging'

Figure 4.23 shows the customer ratings for the attribute 'Shipping packaging' in the customer satisfaction surveys conducted in 2005 to 2009. The mean point of customer rating in 2007 is 4.70 which is the maximum value among the five years, whereas the customer rating is the minimum in 2008 with mean value 4.11. The trend of customer rating for 'Shipping packaging' is slightly decreasing as indicated by the trend line in the figure 4.23.

Customer rating for the Attribute 'Product Packaging'

Customer ratings for the attribute 'Product Packaging' in the customer satisfaction surveys from 2005 to 2009 are illustrated in the figure 4.24.

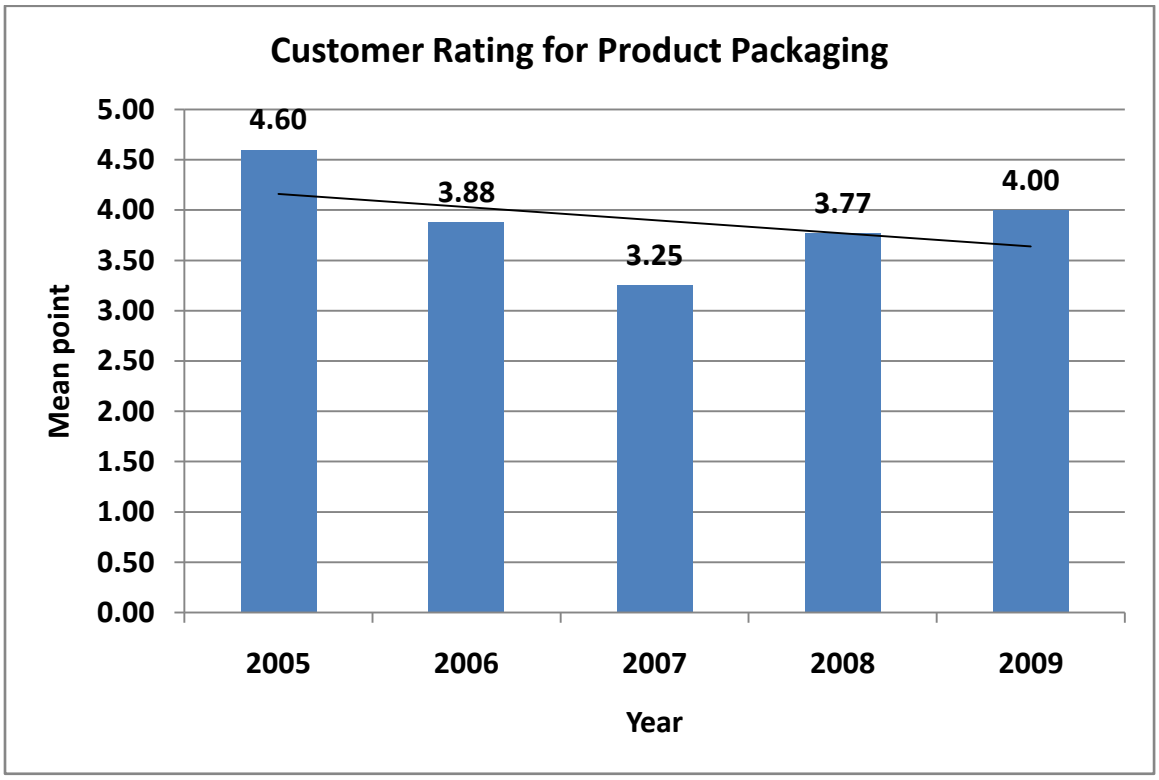


Figure 4.24: Customer rating for the attribute 'Product Packaging'

Figure 4.24 shows the customer ratings for the attribute 'Product packaging' in the customer satisfaction surveys conducted in 2005 to 2009. The mean point of customer rating in 2005 is 4.60 which is the maximum value among the five years, whereas the customer rating is the minimum in 2007 with mean value 3.25. The trend of customer rating for 'Shipping packaging' is decreasing as indicated by the trend line in the figure 4.24.

Customer rating for the Attribute 'Price vs Quality'

Customer ratings for the attribute 'Price vs Quality' in the customer satisfaction surveys from 2005 to 2009 are illustrated in the figure 4.25.

Figure 4.25: Customer rating for the attribute 'Price vs Quality'

Figure 4.25 shows the customer ratings for the attribute 'Price vs Quality' in the customer satisfaction surveys conducted in 2005 to 2009. The mean point of customer rating in 2006 is 4.11 which is the maximum value among the five years, whereas the customer rating is the minimum in 2009 with mean value 3.60. The customer ratings in the year 2007 and 2008 are the same with 4.00 values. The trend of customer rating for 'Price vs Quality' is slightly decreasing as indicated by the trend line in the figure 4.25.

Customer Satisfaction Level

Overall customer satisfaction levels from 2005 to 2009 are illustrated in the following figure 4.26.

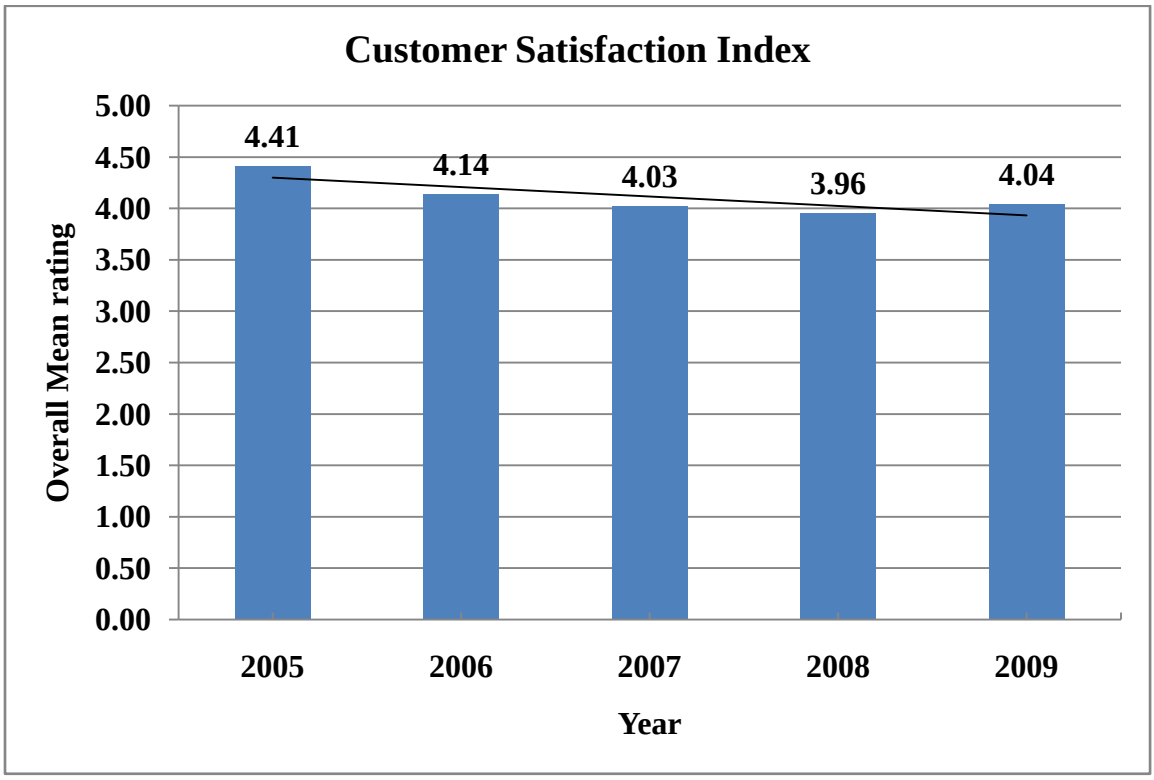


Figure 4.26: Customer Satisfaction Levels (2005-2009)

Figure 4.26 shows the overall customer satisfaction level for 2005 to 2009. The customer satisfaction index in 2005 is 4.41 which is the maximum index value among the five years, whereas the customer satisfaction index is the minimum in 2008 with mean value 3.96. In terms of percentage on total point 5, the customer satisfaction levels for 2005 to 2009 are 88%, 83%, 81%, 79% and 81% respectively. The overall trend of customer satisfaction level is decreasing as indicated by the trend line in the figure 4.26.

4.13 Purchasing

4.13.1 Purchase Process

The FH IOL Lab has identified all the materials, components, reagents needed directly and indirectly for manufacturing process and they are listed with material codes. For each material (material code), a Material Specification Sheet (MSS) has been prepared that includes Material Code, Approved Supplier, Material Specification, Test, Test method, Sampling Plan, Storage condition, Expiry period. The suppliers are approved by the management team. Safety stock is maintained for the materials for uninterrupted availability of reagents, supplies, materials, components to ensure smooth operations. The laboratory also needs to purchase services, such as equipment maintenance and service contracts and referral laboratory testing. For these purposes, the laboratory has formalized its needs and requirements in documented agreements with vendors that specify each party's responsibilities. These agreements are periodically reviewed to determine the vendor's ability to meet the laboratory's needs, and adjusted as necessary.

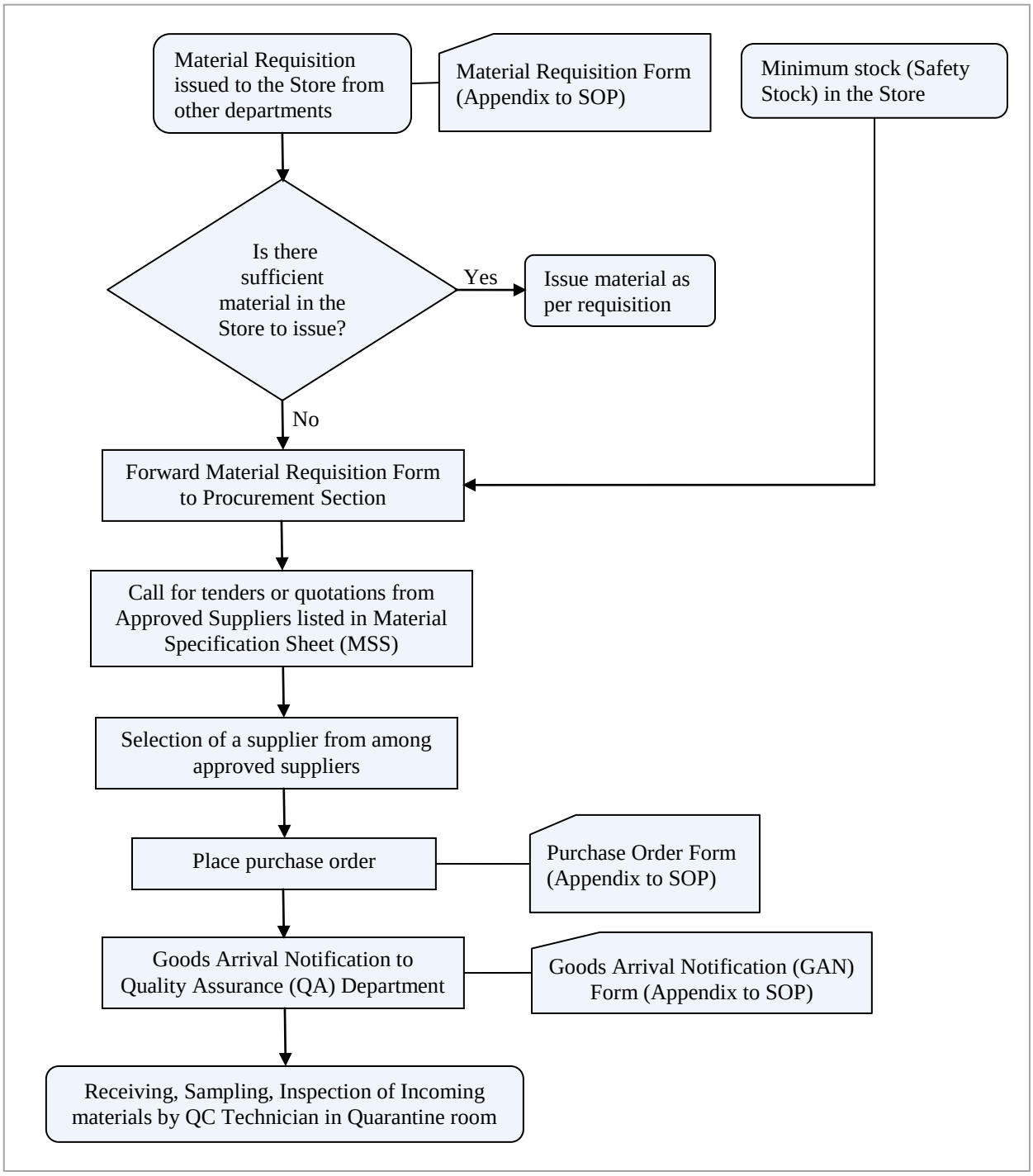


Figure 4.27: Purchase process in the FH IOL Lab

As shown in the figure 4.27, the purchase process begins with the realization of needs of materials, components and services. Material Requisition Form issued to the store and Safety Stock in the store are the inputs for purchase process. The Material Requisition Form is forwarded to the procurement department. The procurement section calls for

quotations/tenders from the approved suppliers which have been already listed in MSS. On the basis of quality, price, service, suitable supplier is selected and purchase order is placed with terms and conditions. After receiving the goods, Goods Arrival Notification is forwarded to QA Department for sampling and inspection of incoming goods as necessary to ensure that necessary quality requirements have been fulfilled before use.

4.13.2 Verification of Purchased Product

In the FH IOL Lab, incoming items are not used or processed until they have been inspected and accepted for use. The incoming materials are received and quarantined. Quarantine is the separation of materials until it is tested to have no negative effect in the quality of products. The materials are sampled and tested for properties and parameters as specified in Material Specification Sheet (MSS). Material Specification Sheet (MSS) includes Material Code, Approved Supplier, Material Specification, Test, Test method, Sampling Plan, Storage condition, Expiry period. The test results are recorded in Analytical Test Record (ATR) which includes Material Code, Material No., Supplier, Sampling, Result of Inspection, Tests compared with MSS. The material properties, usually chemical and biological properties are compared with supplier's Certificate of Analysis (C of A). If all tests meet the specifications, the materials are released for use, otherwise an NC is raised. Wherever appropriate, a sample from the lot is retained for the reference. The verification procedure for incoming materials is illustrated in the figure 4.28.

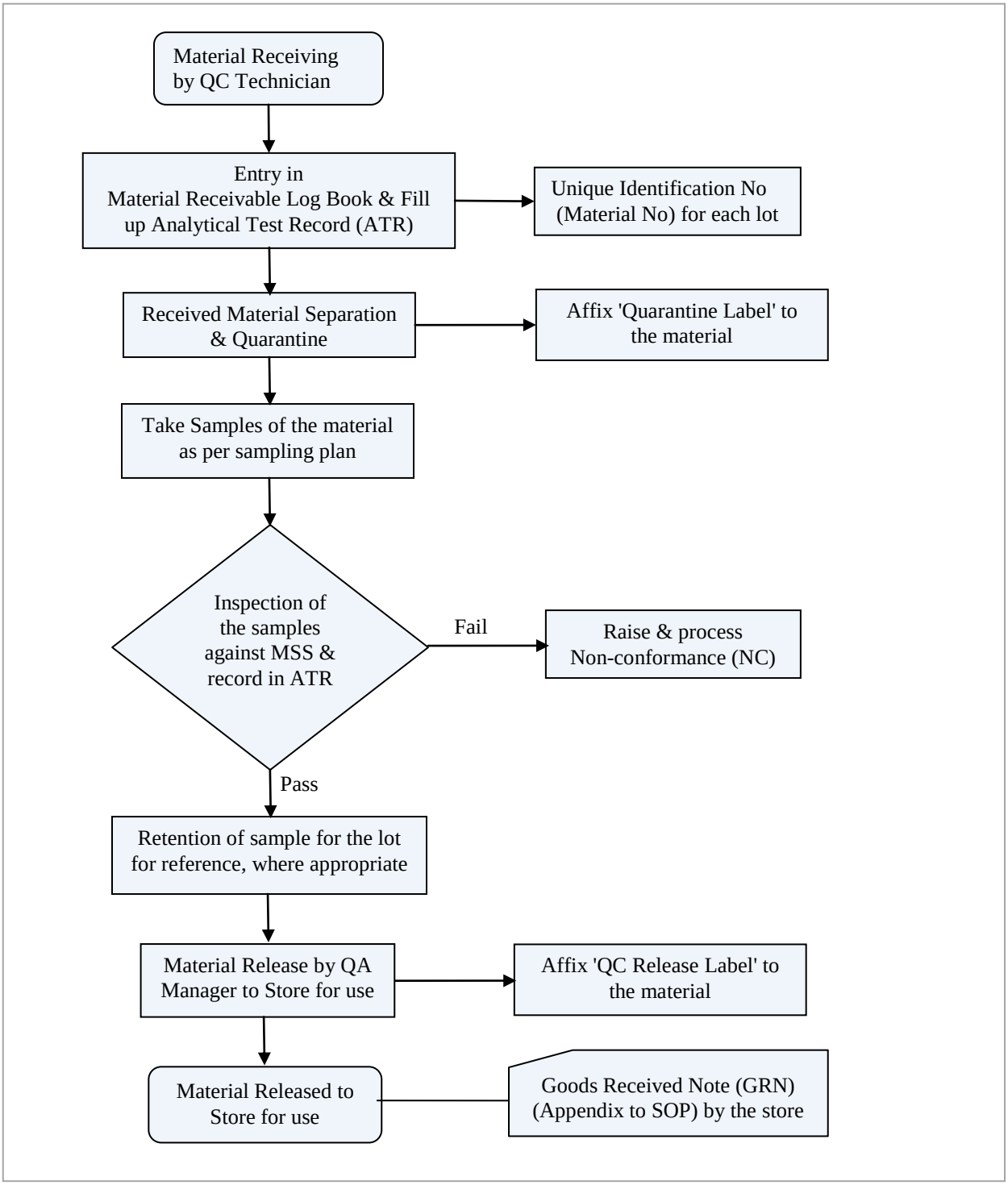


Figure 4.28: Verification process of incoming materials

4.13.3 Acceptance Sampling Plan for Incoming Materials

For sampling plan for incoming materials, the FH IOL Lab uses AQL Inspector's Rule which conforms to MIL STD 105E and ANS/ASQC Z-1.4 Standards. AQL Inspector's rule includes followings:

- Sampling Plan: Single Sampling Plan & Double Sampling Plan
- Inspection Level: I, II, III, S-1, S-2, S-3, S-4
- Severity of Inspection: Normal, Tightened, Reduced

The FH IOL Lab applies the following sampling plan for incoming materials except few sensitive items are 100% inspected:

- Sampling Plan: Single Sampling Plan
- Inspection Level: I
- AQL Level: 1
- Severity of Inspection: Normal
- If sample size equals or exceeds lot or batch size, 100% inspection is applied.

In accordance with the above sampling plan, the sample size and acceptance quality level for corresponding batch/lot size are shown in the following table 4.12.

Table 4.12: Acceptance Sampling Plan for incoming materials

Batch/Lot size (N)	Sample size (n)	Acceptance No (c)	Rejection No
2-8	2	0	1
9-15	2	0	1
16-25	3	0	1
26-50	5	0	1
51-90	5	0	1
91-150	8	0	1
151-280	13	0	1
281-500	20	0	1
501-1200	32	1	2
1201-3200	50	1	2
3201-10000	80	2	3
10001-35000	125	3	4
35001-150000	200	5	6
150001-500000	315	7	8
500001-over	500	10	11

Steps for inspection

N=Lot/Batch size

n=sample size

c=acceptance number i.e. maximum number of allowable defectives in the sample

d=no of defectives in the sample

5. Select a random sample of size n from the lot of size N
6. Inspect all items of the sample and find the no of defectives d
7. If d<c, accept the lot
8. If d>c, reject the lot and raise Nonconformance

4.14 Identification and Traceability

Identification of items is maintained, as necessary, to provide confidence that the correct items are used. When regulatory or customer requirements include traceability of items, procedures are established to provide identification, traceability, and records. Engineering organizations define the traceability requirements in drawings or specifications and provide specific instructions for accomplishing the required identification. If the requirements impact suppliers, appropriate requirements are included in the procurement documentation. Records of item traceability are maintained in accordance with established procedures. Identification of various inputs, processing product & final products is vital information for traceability in the future. The major Identification and traceability elements in the FH IOL Lab are enumerated below in the table 4.13.

Table 4.13: Identification and traceability elements in the FH IOL Lab

Particulars	Unique Identification	Registration	Instrument of Records	Visual Sign
Record of Log Book	Log Book No.	Log Book Register		Label on Log Book
Nonconformance	NC No.	NC Record Log Book	NC Form	'Quarantine Label' on materials
Customer Complaint	Complaint No.	Complaint Log Book	Complaint Form	
Reject Material	Reject Material No.	Reject Materials Destruction Log Book	Reject Material Form	'QC Reject Label' on materials
Incoming Material/ Components	Material No.	Material Receival Log Book	Analytical Test Record (ATR)	Quarantine Label' on materials
Reference of samples	Reference No.	Log Book for Quality References	Reference Form	Label on reference sample
Processing Product	Lens Batch No.	Lens Log Book	Lens Batch Record	'Process Status Label'
Polishing of lenses	Polishing Slurry No.	Polishing Slurry Log Book	Polishing Batch record	Label on polishing slurry
PMMA Buttons	Button No.	PMMA Buttons Log Book	PMMA Batch Record	Batch Label on Buttons
PMMA Strips	Strip No.	PMMA Stripe Log Book	PMMA Strip Batch Record	Batch Label on Strips
Lens case cleaning	Lens case clean No.	Lens Case Cleaning Process	Lens case cleaning record	Batch Label' on container
Materials required	Material Code No.	Material Code Number Log Book	Analytical Test Record (ATR)	
Deviation	Deviation No.	Deviation Record Log Book	Deviation Form	Deviation No. written on BR
Corrective Action	CA No.	Corrective Action Log Book	CA Form	CA No. written on BR
Engineering drawing	Drawing No.	Engineering Drawing Register		
Staff Signature	Staff Name	Authorized Signatures Log Book		
Secondary Packing of lenses	Box No. / Bundle No.	Secondary Packing Record Log Book	Secondary packing list	Label on Box/Bundle
Sterilization of lenses	Run No.		Sterilization Load list	‘Process Status Label’
Machines/Equipment/ Instruments	Item No.			‘Calibration’ / ‘Maintenance’ Label
Primary packing	Batch No-Serial No	Lens Batch Record	Lens Batch Record	‘Case Label' on Lens case

Lenses are produced in a batch or lot of maximum 1000 lenses. A Batch Record (BR) is maintained for each batch of lenses. BR consists of the records of each

process/station/stage of manufacturing from lathe cutting to final release of lenses. In each station, records are maintained regarding date, quantity issued in the station, accept quantity, reject quantity etc. Each finished lens has a label attached, which contains the Batch no.(BN), Serial No (SN), expiry date and other information. Batch no/Serial no gives a unique identification number to each lens. Therefore, a sold lens can be identified/ traced to the source on the basis of Batch no. and Serial No. printed on case label affixed to the lens case.

4.15 Preservation of Product

The FH IOL Lab preserves the product and its constituent parts during internal processing and delivery to the intended destination. The preservation includes identification, handling, packaging, storage and protection.

The incoming materials except those requiring special storage conditions are stored in Quarantine room until inspection and QC release. The Quarantine room is in normal environment. After verification/inspection of materials/goods, they are stored in normal environment in the store situated at the top of the laboratory building. For those materials that require special storage conditions are stored as specified and recommended by the suppliers. The store officer is responsible for handling, recording and storing the materials. As per Analytical Test Record (ATR) the store entry of materials is made.

The laboratory has maintained mini store of materials/consumables inside the laboratory for uninterrupted supply in day to day work. A production technician is responsible for handling, storing and recording materials in the mini store of the Lab. The semi-products are stored in WIP area in the clean room environment of the lab.

The Lab has Finished Product Store for storing the secondary packed lenses which are ready for sale. The sales/marketing department is responsible for handling, storing and recording the finished products. Finished Product Register has been maintained for recording the finished lenses in Finished Product Store. The lenses which are released

from the manufacturing area are entered in the 'IN' section of the register on the basis of Release for Sales Notification Form which is forwarded from the manufacturing premises. The lenses are stored in dry steel racks in the Finished Product Store. The FH IOL Lab has established proper preservation methodologies including environmental parameters temperature, humidity for storing finished goods. The storage temperature for finished product is set within the limit 5ºC to 40ºC and the relative humidity is set less than 99.65%. The temperature and relative humidity is daily recorded by sales assistant. Direct sunlight is prevented in the Finished Product Store to avoid heating effect on lenses. Every Thursday, Finished Product Store is cleaned for warehouse hygiene through vacuum cleaner & clean cloth; no water & no other cleaning solutions are used to avoid contamination. Monthly physical verification of stored lenses and monthly inspection of storage area are carried out by sales assistant and the results are recorded. This monthly monitoring includes verifying dioptre, model, quantity, expiry date of stored lenses, storage conditions and warehouse hygiene.

The lenses which are released for shipping are packed in shipping cartons. The selection of size of shipping cartons is based on quantity of units. The shipping cartons containing lens are wrapped by plastic to prevent from dust particles and liquid solutions. The lenses are delivered through the means- by route; by air; by hand carry. Entry of sold lenses is made in the 'OUT' section of the Finished Product Register on the basis of packing list which is prepared according to the customer order.

4.16 Control of Nonconformance

A nonconformance is any deficiency or defect observed in the process, product, material, documentation or other imposed requirement that renders the quality of an item or activity unacceptable or indeterminate. For the control of non-conforming product, a separate Quality SOP governs the handling procedure of NC in FH IOL Lab. A separate NC Log Book has been maintained to register each NC. All personnel are responsible for reporting nonconformance by filling NC form.

4.16.1 Procedure for Nonconformance

The SOP for NC has established the procedures for the identification, documentation, evaluation, segregation, review, corrective action, and notification to affected organizations. Disposition includes rework, accept as-is, repair, or reject and scrap. Repaired and reworked items are re-verified in accordance with the defined criteria or as specified in the disposition. The procedure for handling nonconformance is illustrated in the following figure 4.29.

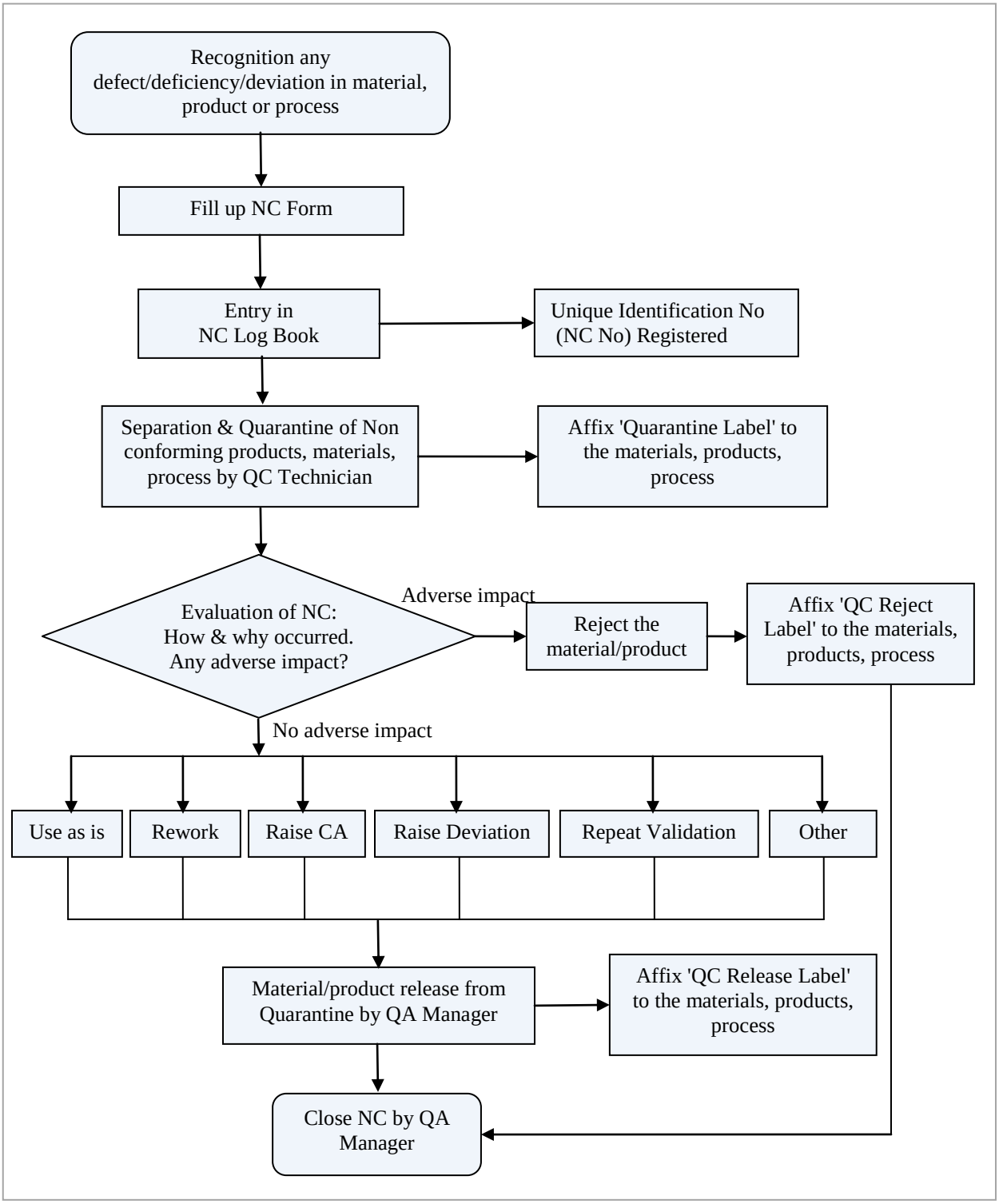


Figure 4.29: Procedure for Non-conformance

The procedure for handling non-conformance can be summarized into following steps:

I. NC is reported by filling NC form by anyone who observes non compliance

II. The products or materials are quarantined i.e. they are separated and kept aside from other batches by QC Technician

III. Evaluation of NC as

How and why NC occurred?

Any impact on WIP, finished products etc.?

IV. Actions includes

- Use as is
- Rework/repair which requires reverification after reworked/repaired
- Repeat validation
- Raise Deviation and use the material if there is no impact on the quality of the product
- Raise CA for further investigation to find out the root cause
- Reject/scrap

V. Nonconforming material, product are released from Quarantine by QA Manager

VI. NC is closed by QA Manager

4.16.2 Batches and Non-conformances

The following table 4.14 reveals the no of batches issued, no of buttons issued for production and no of nonconformance observed from 2005 to 2009.

Table 4.14: Batches and Non-conformances (2005-2009)

Year	No. of Batches	No. of buttons issued	NC Identification No.	No. of NC	No. of Batch per NC	No. of buttons per NC
2005	433	248681	From 1105 to 1159	55	8	4,521
2006	491	235650	From 1160 to 1196	37	13	6,369
2007	566	304002	From 1197 to 1268	72	8	4,222
2008	655	362797	From 1269 to 1385	117	6	3,101
2009	646	375480	From 1386 to 1474	89	7	4,219
Total	**2791**	**1526610**		**370**		

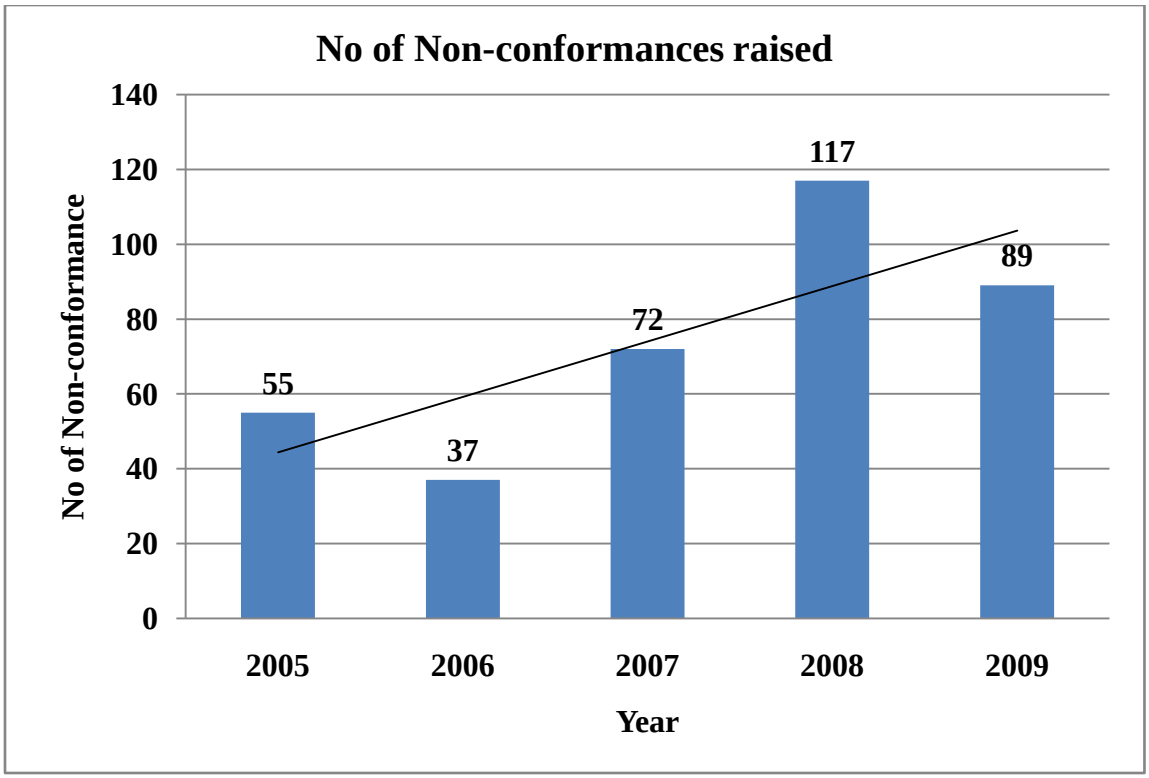


Figure 4.30: Non-conformances (2005-2009)

In 2005, the no of non-conformances (NC) registered are 55, whereas no of batches issued for production is 433 batches with 248,681 PMMA buttons. Similarly, no. of NC booked in 2006, 2007, 2008, and 2009 are 37, 72, 117, and 89 respectively. No. of batches issued with no. of buttons in 2006, 2007, 2008, 2009 are 491 batches with 235,650 buttons, 566 batches with 304,002 buttons, 655 batches with 362,797 buttons & 646 batches with 375,480 buttons respectively. The no of NC observed is highest in 2008 with 117 no of NC whereas the lowest no of NC observed is in 2006 with 37 no. The trend of raising NC is in increasing trend as indicated by the trend line in the figure 4.30.

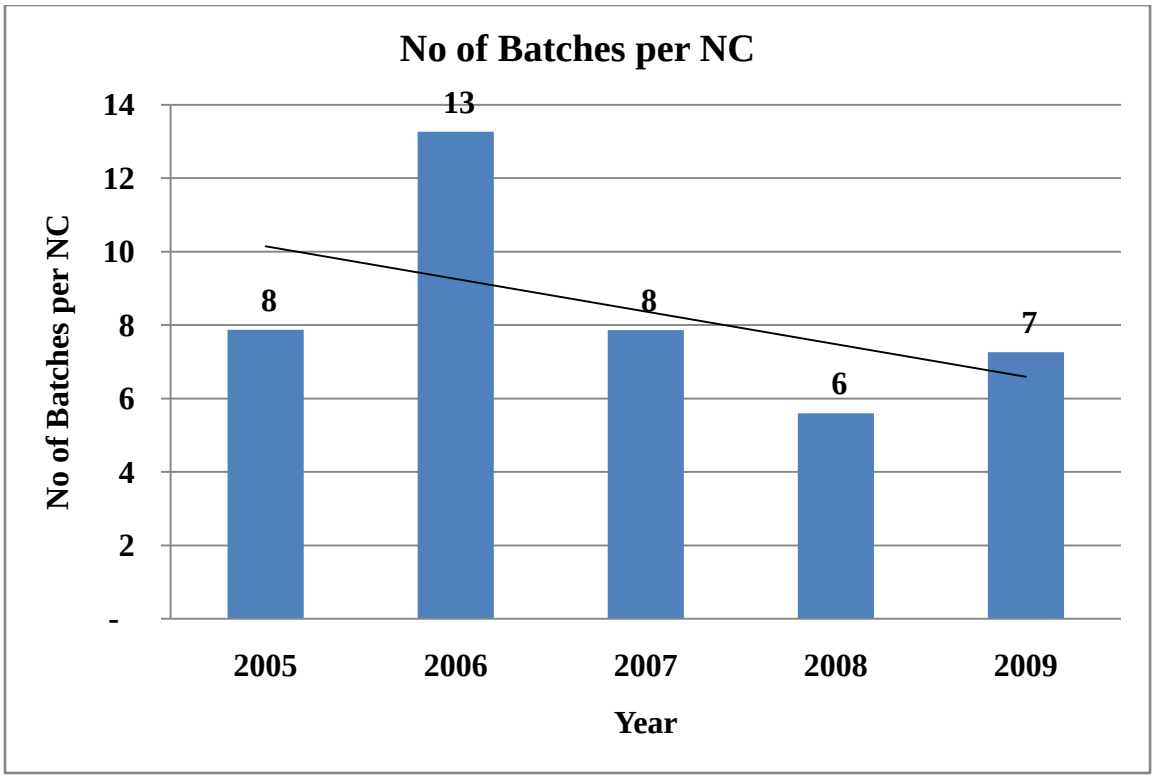


Figure 4.31: No of Batches per NC (2005-2009)

In 2005, there are 55 non-conformances observed against 433 batches issued & average number of batches for 1 non-conformance is 8 batches (433 batches/55 NC). Similarly, 1 NC is observed in 13, 8, 6 and 7 batches in 2006, 2007, 2008 and 2009 respectively. In 2006, the no of batches per NC is 13 which is the highest among other years whereas in 2008 no of batches per NC is 6 which is the lowest. The trend for no of batches per NC is decreasing i.e.no of non-conformances is increasing for less no of batches as shown by the trend line in the figure 4.31.

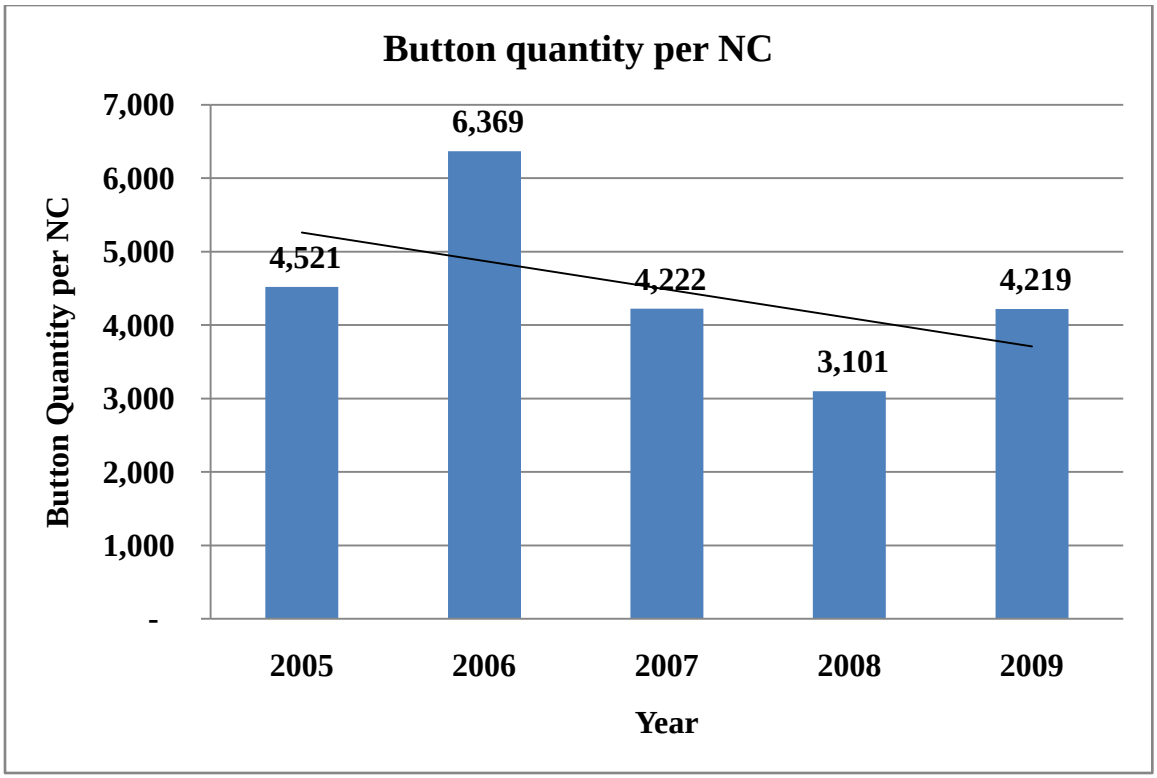


Figure 4.32: No of Buttons per NC (2005-2009)

In 2005, there are 55 non-conformances observed against 248,681 buttons issued & average number of issued buttons for 1 non-conformance is 4521 buttons (248,681 buttons/55 NC). Similarly, 1 NC is observed in 6369, 4222, 3101 and 4219 buttons in 2006, 2007, 2008 and 2009 respectively. In 2006, the no of buttons issued per NC is 6369 which is the highest among other years whereas in 2008 no of buttons per NC is 3101 which is the lowest. The trend for no of buttons per NC is decreasing i.e.no of non-conformances is increasing for less no of buttons as indicated by the trend line in the figure 4.32.

4.17 Corrective and Preventive Actions

Corrective Action (CA) is the action taken to identify, investigate and eliminate the cause of non-conformities in order to prevent re-occurrence. The need for corrective action is identified through sources such as non-conformances, failures, malfunctions, audits, inspections, surveillance, and customer complaints. A separate Quality SOP governs the

procedures for CA in the FH IOL Lab. CA Log Book has been maintained to register each CA. CA is opened for further investigation to determine the root cause of NC so that the recurrence of NC can be prevented through eliminating the root cause. CA Form is filled up and a unique no is registered in CA Log Book. CA procedure in the FH IOL Lab includes problem statement, impact of issue, root cause, actions to manage, monitoring period and closure. When a corrective action request is presented to a functional manager, it is the functional manager's responsibility to take timely action in defining and eliminating the root cause of the nonconformance. The presenter/owner of the CA is responsible for ensuring that the corrective action is taken and that it was effective, so that effective closure can occur. All managers are responsible for the detection, analysis, and the eventual elimination of potential causes of nonconformities through the examination of available data. All managers involve in generating the plan to remove potential causes of the nonconformity and for ensuring the plan results in the effective control of such actions. The functional managers are responsible for collection and analysis of data within their respective areas. From the analysis of the data, the managers decide the appropriate action to be taken. The monitoring period of CA is 3 months. The CA is closed by QA Manager.

Preventive action (PA) is the action taken to detect, analyze and eliminate causes of potential non-conformance in order to prevent their occurrence. Data are analyzed for trends in items, services, processes, and systems that may require action to eliminate causes of potential conditions adverse to quality. The results of these analyses are provided to management to determine the preventive action required to prevent occurrence. When necessary, this action will include the application of controls to ensure that it is effective.

A separate Quality SOP governs the procedures of PA in FH IOL Lab. PA is treated as CA in the FH IOL Lab; so the procedure for PA is same as the procedure for CA and the same CA form is used to define, analyze and closing of PA.

The corrective actions taken in the FH IOL Lab from 2005 to 2009 are listed in the following table 4.15.

Table 4.15: Corrective Actions (2005-2009)

Year	CA Identification No.	No. of CA
2005	From 520 to 537	18
2006	From 538 to 562	25
2007	From 563 to 602	40
2008	From 603 to 656	54
2009	From 657 to 711	55
Total		**192**

In 2005, 18 corrective actions are taken from CA no. 520 to 537. Similarly, the numbers of corrective actions taken from 2006 to 2009 are 25, 40, 54 and 55 respectively. From 2005 to 2009, total 192 corrective actions are taken.

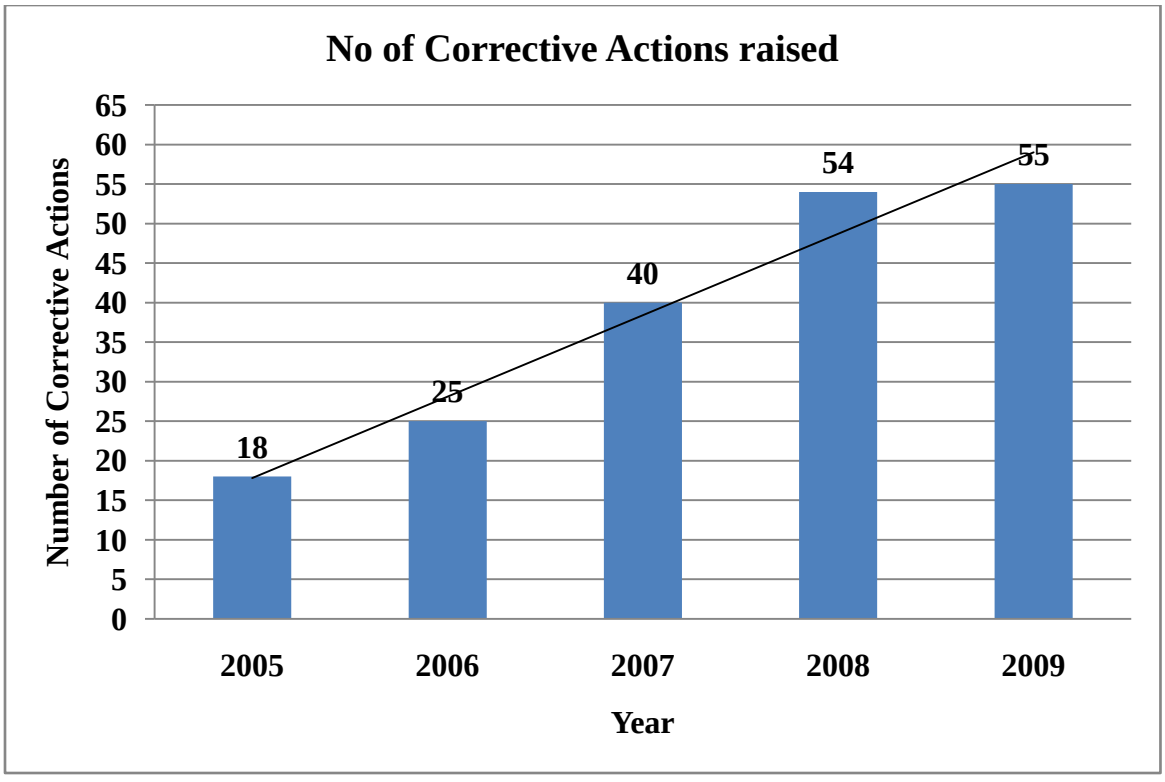


Figure 4.33: Corrective Actions (2005-2009)

In the figure 4.33, it is obvious that the no of corrective actions taken is highest in 2009 with 55 number whereas the no of corrective actions is lowest in 2005 with 18 actions. The trend for taking corrective actions is in increasing trend as shown in the figure 4.33. The increasing trend is due to increase in production volume and addition of product lines and product models.

4.18 Deviation

Deviation is the change of process for a limited time period or a limited quantity of product or material. Non-conforming materials or products shall be accepted by deviation only if there is no adverse effect on the quality of product. A separate Quality SOP governs the procedure for deviation in FH IOL Lab. A Deviation Log Book has been maintained to record each deviation. The department head raises deviation. The deviation procedure includes registering unique no known as deviation no in the Deviation Log Book and filling up Deviation Form which includes deviation requested personnel, date, subject of deviation, description of deviation, reason of deviation and validation/qualification/support data for deviation. To implement the deviation, approvals must be taken from the functional managers- production manager, engineering manager, sales/marketing manager, microbiologist and QA Manager. The purpose of the approvals from the functional managers is to avoid the unnecessary deviation and to ensure that there is no adverse impact in different functional areas from that deviation. If there is non-approval from a single functional manager, the deviation becomes void and cannot be implemented. After getting the approvals from all the functional managers, the implementation date and the responsible personnel for implementation are fixed. When the implementation of the deviation is complete, the deviation is closed by implementing personnel and the deviation closure notification is forwarded to all functional managers.

The deviations made in the FH IOL Lab from 2005 to 2009 are listed in the following table 4.16.

Table 4.16: Deviations (2005-2009)

Year	Deviation Identification No.	No. of Deviation
2005	From 259 to 268	10
2006	From 269 to 279	11
2007	From 280 to 286	7
2008	From 287 to 299	13
2009	From 300 to 303	4
Total		**45**

In 2005, the registration of deviations was made from deviation no. 259 to 268 with total 10 deviations. Similarly, the numbers of deviations from 2006 to 2009 are 11, 7, 13 and 4 respectively. From 2005 to 2009, total 45 deviations are made.

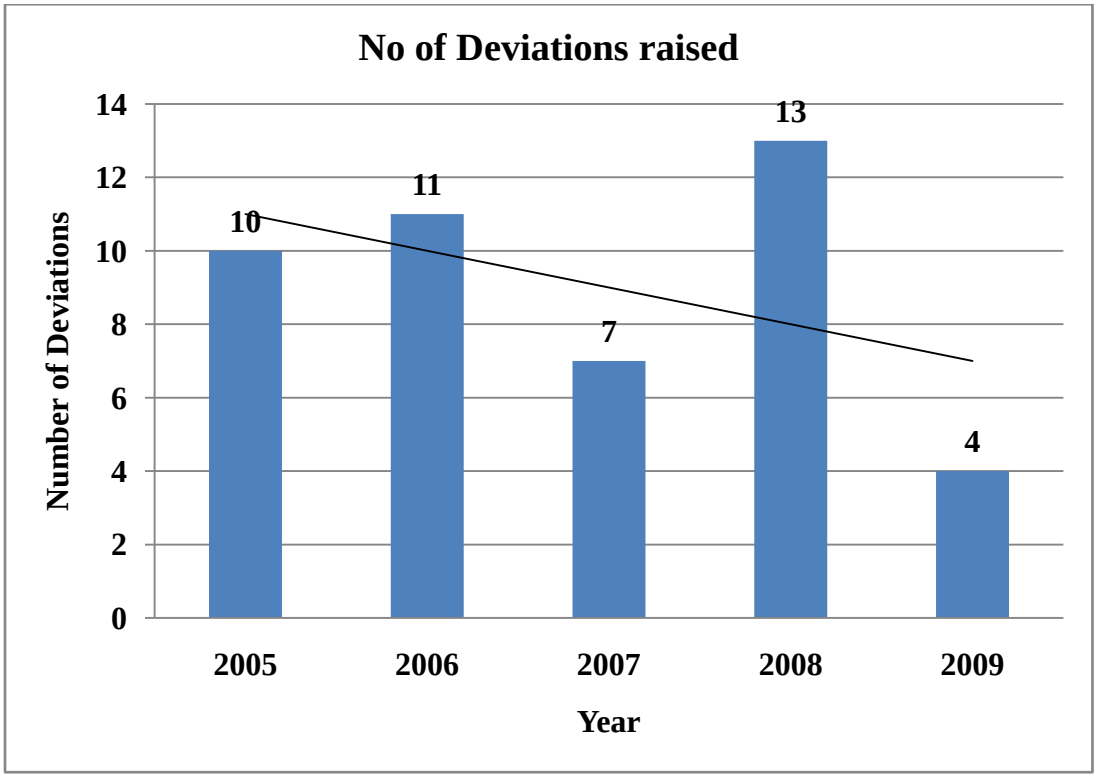


Figure 4.34: Deviations (2005-2009)

From the figure 4.34, it is clear that the no of deviations made is highest in 2008 with 13 deviations whereas the no of deviations is lowest in 2009 with 4 deviations. The trend for making deviations is in decreasing trend as shown in the figure 4.34.

4.19 Internal Quality Audit

Management Representative (MR) i.e. QA Manager in the FH IOL Lab is responsible for Internal quality audit. It is conducted by management team of FH IOL Lab with or without external qualified consultants. It is held at least 6 months. The QA Manager is responsible for selecting, training and managing the quality auditors, scheduling internal audits, monitoring the implementation of the audit schedule and reporting to the Management Review Body. Internal audit covers all departments, functions and procedures included in the scope of QMS- quality assurance, production, engineering, sales & marketing, procurement and store. The auditors are independent of the function or department being audited to prevent or minimize conflicts of interest. The QA Manager produces internal audit schedules. As part of the scheduling process, the QA Manager appoints suitably trained and experienced internal quality auditors and allocates auditors ensuring independence of the auditor from the area being audited. The appointed internal auditors and management team are notified about the internal audit through circulation of internal memo at least 2 days before. Audit checklists of pertinent questions to be covered during the audit are prepared by QA Manager and supplied to internal auditors. The managers conducting audit collects information through interviews, examination of documents/records, observation of activities and conditions of areas. Any non conformance found during the audit is recorded by the auditor. The audit report is submitted to QA Manager. The QA manager circulates the internal audit report to all the functional departments - Production, Engineering, Quality Assurance, and General Manager for verification. Audit records include audit plans, checklists, audit reports, written replies, and documentation of completed corrective actions. The result of the internal audits together with an analysis of those results is reported to top management through the Management Review meeting. This report will identify those issues which require the attention of the top management.

4.20 External Quality Audit

External Quality Audit of the FH IOL Lab is conducted by quality experts from SGS, UK. There are two types of External Audits:

- Surveillance audit held once a year to monitor the quality management system in the Lab.
- Renewable Audit held for every 3 years for renew of ISO certificates which are valid for 3 years.

The auditor performs examination of documents, observation of physical environment, interview of staffs, and observation of processes and a report is prepared. The report is submitted to head office of SGS in UK while a copy of the report is submitted to FH IOL Lab. If any noncompliance is detected in the audit, the auditor can raise following cases as per the degree of the noncompliance.

- *Observation* which is a simple case of noncompliance which gives the opportunity for improvement. Proper justification for the noncompliance may close the observation.
- *Minor corrective action* which is mandatory for action. In the next audit, minor corrective action is followed up.
- *Major corrective action* which demands immediate action for resolution. The ISO certificates are withheld and/or renewal of ISO certification is stopped until the major corrective action is resolved and closed.

4.21 Input, Reject and Production of IOLs (FH model)

PMMA buttons of 18mm diameter are the basic inputs as raw material in the production of FH model of IOLs. These buttons are issued in lots/batches and converted into IOLs in step by step manufacturing stages. During different manufacturing stages, defects occur due to not meeting the specifications as prescribed by the standards. Defected lenses or semi-products are rejected and separated. The following table 4.17 reveals the quantity of batches and buttons issued, reject quantity & final output of lenses of FH models for 5 years 2005 to 2009.

Table 4.17: Issue, Reject & Production Quantity (2005-2009)

Year	No. of Batches	No. of buttons issued	Production (Final Output)	Reject Quantity
2005	433	248681	190321	58360
2006	491	235650	206255	29395
2007	566	304002	240121	63881
2008	655	362797	277483	85314
2009	646	375480	296641	78839
Total	**2791**	**1526610**	**1210821**	**315789**

In table 4.17, Issue = Production + Reject

In 2005 total batches issued for production of FH model of IOLs were 433 batches with 248,681PMMA buttons, among which 58,360 units were rejected during different manufacturing stages leading 190,321IOLs as final output. Similarly, in 2006, 2007, 2008 and 2009, the input quantity of buttons were 235,650, 304,002, 362,797, 375,480 respectively & the quantity of final output as finished products were 190,321, 206,255, 240,121, 277,483, 296,641 respectively. In the 5 years from 2005 to 2009, total lots/batches issued for production of FH model of IOLs were 2791 batches with 1,526,610 PMMA buttons among which 315,789 units were rejected during different manufacturing stages leading 1,210,821 IOLs as final output.

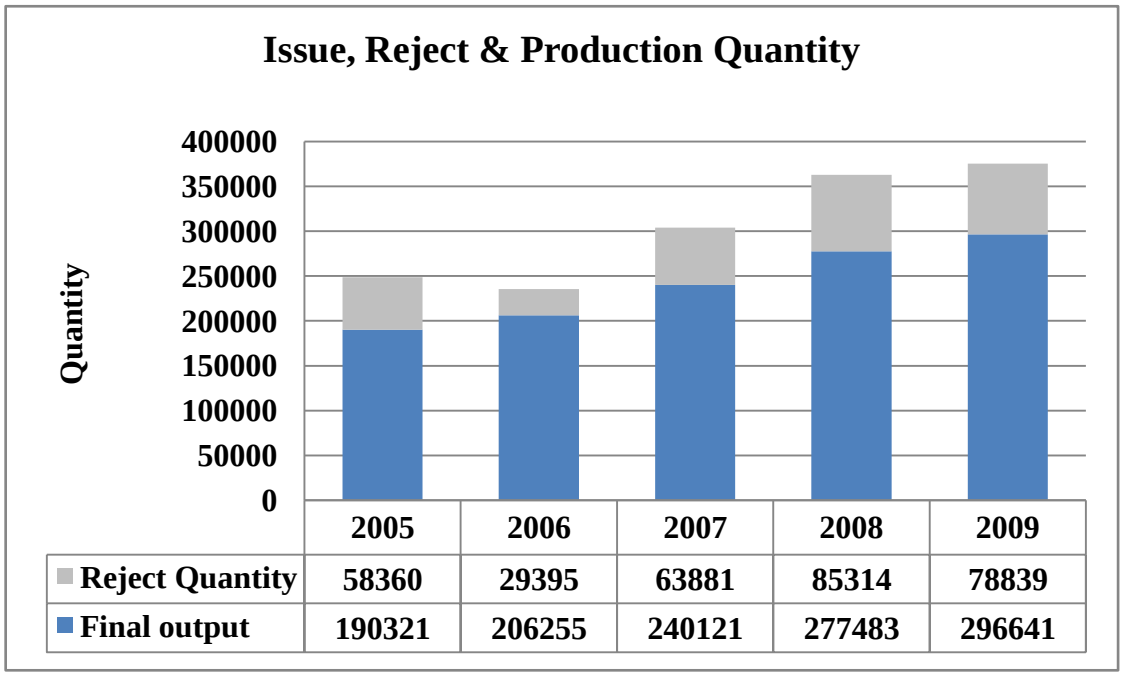


Figure 4.35: Issue, Reject and Production Quantity (FH model of IOLs)

The figure 4.35 shows that every year the production has increased than the previous year from 2005 to 2009. The production was lowest in 2005 and highest in 2009. The production quantity is in increasing trend.

The reject percentages (calculated as reject units divided by issued units) in the years 2005 to 2009 are shown in the table 4.18.

Table 4.18: Reject Percentage (2005-2009)

Year	Reject %
2005	23%
2006	12%
2007	21%
2008	24%
2009	21%

The following figure 4.36 shows the graphical presentation of reject percentages in 2005 to 2009.

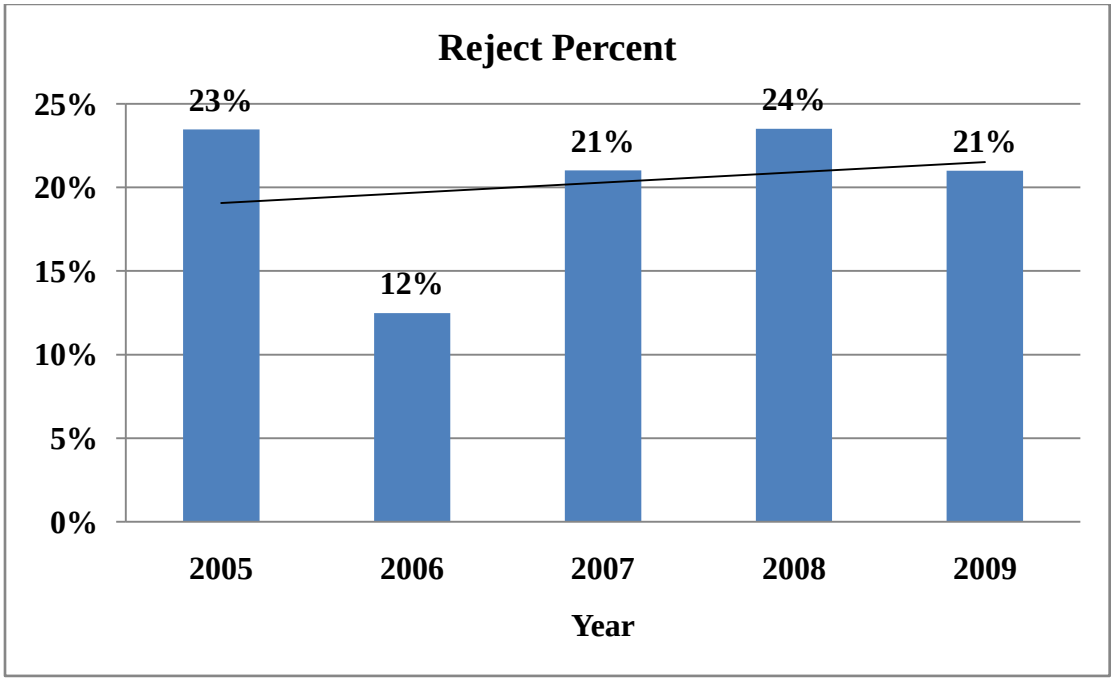


Figure 4.36: Reject Percentage (2005-2009)

In 2005 the total reject quantity constitutes 23% of total PMMA buttons input. Similarly, the reject percentages from 2006 to 2009 are 12%, 21%, 24% & 21% respectively. The reject percentage is highest in 2008 with 24% whereas lowest in 2006 with 12%. The average reject percent during 5 years is 20%. The trend for reject percent is increasing as indicated by the trend line in the figure 4.36.

4.22 Production and Sales of IOLs (FH model)

The sales volumes against the production quantity for 2005 to 2009 are shown in the following table 4.19.

Table 4.19: Production and Sales Quantity (2005-2009)

Year	Production (Final Output)	Sales Quantity
2005	190321	193455
2006	206255	176432
2007	240121	208141
2008	277483	241993
2009	296641	294864
Total	**1210821**	**1114885**

In 2005, production quantity of FH model of lenses is 190,321 whereas sales quantity in the same year is 193,455 units. In 2006, 2007, 2008 & 2009, final output produced are 206,255, 240,121, 277,483 & 296,641 respectively whereas the sales figures in the respective years are 176,432, 208,141, 241,993 & 294,864 units.

The graphical presentation is made for the sales volume against production volume for 2005 to 2009 in the following figure 4.37.

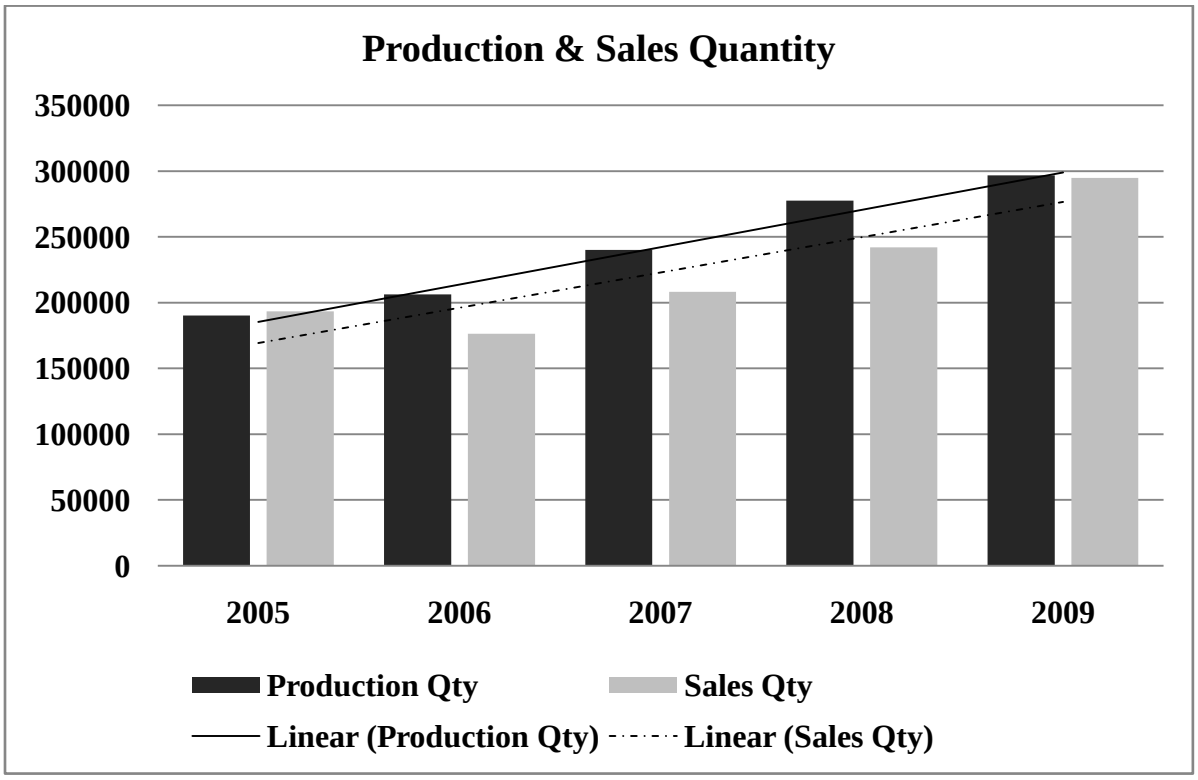


Figure 4.37: Production and Sales Quantity (2005-2009)

From 2005 to 2009, the production is increasing every year than the previous year as indicated by the trend line of production quantity in the figure 4.37. The lowest production is 190,321 units in 2005 whereas the highest produced quantity is 296,641 units in 2009. In 2005 the sales quantity is 193,455 units and the sales quantity decreased to 176,432 units in 2006. But from the years 2006 to 2009 the sales volume has been increasing every year than the previous year. The sales volume is lowest in 2006 with 176,432 units whereas the highest sales volume is 294,864 units in 2009. The sales volume is in increasing trend as indicated by the trend line of sales quantity in the figure 4.37.

4.23 Reject Types and Pareto Analysis

A manufacturing process may produce some defected units during different production stages. Such rejects are separated and scrapped. PMMA buttons of 18mm diameter are the basic inputs as raw material in the production of FH model of IOLs. These buttons are issued in lots/batches & converted into IOLs in step by step manufacturing stages. During different manufacturing stages, defects occur due to not meeting the specifications as prescribed by the standards. Defected lenses/semi-products are rejected, separated & scrapped.

There are many causes for rejected units which are broadly categorized into 5 types of rejects for the Pareto Analysis. The rejects were classified as

- *Type A* for Poor Surface Quality which includes scratches, pimple, dimple, lathe marks, rough edge on optic etc
- *Type B* for Haptic broken, Haptic stress
- *Type C* for Focal length out/Bad resolution which includes those rejects that have focal length out of range than specified standard limits for certain optic power. Type C also includes the rejects due to low optical visual clarity i.e. bad resolution of the lenses.
- *Type D* for Haptic thickness out of range i.e. thin or thick haptic thickness- not meeting standard specification as prescribed.
- *Type E* for Set up rejects which includes trial lenses & other rejects during machinery process before smooth production of lenses by the machines.

For Pareto Analysis i.e. to know the vital or major causes for rejects, the data relevant to the quantity of rejects and causes of rejection were extracted from the year 2005 to 2009 and arranged in tabular formats.

Pareto Analysis 2005

The following table 4.20 shows the causes of rejection (types of defects) and the corresponding reject quantity for 2005.

Table 4.20: Types & Percentages of Defects in 2005

Year		2005		
Defect	**Types of defect**	**No. of rejects**	**Defect %**	**Category**
A	Poor Surface quality	31945	55%	Vital
B	Haptic broken & stress	18355	31%	Vital
C	Focal length out/Bad resolution	1494	3%	Trivial
D	Haptic thickness out of range (thin & thick)	3820	7%	Trivial
E	Set up rejects	2746	5%	Trivial
Total		**58360**	**100%**	

In 2005 total reject quantity during manufacturing process is 58,360 units. Among the total rejects, 31,945 units are rejected due to poor surface quality which constitutes 55% of total rejects. 18,355 units are rejected due to Haptic broken & haptic stress leading 31% to total rejects. Similarly, focal length out/bad resolution causes 1494 rejects which is 3% of total rejects; haptic thickness out of range leads to 3820 rejects which is 7% of total rejects; and machinery set up leads to 2746 rejects which is 5% total rejects.

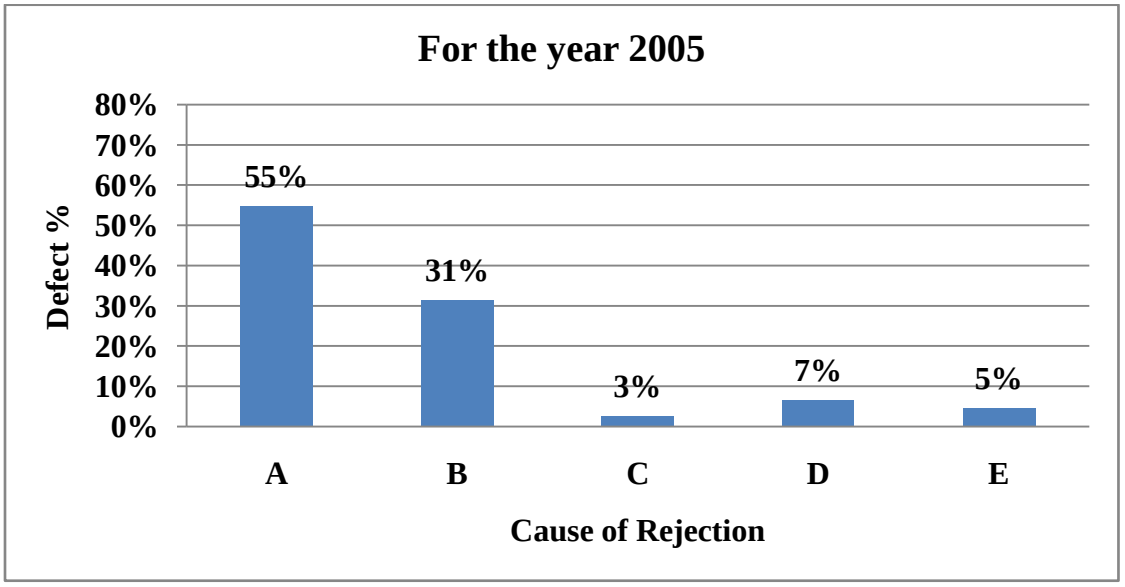


Figure 4.38: Pareto Chart for 2005

The figure 4.38 shows that the highest quantity of rejects is caused by poor surface quality & second highest quantity of rejects is due to Haptic broken/haptic stress. Poor surface quality is the key factor for 55% of total rejects & haptic broken/stress is another key factor for rejection of lenses leading 31% of total rejects.

Pareto Analysis 2006

The following table 4.21 shows the causes of rejection (types of defects) and the corresponding reject quantity for 2006.

Table 4.21: Types & Percentages of Defects in 2006

Year		**2006**		
Defect	**Types of defect**	**No. of rejects**	**Defect %**	**Category**
A	Poor Surface quality	17539	60%	Vital
B	Haptic broken & stress	6891	23%	Vital
C	Focal length out/Bad resolution	965	3%	Trivial
D	Haptic thickness out of range (thin & thick)	869	3%	Trivial
E	Set up rejects	3131	11%	Trivial
Total		**29395**	**100%**	

In 2006 total reject quantity during manufacturing process is 29,395 units. Among the total rejects, 17,539 units are rejected due to poor surface quality which constitutes 60% of total rejects. 6,891 units are rejected due to Haptic broken & haptic stress leading 23% to total rejects. Similarly, focal length out/bad resolution causes 965 rejects which is 3% of total rejects; haptic thickness out of range leads to 869 rejects which is 3% of total rejects; and machinery set up leads to 3131 rejects which is 11% total rejects.

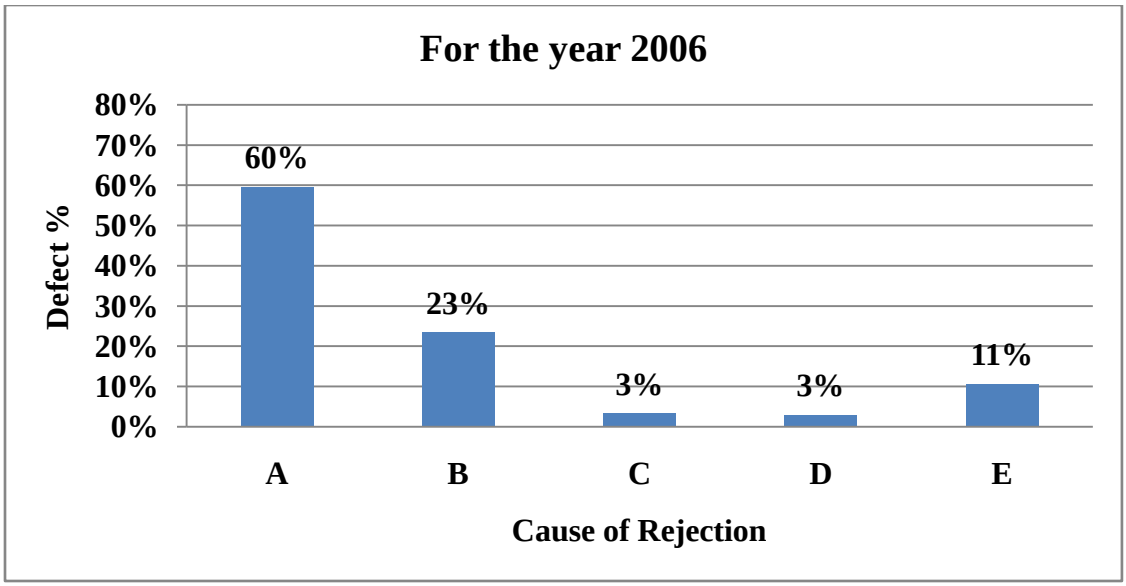


Figure 4.39: Pareto Chart for 2006

The figure 4.39 shows that the highest quantity of rejects is caused by poor surface quality & second highest quantity of rejects is due to Haptic broken/haptic stress. Poor surface quality & Haptic broken/stress are the major and vital causes for rejection of FH model lenses.

Pareto Analysis 2007

The following table 4.22 shows the causes of rejection (types of defects) and the corresponding reject quantity for 2007.

Table 4.22: Types & Percentages of Defects in 2007

Year		**2007**		
Defect	**Types of defect**	**No. of rejects**	**Defect %**	**Category**
A	Poor Surface quality	43612	68%	Vital
B	Haptic broken & stress	12793	20%	Vital
C	Focal length out/Bad resolution	457	1%	Trivial
D	Haptic thickness out of range (thin & thick)	3075	5%	Trivial
E	Set up rejects	3944	6%	Trivial
Total		**63881**	**100%**	

In 2007 total reject quantity during manufacturing process is 63,881 units. Among the total rejects, 43,612 units are rejected due to poor surface quality which constitutes 68% of total rejects. 12,793 units are rejected due to Haptic broken & haptic stress leading 20% to total rejects. Similarly, focal length out/bad resolution causes 457 rejects which is 1% of total rejects; haptic thickness out of range leads to 3075 rejects which is 5% of total rejects; and machinery set up leads to 3944 rejects which is 6% total rejects.

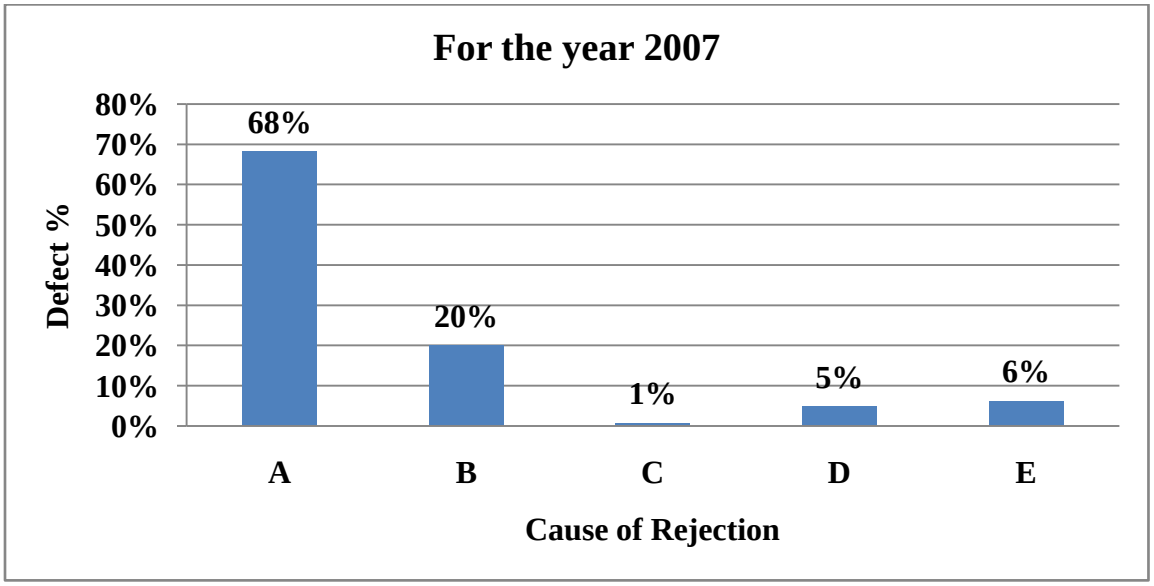


Figure 4.40: Pareto Chart for 2007

The figure 4.40 shows that the highest quantity of rejects is caused by poor surface quality & second highest quantity of rejects is due to Haptic broken/haptic stress. Poor surface quality is the key factor for 68% of total rejects & haptic broken/stress is another key factor for rejection of lenses leading 20% of total rejects.

Pareto Analysis 2008

The following table 4.23 shows the causes of rejection (types of defects) and the corresponding reject quantity for 2008.

Table 4.23: Types & Percentages of Defects in 2008

Year		2008		
Defect	**Types of defect**	**No. of rejects**	**Defect %**	**Category**
A	Poor Surface quality	51093	60%	Vital
B	Haptic broken & stress	24177	28%	Vital
C	Focal length out/Bad resolution	1093	1%	Trivial
D	Haptic thickness out of range (thin & thick)	4399	5%	Trivial
E	Set up rejects	4552	5%	Trivial
Total		**85314**	**100%**	

In 2008 total reject quantity during manufacturing process is 85,314 units. Among the total rejects, 51,093 units are rejected due to poor surface quality which constitutes 60% of total rejects. 24,177 units are rejected due to Haptic broken & haptic stress leading 28% to total rejects. Similarly, focal length out/bad resolution causes 1093 rejects which is 1% of total rejects; haptic thickness out of range leads to 4399 rejects which is 5% of total rejects; and machinery set up leads to 4552 rejects which is 5% total rejects.

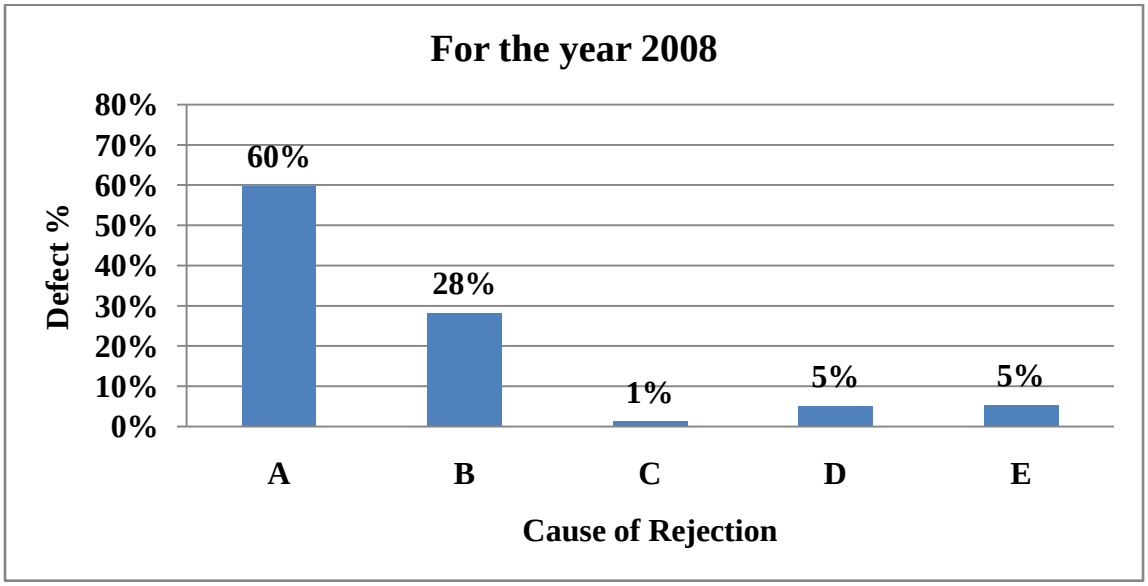


Figure 4.41: Pareto Chart for 2008

The figure 4.41 shows that the highest quantity of rejects is caused by poor surface quality & second highest quantity of rejects is due to Haptic broken/haptic stress. Poor surface quality & Haptic broken/stress are the major and vital causes for rejection of FH model lenses.

Pareto Analysis 2009

The following table 4.24 shows the causes of rejection (types of defects) and the corresponding reject quantity for 2009.

Table 4.24: Types & Percentages of Defects in 2009

Year		**2009**		
Defect	**Types of defect**	**No. of rejects**	**Defect %**	**Category**
A	Poor Surface quality	50541	64%	Vital
B	Haptic broken & stress	15459	20%	Vital
C	Focal length out/Bad resolution	3514	4%	Trivial
D	Haptic thickness out of range (thin & thick)	4415	6%	Trivial
E	Set up rejects	4910	6%	Trivial
Total		**78839**	**100%**	

In 2009 total reject quantity during manufacturing process is 78,839 units. Among the total rejects, 50,541 units are rejected due to poor surface quality which constitutes 64% of total rejects. 15,459 units are rejected due to Haptic broken & haptic stress leading 20% to total rejects. Similarly, focal length out/bad resolution causes 3514 rejects which is 4% of total rejects; haptic thickness out of range leads to 4415 rejects which is 6% of total rejects; and machinery set up leads to 4910 rejects which is 6% total rejects.

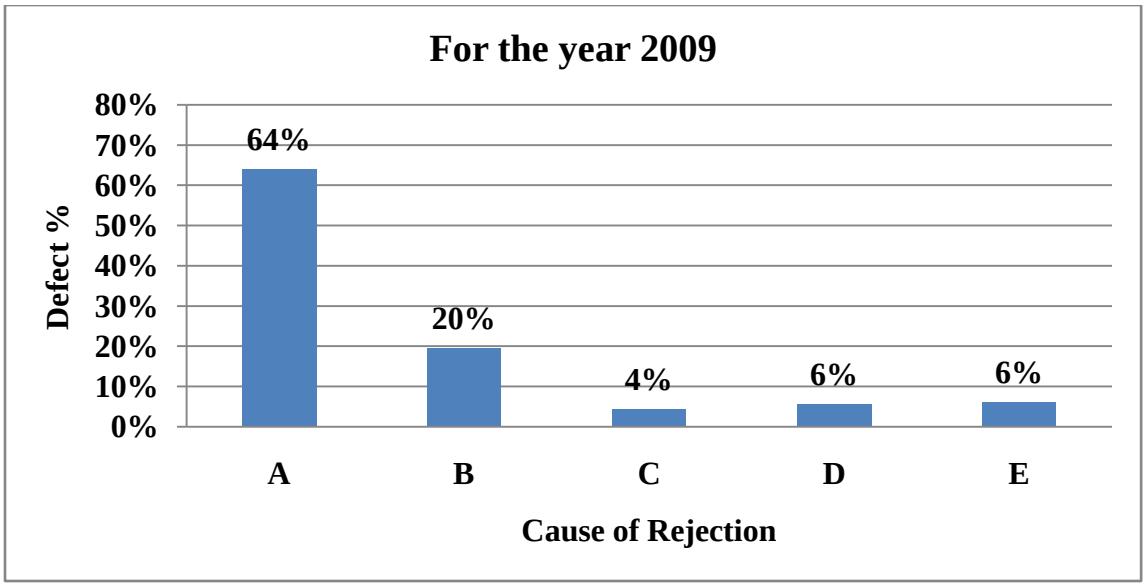


Figure 4.42: Pareto Chart for 2009

The figure 4.42 shows that the highest quantity of rejects is caused by poor surface quality & second highest quantity of rejects is due to Haptic broken/haptic stress. Poor surface quality is the key factor for 64% of total rejects & haptic broken/stress is another key factor for rejection of lenses leading 20% of total rejects.

Pareto Analysis (2005-2009)

The following table 4.25 shows the causes of rejection (types of defects) and the corresponding reject quantity for 2005 to 2009.

Table 4.25: Types & Percentages of Defects (2005-2009)

Year		Total (2005-2009)		
Defect	**Types of defect**	**No. of rejects**	**Defect %**	**Category**
A	Poor Surface quality	194730	62%	Vital
B	Haptic broken & stress	77675	25%	Vital
C	Focal length out/Bad resolution	7523	2%	Trivial
D	Haptic thickness out of range (thin & thick)	16578	5%	Trivial
E	Set up rejects	19283	6%	Trivial
Total		**315789**	**100%**	

For the 5 years 2005 to 2009, total reject quantity during manufacturing process is 315,789 units. Among the total rejects, 194,730 units are rejected due to poor surface quality which constitutes 62% of total rejects. 77,675 units are rejected due to Haptic broken & haptic stress leading 25% to total rejects. Similarly, focal length out/bad resolution causes 7523 rejects which is 2% of total rejects; haptic thickness out of range leads to 16,578 rejects which is 5% of total rejects; and machinery set up leads to 19,283 rejects which is 6% total rejects.

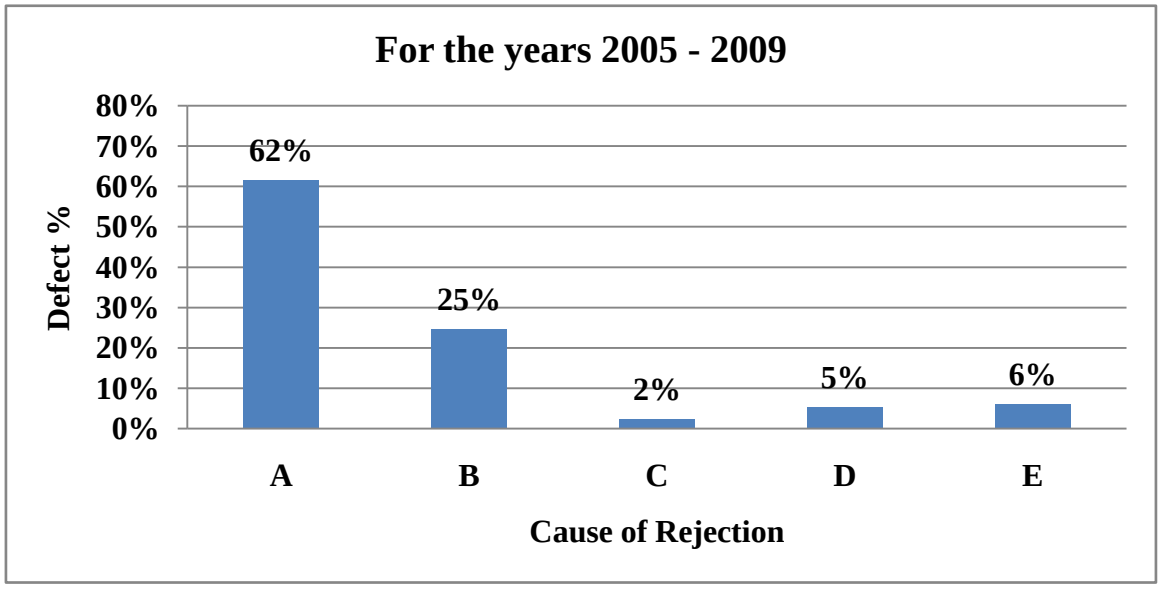


Figure 4.43: Pareto Chart (2005-2009)

The figure 4.43 and 4.44 show that the highest quantity of rejects is caused by poor surface quality & second highest quantity of rejects is due to Haptic broken/haptic stress. Poor surface quality is the key factor for 62% of total rejects & haptic broken/stress is another key factor for rejection of lenses leading 25% of total rejects. Poor surface quality & Haptic broken/stress are the major and vital causes for rejection of FH model lenses.

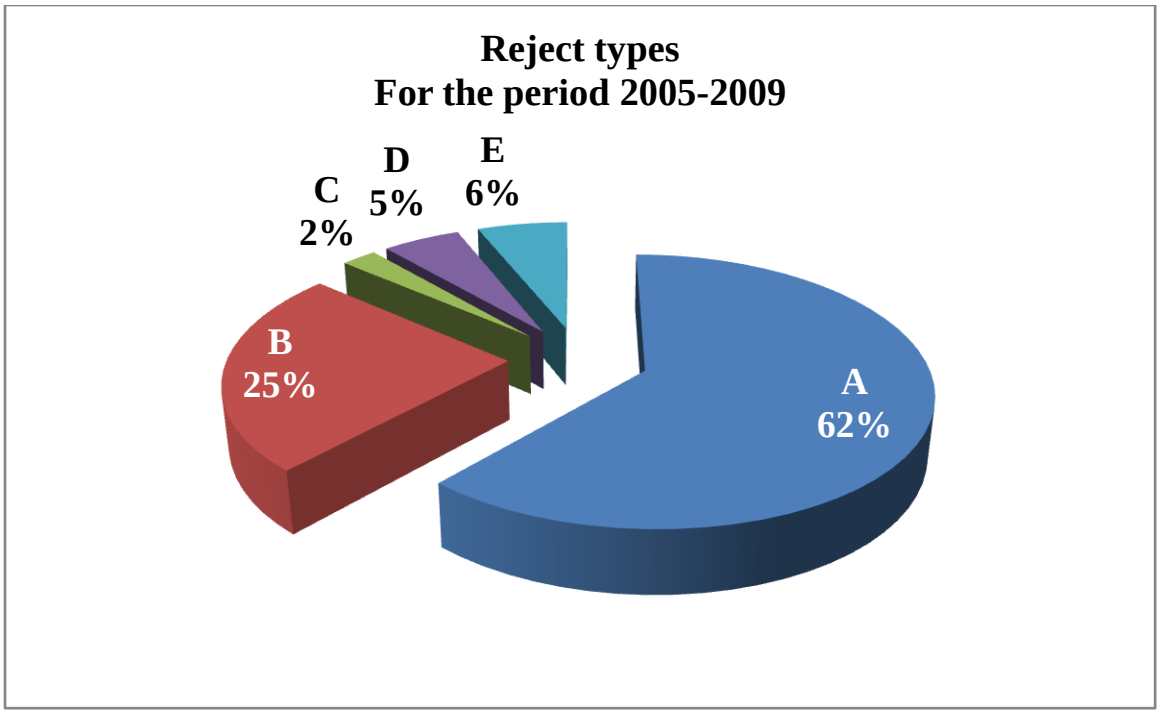


Figure 4.44: Reject types and corresponding percentages (2005-2009)

4.24 Hypothesis Test for Diameter of PMMA Buttons

The raw material for the FH model of IOLs is a special type of optical material known as Poly Methyl Meth Acrylate (PMMA). They are supplied as large rectangular sheets. The PMMA sheets are cut into strips in Circular Sawing machine. The PMMA strips are milled into small round buttons in Button Milling machine.

PMMA buttons are the basic inputs for the manufacturing of FH model of IOLs. The diameter of the buttons is standardized to 18.00 ± 0.08 mm (17.92 mm to 18.08 mm). Before introducing into manufacturing process, the buttons are sampled, inspected and released by QC Technician. From a batch of QC Released buttons, 100 buttons were randomly taken as samples for Hypothesis testing for the diameter of the QC released buttons.

Population mean, μ = 18.00 mm

Sample size, n = 100

Sample Mean, $\bar{X}$ = 18.0172 (from *Appendix–7*)

Sample Standard Deviation, s = 0.0311 mm (from *Appendix–7*)

Hypothesis testing- Mean test (Z test)

Null Hypothesis- $H_0: \mu = 18.00\ mm$ i.e. the mean diameter of the PMMA button is 18.00 mm. There is no significant difference between sample mean & population mean.

Alternative Hypothesis- $H_1: \mu \neq 18.00\ mm$ (Two tailed test) i.e. the mean diameter of the PMMA button is not 18.00 mm. There is significant difference between sample mean & population mean.

Test Statistic under H_0*:*

Z value, $Z_{cal} = \frac{\bar{X}-\mu}{s/\sqrt{n}} = \frac{18.0172-18.00}{0.0311/\sqrt{100}}$ = 5.53

$|Z_{cal}|$ = 5.53

Level of Significance = 5%

Critical Value:

The tabulated value of Z at 5 % level of significance for Two Tailed Test is 1.96 (f*rom Z Table for Standard Normal Distribution*)

i.e. $Z_{tab} = 1.96$

Decision:

Since $|Z_{cal}| > Z_{tab}$ the Null Hypothesis (H_0) is rejected i.e. Alternative Hypothesis (H_1) is accepted. So, it can be concluded that the mean diameter of PMMA button is not 18.00 mm. There is significant difference between sample mean & population mean.

4.25 Process Control

Machinery processes are the main manufacturing processes of lenses; so control charts were constructed for machinery processes- lathe cutting process, milling process and polishing process.

4.25.1 Control Chart for 1st cut lathe process

The buttons are 1st cut by Lathe machine for developing optical power on one side of the buttons with other parameters like optic diameter, vault diameter, outside diameter, vault perimeter thickness, resolution (optical clarity) etc. For monitoring process control of 1st cut lathe, only vault diameter of 1st cut lens was chosen, other parameters/attributes of 1st cut lens ignored.

1st cut lathe process control in relation to parameter 'Vault diameter'

50 successively cut lenses of FH 105 model were taken as samples. The standard limit of range for vault diameter in 1st cut stage is 9.40 mm to 9.60 mm for FH 105 model of lenses. The lenses were measured for vault diameter with the help of calibrated profile projector and the results of 50 successively cut lenses are tabulated below in the table 4.26 in 'sample observation' columns. The results are divided into 10 sample groups. Each sample group consists of 5 successively cut lenses.

Table 4.26: Observation, Sample mean & Sample range of Vault diameter

Sample group no.	sample observation					Total	Sample mean	Sample range
1	9.50	9.48	9.47	9.48	9.53	47.46	9.49	0.06
2	9.52	9.47	9.48	9.49	9.47	47.43	9.49	0.05
3	9.49	9.50	9.52	9.51	9.47	47.49	9.50	0.05
4	9.48	9.51	9.53	9.52	9.53	47.57	9.51	0.05
5	9.50	9.53	9.51	9.49	9.51	47.54	9.51	0.04
6	9.52	9.51	9.52	9.47	9.54	47.56	9.51	0.07
7	9.48	9.49	9.51	9.48	9.47	47.43	9.49	0.04
8	9.54	9.52	9.47	9.53	9.50	47.56	9.51	0.07
9	9.47	9.51	9.49	9.47	9.46	47.40	9.48	0.05
10	9.52	9.53	9.48	9.50	9.53	47.56	9.51	0.05
						Total	**95.00**	**0.53**

For $\bar{X}$-Chart:

*Setting control limits: (*from *Appendix–8)*

Central Line, CL = 9.50 mm

Upper Control Limit, UCL = 9.53 mm

Lower Control Limit, LCL = 9.47 mm

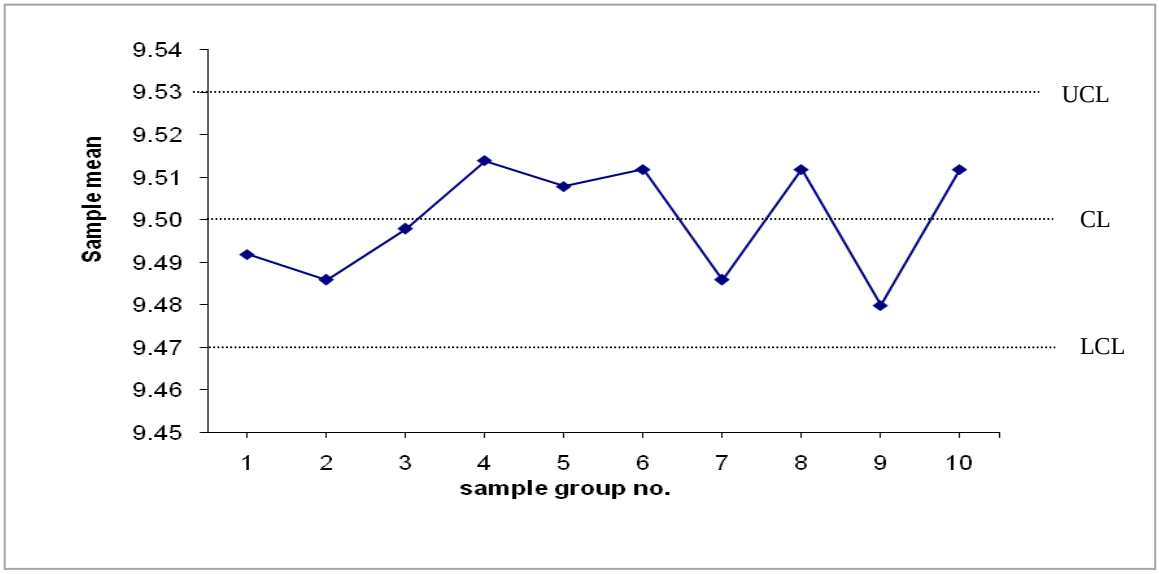


Figure 4.45: $\bar{X}$-Chart for Vault diameter

In the figure 4.45 of mean chart for vault diameter, it is obvious that means of sample groups 1 to 6 have normal tendency. From sample groups 6 to 10 there are consecutive alternate variations as indicated by downward and upward sloping lines. The plot 3 lies in the central line. However, all mean points lie within the upper and the lower limit.

For R-Chart:

Setting control limits :(from *Appendix–8)*

Central Line, CL = 0.05 mm

Upper Control Limit, UCL = 0.11 mm

Lower Control Limit, LCL = 0 mm

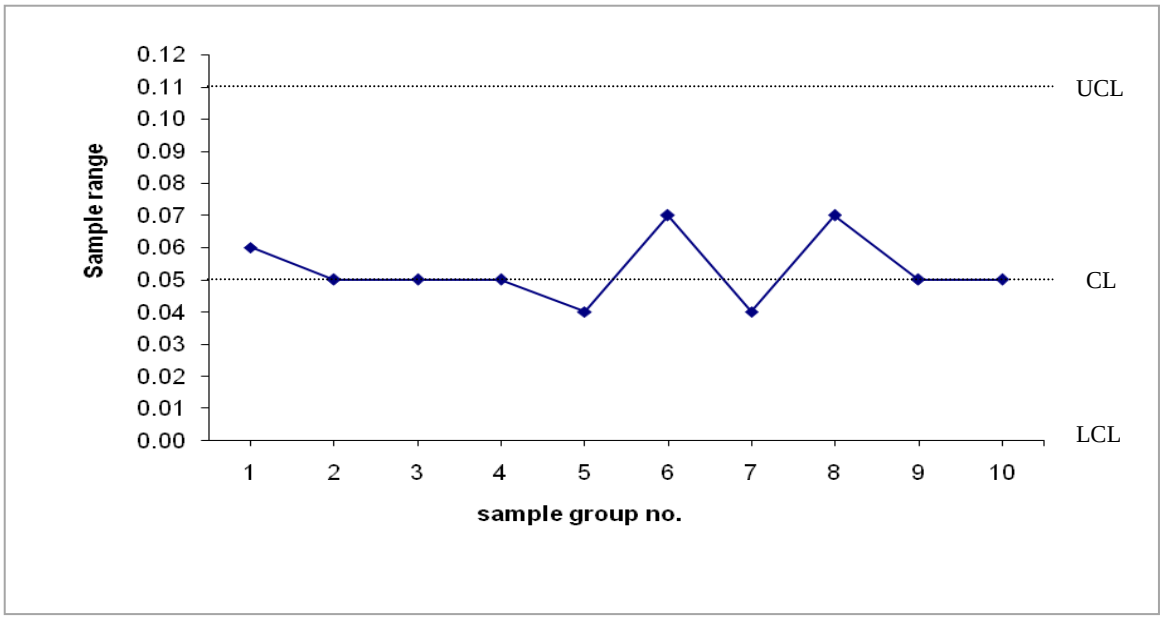


Figure 4.46: R-Chart for Vault diameter

In the figure 4.46 of range chart for vault diameter, it is obvious that ranges of sample groups 1 to 5 have central tendency. From sample groups 5 to 9 there are successive alternate variations of range as indicated by upward and downward sloping lines. The ranges of sample groups 9 to 10 have central tendency. The ranges of sample groups 2, 3, 4, 9 & 10 lie in the central line. All range points lie within the upper and the lower limit.

4.25.2 Control Chart for 2st cut lathe process

1st cut lenses are 2nd cut by Lathe machine for developing optic power on the next side of 1st cut lens with other parameters like optic diameter, vault diameter, vault depth, haptic area thickness, resolution (optical clarity) etc. For monitoring process control of 2nd cut lathe, only two parameters optic power (measured as focal length) and haptic area thickness were considered, other parameters/attributes of 2nd cut lens ignored. 50 successively 2nd cut lenses of FH 105 model were taken as samples and observed for optic power as focal length and haptic area thickness.

2nd cut lathe process control in relation to the parameter 'Focal length'

The sample lenses had been cut for +23.5 D (Dioptre). The corresponding standard focal length for optic power +23.5 Dioptre is 13.14 mm with tolerance range 12.99 mm to 13.29 mm. The focal lengths of those lenses were measured using calibrated Lens Bench and the results of 50 successively cut lenses are tabulated below in the table 4.27 in 'sample observation' columns. The results are divided into 10 sample groups. Each sample group consists of 5 successively cut lenses.

Table 4.27: Observation, Sample mean & Sample range of Focal length

Sample group no.	**sample observation**					**Total**	**Sample mean**	**Sample range**
1	13.18	13.15	13.20	13.16	13.15	65.84	13.17	0.05
2	13.14	13.19	13.15	13.15	13.19	65.82	13.16	0.05
3	13.15	13.17	13.18	13.12	13.14	65.76	13.15	0.06
4	13.17	13.16	13.15	13.20	13.19	65.87	13.17	0.05
5	13.13	13.16	13.14	13.17	13.15	65.75	13.15	0.04
6	13.12	13.18	13.18	13.19	13.14	65.81	13.16	0.07
7	13.14	13.20	13.20	13.20	13.18	65.92	13.18	0.06
8	13.15	13.17	13.15	13.15	13.14	65.76	13.15	0.03
9	13.11	13.14	13.17	13.17	13.13	65.72	13.14	0.06
10	13.18	13.19	13.19	13.14	13.15	65.85	13.17	0.05
						Total	**131.62**	**0.52**

For $\bar{X}$-Chart:

*Setting control limits: (*from *Appendix–9)*

Central Line, CL = 13.16 mm

Upper Control Limit, UCL = 13.19 mm

Lower Control Limit, LCL = 13.13 mm

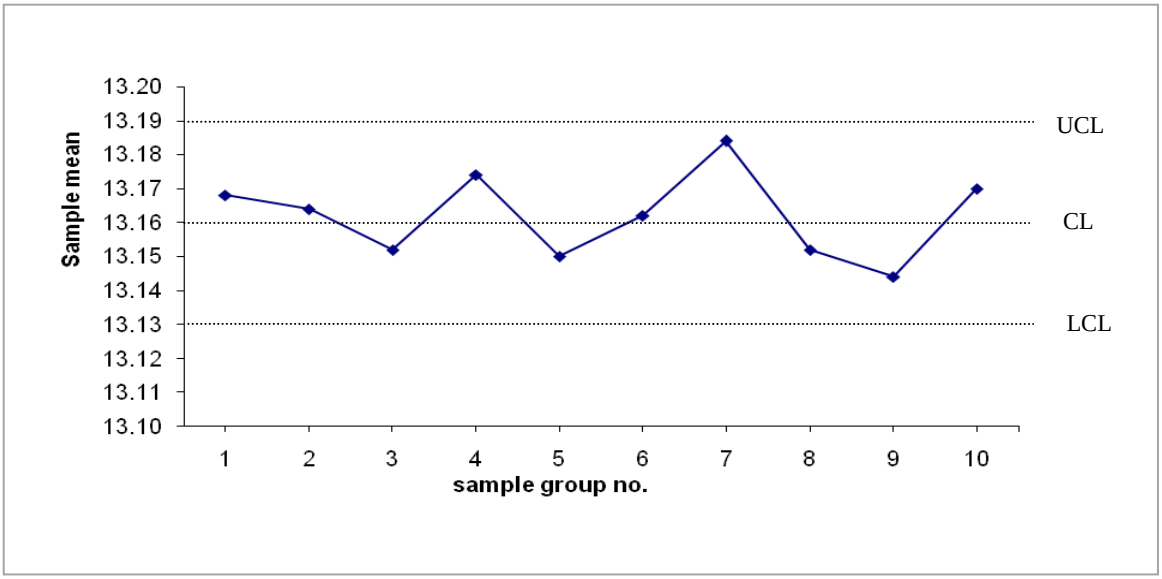


Figure 4.47: $\overline{X}$-Chart for focal length

In the figure 4.47 of mean chart for focal length, it is obvious that means of sample groups 1 to 6 have normal tendency. From sample groups 6 to 7 the mean value increases to near upper control limit. From sample group 7 to 8 the mean value decreases. From points 8 to 10, the mean value has normal tendency. The sample group no 2 and 6 lie in the central line. However, all mean points lie within the upper and the lower limit.

For R-Chart:

Setting control limits :(from *Appendix–9)*

Central Line, CL = 0.05 mm

Upper Control Limit, UCL = 0.11 mm

Lower Control Limit, LCL = 0 mm

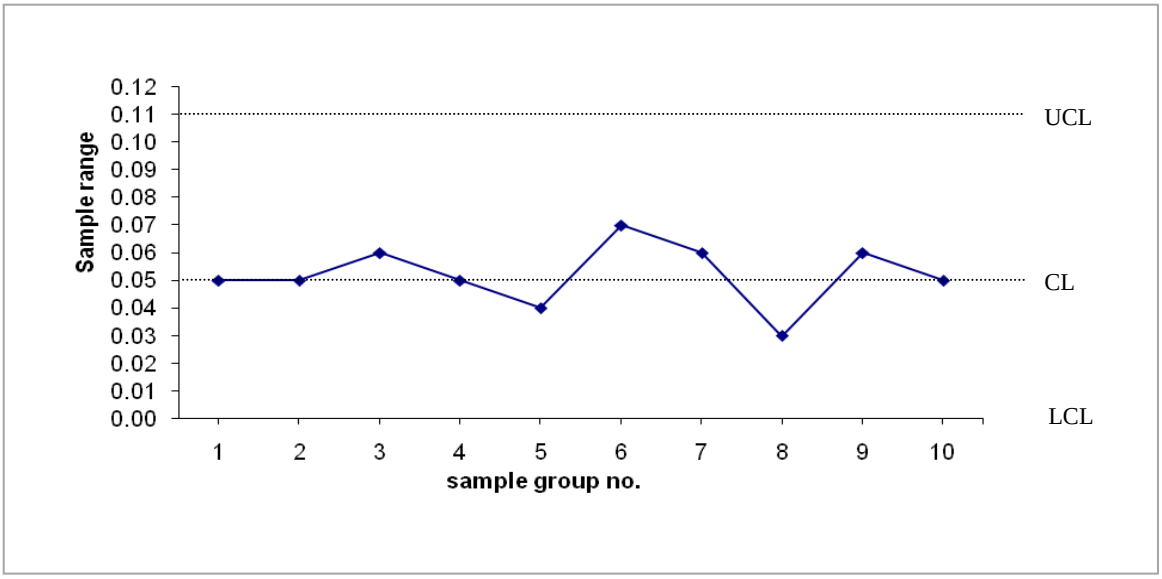


Figure 4.48: R-Chart for focal length

In the figure 4.48 of range chart for focal length, it is obvious that ranges of all sample groups 1 to 10 have normal tendency towards central line. The ranges of sample groups 1, 2, 4 & 10 lie in the central line. All range points lie within the upper and the lower limit.

2nd cut lathe process control in relation to the parameter 'Haptic area thickness'

The standard limit of range for haptic area thickness in 2st cut stage is 0.160 mm to 0.190 mm for FH 105 model of lenses. The lenses were measured for haptic area thickness with the help of calibrated profile projector and the results of 50 successively cut lenses are tabulated below in the table 4.28 in 'sample observation' columns. The results are divided into 10 sample groups. Each sample group consists of 5 successively cut lenses.

Table 4.28: Observation, Sample mean & Sample range of Haptic area thickness

Sample group no.	sample observation					Total	Sample mean	Sample range
1	0.176	0.168	0.182	0.180	0.172	0.878	0.176	0.014
2	0.172	0.182	0.175	0.175	0.169	0.873	0.175	0.013
3	0.178	0.181	0.182	0.175	0.175	0.891	0.178	0.007
4	0.180	0.179	0.182	0.183	0.168	0.892	0.178	0.015
5	0.185	0.177	0.185	0.178	0.169	0.894	0.179	0.016
6	0.182	0.180	0.182	0.184	0.182	0.910	0.182	0.004
7	0.179	0.180	0.182	0.176	0.170	0.887	0.177	0.012
8	0.177	0.181	0.182	0.175	0.169	0.884	0.177	0.013
9	0.175	0.182	0.182	0.178	0.181	0.898	0.180	0.007
10	0.176	0.180	0.182	0.177	0.169	0.884	0.177	0.013
						Total	**1.778**	**0.114**

For $\bar{X}$-Chart:

*Setting control limits: (*from *Appendix–10)*

Central Line, CL = 0.178 mm

Upper Control Limit, UCL = 0.184 mm

Lower Control Limit, LCL = 0.171 mm

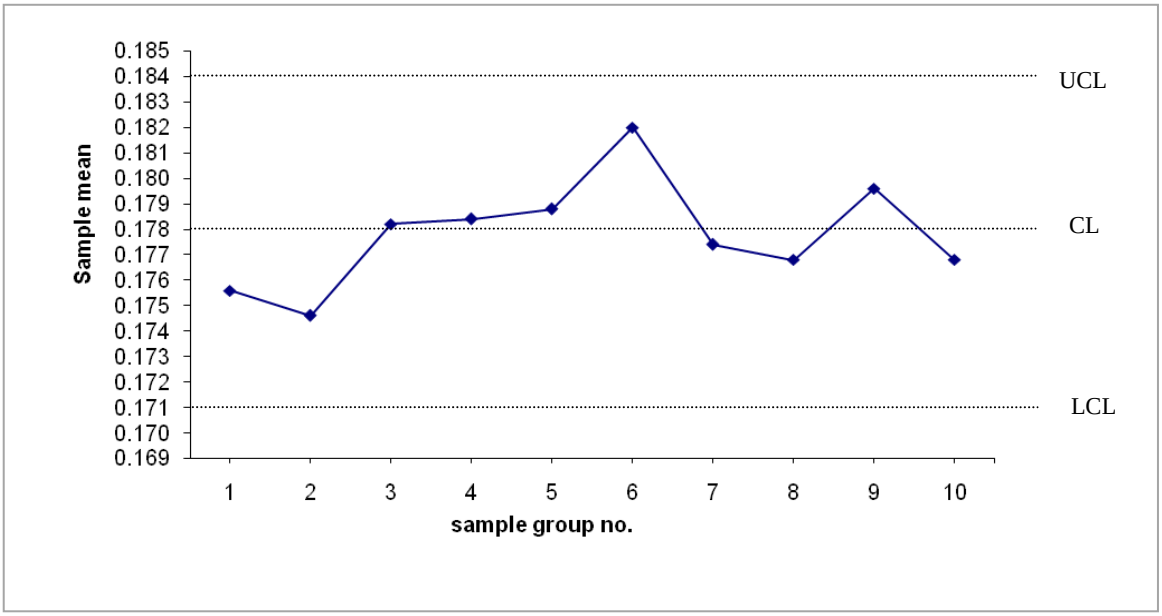


Figure 4.49: $\bar{X}$-Chart for Haptic area thickness

In the figure 4.49 of mean chart for Haptic area thickness, it is obvious that means of sample groups 1 to 5 have normal tendency. From sample groups 5 to 7 there are successive alternate variations as indicated by upward and downward sloping lines. From sample groups 7 to 10 the mean value has normal tendency. The sample means 3 and 4 lie in the central line. However, all mean points lie within the upper and the lower limit.

For R-Chart:

Setting control limits :(from *Appendix–10)*

Central Line, CL = 0.011 mm

Upper Control Limit, UCL = 0.024 mm

Lower Control Limit, LCL = 0 mm

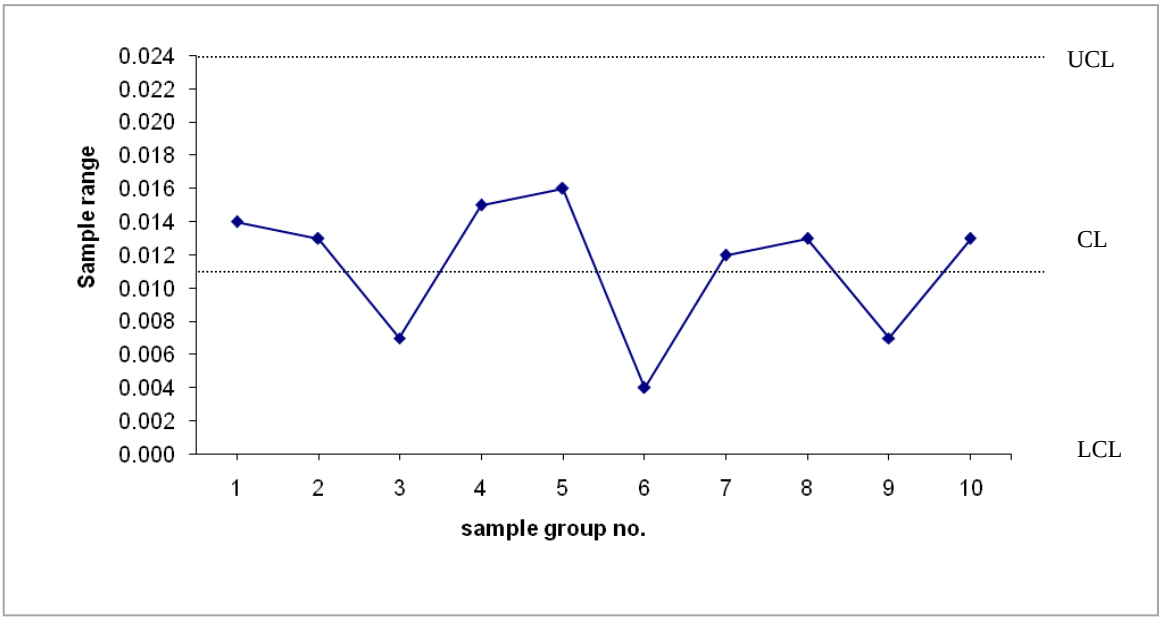


Figure 4.50: R-Chart for Haptic area thickness

In the figure 4.50 of range chart for Haptic area thickness, it is obvious that ranges of sample groups 1 to 2, 4 to 5, 7 to 8 have normal tendency whereas the ranges of 2 to 4, 5 to 7, 8 to 10 have alternative variations as indicated by sharp upward and downward lines. However, all mean points lie within the upper and the lower limit.

4.25.3 Control Chart for Milling of Lens

In the milling process, the profile of lens is developed for shaping the lenses in prescribed profile of standard. 2nd cut lenses are milled by Milling machine for developing physical parameters like optic diameter, overall diameter, haptic width etc. For monitoring process control of milling, three parameters optic diameter, overall diameter & haptic width were considered. 50 successively milled lenses of FH 105 model were taken as samples and measured for optic diameter, overall diameter & haptic width.

Milling process control in relation to the parameter 'Optic diameter'

The standard limit of range for optic diameter in milling stage is 5.60 mm to 5.80 mm for FH 105 model of lenses. The lenses were measured for optic diameter with the help of calibrated profile projector and the results of 50 successively cut lenses are tabulated below in the table 4.29 in 'sample observation' columns. The results are divided into 10 sample groups. Each sample group consists of 5 successively cut lenses.

Table 4.29: Observation, Sample mean & Sample range of Optic diameter

Sample group no.	sample observation					Total	Sample mean	Sample range
1	5.72	5.70	5.67	5.71	5.68	28.48	5.70	0.05
2	5.74	5.71	5.69	5.73	5.75	28.62	5.72	0.06
3	5.70	5.75	5.76	5.72	5.77	28.70	5.74	0.07
4	5.76	5.80	5.79	5.82	5.75	28.92	5.78	0.07
5	5.77	5.71	5.72	5.75	5.76	28.71	5.74	0.06
6	5.72	5.69	5.71	5.70	5.67	28.49	5.70	0.05
7	5.72	5.75	5.69	5.68	5.71	28.55	5.71	0.07
8	5.68	5.71	5.70	5.75	5.69	28.53	5.71	0.07
9	5.71	5.67	5.65	5.72	5.69	28.44	5.69	0.07
10	5.69	5.73	5.69	5.74	5.72	28.57	5.71	0.05
						Total	**57.20**	**0.62**

For $\bar{X}$-Chart:

*Setting control limits: (*from *Appendix–11)*

Central Line, CL = 5.72 mm

Upper Control Limit, UCL = 5.76 mm

Lower Control Limit, LCL = 5.68 mm

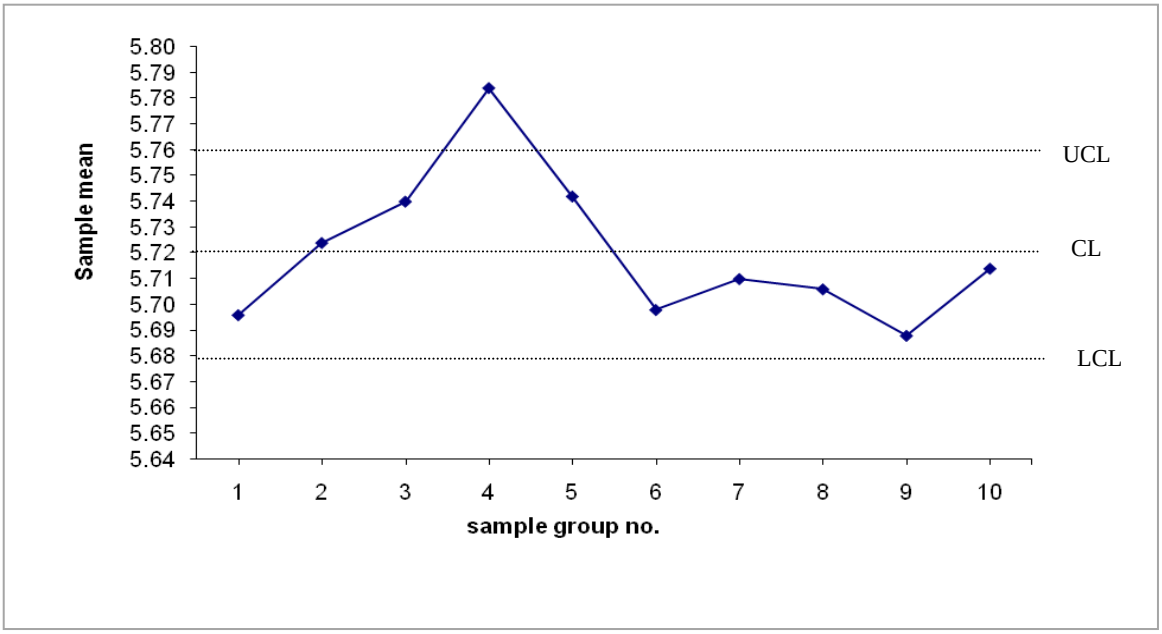


Figure 4.51: $\bar{X}$-Chart for Optic diameter

In the figure 4.51 of mean chart for optic diameter, it is obvious that means of sample groups 1 to 4 have increasing trend indicated by upward sloping lines crossing the upper control limit with the point 4 lying outside. From sample groups 4 to 6, the mean values decreases sharply which are indicated by downward sloping lines. From sample groups 6 to 10, the mean values lie below the central line with less fluctuations. The point 2 lies in the central line and the point 9 lies near the lower control limit. The sample group 4 lies outside the upper control limit indicating the process being out of control.

For R-Chart:

Setting control limits :(from *Appendix–11)*

Central Line, CL = 0.06 mm

Upper Control Limit, UCL = 0.13 mm

Lower Control Limit, LCL = 0 mm

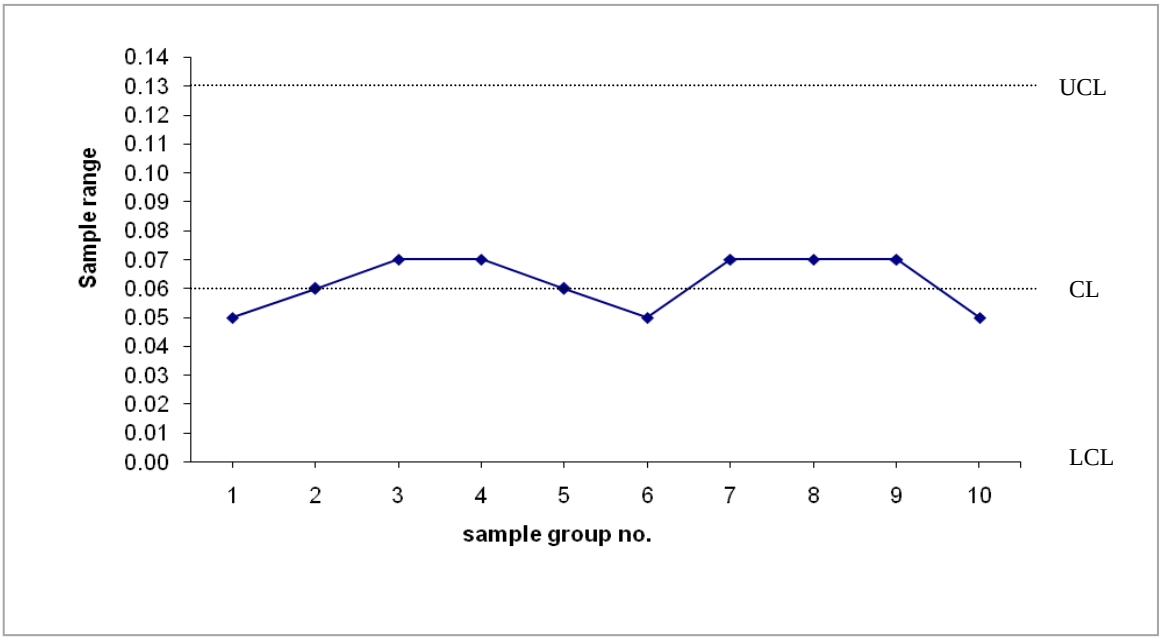


Figure 4.52: R-Chart for Optic diameter

In the figure 4.52 of range chart for optic diameter, it is obvious that all ranges of sample groups 1 to 10 have normal tendency towards central line. The ranges of sample groups 2 & 5 lie in the central line. All range points lie within the upper and the lower limit.

Milling process control in relation to the parameter 'Overall diameter'

The standard limit of range for overall diameter in milling stage is 12.40 mm to 12.60 mm for FH 105 model of lenses. The lenses were measured for optic diameter with the help of calibrated profile projector and the results of 50 successively cut lenses are tabulated below in the table 4.30 in 'sample observation' columns. The results are divided into 10 sample groups. Each sample group consists of 5 successively cut lenses.

Table 4.30: Observation, Sample mean & Sample range of Overall diameter

Sample group no.	sample observation					Total	Sample mean	Sample range
1	12.48	12.52	12.51	12.54	12.50	62.55	12.51	0.06
2	12.50	12.49	12.54	12.55	12.49	62.57	12.51	0.06
3	12.47	12.48	12.50	12.53	12.47	62.45	12.49	0.06
4	12.51	12.52	12.49	12.51	12.50	62.53	12.51	0.03
5	12.47	12.48	12.54	12.53	12.49	62.51	12.50	0.07
6	12.50	12.53	12.49	12.50	12.47	62.49	12.50	0.06
7	12.56	12.52	12.54	12.52	12.57	62.71	12.54	0.05
8	12.54	12.58	12.51	12.54	12.57	62.74	12.55	0.07
9	12.55	12.47	12.49	12.47	12.55	62.53	12.51	0.08
10	12.49	12.51	12.54	12.50	12.56	62.60	12.52	0.07
						Total	**125.14**	**0.61**

For $\bar{X}$-Chart:

*Setting control limits: (*from *Appendix–12)*

Central Line, CL = 12.51 mm

Upper Control Limit, UCL = 12.55 mm

Lower Control Limit, LCL = 12.48 mm

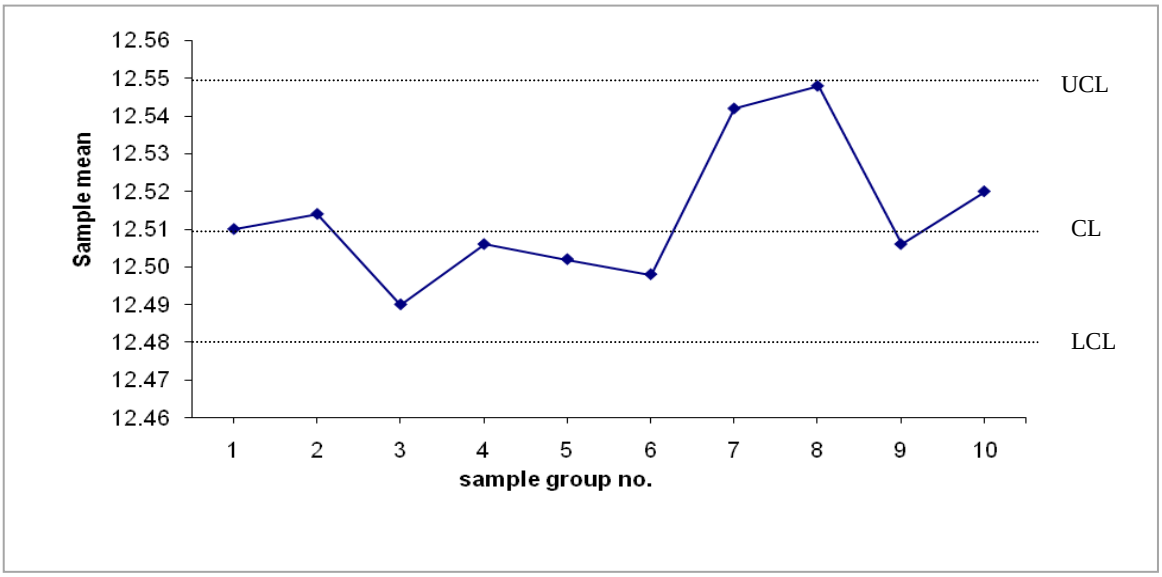


Figure 4.53: $\bar{X}$-Chart for Overall diameter

In the figure 4.53 of mean chart for overall diameter, it is obvious that means of sample groups 1 to 2 have normal tendency towards central line, but from the sample group 2 to 4, the mean value decreases and again increases. From sample groups 4 to 6, the mean value decreases slightly below the central line. From sample group 6 to 7, the mean value increases extremely indicated by upward sloping line. From sample group 7 to 8, the mean value increases slightly meeting upper control limit. Then suddenly the mean value decreases sharply from the sample group 8 to 9 as indicated by the downward sloping line. Then the mean value increases from sample group 9 to 10. The sample points 1, 2, 4 & 9 lie in the central line, but the sample group 8 lies in the upper control limit. However, all mean points lie within the upper and the lower limit, one mean point lying in the upper control limit.

For R-Chart:

Setting control limits :(from *Appendix–12)*

Central Line, CL = 0.06 mm

Upper Control Limit, UCL = 0.13 mm

Lower Control Limit, LCL = 0 mm

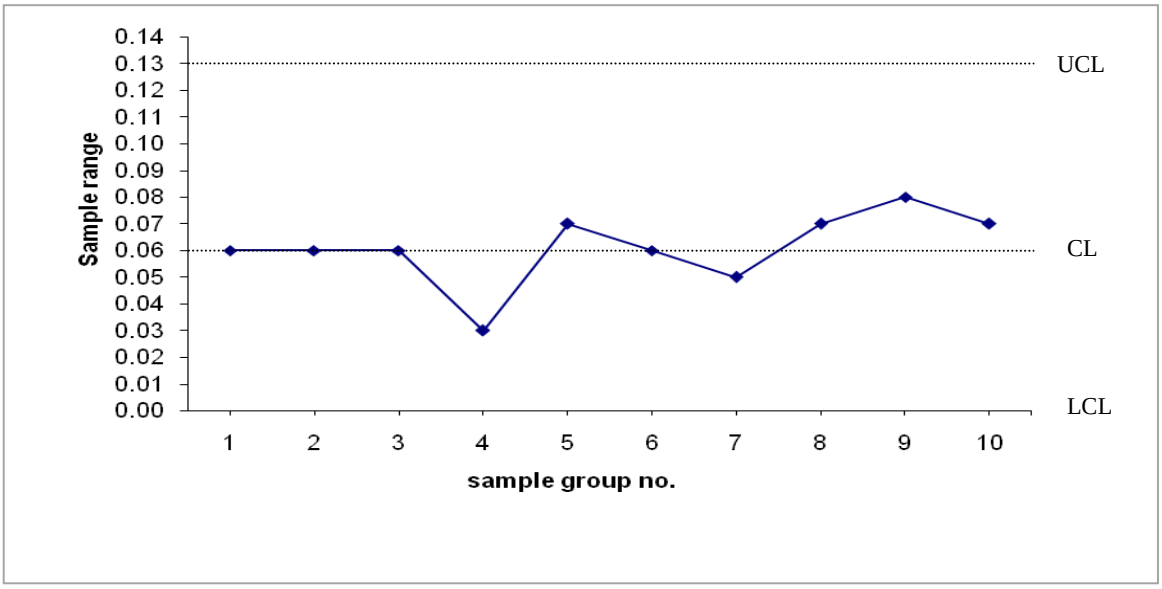


Figure 4.54: R-Chart for Overall diameter

In the figure 4.54 of range chart for overall diameter, it is obvious that ranges of sample groups 1 to 3 and 5 to 10 have normal tendency towards central line. From sample point 3 to 5, the range value decreases and increases as indicated by downward and upward lines. The ranges of sample groups 1, 2, 3 & 6 lie in the central line. All range points lie within the upper and the lower limit.

Milling process control in relation to the parameter 'Haptic width'

The standard limit of range for haptic width in milling stage is 0.160 mm to 0.200 mm for FH 105 model of lenses. The lenses were measured for optic diameter with the help of calibrated profile projector and the results of 50 successively cut lenses are tabulated below in the table 4.31 in 'sample observation' columns. The results are divided into 10 sample groups. Each sample group consists of 5 successively cut lenses.

Table 4.31: Observation, Sample mean & Sample range of Haptic width

Sample group no.	**sample observation**					**Total**	**Sample mean**	**Sample range**
1	0.176	0.174	0.177	0.175	0.180	0.882	0.176	0.006
2	0.175	0.182	0.179	0.182	0.181	0.899	0.180	0.007
3	0.178	0.179	0.176	0.180	0.179	0.892	0.178	0.004
4	0.184	0.186	0.183	0.190	0.188	0.931	0.186	0.007
5	0.190	0.184	0.185	0.181	0.189	0.929	0.186	0.009
6	0.194	0.188	0.185	0.192	0.194	0.953	0.191	0.009
7	0.199	0.200	0.202	0.201	0.199	1.001	0.200	0.003
8	0.200	0.195	0.193	0.196	0.190	0.974	0.195	0.010
9	0.195	0.191	0.192	0.189	0.188	0.955	0.191	0.007
10	0.186	0.185	0.181	0.187	0.180	0.919	0.184	0.007
						Total	**1.867**	**0.069**

For $\bar{X}$-Chart:

*Setting control limits: (*from *Appendix–13)*

Central Line, CL = 0.187 mm

Upper Control Limit, UCL = 0.191 mm

Lower Control Limit, LCL = 0.183 mm

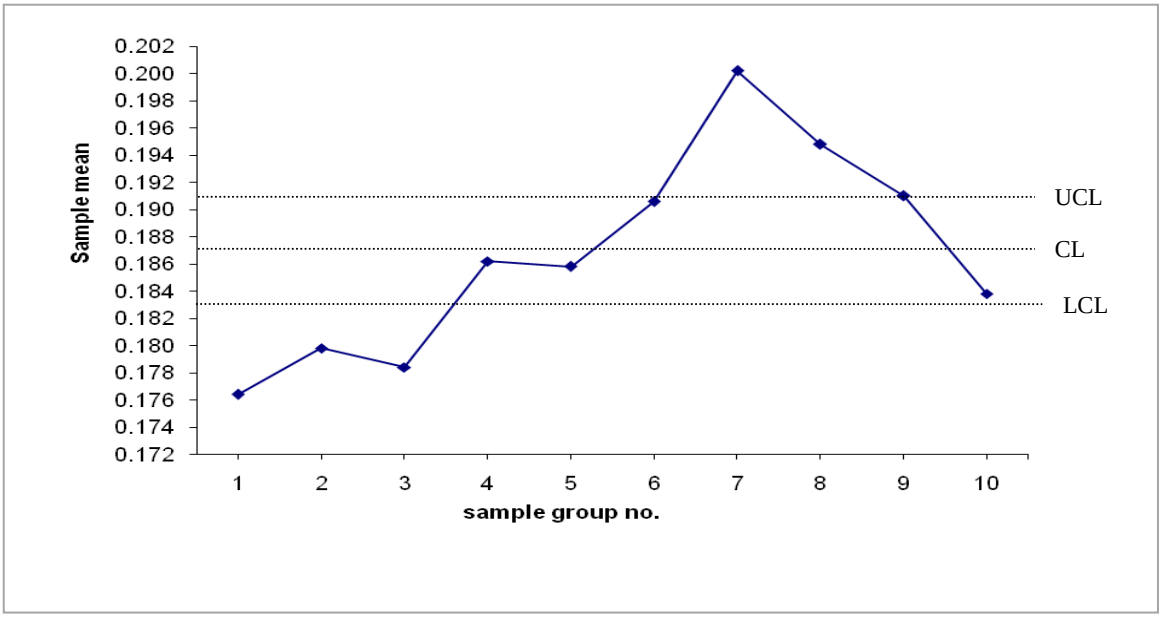


Figure 4.55: $\overline{X}$-Chart for Haptic width

In the figure 4.55 of mean chart for haptic width, it is obvious that means of sample groups 1, 2 and 3 lie outside the lower limit. From point 3 to 5, the mean value increases sharply towards the central line. From point 4 to 5, the mean values have normal tendency, but from the sample group 5 to 6, the mean value increases sharply meeting upper control limit by the point 6. From point 6 to 7, the mean value increases sharply with the point 7 outside the upper control limit. From sample groups 7 to 10, the mean value decreases continuously crossing the UCL and CL towards LCL. The sample points 1, 2 and 3 lie below LCL; the sample points 7 and 8 lie above UCL; and the points 6 and 9 lie in the UCL. The point 10 lies near the LCL.

For R-Chart:

Setting control limits :(from *Appendix–13)*

Central Line, CL = 0.007 mm

Upper Control Limit, UCL = 0.015 mm

Lower Control Limit, LCL = 0 mm

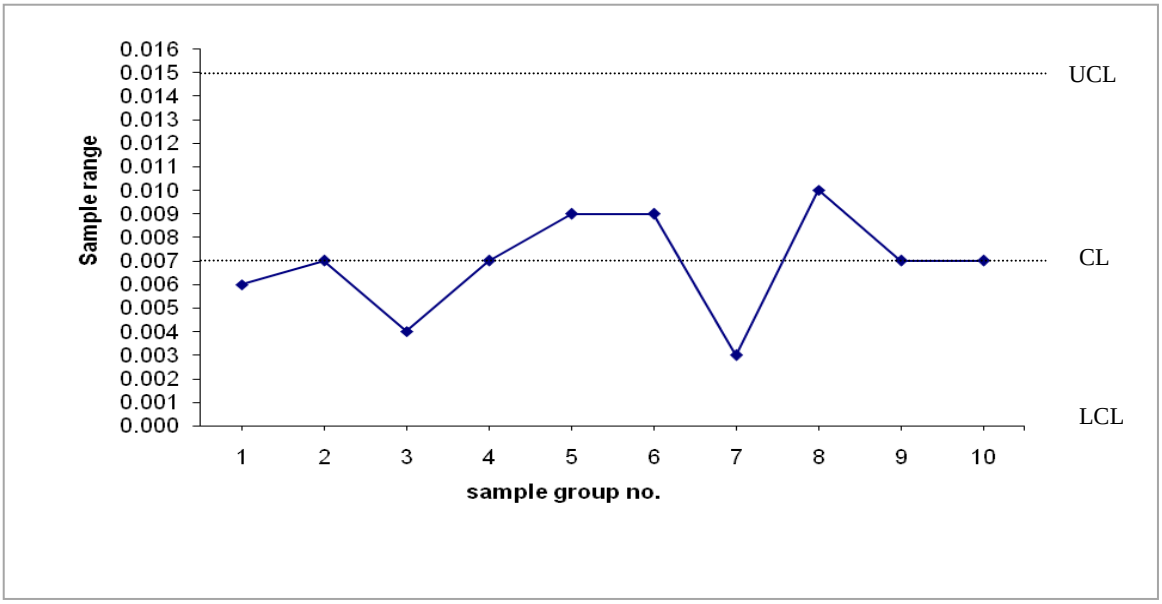


Figure 4.56: R-Chart for Haptic width

In the figure 4.56 of range chart for haptic width, it is obvious that ranges of sample groups 1 to 2 have normal tendency. From sample point 2 to 4, the range values have slight alternate variations. From the point 4 to 6, the range has normal tendency. From point 6 to 9, there are sharp alternate variations indicated by downward and upward lines. The ranges of sample groups 2, 4, 9 & 10 lie in the central line. All range points lie within the upper and the lower limit.

4.25.4 Control Chart for Polishing of Lens

The lenses produced from the lathe machine and then milling machine have physical dimensions - optic body, haptics; and required optical dimensions- optical power in dioptre, resolution etc. These lenses have lathe marks, milling marks, sharp and pointed edges, cutting chips on its surface. So, they need to be removed by smooth polishing process. Polishing slurries are prepared in special type of glass bottles with the composition of different chemicals and mixture of glass/ceramic beads of different sizes. The lenses of one batch/lot are put into the slurry. The polishing slurries with the lenses are kept into tumbling machine for polishing of lenses. The surfaces of lenses- optic body and haptics are polished by tumbling the lenses on tumbling machine with slurry in a barrel and thus polished with acceptable quality level of lenses.

Since a polishing slurry contains a single batch/lot of lenses to avoid batch mix-up, 10 slurries were randomly sampled after finishing polishing process and given them numbers as sample group no. 1 to 10. From each slurry/batch 100 lenses were randomly sampled and checked for surface quality of the lenses on the calibrated microscope. The no of defectives and fraction defective are tabulated below in the table 4.32.

Table 4.32: Defectives and Fraction defective of polished lenses

Sample group no.	No of defectives	Fraction Defective
1	15	0.15
2	21	0.21
3	10	0.10
4	11	0.11
5	18	0.18
6	19	0.19
7	13	0.13
8	17	0.17
9	26	0.26
10	18	0.18
	168	

For p-Chart:

Setting control limits :(from *Appendix–14)*

Central Line, CL = 0.17

Upper Control Limit, UCL = 0.28

Lower Control Limit, LCL = 0.06

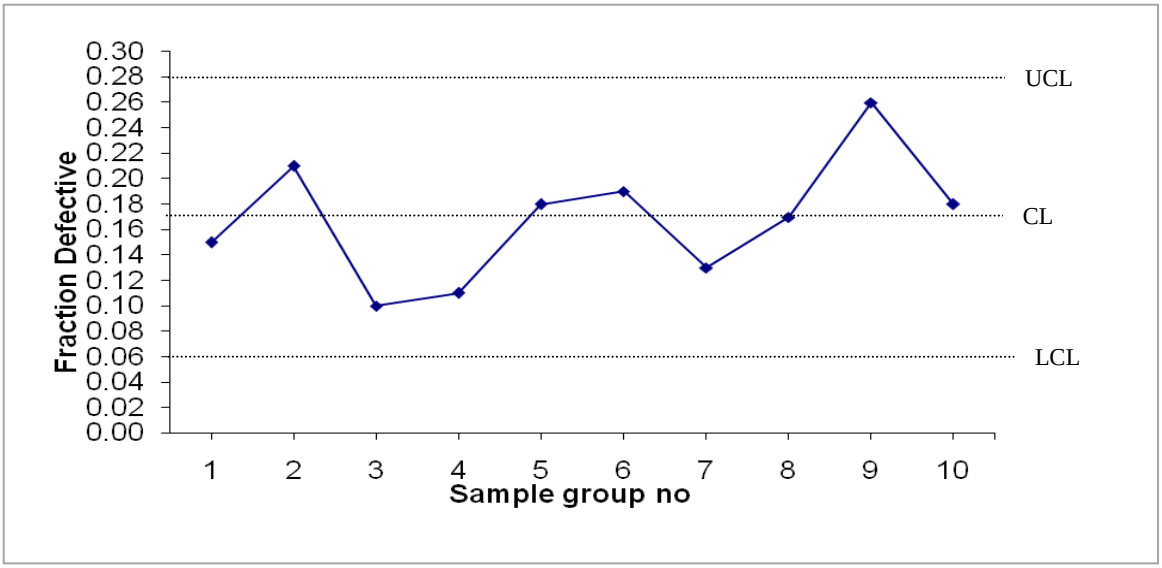


Figure 4.57: p-Chart for Surface quality of polished lenses

In the figure 4.57 of p-chart for fraction defective in polishing process, it is obvious that from sample groups 1 to 2 the fraction defective value increases. From sample group 2 to 3, the fraction defective value decreases sharply. From sample groups 3 to 8, the fraction defective value has normal tendency. From sample groups 8 to 10, the fraction value increases to near UCL and then decreases towards central line. However all the points lie within the limit.

4.26 Major Findings

The major findings from this study are presented below:

General findings

- The management team makes the decisions which are presented to the employees for implementation. The management involves in problem solving activities.
- The employees of the FH IOL Lab have concepts that quality is the issue of only QA department, and that quality is the acceptance or rejection of materials/products on the basis of certain criteria. They have no idea of internal suppliers and internal customers inside the FH IOL Lab.
- The quality control technicians have no idea about the quality control tools- pareto analysis, cause and effect diagram, control charts etc.

Findings on Production vs Quality Assurance personnel

- The ratio of production personnel to quality assurance personnel is 2.5 i.e. the manufacturing activities of 2.5 production personnel are monitored and verified by 1 quality assurance staff in general.

Findings on documentation

- The FH IOL Lab has 4 levels in documentation. At the top, there are mission statement, quality policy and quality objectives that are stated in quality manual. The quality sub manuals cover major functions- production, quality assurance, engineering, microbiology and administration. Each of these quality sub manual consists of Standard Operating Procedures (SOPs). At the bottom lie records, forms, templates, drawings.
- The quality manual of the FH IOL Lab has excluded the ISO clause '7.3 Design and development' under the section '7 Product Realization'.

Findings on authority and responsibility

- The highest position in the organizational hierarchy is General Manager. The Quality Assurance (QA) manager is responsible for overall quality management system (QMS) and implementation throughout the whole organization. The top management had appointed QA Manager as the management representative of FH IOL Lab.
- Management review is the evaluation of QMS by top management. Management Review of FH IOL Lab is held at least twice a year. The Management Review body ensures the involvement of top management by including Medical Director and General Manager of the FH IOL Lab.

Findings on Staff Trainings

- There are 3 types of staff trainings in the FH IOL Lab - *General training* is given to all the employees for general/common purpose; *Job Specific training* is given to an employee to perform his/her particular job. *Supplementary trainings* include retraining, annual general training, skill/knowledge enhancement training.
- Every employee of FH IOL Lab must have training on related SOPs to perform the works. No one is authorized to work without training in related SOPs.

Findings on Hazards and staff safety

- All employees receive annual safety trainings on evacuation procedure in emergency and ETO gas spill.
- To minimize the spread of ETO gas, sterilization rooms have negative pressure inside to prevent spreading ETO gas from ETO room to other areas.
- Annual medical checkup of all staff is conducted.
- The FH IOL Lab lacks adequate safety programs for emergency preparedness (fire, weather, earthquake, disaster), occupational injury/illness, and supportive safety applicable to one's respective job tasks.

Findings on infrastructure and work environment

- The FH IOL Lab has maintained clean room environment in which level of biological, chemical and particulate contaminations are controlled through regular monitoring and controlling particle size, particle number, air pressure, temperature, humidity, microorganisms.

Findings on in-process QC checking

- In every stage of production, QC checks are carried out by QC technician before starting normal work by production technician. *QC Line Clearance check* is made by QC Technician to ensure clean and free workstation; *QC process startup check* is made to ensure required lenses, materials and documents; and *QC Setup check* is done to ensure the setting up of the parameters of lenses in machinery operations.

Findings on purchase

- Incoming items/materials are not used or processed until they have been inspected and accepted for use.

Findings on Customer complaints

- In 2005, one customer complaint was registered and in the following years from 2006 to 2009, there was no customer complaint while sales volume is increasing.

Findings on Customer Satisfaction Surveys 2005-2009

- The customer response rate in 2007, 2008 & 2009 were 40%, 47% & 48% respectively.
- In 2005, the customer rating was minimum (3.70) for 'Price vs Quality' and maximum (4.70) for 'Product Quality'.
- In 2006, the customer rating was minimum (3.80) for 'Product delivery' and maximum (4.44) for 'Shipping packaging'.
- In 2007, the customer rating was minimum (3.25) for ''Product packaging' and maximum (4.70) for 'Shipping packaging'.

- In 2008, the customer rating was minimum (3.50) for 'Attentiveness to Complaints' and maximum (4.22) for ''Relationship'.
- In 2009, the customer rating was minimum for (3.60) 'Price vs Quality' and maximum (4.70) for 'Relationship'.
- For 'Product Quality', the customer rating was maximum (4.70) in 2005 and minimum (4.10) in 2009; and the trend is decreasing.
- For 'Product Delivery', the customer rating was maximum (4.50) in 2005 and minimum (3.75) in 2007; and the trend is decreasing.
- For 'Attentiveness to Complaints', the customer rating was maximum (4.40) in 2005 and minimum (3.50) in 2008; and the trend is decreasing.
- For 'Relationship', the customer rating was maximum (4.70) in 2009 and minimum (4.00) in 2007; the trend is slightly increasing.
- For 'Shipping packaging', the customer rating was maximum (4.70) in 2007 and minimum (4.11) in 2008; and the trend is slightly decreasing.
- For 'Product packaging', the customer rating was maximum (4.60) in 2005 and minimum (3.25) in 2007; and the trend is decreasing.
- For 'Price vs Quality', the customer rating was maximum (4.11) in 2006 and minimum (3.60) in 2009; and the trend is slightly decreasing.
- The customer satisfaction index was maximum (4.11 i.e. 88%) in 2005 and minimum (3.96 i.e. 79%) in 2008; and the trend is decreasing.

Findings on Non-conformances

- The no of NC observed was highest (117) in 2008 and lowest (37) in 2006; and the trend is increasing.
- The no of batches per NC was the highest (13) in 2006 and lowest (6) in 2008; and the trend is decreasing i.e. no of non-conformances is increasing for lesser no of batches.
- The no of issued buttons per NC was the highest (6369) in 2006 and lowest (3101) in 2008; the trend is decreasing i.e. no of non-conformances is increasing for lesser no of buttons.

Findings on Deviations

- The no of deviations made was highest (13) in 2008 and lowest (4) in 2009; and the trend is decreasing.

Findings on Corrective Actions

- The no of corrective actions taken was highest (55) in 2009 and (18) lowest in 2005; and the trend is increasing.

Findings on Issue, Reject, Production & Sales Quantity of FH model of IOLs

- The no of batches issued was highest (646) in 2009 and lowest (433) in 2005; and the trend is increasing.
- The no of buttons issued was highest (375,480) in 2009 and lowest (248,681); and the trend is increasing.
- The reject quantity was lowest (29,395 units) in 2006 and highest (85,314 units) in 2008; and the trend is increasing.
- The reject percentage was highest (24%) in 2008 and lowest (12%) in 2006; and the trend is increasing.
- The production volume was lowest (190,321 units) in 2005 and highest (296,641 units) in 2009; and the trend is increasing.
- The sales volume was lowest (176,641 units) in 2006 and highest (294,864 units) in 2009; and the trend is increasing.

Findings on Pareto Analysis

- In 2005, out of 58,360 total reject units, 31,945 units (55%) were rejected due to poor surface quality causing the highest rejection; and 18,355 units (31%) were rejected due to Haptic broken/stress causing the second highest rejection.
- In 2006, out of 29,395 total reject units, 17,539 units (60%) were rejected due to poor surface quality causing the highest rejection; and 6,891 units (23%) were rejected due to Haptic broken/stress causing the second highest rejection.

- In 2007, out of 63,881 total reject units, 43,612 units (68%) were rejected due to poor surface quality causing the highest rejection; and 12,793 units (20%) were rejected due to Haptic broken/stress causing the second highest rejection.
- In 2008, out of 85,314 total reject units, 51,093 units (60%) were rejected due to poor surface quality causing the highest rejection; and 24,177 units (28%) were rejected due to Haptic broken/stress causing the second highest rejection.
- In 2009, out of 78,839 total reject units, 50,541 units (64%) were rejected due to poor surface quality causing the highest rejection; and 15,459 units (20%) were rejected due to Haptic broken/stress causing the second highest rejection.
- From 2005 to 2009, out of 315,789 total reject units, 194,730 units (62%) were rejected due to poor surface quality causing the highest rejection; and 77,675 units (25%) were rejected due to Haptic broken/stress causing the second highest rejection.

Findings on Hypothesis Test for Button Diameter

- The average diameter of the buttons is not equal to the standard diameter 18.00 mm.

Findings on control charts

- Control charts are made by the management level by extracting the data from the past records.

1st cut lathe process in relation to the parameter 'Vault diameter'

- In Mean chart (X chart), sharp alternative variations were detected from the plot 6 to 10. All plots lie within the limit.
- In Range chart (R chart), alternative variations were detected from the plot 5 to 9. All points lie within the limit.

2nd cut lathe process in relation to the parameter 'Focal length'

- In Mean chart (X chart), the point 7 lies near the UCL. All points lie within the limit.

- In Range chart (R chart), all points have normal tendency towards central line. All points lie within limit.

2nd cut lathe process in relation to the parameter 'Haptic area thickness'

- In Mean chart (X chart), alternate variations were detected from the plot 5 to 7. All plots lie within the limit.
- In Range chart (R chart), sharp alternate variations were detected from the plot 2 to 4, 5 to 7 and 8 to 10. All plots lie within the limit.

Milling process in relation to the parameter 'Optic diameter'

- In Mean chart (X chart), sharp alternate variations were observed from the plot 3 to 6. The plot 4 lies outside the upper control limit. The plot 9 lies near the lower control limit
- In Range chart (R chart), all points have normal tendency towards central line with very low variations.

Milling process in relation to the parameter 'Overall diameter'

- In Mean chart (X chart), extreme alternate variations were observed from the plot 6 to 9. The plot 8 lies in the upper control limit. All plots lie within the limit.
- In Range chart (R chart), all points have normal tendency.

Milling process in relation to the parameter 'Haptic width'

- In Mean chart (X chart), the points 1, 2 and 3 lie below LCL; the points 7 and 8 lie above UCL; the points 6 and 9 lie in the UCL; and the point 10 lies near the LCL.
- In Range chart (R chart), sharp alternate variations were detected from the plot 6 to 8. All plots lie within the limit.

Tumble Polishing process of lenses

- In p-chart for fraction defective, alternate variations were observed from the plot 1 to 3 & 8 to 10. All plots lie within the limit.

CHAPTER 5 • SUMMERY, CONCLUSION AND RECOMMENDATION

5.1 Summary

The entire quality system is reflected in the final products/services. The goods and services of higher quality at reasonable cost certainly increases demand in the market. The production of quality goods/services lead to industrial development which, in turn, results economic development in a country. So quality is being regarded as the major parameter of national growth and development.

Quality has become one of the most important competitive strategic tools for continual success of an organization. The aim of business is long-term profitability. The adoption of quality system and application of quality control tools and techniques lead to cost reduction and productivity improvement. Over a certain period of time, profitability can be ensured through customer satisfaction with quality products by keeping production cost at a minimum. Global competitiveness, consumer rights, quality awareness, public issues like public health and environment issues are the major factors that directly or indirectly demand quality standards in the products.

Though quality is reflected in the final product, the quality is essential in every parts and components of a system. For ensuring quality in the final output, there must be quality inputs and quality processing. For this purpose, Quality Management System (QMS) plays the vital role from system designing and implementation to system evaluation. Quality Management System (QMS) can be defined as a set of co-ordinated activities to direct and control an organization in order to continually improve the effectiveness and efficiency of its performance.

Nepal is a developing country. The quality practice in Nepal is not matured. Due to lack of quality awareness in people and lack of professional quality experts, the quality concepts and practices in Nepal are traditional and confined to only ‘acceptance and rejection’ criteria on products. The productivity movement in Nepal is noticed to begin

only from early 1960s after Nepal joined Asian Productivity Organization (APO) in 1961. The quality movement in the country started with the government's Industrial Policy in 1974. National Standards Body like Nepal Bureau of Standards & Metrology (NBSM) came into existence for the activities concerning standardization and quality control in the industrial production. The establishment of Network for Quality, Productivity and Competitiveness - Nepal (NQPCN) in 2004 has initiated the professionalism in productivity and quality movements in Nepal. Recently, a trend has evolved to get international quality standard certificates in Nepal. Many organizations, from manufacturing to service sector in Nepal are already ISO certified and many industries are on the process of certification. This ratio of quality certification is found increasing year by year.

The Fred Hollows IOL Laboratory was established in 1992 as an integral part of Tilganga Eye Center. The Laboratory was certified by ISO in 1998 and CE Notified Body 0120 in 1998 by SGS, UK. The Lab was the first organization in Nepal to receive ISO certification and the first IOL manufacturer of Southeast Asia to have received the CE mark in. The Laboratory manufactures Intra-ocular Lens (IOL). IOLs are permanent optical implants inside the eye for visual correction by replacing the natural lens of the eye in the treatment of cataract blindness.

This research has combined both methods- qualitative as well as quantitative method. Flow charts were built to explain the major activities or procedures in the FH IOL Lab. Tables were made to enumerate the collected data. Figures were used to present the information. Flow charts, tables and figures were supported by the narrative explanation. Data were taken for 5 years from 2005 to 2009 for analysis. Input, Reject, Production and Sales figures of FH model of lenses were collected and analyzed for their trend. Pareto analysis was conducted to identify the major causes that lead to greater proportion of rejection. The necessary data from customer satisfaction survey reports from 2005 to 2009 were extracted and analyzed to determine the overall customer satisfaction level as well as attribute/factor wise satisfaction level.

The raw material for the production of FH model of lenses is PMMA buttons which are supplied into the manufacturing process with specified standard diameter. Hypothesis testing was performed to determine whether the average diameter of the PMMA button samples equals the standard value of the diameter. Machinery processes are the main manufacturing processes; other processes being cleaning, inspection, packaging. Control charts were constructed for machinery processes- lathe cutting process, milling process and polishing process. The lathe cutting process is for the development of optical power and visual resolution on blank buttons. The milling stage is the profiling/shaping process of lathe cut lenses. Polishing is the smoothing the surface of the lenses for surface quality. Control charts were developed for these processes to determine whether the process is stable or not over the period of time. The data related to nonconformance, corrective actions, deviations, customer complaints were collected for 5 years from 2005 to 2009 for their analysis.

The highest position in the organizational hierarchy is General Manager. The Organizational Structure in FH IOL Lab includes Quality Assurance (QA) Department which is responsible for overall quality management system (QMS) and implementation. The QA Manager is in charge of the department. The QA Manager is the management representative (MR) of FH IOL Lab. Periodic evaluation of QMS by top management is conducted through Management Review meeting. The QA Manager is responsible of regular internal quality audit.

The FH IOL Lab has maintained SOPs to scope the major functional areas- production, quality assurance, microbiology, engineering & administration. For the manufacturing processes to be carried out, the Lab has constructed clean room environment with environmental controls to minimize biological and particulate contamination. Periodic maintenance and calibration of machines/equipments are performed to ensure the proper working order. Periodic biological and chemical tests are conducted on air, water, surface and product to detect the micro-organisms and to analyze chemical properties. Regular cleaning and sanitizing of laboratory facility is done to minimize the physical, chemical and biological contaminations in the Lab. All incoming materials/components are

sampled and inspected before introducing into the manufacturing process. During manufacturing process, in process quality control checks are performed in every stage of production. Every year customer satisfaction survey is performed by the sales/marketing department and survey report is prepared to identify customer requirement and satisfaction level.

5.2 Conclusion

The conclusions drawn from this study are presented below:

General conclusions

- Employee participation and involvement is lacking in problem solving and decision making process.
- The concept of quality and quality system is not clear to the employees.

Conclusions from Production vs Quality Assurance personnel

- The ratio of production personnel to quality assurance personnel is 2.5 i.e. the manufacturing activities of 2.5 production personnel are monitored and verified by 1 quality assurance staff in general. The ratio is very low.

Conclusions from Hazards and staff safety

- All employees receive annual safety trainings and annual medical checkups. It can be concluded that all employees have good health and they are fit for their jobs.
- The FH IOL Lab lacks *hazard analysis* for potential hazards; *critical control point* where contamination increases to unacceptable levels; *control method* to either eliminate or to reduce the hazards to an acceptable level.
- Annual staff safety trainings for evacuation are limited only in formal program lacking practical aspect.

Conclusions from Staff Trainings

- In the FH IOL Lab, no one is authorized to work without training in related SOPs. So, it can be concluded that all the personnel have knowledge in advance to perform their respective jobs.

Conclusions from in-process QC checking

- In every stage of production, QC checks are carried out. So, it can be concluded that the FH IOL Lab has strict and excessive quality control system.

- The excessive paper work and documentation, procedural formalities and strict quality control checks have resulted complications, conflict, delay and low productivity to some degree or greater.

Conclusions from Customer complaints

- Customer complaint rate is very low. Only one customer complaint was registered in 2005 and in the following years from 2006 to 2009, there was no customer complaint while the sales volume was increasing every year.

Conclusions from Customer Satisfaction Surveys

- The customer response rate in 2007, 2008 & 2009 were 40%, 47% & 48% respectively which are considered to be good.
- From 2005 to 2009 for all seven attributes, the minimum customer rating was 3.25 which is 65% of the total point 5. So, all the seven attributes had customer ratings equal to or greater than 65% which indicates that customer perception for all the seven attributes was good.
- From 2005 to 2009, the minimum overall mean rating (satisfaction index) is 3.96 which is 79% to the total point 5. So, the customer satisfaction level is equal to or greater than 79% which indicates that customer satisfaction level was good.
- The trend of customer rating for the attribute 'Product Quality' is decreasing.
- The trend of customer rating for the attribute 'Product Delivery' is decreasing.
- The trend of customer rating for the attribute 'Attentiveness to Complaints' is decreasing.
- The trend of customer rating for the attribute 'Relationship' is slightly increasing.
- The trend of customer rating for the attribute 'Shipping packaging' is slightly decreasing.
- The trend of customer rating for the attribute 'Product packaging' is decreasing.
- The trend of customer rating for the attribute 'Price vs Quality' is slightly decreasing.
- The trend of customer satisfaction level is decreasing.

Conclusions from non-conformances, corrective actions, deviations

- The trend of observing non-conformances is in increasing trend.
- The trend for no of batches per NC is decreasing i.e. no of non-conformances is increasing for lesser no of batches.
- The trend for no of buttons per NC is decreasing i.e. no of non-conformances is increasing for lesser no of buttons.
- The trend for making deviations is in decreasing trend.
- The trend for taking corrective actions is in increasing trend due to increase in production volume and addition of product lines and product models.

Conclusions from Issue, Reject, Production & Sales Quantity of FH model of IOLs

- The issue of batches for production is in increasing trend.
- The no of buttons issued for production is in increasing trend.
- The reject quantity during manufacturing process is in increasing trend.
- The average reject percent during 5 years is 20% and the trend for reject percent is increasing.
- The production volume is in increasing trend.
- The sales volume is in increasing trend.

Conclusions from Pareto Analysis

- In 2005, poor surface quality is the key factor for 55% of total rejects and haptic broken/stress is the 2nd key factor causing 31% of total rejects.
- In 2006, poor surface quality is the key factor for 60% of total rejects and haptic broken/stress is the 2nd key factor causing 23% of total rejects.
- In 2007, poor surface quality is the key factor for 68% of total rejects and haptic broken/stress is the 2nd key factor causing 20% of total rejects.
- In 2008, poor surface quality is the key factor for 60% of total rejects and haptic broken/stress is the 2nd key factor causing 28% of total rejects.
- In 2009, poor surface quality is the key factor for 64% of total rejects and haptic broken/stress is the 2nd key factor causing 20% of total rejects.

- From 2005 to 2009, poor surface quality is the key factor for 62% of total rejects and haptic broken/stress is the 2nd key factor causing 25% of total rejects.

Conclusions from Hypothesis Test for Button Diameter

- The average diameter of PMMA buttons is not equal to the standard value i.e. 18.00 mm.

Conclusions from control charts

1st cut lathe process in relation to the parameter 'Vault diameter'

- In Mean chart (X chart), sharp alternative variations are subject to investigation in order to minimize the variations. The process is not under control.

2nd cut lathe process in relation to the parameter 'Focal length'

- Since all points lie within the limit and there is significant case to address, the process is under control.

2nd cut lathe process in relation to the parameter 'Haptic area thickness'

- In Range chart (R chart), sharp alternative variations are subject to investigation to minimize the variations. The process is not under control.

Milling process in relation to the parameter 'Optic diameter'

- Since a point lies out of the limit, the process is out of control.

Milling process in relation to the parameter 'Overall diameter'

- In Mean chart (X chart), extreme alternate variations and a plot in the upper control limit are subject to investigation. The process is not under control.

Milling process in relation to the parameter 'Haptic width'

- Since points lie out of the limit, the process is out of control.

Tumble Polishing process of lenses

- Since all points lie within the limit and there is significant case to address, the process is under control.

5.3 Recommendation

In view of the challenges and weaknesses detected from this study, the following recommendations are proposed.

- Quality Circles should be established in the key areas- machinery works, cleaning and inspection stations, and packaging works. Quality Circles are considered to be very important approach which encircles human relations, participative management and problem solving for productivity and quality improvement.

- The staffs should be trained for application of quality control tools- control charts, pareto analysis, cause and effect analysis etc.

- The top management of the FH IOL Lab needs to ensure that quality initiatives are understood at all key levels of the organization. These levels are the organization level, the operational/process level, and the individual level. The trainings, seminars, workshops, interactive discussion on TQM, QMS, ISO and other quality related issues should be conducted regularly.

- Since 1 quality assurance personnel is equivalent to 2.5 production personnel in average, the FH IOL Lab should plan to increase the ratio to reduce the cost in indirect human resources since personnel in quality roles are not directly involved in manufacturing activities.

- The production technicians, who directly involve in production, should be empowered with quality control checks/techniques and should be made responsible for quality issues to lessen the burden of quality control checks.

- The management should plan to minimize paper work/documentation and procedural formalities to minimize the complication, conflict, delay and to improve productivity.

- The trend of overall customer satisfaction level is decreasing. So the FH IOL Lab should increase overall customer satisfaction level by meeting/exceeding customer requirements in terms of the seven attributes of the customer satisfaction.

- Strict and excessive quality controls should be minimized to increase the productivity and decrease the cost of production.

- The observation of non-conformances is in increasing trend. The no of non-conformances is increasing for lesser no of batches and for lesser no of buttons issued. Also the trend for taking corrective actions is in increasing trend. So, the FH IOL Lab should focus on the detection, analysis, and the eventual elimination of potential causes of nonconformities through the examination of available data. All managers should be involved in generating the plan to remove potential causes of the nonconformity and for ensuring the plan results in the effective control of such actions. The functional managers should be responsible for collection and analysis of data within their respective areas. From the analysis of the data, the appropriate action should to be taken.

- The average diameter of PMMA buttons is not equal to the standard value. So, the button cutting machine should be set up with the standard diameter value before normal cutting process and diameter should be continuously checked during the normal cutting process.

- The FH IOL Lab should conduct *hazard analysis* for potential hazards; determine *critical control point* where contamination increases to unacceptable levels; *control method* to either eliminate or to reduce the hazards to an acceptable level.

- Annual staff safety trainings for evacuation are limited only in formal program lacking practical aspect. So, the safety trainings should be empowered with rehearsal, simulations and demonstrations.

- The average reject percent is 20% which is high and the trend for reject percent is increasing. Moreover, the scrap value of reject is zero. So the FH IOL Lab should plan and implement actions for reduction of rejects for higher productivity and cost reduction.

- Poor surface quality & Haptic broken/stress are the major and vital causes for rejection of FH model lenses. So, the FH IOL Lab should focus on resolving poor surface quality and haptic broken/stress.

- Control charts are made by management level from the records of historical data. So firstly production and quality control technician, who directly involve in day to day operations, should be trained in constructing control charts; secondly control charts should be constructed during the continuous process of manufacturing rather than extracting data from the past records so that process control can be achieved during the process.

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APPENDIX - 1

General Questions for Unstructured Interviews

Following questions were designed in order to have guidance in unstructured interviews. The objectives of the questions are to gain knowledge and information on overall Quality Management System (QMS), documentation system, quality control practices and physical work environment in the FH IOL Lab, Tilganga Eye Centre.

Questions related to management and documentation

- How does top management demonstrate its involvement in QMS?
- What functions are covered by the scope of the Quality Manual?
- Is there any exclusion of any ISO clause? Why?
- How Quality policy and Quality objectives are communicated within the FH IOL Lab?
- Explain the documentation structure- top level to bottom level?
- How are the documents and records controlled?

Questions related to Responsibility and authority

- Do the FH IOL Lab has organizational chart?
- Who assumes the overall responsibility of the FH IOL Lab?
- Is there a separate section/department for quality control? Who is in-charge?
- Who is the Management Representative (MR) of the FH IOL Lab?
- Is the Management review meeting carried out at regular intervals? How often?
- Who are the members of the Management Review body?
- Does top management participate in management review meeting? How?

Questions related to Human resource

- How can be ensured that employees are competent for their jobs and aware of quality objectives?
- Are there training programs in the FH IOL Lab? What types of training? Who give the training?
- How does the FH IOL Lab recognize the training needs of staffs?
- Is there regular training programs? How often?

- Is there extra training besides the training on regular jobs?
- What is the basis for staff training?
- How is effectiveness of training evaluated? Who evaluates?
- What are the possible hazards for staffs? What measures are taken to prevent them?
- Is there any staff safety programs/training in the FH IOL Lab?
- Do the management conduct *hazard analysis* for potential hazards; *critical control point* where contamination increases to unacceptable levels; *control method* to either eliminate or to reduce the hazards to an acceptable level?
- Is there any safety program for emergency preparedness (fire, weather, earthquake, disaster)?
- Is there any safety program for occupational injury/illness?
- Is there any supportive safety applicable to one's respective job tasks?
- Are the safety trainings supported by rehearsal, simulations and demonstrations?

Questions related to infrastructure and work environment

- How is clean room environment maintained in manufacturing area inside the FH IOL Lab?
- How are particulate and chemical contaminations monitored and controlled?
- How are biological contaminations monitored and controlled?
- How can be ensured that machines/equipments are in proper working order?
- How can be ensured that measuring equipments/instruments give accurate results?
- Are measuring equipments/instruments regularly calibrated? Are calibration records kept?

Questions related to Product realization and in-process QC checks?

- What are the stages/steps in manufacturing process?
- How is in-process quality control conducted in different manufacturing stages?
- At which stages/process inspections are carried out?
- Is material / goods traceability to source maintained during the manufacturing process? How?

- Are detailed step by step work instructions used?
- What types of rejects occur during manufacturing process?

Questions related to customer

- Who is the customer of the FH IOL Lab?
- How are the customers communicated?
- Explain about sales procedure?
- How customer complaint is handled? Who is responsible?
- What is the method for obtaining information related to customer satisfaction?
- How often is the customer satisfaction measured?
- What are the elements/attributes used in measuring customer satisfaction?

Questions related to purchase

- How are suppliers communicated?
- Has the FH IOL Lab maintained the list of approved suppliers?
- How is supplier approval carried out?
- How are purchased or incoming materials/items verified for acceptance?
- Who is responsible for inspection of incoming materials?
- How are sample size and acceptance quality level (AQL) determined for incoming material?
- Are incoming goods segregated and identified?
- Are all received materials traceable to the source? How?

Questions related to Nonconformance, Corrective Action, Preventive Action, Deviation

- What is the process for handling non-conformance?
- Are non-conforming materials/products separated? How?
- When does the need for taking Corrective action arise?
- How is Corrective action taken?
- Who is responsible for taking/implementing Corrective action?
- When does the need for taking Corrective action arise?

- How is Preventive action taken?
- Who is responsible for taking/implementing Preventive action?
- Is there any defined deviation procedure when change from established procedure is needed?
- How deviation is controlled?

Questions related to Preservation of Product

- How do you preserve incoming materials/items?
- How do you preserve materials/items in the main store?
- How to ensure uninterrupted supply of materials/items in daily operation?
- Where are semi-products stored? How are they identified?
- What are the storage conditions of the finished products?
- What measures are taken to protect the finished products in the finished product store?
- What measures are taken to protect the shipped products during delivery to the customers?

Questions related to Internal and External Quality Audit

- How often is internal quality audit conducted in the FH IOL Lab?
- Who is the responsible personnel for conducting internal quality audit?
- Who can become internal quality auditors? How are internal auditors selected?
- How to ensure impartiality and how to avoid conflict of interest in the audit process?
- How internal audit is conducted?
- When is external quality audit conducted?
- Who conducts external quality audit in the FH IOL Lab?
- Explain the case when a non compliance is observed in external auditing?

General Questions

- Are employees involved in problem solving and decision making?
- Are suggestions taken from employee?
- Are organizational policies and plans well communicated to the employees?
- Who are your internal customers? What are the requirements of your internal customers?
- Who are your internal suppliers? Do your internal suppliers know your requirements?
- In which station do you work? What are the objectives of your work?
- What are the quality policy and quality objective of your organization? How valuable are they?
- At which level is the responsibility felt for achieving the organization's goals- top level, middle level, lower level, all level?
- Does top management learn quality-related concepts and skills?
- Does top management discuss quality-related issues in top management meetings?
- How does top management actively participate in quality management activities?
- Who is responsible for the quality management?
- Are there Quality Circles established? If yes, areas/functions where Quality Circles are established?
- How the quality of the product is judged? What factors impact the quality?
- Do you have any idea about seven QC tools? If yes, how they are applied?
- Is there quality awareness programs held in the FH IOL Lab like QMS, ISO, TQM?
- What does the management focus on- quality or yield?
- Is there frequent conflict between Production personnel vs Quality personnel?

APPENDIX - 2

Data Sheet for recording PMMA Button Diameter in Button cutting

Sample size: 100 buttons randomly

I. Please fill up:

Model/Code of Product: …….	**Parameter of Measurement**
	Button Diameter
1 Unit of measurement:	……
2 Standard Range (Acceptable):	……
3 Measuring Equipment/Instrument:	……

II. Please enter the value:

SN	Button Diameter	SN	Button Diameter	SN	Button Diameter	SN	Button Diameter
1		26		51		76	
2		27		52		77	
3		28		53		78	
4		29		54		79	
5		30		55		80	
6		31		56		81	
7		32		57		82	
8		33		58		83	
9		34		59		84	
10		35		60		85	
11		36		61		86	
12		37		62		87	
13		38		63		88	
14		39		64		89	
15		40		65		90	
16		41		66		91	
17		42		67		92	
18		43		68		93	
19		44		69		94	
20		45		70		95	
21		46		71		96	
22		47		72		97	
23		48		73		98	
24		49		74		99	
25		50		75		100	

Data entry by:
Designation:
Date:

APPENDIX - 3

Data Sheet for recording Vault Diameter in 1st cut Lathe

Sample size: 50 successively cut lenses

I. Please fill up:

Model/Code of Product: …….	**Parameter of Measurement**
	Vault Diameter
1 Unit of measurement:	……
2 Standard Range (Acceptable):	……
3 Measuring Equipment/Instrument:	……

II. Please enter the value:

SN	Vault Diameter	SN	Vault Diameter
1		26	
2		27	
3		28	
4		29	
5		30	
6		31	
7		32	
8		33	
9		34	
10		35	
11		36	
12		37	
13		38	
14		39	
15		40	
16		41	
17		42	
18		43	
19		44	
20		45	
21		46	
22		47	
23		48	
24		49	
25		50	

Data entry by:
Designation:
Date:

APPENDIX - 4

Data Sheet for recording Focal length, Haptic area thickness and optic diameter in 2nd cut Lathe

Sample size: 50 successively cut lenses

I. Please fill up:

Model/Code of Product: …….	**Parameter of Measurement**	
	Focal length	**Haptic area Thickness**
1 Unit of measurement:	……..	……
2 Standard Range (Acceptable):	……..	……
3 Measuring Equipment/Instrument:	……..	……

II. Please enter the value:

SN	Focal length	Haptic area thickness	SN	Focal length	Haptic area thickness
1			26		
2			27		
3			28		
4			29		
5			30		
6			31		
7			32		
8			33		
9			34		
10			35		
11			36		
12			37		
13			38		
14			39		
15			40		
16			41		
17			42		
18			43		
19			44		
20			45		
21			46		
22			47		
23			48		
24			49		
25			50		

Data entry by:
Designation:
Date:

APPENDIX - 5

Data Sheet for recording Optic diameter, Overall diameter and Haptic width in Milling process of lenses

Sample size: 50 successively cut lenses

I. Please fill up:

Model/Code of Product: ……...…	Parameter of Measurement		
	Optic diameter	Overall diameter	Haptic width
1 Unit of measurement:	…… …..	……..	……. .
2 Standard Range (Acceptable):	…… …..	……..	……. .
Measuring	……		……
3 Equipment/Instrument:	…..	……..	…

II. Please enter the value:

SN	Optic diameter	Overall diameter	Haptic width	SN	Optic diameter	Overall diameter	Haptic width
1				26			
2				27			
3				28			
4				29			
5				30			
6				31			
7				32			
8				33			
9				34			
10				35			
11				36			
12				37			
13				38			
14				39			
15				40			
16				41			
17				42			
18				43			
19				44			
20				45			
21				46			
22				47			
23				48			
24				49			
25				50			

Data entry by:
Designation:
Date:

APPENDIX - 6

Data Sheet for recording no of defectives in tumbling polishing of lenses

Sample size: 100 lenses randomly from each 10 lots of polishing slurries

I. Please fill up:

Model/Code of Product: …….	**Parameter of Measurement**
	Vault Diameter
1 Unit of measurement:	……
2 Standard Range (Acceptable):	……
3 Measuring Equipment/Instrument:	……

II. Please enter the value:

Sample group no. (Polishing Slurry no)	**Sample Size: no of lenses observed**	**No of defectives**	
		Tally Bar	**No.**
1	100		
2	100		
3	100		
4	100		
5	100		
6	100		
7	100		
8	100		
9	100		
10	100		
Total	**1000**		

Data entry by:
Designation:
Date:

APPENDIX - 7

Computation of Z value for Hypothesis Testing (Mean test)

Stage of Production: Milling of PMMA buttons
Parameter of measurement: button diameter
Unit of measurement: millimeter (mm)
Standard Parameter Range (Acceptable): 17.92 mm – 18.08 mm
Measuring Equipment/Instrument: calibrated Digital Caliper
Sample size: 100 buttons randomly from QC released lot of buttons

Population mean, μ = 18.00 mm
Sample size, n = 100

Computation of Sample Mean and Sample Standard Deviation

Diameter (X)	**Frequency (f)**	**d=X-A**	**fd**	**fd^2**
17.94	1	-0.06	-0.0600	0.0036
17.95	3	-0.05	-0.1500	0.0075
17.96	4	-0.04	-0.1600	0.0064
17.97	4	-0.03	-0.1200	0.0036
17.98	5	-0.02	-0.1000	0.0020
17.99	7	-0.01	-0.0700	0.0007
18.00	9	0.00	0.0000	0.0000
18.01	9	0.01	0.0900	0.0009
18.02	11	0.02	0.2200	0.0044
18.03	13	0.03	0.3900	0.0117
18.04	12	0.04	0.4800	0.0192
18.05	13	0.05	0.6500	0.0325
18.06	8	0.06	0.4800	0.0288
18.07	1	0.07	0.0700	0.0049
Total	**100**		**1.720**	**0.1262**

Where Assumed Mean, A = 18.00

Sample Mean, $\bar{X} = A + \frac{\sum fd}{n} = 18.00 + \frac{1.720}{100}$ = 18.0172

Sample Standard Deviation, $s = \sqrt{\frac{\sum fd^2}{n} - \left(\frac{fd}{n}\right)^2} = \sqrt{\frac{0.1262}{100} - \left(\frac{1.720}{100}\right)^2}$ = 0.0311

Z value, $Z_{cal} = \frac{\bar{X}-\mu}{s/\sqrt{n}} = \frac{18.0172-18.00}{0.0311/\sqrt{100}}$ = 5.53

$|Z_{cal}|$ = 5.53

APPENDIX - 8

Computation of Control Limits

Stage of Production: 1st cut Lathe process
Parameter of measurement: Vault diameter
Unit of measurement: millimeter (mm)
Standard Parameter Range (Acceptable): 9.40 mm - 9.60 mm (for lens of FH 105 Model)
Measuring Equipment/Instrument: calibrated Profile Projector
Sample size: 50 successively cut lenses (one group for 5 successively cut lenses- total 10 groups)

Observation, Sample means & Sample range for vault diameter

Sample group no.	sample observation					Total	Sample mean	Sample range
1	9.50	9.48	9.47	9.48	9.53	47.46	9.49	0.06
2	9.52	9.47	9.48	9.49	9.47	47.43	9.49	0.05
3	9.49	9.50	9.52	9.51	9.47	47.49	9.50	0.05
4	9.48	9.51	9.53	9.52	9.53	47.57	9.51	0.05
5	9.50	9.53	9.51	9.49	9.51	47.54	9.51	0.04
6	9.52	9.51	9.52	9.47	9.54	47.56	9.51	0.07
7	9.48	9.49	9.51	9.48	9.47	47.43	9.49	0.04
8	9.54	9.52	9.47	9.53	9.50	47.56	9.51	0.07
9	9.47	9.51	9.49	9.47	9.46	47.40	9.48	0.05
10	9.52	9.53	9.48	9.50	9.53	47.56	9.51	0.05
						Total	**95.00**	**0.53**

Sample mean & Sample range are computed as

Sample mean, $\bar{X} = \frac{\sum X}{n}$ where n = sample size = 5

Sample Range, $\overline{R}$ = Highest value – Lowest value

Mean of mean, $\bar{\bar{X}} = \frac{\sum \bar{X}}{k} = \frac{95}{10}$ = 9.50 where k = no of sample subgroups = 10

Mean of Range, $\bar{R} = \frac{\sum R}{k} = \frac{0.53}{10}$ = 0.05

For $\bar{X}$-Chart

For sample size n = 5, A2 = 0.577 (*from Factor for Control Chart table*)
Setting control limits:

Central Line, CL = $\bar{\bar{X}}$ = 9.50

Upper Control Limit, UCL = $\bar{\bar{X}} + A_2\bar{R}$ = 9.50 + 0.577 X 0.05 = 9.53

Lower Control Limit, LCL = $\bar{\bar{X}} - A_2\bar{R}$ = 9.50 - 0.577 X 0.05 = 9.47

For R-Chart

For sample size n = 5, D_4 = 2.115, D_3 = 0 (*from Factor for Control Chart table*)
Setting control limits:

Central Line, CL = $\bar{R}$ = 0.05

Upper Control Limit, UCL = $D_4\bar{R}$ = 2.115 X 0.05 = 0.11

Lower Control Limit, LCL = $D_3\bar{R}$ = 0 X 0.05 = 0

APPENDIX - 9

Computation of Control Limits

Stage of Production: 2nd cut Lathe process
Parameter of measurement: Focal length (Optical power)
Unit of measurement: millimeter (mm)
Standard Parameter Range (Acceptable): 12.99 mm - 13.29 mm (for +23.5 Dioptre)
Measuring Equipment/Instrument: calibrated Lens bench
Sample size: 50 successively cut lenses (one group for 5 successively cut lenses- total 10 groups)

Observation, Sample means & Sample range for focal length

Sample group no.	**sample observation**					**Total**	**Sample mean**	**Sample range**
1	13.18	13.15	13.20	13.16	13.15	65.84	13.17	0.05
2	13.14	13.19	13.15	13.15	13.19	65.82	13.16	0.05
3	13.15	13.17	13.18	13.12	13.14	65.76	13.15	0.06
4	13.17	13.16	13.15	13.20	13.19	65.87	13.17	0.05
5	13.13	13.16	13.14	13.17	13.15	65.75	13.15	0.04
6	13.12	13.18	13.18	13.19	13.14	65.81	13.16	0.07
7	13.14	13.20	13.20	13.20	13.18	65.92	13.18	0.06
8	13.15	13.17	13.15	13.15	13.14	65.76	13.15	0.03
9	13.11	13.14	13.17	13.17	13.13	65.72	13.14	0.06
10	13.18	13.19	13.19	13.14	13.15	65.85	13.17	0.05
						Total	**131.62**	**0.52**

Sample mean & Sample range are computed as

Sample mean, $\bar{X} = \frac{\sum X}{n}$ where n = sample size = 5

Sample Range, $\overline{\mathrm{R}}$ = Highest value – Lowest value

Mean of mean, $\bar{\bar{X}} = \frac{\sum \bar{X}}{k} = \frac{131.62}{10}$ = 13.16 where k = no of sample subgroups = 10

Mean of Range, $\bar{R} = \frac{\sum R}{k} = \frac{0.52}{10}$ = 0.05

For $\bar{X}$-Chart

For sample size n = 5, A2 = 0.577 (*from Factor for Control Chart table*)
Setting control limits:

Central Line, CL = $\bar{\bar{X}}$ = 13.16

Upper Control Limit, UCL = $\bar{\bar{X}} + A_2\bar{R}$ = 13.16 + 0.577 X 0.05 = 13.19

Lower Control Limit, LCL = $\bar{\bar{X}} - A_2\bar{R}$ = 13.16 - 0.577 X 0.05 = 13.13

For R-Chart

For sample size n = 5, D_4 = 2.115, D_3 = 0 (*from Factor for Control Chart table*)
Setting control limits:

Central Line, CL = $\bar{R}$ = 0.05

Upper Control Limit, UCL = $D_4\bar{R}$ = 2.115 X 0.05 = 0.11

Lower Control Limit, LCL = $D_3\bar{R}$ = 0 X 0.05 = 0

APPENDIX - 10

Computation of Control Limits

Stage of Production: 2nd cut Lathe process
Parameter of measurement: Haptic area thickness
Unit of measurement: millimeter (mm)
Standard Parameter Range (Acceptable): 0.160 mm – 0.190 mm
Measuring Equipment/Instrument: calibrated Profile Projector
Sample size: 50 successively cut lenses (one group for 5 successively cut lenses- total 10 groups)

Observation, Sample means & Sample range for Haptic area thickness

Sample group no.	**sample observation**					**Total**	**Sample mean**	**Sample range**
1	0.176	0.168	0.182	0.180	0.172	0.878	0.176	0.014
2	0.172	0.182	0.175	0.175	0.169	0.873	0.175	0.013
3	0.178	0.181	0.182	0.175	0.175	0.891	0.178	0.007
4	0.180	0.179	0.182	0.183	0.168	0.892	0.178	0.015
5	0.185	0.177	0.185	0.178	0.169	0.894	0.179	0.016
6	0.182	0.180	0.182	0.184	0.182	0.910	0.182	0.004
7	0.179	0.180	0.182	0.176	0.170	0.887	0.177	0.012
8	0.177	0.181	0.182	0.175	0.169	0.884	0.177	0.013
9	0.175	0.182	0.182	0.178	0.181	0.898	0.180	0.007
10	0.176	0.180	0.182	0.177	0.169	0.884	0.177	0.013
						Total	**1.778**	**0.114**

Sample mean & Sample range are computed as

Sample mean, $\bar{X} = \frac{\sum X}{n}$ where n = sample size = 5

Sample Range, $\overline{\mathrm{R}}$ = Highest value – Lowest value

Mean of mean, $\bar{\bar{X}} = \frac{\sum \bar{X}}{k} = \frac{1.778}{10}$ = 0.178 where k = no of sample subgroups = 10

Mean of Range, $\bar{R} = \frac{\sum R}{k} = \frac{0.114}{10}$ = 0.011

For $\bar{X}$-Chart

For sample size n = 5, A2 = 0.577 (*from Factor for Control Chart table*)
Setting control limits:

Central Line, CL = $\bar{\bar{X}}$ = 0.178

Upper Control Limit, UCL = $\bar{\bar{X}} + A_2\bar{R}$ = 0.178 + 0.577 X 0.011 = 0.184

Lower Control Limit, LCL = $\bar{\bar{X}} - A_2\bar{R}$ = 0.178 - 0.577 X 0.011 = 0.171

For R-Chart

For sample size n = 5, D_4 = 2.115, D_3 = 0 (*from Factor for Control Chart table*)
Setting control limits:

Central Line, CL = $\bar{R}$ = 0.011

Upper Control Limit, UCL = $D_4\bar{R}$ = 2.115 X 0.011 = 0.024

Lower Control Limit, LCL = $D_3\bar{R}$ = 0 X 0.011 = 0

APPENDIX - 11

Computation of Control Limits

Stage of Production: Milling of lens
Parameter of measurement: Optic diameter
Unit of measurement: millimeter (mm)
Standard Parameter Range (Acceptable): 5.60 mm – 5.80 mm (for lens of FH 105 Model)
Measuring Equipment/Instrument: calibrated Profile Projector
Sample size: 50 successively cut lenses (one group for 5 successively cut lenses- total 10 groups)

Observation, Sample means & Sample range for optic diameter

Sample group no.	**sample observation**					**Total**	**Sample mean**	**Sample range**
1	5.72	5.70	5.67	5.71	5.68	28.48	5.70	0.05
2	5.74	5.71	5.69	5.73	5.75	28.62	5.72	0.06
3	5.70	5.75	5.76	5.72	5.77	28.70	5.74	0.07
4	5.76	5.80	5.79	5.82	5.75	28.92	5.78	0.07
5	5.77	5.71	5.72	5.75	5.76	28.71	5.74	0.06
6	5.72	5.69	5.71	5.70	5.67	28.49	5.70	0.05
7	5.72	5.75	5.69	5.68	5.71	28.55	5.71	0.07
8	5.68	5.71	5.70	5.75	5.69	28.53	5.71	0.07
9	5.71	5.67	5.65	5.72	5.69	28.44	5.69	0.07
10	5.69	5.73	5.69	5.74	5.72	28.57	5.71	0.05
						Total	**57.20**	**0.62**

Sample mean & Sample range are computed as

Sample mean, $\bar{X} = \frac{\sum X}{n}$ where n = sample size = 5

Sample Range, $\overline{\mathrm{R}}$ = Highest value – Lowest value

Mean of mean, $\bar{\bar{X}} = \frac{\sum \bar{X}}{k} = \frac{57.20}{10}$ = 5.72 where k = no of sample subgroups = 10

Mean of Range, $\bar{R} = \frac{\sum R}{k} = \frac{0.62}{10}$ = 0.06

For $\bar{X}$-Chart

For sample size n = 5, A2 = 0.577 (*from Factor for Control Chart table*)
Setting control limits:

Central Line, CL = $\bar{\bar{X}}$ = 5.72

Upper Control Limit, UCL = $\bar{\bar{X}} + A_2\bar{R}$ = 5.72 + 0.577 X 0.06 = 5.76

Lower Control Limit, LCL = $\bar{\bar{X}} - A_2\bar{R}$ = 5.72 - 0.577 X 0.06 = 5.68

For R-Chart

For sample size n = 5, D_4 = 2.115, D_3 = 0 (*from Factor for Control Chart table*)
Setting control limits:

Central Line, CL = $\bar{R}$ = 0.06

Upper Control Limit, UCL = $D_4\bar{R}$ = 2.115 X 0.06 = 0.13

Lower Control Limit, LCL = $D_3\bar{R}$ = 0 X 0.06 = 0

APPENDIX - 12

Computation of Control Limits

Stage of Production: Milling of lens
Parameter of measurement: Overall diameter
Unit of measurement: millimeter (mm)
Standard Parameter Range (Acceptable): 12.40 mm – 12.60 mm (for lens of FH 105 Model)
Measuring Equipment/Instrument: calibrated Profile Projector
Sample size: 50 successively cut lenses (one group for 5 successively cut lenses- total 10 groups)

Observation, Sample means & Sample range for overall diameter

Sample group no.	**sample observation**					**Total**	**Sample mean**	**Sample range**
1	12.48	12.52	12.51	12.54	12.50	62.55	12.51	0.06
2	12.50	12.49	12.54	12.55	12.49	62.57	12.51	0.06
3	12.47	12.48	12.50	12.53	12.47	62.45	12.49	0.06
4	12.51	12.52	12.49	12.51	12.50	62.53	12.51	0.03
5	12.47	12.48	12.54	12.53	12.49	62.51	12.50	0.07
6	12.50	12.53	12.49	12.50	12.47	62.49	12.50	0.06
7	12.56	12.52	12.54	12.52	12.57	62.71	12.54	0.05
8	12.54	12.58	12.51	12.54	12.57	62.74	12.55	0.07
9	12.55	12.47	12.49	12.47	12.55	62.53	12.51	0.08
10	12.49	12.51	12.54	12.50	12.56	62.60	12.52	0.07
						Total	**125.14**	**0.61**

Sample mean & Sample range are computed as

Sample mean, $\bar{X} = \frac{\sum X}{n}$ where n = sample size = 5

Sample Range, $\overline{\mathrm{R}}$ = Highest value – Lowest value

Mean of mean, $\bar{\bar{X}} = \frac{\sum \bar{X}}{k} = \frac{125.14}{10}$ = 12.51 where k = no of sample subgroups = 10

Mean of Range, $\bar{R} = \frac{\sum R}{k} = \frac{0.61}{10}$ = 0.06

For $\bar{X}$-Chart

For sample size n = 5, A2 = 0.577 (*from Factor for Control Chart table*)
Setting control limits:

Central Line, CL = $\bar{\bar{X}}$ = 12.51

Upper Control Limit, UCL = $\bar{\bar{X}} + A_2\bar{R}$ = 12.51 + 0.577 X 0.06 = 12.55

Lower Control Limit, LCL = $\bar{\bar{X}} - A_2\bar{R}$ = 12.51 - 0.577 X 0.06 = 12.48

For R-Chart

For sample size n = 5, D_4 = 2.115, D_3 = 0 (*from Factor for Control Chart table*)
Setting control limits:

Central Line, CL = $\bar{R}$ = 0.06

Upper Control Limit, UCL = $D_4\bar{R}$ = 2.115 X 0.06 = 0.13

Lower Control Limit, LCL = $D_3\bar{R}$ = 0 X 0.06 = 0

APPENDIX - 13

Computation of Control Limits

Stage of Production: Milling of lens
Parameter of measurement: Haptic width
Unit of measurement: millimeter (mm)
Standard Parameter Range (Acceptable): 0.160 mm – 0.200 mm (for lens of FH 105 Model)
Measuring Equipment/Instrument: calibrated Profile Projector
Sample size: 50 successively cut lenses (one group for 5 successively cut lenses- total 10 groups)

Observation, Sample means & Sample range for Haptic width

Sample group no.	**sample observation**					**Total**	**Sample mean**	**Sample range**
1	0.176	0.174	0.177	0.175	0.180	0.882	0.176	0.006
2	0.175	0.182	0.179	0.182	0.181	0.899	0.180	0.007
3	0.178	0.179	0.176	0.180	0.179	0.892	0.178	0.004
4	0.184	0.186	0.183	0.190	0.188	0.931	0.186	0.007
5	0.190	0.184	0.185	0.181	0.189	0.929	0.186	0.009
6	0.194	0.188	0.185	0.192	0.194	0.953	0.191	0.009
7	0.199	0.200	0.202	0.201	0.199	1.001	0.200	0.003
8	0.200	0.195	0.193	0.196	0.190	0.974	0.195	0.010
9	0.195	0.191	0.192	0.189	0.188	0.955	0.191	0.007
10	0.186	0.185	0.181	0.187	0.180	0.919	0.184	0.007
						Total	**1.867**	**0.069**

Sample mean & Sample range are computed as

Sample mean, $\bar{X} = \frac{\sum X}{n}$ where n = sample size = 5

Sample Range, $\overline{\mathrm{R}}$ = Highest value – Lowest value

Mean of mean, $\bar{\bar{X}} = \frac{\sum \bar{X}}{k} = \frac{1.867}{10}$ = 0.187 where k = no of sample subgroups = 10

Mean of Range, $\bar{R} = \frac{\sum R}{k} = \frac{0.069}{10}$ = 0.007

For $\bar{X}$-Chart

For sample size n = 5, A2 = 0.577 (*from Factor for Control Chart table*)
Setting control limits:

Central Line, CL = $\bar{\bar{X}}$ = 0.187

Upper Control Limit, UCL = $\bar{\bar{X}} + A_2\bar{R}$ = 0.187 + 0.577 X 0.007 = 0.191

Lower Control Limit, LCL = $\bar{\bar{X}} - A_2\bar{R}$ = 0.187 - 0.577 X 0.007 = 0.183

For R-Chart

For sample size n = 5, D_4 = 2.115, D_3 = 0 (*from Factor for Control Chart table*)
Setting control limits:

Central Line, CL = $\bar{R}$ = 0.007

Upper Control Limit, UCL = $D_4\bar{R}$ = 2.115 X 0.007 = 0.015

Lower Control Limit, LCL = $D_3\bar{R}$ = 0 X 0.007 = 0

APPENDIX - 14

Computation of Control Limits

Stage of Production: Tumble polishing of lens
Parameter of measurement: Lens Surface quality
Unit of measurement: either acceptance or rejection
Standard Parameter Range (Acceptable): N/A
Measuring Equipment/Instrument: calibrated Microscope
Sample size: 100 lenses randomly from each 10 lots of polishing slurries (Total group -10 & Total lenses - 100)

Observation

Sample group no.	No of defectives	Fraction Defective
1	15	0.15
2	21	0.21
3	10	0.10
4	11	0.11
5	18	0.18
6	19	0.19
7	13	0.13
8	17	0.17
9	26	0.26
10	18	0.18
	168	

For p-Chart

Mean fraction defective in the sample is given by

$$\bar{p} = \frac{total\ no\ of\ defects}{total\ no\ of\ observation} = \frac{168}{10 \times 100} = 0.17$$

Standard deviation of the sampling distribution is given by
sample size, n = 100

$$\sigma_{\bar{p}} = \sqrt{\frac{\bar{p}(1-\bar{p})}{n}} = \sqrt{\frac{0.17(1-0.17)}{100}} = 0.0374$$

Setting control limits:
z = 3 for 99.7 % confidence level

Central Line, $CL = \bar{p} = 0.17$

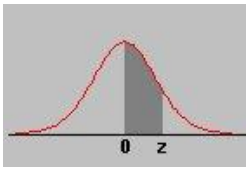
Upper Control Line, $UCL = \bar{p} + z\sigma_{\bar{p}} = 0.17 + 3 \times 0.0374 = 0.28$

Lower Control Line, $LCL = \bar{p} - z\sigma_{\bar{p}} = 0.17 - 3 \times 0.0374 = 0.06$

APPENDIX - 15

Standard Normal (Z)

Area between 0 and z



	0.00	0.01	0.02	0.03	0.04	0.05	0.06	0.07	0.08	0.09
0.0	0.0000	0.0040	0.0080	0.0120	0.0160	0.0199	0.0239	0.0279	0.0319	0.0359
0.1	0.0398	0.0438	0.0478	0.0517	0.0557	0.0596	0.0636	0.0675	0.0714	0.0753
0.2	0.0793	0.0832	0.0871	0.0910	0.0948	0.0987	0.1026	0.1064	0.1103	0.1141
0.3	0.1179	0.1217	0.1255	0.1293	0.1331	0.1368	0.1406	0.1443	0.1480	0.1517
0.4	0.1554	0.1591	0.1628	0.1664	0.1700	0.1736	0.1772	0.1808	0.1844	0.1879
0.5	0.1915	0.1950	0.1985	0.2019	0.2054	0.2088	0.2123	0.2157	0.2190	0.2224
0.6	0.2257	0.2291	0.2324	0.2357	0.2389	0.2422	0.2454	0.2486	0.2517	0.2549
0.7	0.2580	0.2611	0.2642	0.2673	0.2704	0.2734	0.2764	0.2794	0.2823	0.2852
0.8	0.2881	0.2910	0.2939	0.2967	0.2995	0.3023	0.3051	0.3078	0.3106	0.3133
0.9	0.3159	0.3186	0.3212	0.3238	0.3264	0.3289	0.3315	0.3340	0.3365	0.3389
1.0	0.3413	0.3438	0.3461	0.3485	0.3508	0.3531	0.3554	0.3577	0.3599	0.3621
1.1	0.3643	0.3665	0.3686	0.3708	0.3729	0.3749	0.3770	0.3790	0.3810	0.3830
1.2	0.3849	0.3869	0.3888	0.3907	0.3925	0.3944	0.3962	0.3980	0.3997	0.4015
1.3	0.4032	0.4049	0.4066	0.4082	0.4099	0.4115	0.4131	0.4147	0.4162	0.4177
1.4	0.4192	0.4207	0.4222	0.4236	0.4251	0.4265	0.4279	0.4292	0.4306	0.4319
1.5	0.4332	0.4345	0.4357	0.4370	0.4382	0.4394	0.4406	0.4418	0.4429	0.4441
1.6	0.4452	0.4463	0.4474	0.4484	0.4495	0.4505	0.4515	0.4525	0.4535	0.4545
1.7	0.4554	0.4564	0.4573	0.4582	0.4591	0.4599	0.4608	0.4616	0.4625	0.4633
1.8	0.4641	0.4649	0.4656	0.4664	0.4671	0.4678	0.4686	0.4693	0.4699	0.4706
1.9	0.4713	0.4719	0.4726	0.4732	0.4738	0.4744	0.4750	0.4756	0.4761	0.4767
2.0	0.4772	0.4778	0.4783	0.4788	0.4793	0.4798	0.4803	0.4808	0.4812	0.4817
2.1	0.4821	0.4826	0.4830	0.4834	0.4838	0.4842	0.4846	0.4850	0.4854	0.4857
2.2	0.4861	0.4864	0.4868	0.4871	0.4875	0.4878	0.4881	0.4884	0.4887	0.4890
2.3	0.4893	0.4896	0.4898	0.4901	0.4904	0.4906	0.4909	0.4911	0.4913	0.4916
2.4	0.4918	0.4920	0.4922	0.4925	0.4927	0.4929	0.4931	0.4932	0.4934	0.4936
2.5	0.4938	0.4940	0.4941	0.4943	0.4945	0.4946	0.4948	0.4949	0.4951	0.4952
2.6	0.4953	0.4955	0.4956	0.4957	0.4959	0.4960	0.4961	0.4962	0.4963	0.4964
2.7	0.4965	0.4966	0.4967	0.4968	0.4969	0.4970	0.4971	0.4972	0.4973	0.4974
2.8	0.4974	0.4975	0.4976	0.4977	0.4977	0.4978	0.4979	0.4979	0.4980	0.4981
2.9	0.4981	0.4982	0.4982	0.4983	0.4984	0.4984	0.4985	0.4985	0.4986	0.4986
3.0	0.4987	0.4987	0.4987	0.4988	0.4988	0.4989	0.4989	0.4989	0.4990	0.4990

APPENDIX - 16

Factor for Control Chart

No of Observations in Sample	Chart for Averages			Chart for Ranges			
	Factors for Control Limits			Factors for Control Limits			
n	A	A2	A3	D1	D2	D3	D4
2	2.121	1.880	2.659	0.000	3.686	0.000	3.267
3	1.732	1.023	1.954	0.000	4.358	0.000	2.575
4	1.500	0.729	1.628	0.000	4.698	0.000	2.282
5	1.342	0.577	1.427	0.000	4.918	0.000	2.115
6	1.225	0.483	1.287	0.000	5.079	0.000	2.004
7	1.134	0.419	1.182	0.205	5.204	0.076	1.924
8	1.061	0.373	1.099	0.388	5.307	0.136	1.864
9	1.000	0.337	1.032	0.547	5.394	0.184	1.816
10	0.949	0.308	0.975	0.686	5.469	0.223	1.777
11	0.905	0.285	0.927	0.811	5.535	0.256	1.744
12	0.866	0.266	0.886	0.923	5.594	0.283	1.717
13	0.832	0.249	0.850	1.025	5.647	0.307	1.693
14	0.802	0.235	0.817	1.118	5.696	0.328	1.672
15	0.775	0.223	0.789	1.203	5.740	0.347	1.653
16	0.750	0.212	0.763	1.282	5.782	0.363	1.637
17	0.728	0.203	0.739	1.356	5.820	0.378	1.622
18	0.707	0.194	0.718	1.424	5.856	0.391	1.609
19	0.688	0.187	0.698	1.489	5.889	0.404	1.596
20	0.671	0.180	0.680	1.549	5.921	0.415	1.585
21	0.655	0.173	0.663	1.606	5.951	0.425	1.575
22	0.640	0.167	0.647	1.660	5.979	0.435	1.565
23	0.626	0.162	0.633	1.711	6.006	0.443	1.557
24	0.612	0.157	0.619	1.759	6.032	0.452	1.548
25	0.600	0.153	0.606	1.805	6.056	0.459	1.541